Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Shima Bahrani
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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≤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
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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
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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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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

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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