Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity
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Iran (Islamic Republic of)
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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phd counseling 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