Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the Effectiveness of Mindfulness Based Cognitive Therapy (MBCT) and Short-Term Axis-based treatment as Therapeutic Supplements with Drug Therapy in Improving the Quality of Life in Multiple Sclerosis(MS) Patients

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Protocol summary

Study aim

Comparison the Effectiveness of Mindfulness Based Cognitive Therapy and Short-Term Axis-based treatment as Therapeutic Supplements with Drug Therapy in Improving the Quality of Life in Multiple Sclerosis Patients

Design

The present study is a semi-experimental study with pre-test and post-test with control group. The sample size in this study is 60 people, Each group has 20 subjects.

Settings and conduct

The statistical population of patients with multiple sclerosis is a recurrent type that will be referred to Mashhad's treatment centers in the second six months of 1396. The statistical sample will be selected from the statistical community in an accessible manner according to the criteria of entry, and then will be randomly assigned to the control and testing groups

Participants/Inclusion and exclusion criteria

Entry requirements : Diagnosis of Multiple Sclerosis . Age between18_50Year . Minimum Diploma Education . Being in the Phases of Relapsing Remiting . Conditions of failure to enter : Pass the stage of Relapsing Remiting . Taking psychedelic Drugs .

Intervention groups

A group based on knowledge-based cognitive therapy as well as another experimental group will be treated as a complementary treatment based on the short-term solution-based treatment, but the control group will have drug treatment, and all groups will respond to pre-test and post-test at the same time

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039785N1**
Registration date: **2019-02-02, 1397/11/13**
Registration timing: **retrospective**

Last update: **2019-02-02, 1397/11/13**
Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name

hamid afshar shandiz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3727 5753

Email address

mind200011@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2018-11-22, 1397/09/01

Trial completion date

empty

Scientific title

Comparison the Effectiveness of Mindfulness Based Cognitive Therapy (MBCT) and Short-Term Axis-based treatment as Therapeutic Supplements with Drug Therapy in Improving the Quality of Life in Multiple Sclerosis(MS) Patients

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Public title

Comparison the Effectiveness of Mindfulness Based Cognitive Therapy and Short-Term Axis-based treatment as Therapeutic Supplements with Drug Therapy in Improving the Quality of Life in Multiple Sclerosis Patients

._____

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Multiple Sclerosis. Age between18_50Year. Minimum Diploma Education. Being in the Phase of Relapsing Remiting

Exclusion criteria:

Pass the Stage of Relapsing Remiting Taking Psychedlic Drugs

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: **60**

Randomization (investigator's opinion)

Not 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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

.Mashhad University of Medical Sciences.University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.MUMS.REC.1397.027

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Quality of Life

Timepoint

The quality of life questionnaire is taken before the intervention and after the intervention, pre-test and post-test

Method of measurement

Measurement based on the scale of the questionnaire was used to quantify the quality of life of multiple sclerosis patients in 54 questions

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group receives mindfulness based cognitive therapy,which is for a period of 8 weeks, a weekly session of 2 hours. Intervention includes components such as internal experience, thoughts and mood, and external experiences and interactions with other people.It should be noted that the group is taking cinnovex drug .

Category

Behavior

2

Description
Intervention group: . The second intervention group receives a short-term axis-based treatment, which is for a period of 8 weeks, a weekly session of 2 hours. The intervention includes components such as positive seeing, no labeling, and having a referral capability.It should be noted that the group is taking cinnovex drug .

Category
Behavior

3

Description
Control group: . The third group is a control group that does not receive any intervention. It should be noted that the group is taking cinnovex drug .

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital in Mashhad

Full name of responsible person
Hamid afshar shandiz

Street address
Ghaem Hospital in Mashhad.Ahmadabad Street

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9176999311

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i_rahimian@semnan.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University, Faculty of Psychology and Educational Sciences

Full name of responsible person
Isaac Rahimian Booger

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Mahdish Shahr - Faculty of Psychology and Educational Science

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i_rahimian@semnan.ac.ir

Web page address
http://psy.semnan.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Semnan University, Faculty of Psychology and Educational 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
Semnan University - Faculty of Psychology and Educational Sciences

Full name of responsible person
ÎHamid Afshar Shandiz

Position
Phd Student

Latest degree
Master

Other areas of specialty/work
Psychology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Related data can share.
When the data will become available and for how long
Starting the access period from 1399
To whom data/document is available
Data will only be available to researchers working in academic institutions.
Under which criteria data/document could be used
Data is provided by researchers for statistical use and statistical analysis.
From where data/document is obtainable
Visit the Central Library of Ferdowsi University of Mashhad to receive data.
What processes are involved for a request to access data/document
Usually, the use of data is done in person and on the Internet.
Comments