

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The impact of family empowerment model on life quality of children with epilepsy in selected centers of Shiraz and Kerman universities of medical sciences, 2018

Protocol summary

Study aim

This study aims to conduct the family empowerment program.

Design

The participants will be divided into two groups via permuted block randomization. Then, groups A and B will be assigned to intervention and control groups, respectively. The two groups will be required to fill out the QOLCE questionnaire in the first session.

Settings and conduct

A total of 80 parents who have children with epilepsy referred to Besat Clinic in Kerman and Imam Reza Clinic in Shiraz will be selected purposely according to the inclusion criteria of the research. After obtaining their written informed consent forms for taking part in the study, they will be randomly allocated to intervention (n=40) and control (n=40) groups.

Participants/Inclusion and exclusion criteria

Parents who have children of 3-7 years old suffering from epilepsy with passage of at least six months from disease diagnosis and treatment onset who have to be followed up for at least a year according to their physicians' diagnoses and medical records, willingness to participate in the study, signing written informed consent forms to take part in the research, having diploma to Bachelor's degrees, having sufficient monthly income, not having participated in similar educational programs, not suffering from physical and mental disorders disturbing their daily living activities, and not working in health and treatment fields.

Intervention groups

The intervention program and the empowerment of parents in the test group will include two training sessions. Considering ethics, the control group parents will receive the educational pamphlets after completing the questionnaire.

Main outcome variables

Conducting the family empowerment program will result in responsibility, more efficient interaction with the treatment team, better response to treatment, and reduction of treatment costs, length of hospital stay, and disease complications.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160618028524N3**

Registration date: **2018-11-26, 1397/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-26, 1397/09/05**

Update count: **0**

Registration date

2018-11-26, 1397/09/05

Registrant information

Name

Hamid Nemati

Name of organization / entity

Child Neurologist, Assistant Professor of Shiraz University of Medical Sciences, Shiraz, Iran

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-26, 1397/09/05

Expected recruitment end date

2019-02-14, 1397/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of family empowerment model on life quality of children with epilepsy in selected centers of Shiraz and Kerman universities of medical sciences, 2018

Public title

The impact of family empowerment model on life quality of children with epilepsy in selected centers of Shiraz and Kerman universities of medical sciences, 2018

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents of children aged 3-7 years with epilepsy who have 6 months of diagnosis and initiation of treatment, and according to the doctor's records and diagnosis, need to go and follow up for at least one year. Acquiring informed consent and willingness to participate in research by parents Having Diploma education to bachelor's degree and enough monthly income Not participating in the same educational program The absence of physical and psychological disruption of daily activities Parents are not personnel and health care providers

Exclusion criteria:

Parents of children hospitalized with febrile of convulsion

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done via permuted block randomization. In doing so, a digit will be randomly selected among random numbers and then, 40 blocks with block size of two will be chosen successively as follows: AB (4-0) and BA (9-5). After that, groups A and B will be allocated to intervention and control groups, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic's committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, opposite Felestine St. Zand St. Shiraz, Fars

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Shiraz

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Postal code

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Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR-SUMS.REC.1397.565

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

The family empowerment

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The main outcome measures of this study are executing the family empowerment program and enhancing the life quality of children suffering from epilepsy. The data will be collected using the Quality of Life in Children with Epilepsy (QOLCE) questionnaire, which is a specific instrument for assessing such children's quality of life. This instrument has been derived from Health-Related Quality of Life (HRQoL) questionnaire, which is used to evaluate healthcare and medical interventions in both clinical and social domains.

Timepoint

The QOLCE questionnaire will be completed by the two groups in the first session. The intervention group will receive the family empowerment program over two educational sessions. In the first session, the parents will be trained regarding the process, clinical symptoms, diagnosis, and probable complications of the disease through question and answer and educational pamphlets. The second session will involve face-to-face training during seizure, available treatments, recovery process after treatment, and necessity for long-term follow-ups. The training will be carried out both

individually and in groups using educational pamphlets. After a month, the questionnaire will be completed by the parents again. Considering ethics, the control group parents will receive the educational pamphlets after completing the questionnaire.

Method of measurement

The data will be collected using the QOLCE questionnaire, which is a specific instrument for assessing quality of life in children suffering from epilepsy. This instrument has been derived from HRQoL questionnaire, which is used to evaluate healthcare and medical interventions in both clinical and social domains. Children with seizure disorders are normally faced with an increased risk of behavioral and emotional problems, familial and social decline, and lower quality of life. QOLCE evaluates such children's quality of life in four dimensions, namely cognitive function (22 items), emotional function (17 items), social function (7 items), and physical function (9 items). The items are responded via a 5-point Likert scale. Accordingly, scores 0, 25, 50, 75, and 100 represent very low, low, average, high, and very high functions, respectively. The reliability of QOLCE was approved by Goodwin et al. in 2015.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group includes the parents who have children with epilepsy, meet the inclusion criteria, and are willing to participate in the research. In the first session, the parents will be required to complete the QOLCE questionnaire. The family empowerment intervention is carried out through two educational sessions. In the first session, the parents will be trained regarding the process, clinical symptoms, diagnosis, and probable complications of the disease through question and answer and educational pamphlets. The second session will involve face-to-face training during seizure, available treatments, recovery process after treatment, and necessity for long-term follow-ups. The training will be carried out both individually and in groups using educational pamphlets. After a month, the questionnaire will be completed by the parents again.

Category

Lifestyle

2

Description

Control group: After selecting the control group participants, they will be required to complete the QOLCE questionnaire in the first session. Considering ethics, the control group parents will receive the educational pamphlets after completing the questionnaire. After a month, the questionnaire will be completed by the parents again.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Clinic, Namazi Hospital, Dastghieb Hospital

Full name of responsible person

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Shiraz 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
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Full name of responsible person
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Faculty member

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Master

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Web page address

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

A large proportion of the data, including the information related to the main outcome measure, will be shared after the end of the study.

When the data will become available and for how long

After the end of the study

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Researchers in academic and scientific institutions can use the present study results for their scientific and research works after gaining permission from the authors.

From where data/document is obtainable

meshham5@gmail.com zahra.mahdavi@iauk.ac.ir

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

Researchers in academic and scientific institutions can use the present study results for their scientific and research works after gaining permission from the authors.

Comments