

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of mindfulness-based cognitive therapy(MBCT) and acceptance and commitment therapy(ACT) on improving self-efficacy, self-esteem and quality of life in patients with focal epilepsy

Protocol summary

Study aim

Determining the effect of MBCT and acceptance and commitment therapy (ACT) on increasing self-efficacy, self esteem, improving the quality of life of patients with focal epilepsy and comparing the effect of the two above-mentioned treatments

Design

Sample available for 36 people

Settings and conduct

Coordination with predicted centers, satisfaction, inclusion of patients randomly in two groups of experimental and control groups of Achievements in three levels of self-efficacy of patients with epilepsy (ESE), Cooper Smith's self-esteem and Ware and Sherborne's quality of life - 31 questions Specified for patients with epilepsy (QOLIE-31) as a pretest, then intervention and cognitive-mindedness-based cognitive therapy (MBCT) in a test group for 8 sessions of 2 hours, intervention and acceptance and commitment therapy (ACT) in the other group Experiments for 6 to 8 sessions, then again, all three groups will be tested and evaluated with three scales, to ensure the effectiveness of the intervention methods

Participants/Inclusion and exclusion criteria

All patients with focal epilepsy living in East Azarbaijan who referred to medical centers from the beginning of 1397 to the end of September 1398 Entry criteria: Diagnosis of focal epilepsy by a specialist physician, aged 18 to 30 years, written consent of the patient or his or her family. Exit criteria: Patient or family request, trauma and brain lesions, other severe physical illnesses, other severe psychiatric disorders, absences in more than two sessions of treatment

Intervention groups

The experimental group 1 (ACT intervention), the experimental group 2 (MBCT intervention) and group 3 (control)

Main outcome variables

Improve self-esteem, self-efficacy, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190205042634N1**

Registration date: **2019-02-24, 1397/12/05**

Registration timing: **prospective**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

mohammad mohammadpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3669 4279

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mmpour2009@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of mindfulness-based cognitive therapy(MBCT) and acceptance and commitment therapy(ACT) on improving self-efficacy, self-esteem and quality of life in patients with focal epilepsy

Public title
Comparison of the effect of mindfulness-based cognitive therapy(MBCT) and acceptance and commitment therapy(ACT) on epilepsy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of focal epilepsy by specialist physician age 18 to 30 years of patients written consent of the patient or his or her family
Exclusion criteria:
 Lack of readiness of the patient or his or her family
 Trauma and brain lesions Other severe physical illnesses
 Excessive psychiatric disorders Failure to continue the treatment session

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly and simply assigned to each individual and using the lottery containing the titles of the three groups (1,2 and 3) in both the experimental and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In order to ensure the effectiveness of interventions and improve the quality of life and control the relative symptoms of the disease, the test group will be re-evaluated at a follow-up period of about three months.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Central Headquarter of University, Bassij Blvd

City

semnan

Province

Semnan

Postal code

3514799422

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.SEMUMS.REC.1397.237

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

The quality of life scores obtained by the subjects in the Ver-Sherborne Quality of Life Questionnaire (SF-36), the self-efficacy scores obtained by the subjects on the self-efficacy scale of patients with epilepsy (ESE), and the self-esteem score that subjects were given in the Dignity Inventory Breathe coprasmith

Timepoint

Before the intervention, after the intervention and three months after the intervention in the follow up period

Method of measurement

ware and Sherbourne Quality of Life Questionnaire (SF-36) for Quality of Life, Self-Efficacy Scale for Epilepsy Patients (ESE), to assess self-efficacy and Cooper smith's self-esteem questionnaire for assessing self-esteem

Secondary outcomes

1

Description

Reduce the frequency of seizure attacks

Timepoint

Three months after the intervention

Method of measurement

Intervention groups

1

Description

Acceptance and Commitment therapy (ACT) and meetings that will be conducted in 8 consecutive weeks in accordance to protocol for 8 consecutive 90-minute sessions.

Category

Treatment - Other

2

Description

Mindfulness-based cognitive therapy and the use of techniques that the experimental group No 2, the eighth consecutive session and in accordance with the protocol in question will receive 8 weeks.

Category

Treatment - Other

3

Description

Control group:

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital in Tabriz

Full name of responsible person

Dr. <Ghasem khazan

Street address

Shahid Bakeri Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Seyf A ... Saadoddin

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences

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

2

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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Semnan University of Medical Sciences

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

mmpour2009@gmail.com

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

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Mohammadpour

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Psychology

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Email**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 original outcome data can be shared

When the data will become available and for how long

The start of the access period will be from the beginning of 2020

To whom data/document is available

Data will only be available to researchers working in academic and academic institutions

Under which criteria data/document could be used

For statistical purposes, statistical analysis is available to researchers

From where data/document is obtainable

Refer to Tabriz Central Library Department to receive data

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

The use of data is available In person and on-line
Comments