Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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 Effectivenss 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 dont 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
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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
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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
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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
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, Kerm صan 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