# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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 tensin 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**
Iran (Islamic Republic of)

**Phone**
+98 81 3225 2488

**Email address**
sarapournaghiii@gmail.com

**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

Emotional Adjustment in Patients with Multiple Sclerosis

**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**
IR.BASU.REC.1398.012

## 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
**Street address**
Sina hospital, Mirzade Eshqi street
**City**
Hamadan
**Province**
Hamadan
**Postal code**
1111111111
**Phone**
+98 81 3827 4191
**Email**
sarapournaghiii@gmail.com

## 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
**City**
Hamadan
**Province**
Hamadan
**Postal code**
۶۵۱۷۴۳۳۳۹۱
**Phone**
+98 81 3838 1601
**Email**
zoghi.p@basu.ac.ir
**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
**Street address**
Khaleghi Alley; Ghaem Magham boulevard
**City**
Malayer
**Province**
Hamadan
**Postal code**
6571611316
**Phone**
+98 81 3838 1601
**Email**
sarapournaghiii@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Bu Ali Sina University
**Full name of responsible person**
Sara Pournaghi
**Position**
Graduated
**Latest degree**
Master
**Other areas of specialty/work**
Psychology
**Street address**
Faculty of Economics and Social Sciences, Bu Ali Sina University, Charbagh Ahmadi Roshan
**City**
Hamadan
**Province**
Hamadan
**Postal code**
6517838695
**Phone**
+98 81 3838 1601

**Fax**

**Email**

sarapournaghiii@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Bu Ali Sina University

**Full name of responsible person**

Sara Pournaghi

**Position**

Graduated

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

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

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6571611316

**Phone**

+98 81 3838 1601

**Fax**

**Email**

sarapournaghiii@gmail.com

## 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**