Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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(2hours), 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 Rajaee avenue

City
Kerman

Province
Kerman

Postal code
7619875994

Phone
+98 34 3271 2001

Email
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

City
Kerman

Province
Kerman

Postal code
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.

Other areas of specialty/work
psychology

Street address
Imam Khomeini Blv

City
کرمان

Province
Kerman

Postal code
7616914111

Phone
+98 34 3132 2393

Email
fazilatm@uk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Bahonar university

Full name of responsible person
Masoud Fazilatpour

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
psychology

Street address
Imam Khomeini Highway, Pajoohesh Sq., Shahid Bahonar University, Kerman

City
Kerman

Province
Kerman

Postal code
7616913439

Phone
+98 34332571415

Email
Fazilatm@uk.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Bahonar university

Full name of responsible person
Masoud Fazilatpour

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
psychology

Street address
Imam Khomeini Highway, Pajoohesh Sq., Shahid Bahonar University, Kerman

City
Kerman

Province
Kerman

Postal code
7616913439

Phone
+98 34332571415

Email
Fazilatm@ul.ac.ir

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