Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of group psychoeducational program on caregiverburden and quality of life for families of children & adolescents with epilepsy admitted to selected centers of Isfahan University of Medical Sciences in 2017 – 2018

Protocol summary

Summary

The present study aims to investigate the ways to improve the care and quality of life among families of the children and adolescents suffering from epilepsy. This study is a two-group, three-stage, and one-blind clinical trial. In this study, 70 family caregivers of children & adolescents with epilepsy who met the inclusion criteria are selected via simple sampling. The samples are randomly assigned to two groups of test and control. Having a member with epilepsy and the ability to attend training sessions were the most important criteria for entering this study. If, for any reason, caregivers have more than two absences in the sessions, they will be eliminated. (If, for any reason, the caregiver misses more than one meeting of the training sessions, he/she will be eliminated). Data collection was done by the Zarit Care Weight Questionnaires and World Health Organization Quality of Life Questionnaire (WHOQOL-BREF). They were completed by the two groups in three steps of before, immediately after and one month after the intervention. By comparing the results obtained from this study, we can determine the effect of group psychosocial training on care burden and quality of life of the caregivers and, in case of being positive, to be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080335483N1**
Registration date: **2017-09-15, 1396/06/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

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Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group psychoeducational program on caregiverburden and quality of life for families of children & adolescents with epilepsy admitted to selected centers of Isfahan University of Medical Sciences in 2017 – 2018

Public title

The effect of group psychoeducational program on

caregiverburden and quality of life for families of children & adolescents with epilepsy

Purpose

Supportive

Inclusion/Exclusion criteria

Entry criterion: Family care is considered as the main caregiving agent of the patient and they have a great deal of responsibility. In each family, the one who is the main caregiver, attends the study; he or she must not be drug-addicted and not to be treated with psychosocial drugs. The must not have participated in family education meetings. (any other researcher project in this field); there must be only one chronic caregiver in the family; must not have psychosocial problems that may cause the disease to develop; they must have at least one year of patient care; patients must be aged 6-18 years, the caregiver age is over 18 and under 65 years old. Exclusion criteria: there are physical and psychological problems that cannot continue to participate in the study; they have irregular participation in the sessions (having more than two absences).

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University Of Medical Sciences

Street address

College of Nursing and Midwifery, Isfahan University Of Medical Sciences, Hezar Jarib, Isfahan, Iran

City

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8174673461

Approval date

2017-05-17, 1396/02/27

Ethics committee reference number

IR.MUI.REC.3.052

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy

Primary outcomes

1

Description

Caregiver burden

Timepoint

Before, immediately after and one months after the intervention

Method of measurement

zarit burden Questionnaire

Secondary outcomes

1

Description

quality of life

Timepoint

Before, immediately after and one month after the intervention

Method of measurement

WHOQOL-BREF instrument

Intervention groups

1

Description

The researcher of his intervention program, which is a supportive educational tool, performs in 8 (90-minute) sessions for family members of children and adolescents with epilepsy who are eligible

Category

N/A

2

Description

the control group will participate in 3 sessions that organized by fellow researcher, and they will discuss and share their experiences

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Zeinab Balouchi
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Ayatollah Kashani Hospital, Ayatollah Kashani st.
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2

Recruitment center
Name of recruitment center
Imam Hossein Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Ashraf Kazemi
Street address
Isfahan University of Medical Sciences, Hezar Jereb St.
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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
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty