Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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.
Age
From **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
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Chamran University of Ahvaz
Full name of responsible person
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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
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Position
Associate professor
Latest degree
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Other areas of specialty/work
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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
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