

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effectiveness of Mindfulness-Integrated Cognitive Behaviour Therapy and Schema Therapy on the Emotional States and the Quality of life of People with Multiple Sclerosis

#### Protocol summary

##### Study aim

Effectiveness of Mindfulness-Integrated Cognitive Behavior Therapy and Schema Therapy on the Emotional States (Depression, anxiety, stress) and the Quality of life of People with Multiple Sclerosis.

##### Design

The sample consisted of 45 patients with MS. At first, the sample of this study was considered for each group of 20. MiCBT intervention was applied based on the protocol developed by Cayon (2011) at nine sessions (2 hours) in , as well as ST was applied based on the protocol developed by Jeffrey Young (2003) at 12 sessions (2 hours), and no intervention was presented in the control group. These psychological interventions were considered as independent variables and emotional states, and quality of life of patients with ms as dependent variables.

##### Settings and conduct

at first, we referred to MS society of Kerman. MS patients were invited to participate in this intervention by calling and informing them in person. Then, among those who enrolled, some that had criteria to entry into the research were informed to be present at intervention. They were randomly assigned into two experimental groups: micbt, ST and one control group.

##### Participants/Inclusion and exclusion criteria

being patient based on Neurologist diagnosis no addiction Non-use of psychiatric medication simultaneously with the intervention Not using other psychological treatments simultaneously

##### Intervention groups

This study was applied on two experimental groups and one control group, each group was include of 20 people with multiple sclerosis. Psychological intervention was applied on two levels: level 1 MiCBT and Level 2, ST, and the control group did not receive any therapeutic intervention.

#### Main outcome variables

improving depression, anxiety and stress of MS patients  
Improving the quality of life of MS patients  
Evaluating the effectiveness of MiCBT and ST therapy on emotional states and quality of life in MS patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180922041082N2**  
Registration date: **2019-01-28, 1397/11/08**  
Registration timing: **retrospective**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

##### Registration date

2019-01-28, 1397/11/08

##### Registrant information

##### Name

Masoud Fazilat-Pour

##### Name of organization / entity

Shiraz University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3613 4670

##### Email address

fazilatm@uk.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-05, 1395/12/15

##### Expected recruitment end date

2017-04-09, 1396/01/20  
**Actual recruitment start date**  
2017-03-05, 1395/12/15  
**Actual recruitment end date**  
2017-04-09, 1396/01/20  
**Trial completion date**  
2017-07-21, 1396/04/30

### Scientific title

Effectiveness of Mindfulness-Integrated Cognitive Behaviour Therapy and Schema Therapy on the Emotional States and the Quality of life of People with Multiple Sclerosis

### Public title

Effectiveness of Mindfulness-Integrated Cognitive Behaviour Therapy and Schema Therapy on the Emotional States and the Quality of life of People with Multiple Sclerosis

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Being patient based on Neurologist diagnosis no addiction Non-use of psychiatric medication simultaneously with the intervention Not using other psychological treatments simultaneously with the intervention

#### Exclusion criteria:

Failure to perform treatment exercises Abandoned Over-Allowed

### Age

From **20 years** old to **50 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **55**

Actual sample size reached: **45**

### Randomization (investigator's opinion)

Randomized

### Randomization description

At first, referred to the Kerman province, ms patients were invited to attend in intervention. Then, among those who enrolled, they were randomly selected and drawn into two groups.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

The present research is a semi-experimental design with pre-test and post-test with the control group.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee, Department of Psychology, Shahid-Bahonar University, Kerman

##### Street address

Literature and Human Science department, Shahid Bahonar university, Research Square, Imam Khomeini highway

##### City

Kerman

##### Province

Kerman

##### Postal code

7616914111

#### Approval date

2017-03-05, 1395/12/15

#### Ethics committee reference number

E.A.95.12.22-02

## Health conditions studied

### 1

#### Description of health condition studied

Multiple sclerosis

#### ICD-10 code

G35

#### ICD-10 code description

Multiple sclerosis

### 2

#### Description of health condition studied

Emotional states (depression, anxiety, stress)

#### ICD-10 code

R45

#### ICD-10 code description

Symptoms and signs involving emotional state

## Primary outcomes

### 1

#### Description

Emotional states that include depression, anxiety and stress are measured by the scale of depression, anxiety and stress (DASS-21). And they can be mild, moderate, and severe.

#### Timepoint

The emotional states were measured once before the intervention in the first session (pre-test) and one time at the end of the intervention in the final session (post-test).

#### Method of measurement

The DASS-21 scale was used to measure emotional states, which has 21 questions with Likert scale and has a good validity and reliability.

## 2

### **Description**

Quality of life of MS patients measured by MS-QOL scale. And the 3 overall scales includes physical health, health and quality of life.

### **Timepoint**

The Quality of life was measured once before the intervention in the first session (pre-test) and one time at the end of the intervention in the final session (post-test).

### **Method of measurement**

The quality of life of MS patients was measured by MS-QOL scale, which is specific to assessing the quality of life of these patients. This scale has 54 questions for assessing 14 areas related to physical health and mental health, and its validity and reliability are confirmed by studies.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Mindfulness integrated cognitive behavioral therapy (MICBT) in 8 sessions based on Cayon protocol.

#### **Category**

Behavior

### 2

#### **Description**

Intervention group: Group Schema Consulting Group in 12 sessions based on the Yang Protocol (2003)

#### **Category**

Behavior

### 3

#### **Description**

Control group: no treatment has been applied

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Samen Al-Hojaj charity

##### **Full name of responsible person**

Hossein Nakhai Abdul Abadi

##### **Street address**

the end of Shahid Rajaei avenue

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www.kmu\_nrc@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kerman University of Medical Sciences

##### **Full name of responsible person**

Hossein Ali Ebrahimi

##### **Street address**

Kosar Blv

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۷۶۱۸۷۵۱۱۵۱

##### **Phone**

+98 34 3211 5780

##### **Email**

kmu\_nrc@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Kerman University of Medical Sciences

#### **Proportion provided by this source**

50

#### **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**

Shaid Bahonar University

##### **Full name of responsible person**

Masoud Fazilat pour

##### **Position**

Associat professor

##### **Latest degree**

Ph.D.  
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psychology  
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## Person responsible for scientific inquiries

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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

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

### Title and more details about the data/document

the data are collected anonymously

### When the data will become available and for how long

in case of request the data are available anonymous

### To whom data/document is available

the further researchers with credible studies from reputable constitutions

### Under which criteria data/document could be used

researchers with credible studies from reputable constitutions

### From where data/document is obtainable

after the article got published

### What processes are involved for a request to access data/document

contact with the corresponding author

### Comments