

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

#### 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 between 18\_50 Year . 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

**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 between 18\_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

##### City

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##### Province

Razavi Khorasan

##### Postal code

9176999311

##### Phone

+98 51 3840 0000

##### Email

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

##### Street address

Mahdish Shahr - Faculty of Psychology and Educational Science

##### City

semnan

##### Province

Semnan

##### Postal code

3564111556

##### Phone

+98 23 3362 3300

##### Email

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

ĤHamid Afshar Shandiz

##### Position

Phd Student

##### Latest degree

Master

##### Other areas of specialty/work

Psychology

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No426.Tohid18.Tohid street

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9139786555

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mind200011@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

University of Semnan, Faculty of Psychology and Educational Sciences

##### Full name of responsible person

Hamid Afshar Shandiz

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Phd Student  
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Master  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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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