

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of compassion focused acceptance and commitment therapy on psychological flexibility and psychological distress in patients with multiple sclerosis

Protocol summary

Study aim

The purpose of this research is evaluation of the effectiveness of compassion focused acceptance and commitment therapy on psychological flexibility and psychological distress in patients with multiple sclerosis.

Design

The design of this study will be a randomized controlled clinical trial or a pretest-posttest-follow-up design with a control group. Participants will be randomly assigned to the intervention group (n= 16) and the control group (n=16). In this non-blind study, lottery will be used for randomization.

Settings and conduct

Therapeutic sessions will be held at the Faculty of Rehabilitation, Ahvaz Jundishapur University of Medical Sciences. The experimental group and the control group will respond to the research tools in the pre-test phase. Upon completion of the intervention for the experimental group, all sample subjects (experimental group and control group) will be tested in one posttest session and participants will be re-evaluated for follow-up 2 months after posttest.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Being residence in Ahvaz, Getting a score between 0 and 5 on the Expanded Disability Status Scale, Inclination to participate in the psychological intervention sessions, The diagnosis of the disease by a neurologist. Exclusion criteria are: Use of psychiatric and psychotropic drugs, Simultaneous participation in other psychological therapies, Three absences in treatment sessions.

Intervention groups

The experimental group will receive 10 sessions of 90 minutes of compassion-focused acceptance and commitment therapy (The ACT practitioner's guide to the science of compassion : tools for fostering psychological flexibility) twice a week. The control group does not

receive any Psychological intervention. Both groups receive routine drug treatment for MS

Main outcome variables

Psychological flexibility; Psychological distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210101049903N1**

Registration date: **2021-11-23, 1400/09/02**

Registration timing: **retrospective**

Last update: **2021-11-23, 1400/09/02**

Update count: **0**

Registration date

2021-11-23, 1400/09/02

Registrant information

Name

Reza Mansouri Koryani

Name of organization / entity

Shahid Chamran University of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 84 2439 3006

Email address

rmansouri.psychology@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-04, 1398/06/13

Expected recruitment end date

2019-10-05, 1398/07/13

Actual recruitment start date

2019-09-04, 1398/06/13

Actual recruitment end date

2019-10-05, 1398/07/13

Trial completion date

2020-03-17, 1398/12/27

Scientific title

The effectiveness of compassion focused acceptance and commitment therapy on psychological flexibility and psychological distress in patients with multiple sclerosis

Public title

The effectiveness of compassion focused acceptance and commitment therapy in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being residence in Ahvaz Being in the age range of 18 to 52 With at least a diploma degree Getting a score between 0 and 5 on the Expanded Disability Status Scale (EDSS) Inclination to participate in the psychological intervention sessions The diagnosis of the disease by a neurologist

Exclusion criteria:

Use of psychiatric and psychotropic drugs Simultaneous participation in other psychological therapies Three absences in treatment sessions.

AgeFrom **18 years** old to **52 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **32**Actual sample size reached: **32****Randomization (investigator's opinion)**

Randomized

Randomization description

A simple randomization method was used, so that first the names of the subjects were listed and each one was assigned a number from 1 to 32, then we put the numbers in a box and started removing the numbers from the box. The first 16 issues were assigned to the experimental group and the remaining 16 issues were assigned to the control group.

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**

Shahid Chamran University of Ahvaz

Street address

Golestan Boulevard, Shahid Chamran University of Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

،اهواز، بلوار گلستان

Approval date

2019-06-13, 1398/03/23

Ethics committee reference number

EE/98.24.3.58272 /scu.ac.ir

Health conditions studied**1****Description of health condition studied**

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple Sclerosis

Primary outcomes**1****Description**

Psychological flexibility

Timepoint

Before the intervention, After the intervention, 2 months later(follow-up)

Method of measurement

Open and Engaged State Questionnaire(OESQ)

2**Description**

Psychological Distress

Timepoint

Before the intervention, After the intervention, 2 months later(follow-up)

Method of measurement

Depression Anxiety Stress Scale (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: compassion focused acceptance and commitment therapy+ routine drug treatment for MS

Category

Behavior

2

Description

Control group: routine drug treatment for MS

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Khuzestan MS Society

Full name of responsible person

Nastaran Majdi Nasab

Street address

Ahvaz-Golestan Hospital-Faculty of Rehabilitation

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Khuzestan

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6135733133

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golestanhospital@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Chamran University of Ahvaz

Full name of responsible person

Soodabeh Bassak Nejad

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Golestan Boulevard, Shahid Chamran University of Ahvaz

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Email

Public@scu.ac.ir

Web page address

<https://scu.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Chamran University of Ahvaz

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

Shahid Chamran University of Ahvaz

Full name of responsible person

Soodabeh Bassak Nejad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Chamran University of Ahvaz

Full name of responsible person

Reza Mansouri Koryani

Position

Masters student

Latest degree

Master

Other areas of specialty/work

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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

All potential data can be shared after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Any kind of analysis on the delivered data is allowed

From where data/document is obtainable

Reza Mansouri Koryani
rmansouri.psychology@gmail.com

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

Sending an email is enough In the shortest possible time, maximum within a week

Comments