

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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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Name of organization / entity

Kashan University of Medical Sciences

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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 questionnaire (CFQ)

6

Description

components of acceptance and commitment

Timepoint

Before intervention (baseline), after two month (post)

Method of measurement

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

Contact

Name of organization / entity

MS Research Center, Neuroscience Institute, Tehran University of Medical Sciences

Full name of responsible person

Dr. Abdorreza Naser Moghadasi

Position

MD, Neurologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Fax**Email****Web page address****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

Person responsible for updating data**Contact****Name of organization / entity**

Department of Clinical Psychology, Faculty of
Medicine, Kashan University of Medical Sciences,
Kasha

Full name of responsible person

Ali Gholami

Position

MSc

Other areas of specialty/work**Street address**