

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The Study Effectiveness of Mindfulness integrated Cognitive Behavior Group Therapy on psychological symptoms in patients with Multiple Sclerosis

Protocol summary

Study aim

Determining the Effectiveness of Mindfulness integrated Cognitive Behavior Group Therapy with Mindfulness on Psychological Symptoms in Patients with Multiple Sclerosis

Design

Clinical trial with control ,group Double blind, randomized

Settings and conduct

Shafa hospital in Kerman

Participants/Inclusion and exclusion criteria

The main inclusion criterion:MS-type retardation-related disease with diagnosis of a neurologist The main inclusion criteria:Cause of other physical illnesses

Intervention groups

10 people receive cognitive-behavioral therapy integrated with mind-awareness, and 10 do not receive any treatment.

Main outcome variables

Depression, anxiety, sleep quality, fatigue, life expectancy

General information

Reason for update

Acronym

MiCBT

IRCT registration information

IRCT registration number: **IRCT20160103025817N4**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

Ali Akbar Parvizi Far

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 918 330 8692

Email address

aa.parvizif@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Study Effectiveness of Mindfulness integrated Cognitive Behavior Group Therapy on psychological symptoms in patients with Multiple Sclerosis

Public title

The Study Effectiveness of Mindfulness integrated Cognitive Behavior Group Therapy on patients with Multiple Sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Incidence of recurrent MS-type MS with diagnosis of

neurologist Confirmation of MS disease based on the results of diagnostic procedures (such as cerebrospinal fluid test, magnetic resonance imaging, MRI) Awareness of patients from MS in the last year The age range is between 50 to 18 years old Conscious and written consent for participation in the research Having at least a cycle education to complete questionnaires

Exclusion criteria:

affected by other physical illnesses affected by Psychosis and delusional states Existence of severe arousal (such as extreme anxiety or anger, impulsivity or uncontrollable restlessness) Patients who use psychotherapy during research.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

By simple randomized simple method, the individuals are assigned to the control and test group using the sealed envelope

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

Kermanshah University of Medical Sciences

Street address

Headquarter, Shahid Beheshti Blvd, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-02-14, 1396/11/25

Ethics committee reference number

KUMS.REC.1396.616

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

C81.18

ICD-10 code description

Nodular sclerosis classical Hodgkin lymphoma, lymph nodes of multiple sites

Primary outcomes

1

Description

Depression

Timepoint

First study,after the study,Follow up

Method of measurement

Beck Depression Inventory

2

Description

Anxiety

Timepoint

First study, after the study, follow up

Method of measurement

Beck Anxiety Inventory

3

Description

sleep quality

Timepoint

First study, after study, follow up

Method of measurement

Pittsburgh Sleep Quality Index

4

Description

Fatigue

Timepoint

First study, after study, follow up

Method of measurement

Fatigue Severity Scale

5

Description

Life expectancy

Timepoint

First study, after study, follow up

Method of measurement

Miller Life expectancy questionnaire

Secondary outcomes

1

Description

Quality of Life Score

Timepoint

First study, after study, follow up

Method of measurement

Beck Depression Inventory

2

Description

Life expectancy score

Timepoint

First study, after study, follow up

Method of measurement

Miller Life expectancy questionnaire

3

Description

Changing the cost of treatment

Timepoint

First study, after study, follow up

Method of measurement

Miller Life expectancy questionnaire

Intervention groups

1

Description

Intervention group: For eight consecutive two-hour sessions, Mindfulness integrated Cognitive Behavior Group Therapy .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital in Kerman

Full name of responsible person

DR Akram Farmanbar

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Kosar BLVD.Shafa Hospital in Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

farid najafi

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Grant name

Grant code / Reference number

دانشگاه علوم پزشکی کرمانشاه

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. AA. parvizifard

Position

phd counseling psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The participants are unclear

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available