# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effectiveness of Acceptance and Commitment Therapy on death and health anxiety, cognitive and somatic symptoms of anxiety, and component of acceptance and commitment in patients with multiple sclerosis

## Protocol summary


**Summary**

The aim of current study is examination the impact of Acceptance and Commitment Therapy on death anxiety, health anxiety, symptoms of anxiety and component of acceptance and commitment in patients with multiple sclerosis. Inclusion criteria (being female, diagnosis of MS by a neurologist) and exclusion criteria (get interventions psychological treatment in the past year and the time of study; history of alcohol abuse or drugs; two sessions of absence for each patient) employed for sampling. Statistical population was all female with primary diagnosis of multiple sclerosis in Tehran, Iran. 48 patients with primary diagnosis of multiple sclerosis disorder were selected. Primary evaluation was carried out with Kurtzke Expanded Disability Status Scale (EDSS), and Structured Clinical Interview for DSM-IV (SCID-I). Working Alliance Inventory-Short Revised (WAI-SR) was carried out in experimental group after intervention. The study design was randomized controlled clinical trials or pre-test and post-test with the control group. Participants were randomly assigned to the intervention group (that receive acceptance and commitment therapy); n=24 and control group (Received routine medical treatment.), n=24. We expect this study show reduction of death anxiety, health anxiety and symptoms of anxiety as well as increasing components of acceptance and commitment therapy in patients with multiple sclerosis.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017040833079N2**
Registration date: **2017-05-02, 1396/02/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

**Registration date**

2017-05-02, 1396/02/12

**Registrant information**


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**Recruitment status**

**Recruitment complete**

**Funding source**

Kashan University of Medical Sciences

**Expected recruitment start date**

2017-02-01, 1395/11/13

**Expected recruitment end date**

2017-07-30, 1396/05/08

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of Acceptance and Commitment Therapy on death and health anxiety, cognitive and somatic symptoms of anxiety, and component of acceptance and commitment in patients with multiple sclerosis

**Public title**
Effectiveness of Acceptance and Commitment Therapy on death and health anxiety, cognitive and somatic symptoms of anxiety, and component of acceptance and commitment in patients with multiple sclerosis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: being female; diagnosis of MS by a neurologist; satisfaction and commitment to participate in the study. Exclusion criteria: get interventions psychological treatment in the past year and the time of study; current mania or psychotic episode history of alcohol abuse or drugs; two sessions of absence for each patient.
**Age**
From **20 years** old to **40 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **50**
**Randomization (investigator's opinion)**
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**
Research and Technology Management
**Street address**
Ravand highway، Kashan University of Medical Sciences
**City**
kashan
**Postal code**
**Approval date**
2017-01-18, 1395/10/29
**Ethics committee reference number**
IR.KAUMS.REC.1395.119

## 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**
somatic Symptoms of anxiety
**Timepoint**
Before intervention (baseline), after two month (post)
**Method of measurement**
beck anxiety inventory (BAI)

### 2

**Description**
Death anxiety
**Timepoint**
Before intervention (baseline), after two month (post)
**Method of measurement**
Death Anxiety Inventory

### 3

**Description**
health anxiety
**Timepoint**
Before intervention (baseline), after two month (post)
**Method of measurement**
Health Anxiety Inventory

### 4

**Description**
cognitive Symptoms of anxiety
**Timepoint**
Before intervention (baseline), after two month (post)
**Method of measurement**
Penn State Worry Questionnaire (PSWQ)

### 5

**Description**
cognitive fusion
**Timepoint**
Before intervention (baseline), after two month (post)
**Method of measurement**
cognitive fusion questionaire (CFQ)

### 6

**Description**
components of acceptance and commitment
**Timepoint**
Before intervention (baseline), after two month (post)
**Method of measurement**

Acceptance and Action Questionnaire (AAQ-II)

## Secondary outcomes

**1**

**Description**
therapeutic alliance
**Timepoint**
after intervention on experimental group
**Method of measurement**
Working Alliance Inventory-Short Revised (WAI-SR)

**2**

**Description**
MS symptoms
**Timepoint**
Before intervention (baseline)
**Method of measurement**
Multiple Sclerosis Impact Scale (MSIS-29)

## Intervention groups

**1**

**Description**
Intervention group: acceptance and commitment group therapy + routine medical treatment
**Category**
Behavior

**2**

**Description**
Control group: Routine medical treatment
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Sina Hospital
**Full name of responsible person**
**Street address**
Hasan Abad Sq., Imam Khomeini St.
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kashan University of Medical Science
**Full name of responsible person**
Gholamali Hamidi
**Street address**
Ravand 5 km road, Kashan Medical Science Collection
**City**
Kashan
**Grant name**
95115
**Grant code / Reference number**
95115
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kashan University of Medical Science
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**
*empty*
**Statistical Analysis Plan**
*empty*
**Informed Consent Form**
*empty*
**Clinical Study Report**
*empty*
**Analytic Code**
*empty*
**Data Dictionary**
*empty*