

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effectiveness of Acceptance and Commitment Therapy(ACT) on Mental Health,Death Anxiety,Quality of Life and Alpha and Beta Brain Waves in Generalized Epilepsy

#### Protocol summary

##### Study aim

1-Determine the effectiveness of acceptance and commitment treatment on general health in Generalized epilepsy based on demographic variables) Education, gender, age, job) 2- Determine the effectiveness of acceptance and commitment treatment on death anxiety in Generalized epilepsy based on demographic variables) Education, gender, age, job) 3- Determine the effectiveness of acceptance and commitment treatment on quality of life in Generalized epilepsy based on demographic variables) Education, gender, age, job) 4- Determine the effectiveness of acceptance and commitment treatment on alpha brain wave in Generalized epilepsy based on demographic variables) Education, gender, age, job) 5- Determine the effectiveness of acceptance and commitment treatment on beta brain wave in Generalized epilepsy based on demographic variables) Education, gender, age, job)

##### Design

A clinical trial with group control and with one-side blind and with non-specific randomized with a sample size of 24 subjects in both experimental and control groups

##### Settings and conduct

In this scheme , which is carried out at the Shafa Hospital epilepsy center , a psychological method is performed collectively on epileptic patients, aimed at psychological improvement as well as changes in the brain A and B

##### Participants/Inclusion and exclusion criteria

1)Patients at the Epilepsy Home of Shafa Hospital in Kerman 2)Generalized epilepsy without psychological problems

##### Intervention groups

One of the treatments that relate to the third generation of treatments is acceptance and commitment therapy (ACT). Third-generation therapies do not attempt to change one's cognition, and the main focus of treatment is to focus on improving the psychological relationship of

an individual with his thoughts and feelings

##### Main outcome variables

Improve the participants psychological dimension

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190619043944N1**

Registration date: **2019-12-01, 1398/09/10**

Registration timing: **retrospective**

Last update: **2019-12-01, 1398/09/10**

Update count: **0**

##### Registration date

2019-12-01, 1398/09/10

##### Registrant information

##### Name

Amirhossein Mahmoodi meymand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3251 0696

##### Email address

kmu.nrc@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-21, 1398/03/31

##### Expected recruitment end date

2019-07-15, 1398/04/24

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of Acceptance and Commitment Therapy(ACT) on Mental Health,Death Anxiety,Quality of Life and Alpha and Beta Brain Waves in Generalized Epilepsy

**Public title**

The Effectiveness of Acceptance and Commitment Therapy(ACT) on psychological problems in Generalized Epilepsy

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The benchmark for entering this treatment is have generalized epilepsy Having psychological problems mentioned age top of 18 and under 70

**Exclusion criteria:**

have Mental retardation Having a mental disorder according to medical records or any item that may interfere with learning There is a history of drug abuse or drug dependence

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Blinding is used in this method of the first type, and the research is one-side blind, and we don't say to patients that they are in which groups study, and it is not necessary to tell patients how many groups in the This study is there.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

use a psychological method on neurology groups patients

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Kerman University of Medical Sciences,Deputy of Research and Technology,Neurology Research Center

**Street address**

22 Alley, Shafa Bolivard, Kowsar Square, Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

7618759639

**Approval date**

2019-10-21, 1398/07/29

**Ethics committee reference number**

IR.KMU.REC.1398.389

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

Generalized Epilepsy

**ICD-10 code**

G40.4

**ICD-10 code description**

Other generalized epilepsy and epileptic syndromes

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

Grade of general health in GHQ-28 questionnaire

**Timepoint**

At two section pre-test and post-test intervals that are within three months

**Method of measurement**

With GHQ-28 questionnaire

**2****Description**

Grade of Quality of Life especially for Epilepsy QOLIF-31-P questionnaire

**Timepoint**

At two section pre-test and post-test intervals that are within three months

**Method of measurement**

Quality of Life questionnaire especially for Epilepsy QOLIF-31-P

**3****Description**

Grade of Templer death anxiety questionnaire

**Timepoint**

At two section pre-test and post-test intervals that are

within three months

**Method of measurement**

Templer's death anxiety questionnaire

**4****Description**

Brain's alpha wavelength

**Timepoint**

At two section pre-test and post-test intervals that are within three months

**Method of measurement**

Electroencephalogram

**5****Description**

Brain's Beta wavelength

**Timepoint**

At two section pre-test and post-test intervals that are within three months

**Method of measurement**

Electroencephalogram

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: We perform pre-test and post-test before the treatment and then we perform a psychological treatment on our intervention group, which includes 12 sessions of treatment.

**Category**

Treatment - Other

**2****Description**

Control group: Here we have 12 people who have pre-test and post-tests, but there is no intervention to compare with the experimental group

**Category**

Diagnosis

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Neurology Research Center, Kerman University of Medical Sciences

**Full name of responsible person**

Hosseinali Ebrahimi Meymand

**Street address**

No.22,Shafa Street ,Kosar Blvd

**City**

Kerman

**Province**

Kerman

**Postal code**

۷۶۱۸۷۵۱۱۵۱

**Phone**

+98 34 3212 4727

**Email**

research\_office@kmu.ac.ir

**Web page address**

http://kmu.ac.ir/fa/nrc

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences,Deputy of Research and Technology,Neurology Research Center

**Full name of responsible person**

Hosseinali Ebrahimi Meymand

**Street address**

No.22.Alley,Shafa Street ,Kosar Blvd

**City**

Kerman

**Province**

Kerman

**Postal code**

۷۶۱۸۷۵۱۱۵۱

**Phone**

+98 34 3212 4727

**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,Deputy of Research and Technology,Neurology Research Center

**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**

Kerman University of Medical Sciences

**Full name of responsible person**

Amirhossein Mahmoodi Meymand

**Position**

Master of arts student

**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No.102,alley.10.North Abozar Street,Kerman  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7617874834  
**Phone**  
+34 32510696  
**Email**  
amirhosseinmahmoodi1995@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Amirhossein Mahmoodi Meymand  
**Position**  
Student master art  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No.102,Alley.10, North Abozar Street,Kerman  
**City**  
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**Province**  
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7617874834  
**Phone**  
+98 34 3251 0696  
**Fax**  
**Email**  
kmu.nrc@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Amirhossein Mahmoodi Meymand  
**Position**  
Master of arts student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No.102,Alley.10, North Abozar Street,Kerman  
**City**  
Kerman

**Province**  
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**Phone**  
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**Fax**  
**Email**  
kmu.nrc@gmail.com

## 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

Undecided - It is not yet known if there will be 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 data obtained from the questionnaires and the Electroencephalogram(EEG) each have a score that only the individual's score in the primary variables with its secondary variables is published and does not refer to the identity of the individual.

### When the data will become available and for how long

The onset of the date of access to the information is 6 months after the complete treatment and publication of the results.

### To whom data/document is available

Only those who are in the field of neuroscience and neurological diseases as well as educational centers in these fields and academic fields as well as those who want to complete this plan have the right to receive data and information.

### Under which criteria data/document could be used

Researchers in the field of epilepsy and aspects affecting this neurological disease, all psychologists who seek a change in the brain wave of these individuals through with psychological approach.

### From where data/document is obtainable

Neurosurgical Center at Shafa Hospital, Kerman  
Center of Epilepsy, Referring to neuroscience website.

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

After 6 months of the complete process of treatment, if the person requesting the information was among the people who could provide information to him, by asking questions about the impact of this information on the scientific study process or raising his level of knowledge, Its provided to him/her,By consulting with another person who contributing in this schema .

### Comments

