

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The Effectiveness of Acceptance and Commitment Therapy on Chronic Fatigue Syndrome and Pain Perception in People with Multiple Sclerosis

Protocol summary

Study aim

The purpose of this study was the effectiveness of acceptance and commitment therapy on Chronic Fatigue Syndrome and Pain Perception in people with multiple sclerosis.

Design

Treatment interventions were performed according to a model adapted from a six-point protocol for chronic Brassington pain in the form of 120-minute sessions, once a week for the experimental group, and the control group did not receive the therapeutic intervention.

Settings and conduct

MS forum in Ahvaz city

Participants/Inclusion and exclusion criteria

Entry criteria (having a history of illness for more than three years, a diagnosis of mild MS, and obtaining a minimum score of 40 in the fatigue measurement questionnaire) and exit criteria (no addiction, cancer, epilepsy, renal failure, heart disease, and major psychological problems such as psychosis)

Intervention groups

Two groups of patients with MS who received acceptance and commitment treatment were applied to one group and the other group did not receive any treatment.

Main outcome variables

Chronic Fatigue Syndrome and Pain Perception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181124041742N1**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **retrospective**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

Registration date

2019-04-28, 1398/02/08

Registrant information

Name

Leila Shameli

Name of organization / entity

Salman Farsi University of Kazeroun

Country

Iran (Islamic Republic of)

Phone

+98 71 4222 6050

Email address

dr.shameli@kazerunsfu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-15, 1397/03/25

Actual recruitment start date

2018-05-05, 1397/02/15

Actual recruitment end date

2018-06-20, 1397/03/30

Trial completion date

2018-08-21, 1397/05/30

Scientific title

The Effectiveness of Acceptance and Commitment Therapy on Chronic Fatigue Syndrome and Pain Perception in People with Multiple Sclerosis

Public title

"Effect of Acceptance and Commitment Treatment in MS Patients"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a history of MS for more than three years Having a diagnosis of mild grade of MS Obtaining a minimum score of 40 in the fatigue measurement questionnaire

Exclusion criteria:

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
By simple random sampling based on the lottery, intervention group received a treatment course and the control group did not receive any treatment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The intervention group received the course of treatment, but the control group did not receive any treatment during the study, and after finishing the study, the control group received a course of treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Biomedical Research of Islamic Azad University, Kazerun Branch

Street address

5 km of Kazeroun-Bushehr road

City

Kazerun

Province

Fars

Postal code

7319846451

Approval date

2019-03-07, 1397/12/16

Ethics committee reference number

IR.IAU.KAU.REC.1397.029

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis (MS)

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Chronic Fatigue Syndrome and Pain Perception

Timepoint

summer

Method of measurement

Fatigue Severity Scale (FSS) and McGill Pain Questionnaire (MGPQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with multiple sclerosis that receiving an acceptance and commitment treatment course in 6 sessions of 120 minutes and once a week.

Category

Treatment - Other

2

Description

Control group: Patients with multiple sclerosis disorder did not receive any treatment interventions during the 6-week period of the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

MS Forum of Ahvaz city

Full name of responsible person

Dr Nastaran Majdinasab

Street address

Jondishapur University of Medical Sciences, Faculty of Rehabilitation

City

Ahvaz

Province

Khouzestan

Postal code

6136954669

Phone

+98 61 3374 3660

Email

Ms.Ahvaz.counseling@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Salman Farsi University of Kazerun

Full name of responsible person

Aboozar Khosravi

Street address

Cross Culture, University of St. Taleghani

City

Kazerun

Province

Fars

Postal code

73196-73544

Phone

+98 71 4222 6050

Email

Lshameli29@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Salman Farsi University of Kazerun

Proportion provided by this source

40

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

Salman Farsi University of Kazerun

Full name of responsible person

Leila Shameli

Position

Assistant Professor of university

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Full name of responsible person

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Person responsible for updating data

Contact

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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

The Effectiveness of Acceptance and Commitment
Therapy on Chronic Fatigue Syndrome and Pain
Perception in People with Multiple Sclerosis

When the data will become available and for how long

2019

To whom data/document is available

public

Under which criteria data/document could be used

scientific journal

From where data/document is obtainable

finding of scientific journal

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

Refer to printed journal

Comments