Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

The effects of mindfulness-based cognitive therapy on promoting medication adherence among patient with epilepsy: an application of social media intervention

Protocol summary

Study aim

Determining the effectiveness of mindfulness based cognitive-behavioral therapy on promoting medication adherence among patient with epilepsy

Design

This research is a prospective cluster randomized controlled trial and It is a single blind with parallel groups.256 patients are selected from 4 neurology clinics by simple randomization method. People receive a special code and then will be randomly divided into intervention and control groups.

Settings and conduct

This study will conduct among 4 neurology clinics in Qazvin.The study sample is patients with epilepsy who are referred to neurology clinics for routine examinations by physicians.Randomization will be performed at a center level. Randomization and allocation will be performed by an independent statistician who is blinded to participants' clinical histories.

Participants/Inclusion and exclusion criteria

Inclusion criteria: confirmed diagnosis of epilepsy in patients by a physician specializing in neurology; age of 18 years or older; prescribing antiepileptic drugs. Exclusion criteria: suffering from progressive neurological disease; diagnosis of an intellectual disability.

Intervention groups

The content of the 4 sessions of mindfulness training is sent to the participants weekly and online through social networks. The content will be an online version of the face-to-face eight-week mindfulness course in Mindfulness-Based Stress Reduction program (MBSR). Patients are provided with information about the etiology, prognosis of epilepsy, as well as antiepileptic drugs. Also the group mindfulness training sessions will lead by a licensed clinical psychologist who have 5 years of experience in teaching mindfulness meditation.

Main outcome variables

The Medication Adherence Report; Mindful Attention Awareness

General information

Reason for update

Complete all variables related to the study outcomes that will be measured.

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042140N2**
Registration date: **2020-07-03, 1399/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-23, 1400/01/03**
Update count: **3**

Registration date

2020-07-03, 1399/04/13

Registrant information

Name

sara fazelirooshande

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of mindfulness-based cognitive therapy on promoting medication adherence among patient with epilepsy: an application of social media intervention

Public title

Investigating the intervention of mindfulness on on promoting medication adherence among patient with epilepsy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

A confirmed diagnosis of epilepsy in patients by a physician specializing in neurology An age of 18 years or older Prescribing antiepileptic drugs Being responsible for taking the medicine by oneself or an independent person

Exclusion criteria:

Suffering from progressive neurological disease Do not prescribed antiepileptic drugs Diagnosis of an intellectual disability Having a major cognitive impairment

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **256**

Randomization (investigator's opinion)

Randomized

Randomization description

Regarding the stratified block ranomization in this study, it is stated that the randomization is performed in 4 neurology clinics. Two groups are selected from each of these centers, one for the intervention group and the other for the control group. Of these 128 are in the intervention group and 128 are in the control group. Randomization is done using software, and after the groups are identified, the code for the intervention group and control group is placed in the envelope and the envelopes are numbered. This is determined by whether the patient is in the intervention group or the control group, after he or she visits the center and receives the envelope and sees the content inside.

Blinding (investigator's opinion)

Single blinded

Blinding description

Randomization will be performed at a center level. Neurology clinics will randomly allocate (1:1) in intervention and treatment as usual groups. Randomization and allocation will be performed by an independent statistician who is blinded to participants' clinical histories.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of the National Institute for Medical Research Development in Sciences

Street address

No.21, Besat Ave., Western Fatemi Ave.

City

Tehran

Province

Tehran

Postal code

1419693111

Approval date

2019-12-06, 1398/09/15

Ethics committee reference number

IR.NIMAD.REC.1399.008

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40.1

ICD-10 code description

Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures

Primary outcomes

1

Description

The medication adherence score

Timepoint

Immediately after the intervention and 6 months after the intervention

Method of measurement

The Medication Adherence Report Scale(MARS)

2

Description

Mindful Attention Awareness score

Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Mindful Attention Awareness Scale(MAAS)

Secondary outcomes

1

Description
Severity of a patient's seizures score
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Liverpool Seizure Severity Scale(LSSS)

2

Description
Quality of life in epilepsy score
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Health-related quality of life

3

Description
Perceived behavioral control questions
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Perceived behavioral control(PBC)

4

Description
Anxiety and depression score
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Hospital Anxiety and Depression Scale (HADS)

5

Description
Patient's beliefs about medication
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Beliefs about Medications Questionnaire (BMQ)

6

Description
Intention to adhere to medication
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Behavioral intention Questions

7

Description
Self-monitoring by the patient in taking his medications
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Self-monitoring questions

8

Description
Plan for time, place, how to take medicine
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Questions about Action planning

9

Description
Predicting drug use barriers and creating strategies to overcome those barriers
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Questions about Coping planning

10

Description
Investigation of automatic drug use by patients with epilepsy
Timepoint
Immediately after the intervention and 6 months after the intervention
Method of measurement
Self-Report Behavioural Automaticity Index (SRBAI)

Intervention groups

1

Description
Intervention group: It will be the first trial targeting medication adherence through an online mindfulness intervention.Each week, the intervention group will receive an email from the primary researcher to inform them that a class has uploaded to the social media group to be completed at a time that suited them and would be accessible for one week.It will be 4 sessions of online psychoeducation in the treatment as usual group. At the sessions, the patients will give information about the aetiology, symptoms, and prognosis of epilepsy, as well as antiepileptic drug, and their possible side effects.

Each patient member is also provided with information about the importance of medication adherence and the risks of discontinuing the medication. An online booklet providing information about epilepsy and possible drug treatments will be provided for the patients.Patients with epilepsy will randomly assig into two groups 1) intervention and 2) treatment as usual. All participants will complete measurements at baseline (before randomization) and post intervention and six months after completing the intervention.

Category
Behavior

2

Description
Control group: They receive their medications as usual.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Boali clinic

Full name of responsible person
Mahdi Nikobakht

Street address
Ferdowsi Cross.,Ferdowsi Ave

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Recruitment center

Name of recruitment center
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Full name of responsible person
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3

Recruitment center

Name of recruitment center
Velayat clinic

Full name of responsible person
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4

Recruitment center

Name of recruitment center
Shahid Rajaei clinic

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Institute for Medical Research Development

Full name of responsible person
National Institute for Medical Research Development

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Email
NIMAD@RESEARCH.AC.IR

Grant name
Bridging Grant Call

Grant code / Reference number
987827
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Development
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
Qazvin University of Medical Sciences
Full name of responsible person
Amir Pakpour
Position
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Latest degree
Ph.D.
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)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available