

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The Effectiveness of Acceptance and Commitment-Based Treatment Approach on Perceived Stress Scales and Emotional Adjustment in Patients with Multiple Sclerosis

Protocol summary

Study aim

The purpose of this study was to evaluate the effectiveness of treatment based on acceptance and commitment on perceived stress components (perceived tension and self-efficacy) and emotional adjustment in patients with multiple sclerosis.

Design

Clinical trial with experimental and control groups, parallel groups, not-blind, non-random allocation to control and experimental groups; sample size is 40 patients

Settings and conduct

Intervention sessions were held during 8 sessions and for 2 months (one session per week) at Sina Hospital in Hamadan Province.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Multiple sclerosis according to neurologist diagnosis; willingness and conscious consent to participate in the research project; being literate; Ability to attend meetings; age range between 20 to 50 years old; The duration of the disease ranges from 2 to 5 years. Non-inclusion criteria: severe physical problems.

Intervention groups

The research groups consisted of experimental group and control group. The experimental group received admission and commitment-based treatment interventions within two months, but the control group did not receive any intervention.

Main outcome variables

Perceived tension; Perceived self-efficacy; Emotional adjustment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200331046905N1**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **retrospective**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

Registrant information

Name

sara pournaghi

Name of organization / entity

Bu Ali Sina University

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2019-04-21, 1398/02/01

Trial completion date

2019-07-06, 1398/04/15

Scientific title

The Effectiveness of Acceptance and Commitment-Based Treatment Approach on Perceived Stress Scales and

Public title

The Effectiveness of Acceptance and Commitment-Based Treatment in Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Multiple sclerosis is diagnosed by a neurologist Ability to attend meetings Being literate Conscious desire and satisfaction to participate in research The duration of the disease is between 2 to 5 years Age range 20 to 50 years

Exclusion criteria:

Existence of severe physical condition

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **26**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Bu Ali Sina University of Hamadan

Street address

Faculty of Economics and Social Sciences, Bu Ali Sina University, Chaharbagh Ahmadi Roshan

City

Hamadan

Province

Hamadan

Postal code

3869565178

Approval date

2019-10-15, 1398/07/23

Ethics committee reference number**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**

Perceived tension

Timepoint

Before and after Intervention

Method of measurement

Perceived stress questionnaire

2**Description**

Emotional adjustment

Timepoint

Before and after Intervention

Method of measurement

emotional adjustment questionarie

3**Description**

Perceived self-efficacy

Timepoint

Before and after Intervention

Method of measurement

Perceived stress questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: People in the intervention group underwent psychological treatment based on acceptance and commitment for two months. 8 weekly sessions were held over two months and lasted between 60 and 90 minutes. At acceptance and commitment-based psychological sessions, home exercises were given to patients to do during the week, followed by a group discussion and instructional intervention. The number of exercises was determined according to the course of the sessions and each time in a way that challenged the patients' thoughts.

Category

Treatment - Other

2**Description**

Control group: The control group did not receive any intervention in this study.

Category

Other

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

Sina hospital

Full name of responsible person

Dr Mahyar Motaghed

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Sina hospital, Mirzade Eshqi street

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

Bu-ali Sina University

Full name of responsible person

Mohamad Reza Zoghipaydar

Street address

Charbaq Khaje Rashid, Bu ali Sina University

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Bu-ali Sina 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**

Bu ali Sina univercity

Full name of responsible person

Sara Pournaghi

Position

gratuated

Latest degree

Master

Other areas of specialty/work

Psychology

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

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The information of the participants is completely confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information on the questionnaires is available

When the data will become available and for how long

Start of access 2 years after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Data will be available for related researchers

From where data/document is obtainable

It will be refereed to the supervisor.

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

The data file will be reachable receiving the request.

Comments