Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of a Program based on Emotional Intelligence components on Coping Strategies and Happiness in Epileptic Patients

Protocol summary

Study aim
If the Program is Effective, an Educational Program Based on Emotional Intelligence can be presented as a Scientific and Simple way to promote Coping Strategies and Happiness in Epileptic Patients

Design
Randomized clinical trials, two parallel groups and three-step

Settings and conduct
The training will be conducted in the classroom at Masih Epilepsy Specialty Clinic. The questioner is collecting demographic data and completing questionnaires, and unaware about type of intervention on the units under study, this is done to blind the study to the questioner. The researcher will not be aware of the information obtained from the research units by the questioner during the study.

Participants/Inclusion and exclusion criteria
Have a medical record with diagnosis of hypertensive epilepsy and have been at least 6 months since the onset of their illness; Able to communicate; Aware of their illness and are interested in participating in the study; Having the physical and mental ability to participate in the study; aged 18-60; Lack of cognitive impairment and no other mental or physical illness; Having the ability to read and write; Not participating in other psychotherapy programs during the study; Lack of drug and psychotropic drugs; Lack of pregnancy; possibility of using Sorush's program; No major stress for the person; Unwillingness to continue studying; Absence in two sessions; Make any physical or psychological damage

Intervention groups
Teaching Emotional Intelligence in 8 sessions of 90 minutes over a period of 8 weeks (one session each week) in groups of 17-18 with a tutorial on the subject of each session and delivery of homework at the next session. For the control group, 2 training sessions will be held on the subject of epilepsy and its challenges

Main outcome variables
Effect of a program based on emotional intelligence on coping strategies and happiness in epileptic patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180612040077N1**
Registration date: **2018-08-01, 1397/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-01, 1397/05/10**
Update count: **0**

Registration date
2018-08-01, 1397/05/10

Registrant information

Name
Niloufar Hajisabbagh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3661 6759

Email address
n.hajisabbagh@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-11, 1397/03/21

Expected recruitment end date
2018-08-11, 1397/05/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of a Program based on Emotional Intelligence components on Coping Strategies and Happiness in Epileptic Patients

Public title

Investigating Emotional Intelligence in Epilepsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients at this Center have a Medical Record with Diagnosis of Grandmal Epilepsy and at least six months have passed since the onset of their Illness Able to Communicate They are aware of their Illness and are Interested in Participating in the Study Having the Physical and Mental Ability to Participate in the Study Patients are Selected from People aged 18 to 60 years The Absence of Cognitive Impairments and the Absence of other Mental or Physical Illnesses confirmed by the Physician and according to the Medical Records of the People under Study Having the Ability to Read and Write Not Participating in other Psychotherapy Programs during the Study No Drug Addiction and Psychotropic Substance Lack of Pregnancy Power and Possibility of Using the Sorosh Program No major Stress for the Person during the last month or during the Session

Exclusion criteria:

Unwillingness to Continue to Participate in the Study The Absence of a Patient in two Consecutive Sessions of Interventional Training Sessions for any Reason Make any Physical or Psychological Damage to the People who are not Able to Attend the Meetings

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The Researcher referred to the Epilepsy Society in Consecutive days and will list the Volunteers who come to the Society with Acceptable Criteria for entering the Research. Substitution of the Samples in the Groups will then be done Randomly using the Lottery Method and each Sample will be Divided into the Control and Test Groups at the time of entering the study 1: 1. In this way, the number of 35 Cards on which the Test Word and the 35 Cards on which the Control Word written on them will be cast in a box. Each of the Samples will be asked to Select one of the Cards Randomly. Then, People with a Test Card will be Placed in the Test Group and those with a Control Card will be placed in the Control Group. It should be Noted that all Cards are the Same Size.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this Research, the Questioner was asked to collect Demographic Data and complete Questionnaires in both Groups before Intervention, Immediately after the Intervention and one month after the Intervention. The Questioner is unaware of the research units that this is done in order to Blind the Study to the Questioner. The Researcher will not be aware of the Information obtained from the Research units by the Questioner during the Study.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jirib Ave, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.MUI.REC.1396.3.138

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
Coping Strategies
Timepoint
Before, Immediately, One month after the intervention
Method of measurement
Andler & Parker Coping Strategies Questionnaire

2

Description
Happiness
Timepoint
Before, Immediately, One month after the intervention
Method of measurement
Oxford Happiness Test Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention in the experimental group was implemented as Emotional Intelligence Training Program in 8 sessions of 90 minutes over a period of 8 weeks (one session per week) in groups of 17-18, using lecture, group discussion, presentation Movies and slideshows and role plays will be held in the classroom. The content of the sessions is the same for all groups and all study groups provide an educational pamphlet based on the subject of each session, and they are asked to practice the homework daily until the next session, and at the beginning of the next meeting, the discussions will be held.In addition, the researcher for the coordination of the timely presence of the research units and the presentation of the subject of each session beforehand and the possibility of asking and discussing the course during the training process, a group will be created in the Sorosh program and the units of the study group will addes into the group. It also continually monitors and controls the interval between sessions to ensure that the exercises are carried out.
Category
Rehabilitation

2

Description
Control group: in order to eliminate the possible effects of the presence of individuals in a group, 2 training sessions will be held on the topic of epilepsy and its challenges, without reference to the emotional intelligence component.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Masih Epilepsy Specialty Clinic
Full name of responsible person
Dr. Masoud Etemadifar
Street address
Next to Masjed al-Mousaum, After alley 119, Keshavarz Blvd, Suhrawardi Intersection, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8177795137
Phone
+98 31 3777 1572
Fax
+98 31 3777 1572
Email
isfahan_epilepsy@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fariba Taleghani
Street address
Isfahan, Azadi Square, Hezar Jirib St., Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7565
Fax
+98 31 3669 9398
Email
m.fereidooni@nm.mui.ac.ir
Web page address
http://nm.mui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Niloufar Hajisabbagh

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Third Floor, Diba Complex, Shahid Amini Nezhad Street, Sheikh Sadoogh Shomali Ave, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8167719986

Phone

+98 31 3661 6759

Email

niloufar.hajisabbagh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Malek Fereidooni Moghadam

Position

Faculty Member of Isfahan University of Medical Sciences, Ph.D.

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Psychiatric Nursing Department, Nursing and Midwifery Faculty, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 7586

Fax

Email

m.fereidooni@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Niloufar Hajisabbagh

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Third Floor, Diba Complex, Shahid Amini Nezhad Street, Sheikh Sadoogh Shomali Ave, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8167719986

Phone

+98 31 3661 6759

Email

niloufar.hajisabbagh@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

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

Tez

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to influence the care and treatment

From where data/document is obtainable

Niloufar Hajisabbagh, niloufar.hajisabbagh@gmail.com

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

SMS or Email

Comments