

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effectiveness of Mindfulness-Integrated Cognitive Behavior Therapy on executive function and psychological symptoms in patients with multiple sclerosis

#### Protocol summary

##### Summary

(1) Objectives: This study aims to determine the effectiveness of mindfulness-integrated cognitive behavior therapy on executive function and psychological symptoms in patients with multiple sclerosis in Shiraz. (2) Design: The general design of this study is experimental pre-test and post-test. (3) Setting and conduct: Fifty patients with MS who are eligible for inclusion and exclusion criteria are selected by convenient sampling and are randomly assigned in two groups (MICBT and UC). Participants of both groups fill out Trail Making Test (TMT), Cognitive Abilities Questionnaire and the Depression Anxiety and Stress Scale (DASS-21) as pre-test and post-test. The data will be analyzed by SPSS-18, using the Multivariate Analysis of Covariance (MANCOVA). (4) Participants including major eligibility criteria: Inclusion criteria are patients with the diagnosis of multiple sclerosis by a neurologist; aged 20-45 years; female and exclusion criteria are a history of substance abuse; a history of receiving psychological interventions during the past month. (5) Interventions: The intervention consists of 8 sessions (each session is 90 minutes) of mindfulness-integrated cognitive behavior therapy in conjunction with the routine pharmacotherapy of the disease for the experimental group while control group only receives the routine drug therapy. (6) Main outcome measures: Main outcome measures variables are executive function and psychological symptoms.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015041321722N1**

Registration date: **2015-06-15, 1394/03/25**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-06-15, 1394/03/25

##### Registrant information

###### Name

Shima Bahrani

###### Name of organization / entity

Kashan University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0021

###### Email address

bahrani-sh@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Kashan University of Medical Sciences

##### Expected recruitment start date

2015-11-01, 1394/08/10

##### Expected recruitment end date

2015-12-21, 1394/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of Mindfulness-Integrated Cognitive Behavior Therapy on executive function and psychological symptoms in patients with multiple sclerosis

**Public title**

The effect of mindfulness on executive function and psychological symptoms of multiple sclerosis patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Having been diagnosed as a multiple sclerosis patient by a neurologist; being under the care of a neurologist; having been diagnosed with multiple sclerosis for at least one year; EDSS $\leq$ 5/5; being a 20-45 year-old female with the minimum education level of diploma; being in the suppression level of the disease; having willingness to participate in the research. Exclusion criteria: A history of cognitive deficits (dementia, delirium, ...); a history of substance abuse; a history of psychotic disorders; a history of epilepsy or seizures within 6 months before the first meeting; a history of suicide; dependence on wheelchair; a history of hearing or speech problem; pregnancy or lactation period; a history of receiving psychological interventions during the past month; more than two sessions absence in the meetings.

**Age**

From **74 years** old to **49 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**

Ethics committee of Kashan University of Medical Sciences and Health Services

**Street address**

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran

**City**

Kashan

**Postal code**

8715988141

**Approval date**

2015-05-27, 1394/03/06

**Ethics committee reference number**

IR.KAUMS.REC.1394.20

**2****Ethics committee****Name of ethics committee**

Added at 2016-10-07: Shiraz University of Medical Sciences

**Street address**

Added at 2016-10-07: Central building, Shiraz university of medical sciences, Zand st

**City**

Added at 2016-10-07: Shiraz

**Postal code**

Added at 2016-10-07:

**Approval date**

2015-07-13, 1394/04/22

**Ethics committee reference number**

Added at 2016-10-07: IR.SUMS.REC.1394.64

**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**

Executive Function

**Timepoint**

Before intervention, After intervention

**Method of measurement**

Trail Making Test; Cognitive Abilities Questionnaire

**2****Description**

Psychological Psymptoms

**Timepoint**

Before intervention, After intervention

**Method of measurement**

Depression Anxiety Stress Scale-21

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: The MICBT (Mindfulness-Integrated Cognitive Behavior Therapy) method that is carried out in 8 sessions, once a week, each session lasts 90 minutes plus pharmacotherapy.

#### Category

Behavior

### 2

#### Description

Control group : Only pharmacotherapy

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fars MS Society

##### Full name of responsible person

Dr. Gholamali Yousefipour

##### Street address

No. 216, opposite to Mehr St., Ghasrdasht Ave., Shiraz, Iran

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

##### Full name of responsible person

Dr. Gholamali Hamidi

##### Street address

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

##### City

Kashan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services

#### 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

Kashan University of Medical Sciences and Health Services

##### Full name of responsible person

Shima Bahrani

##### Position

M.Sc Candidate in Clinical Psychology

##### Other areas of specialty/work

##### Street address

Department of Clinical Psychology, School of Medicine, Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

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##### Full name of responsible person

Fatemeh Zargar

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Assistant Professor in Clinical Psychology

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### 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*