

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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

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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

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Full name of responsible person

Shima Bahrani

Position

M.Sc Candidate in Clinical Psychology

Other areas of specialty/work

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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