

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effect of family-centered care on the family caregivers' burden, stress, anxiety and depression of epilepsy patients .

#### Protocol summary

##### Summary

The aim of study was to investigate the effect of family-centered care burden, stress, anxiety and depression in caregivers of patients with epilepsy is eligible after selecting samples (n = 100) and easy conditions for obtaining the informed consent from caregivers, initially based their pretest Inventory burden of care and stress, anxiety and depression DOS will come into action. Afterwards, the random allocation of samples (table of random numbers) to experimental and control groups to participate in family-centered care program (common time executive include: (i) the perceived threat, the second: self-promotion through Problem Solving Group, the third : increased self-esteem through educational partnership and (iv) process evaluation and final evaluation using a questionnaire immediately after and two months after intervention) in Hospital of Ayatollah Kashani invited incorporation. Researcher after the intervention, the control group caregivers, are invited to participate in training sessions and shall manual and training CD delivered to them and their blogs are designed to introduce. The program for the experimental group during the 4 sessions of 2 hours with caregivers and with a constant research team includes neurologist, researcher and done. Each training session presentation and discussion about the experiences of caregivers and care-related problems raised by caregivers, will be held. This care program and give PowerPoint presentations and use the manual, training CD and blog designed for rest. The burden of care variables, caregivers is stress, anxiety and depression. Of the conditions of entry and literacy and the age of consent was 18.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016050212452N3**

Registration date: **2017-01-07, 1395/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-01-07, 1395/10/18

##### Registrant information

###### Name

Shahram Etemadifar

###### Name of organization / entity

Isfahan University of Medical Sciences, Faculty of Nursing and Midwifery

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2969

###### Email address

etemadifar@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shahrekord University of Medical Sciences

##### Expected recruitment start date

2016-07-02, 1395/04/12

##### Expected recruitment end date

2016-08-20, 1395/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of family-centered care on the family caregivers' burden, stress, anxiety and depression of epilepsy patients .

**Public title**

Effectiveness of care plan on problems caregivers of patients with epilepsy.

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: According to patient, their family or carer as caregivers and bear a lot of responsibility of patients. Age over 18 (and caregivers of patients) years. Be able to communicate and participate in all training sessions. Is not involved in the family training sessions (any other research project) earlier. According to medical records are not known history of severe physical illness and mental disorder. No other patient care at the same time. Lack of crisis or major stress during the past year. patients have Grand Mal epilepsy type. Caregiver care of patient at least 3 hours daily. Exclusion criteria: Carers are not willing to continue to participate in the study. Other disease during the study, which followed patients require extra care needs. Those are who care for patients who have other diseases in addition to epilepsy, neuromuscular spinal cord injuries, head injuries decreased level of consciousness, mental retardation and visual cognitive disorders, alcoholism and drug abuse, former multiple strokes, mentally ill. Stressful events occurring during the intervention for caregivers. Serious physical disease

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

Randomized with a random numbers table

**Secondary Ids**

empty

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

Ethics committee of shahrekord University of Medical Sciences

**Street address**

Shahr e Kord. Kashani Ave.

**City**

shahrekord

**Postal code****Approval date**

2016-11-24, 1395/09/04

**Ethics committee reference number**

R.skums.REC.46.2125

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

epilepsy

**ICD-10 code**

g41.0

**ICD-10 code description**

Grand mal status epilepticus Tonic-clonic status epilepticus Excl.: epilepsia partialis continua [Kozhevnikof] (G40.5)

**Primary outcomes****1****Description**

Burden of care

**Timepoint**

Before, immediately after and two months after intervention

**Method of measurement**

Persian and standardized questionnaire Zaryt

**2****Description**

Stress

**Timepoint**

Before, immediately after and two months after intervention

**Method of measurement**

A standard questionnaire was summarized and Persian DOS (Form 21 questions

**3****Description**

Anxiety

**Timepoint**

Before, immediately after and two months after intervention

**Method of measurement**

A standard questionnaire was summarized and Persian DOS (Form 21 questions

**4****Description**

depration

**Timepoint**

Before, immediately after and two months after intervention

#### Method of measurement

A standard questionnaire was summarized and Persian DOS (Form 21 questions

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Group test: the implementation of family-centered care program (first step: the perceived threat Step two: self-efficacy Upgrade Step Three: Self-Esteem Step Four: Evaluation) of caregivers of patients with epilepsy for four meeting two-hour , issues related to epilepsy, causes epilepsy, treatment, emergency of epilepsy,role of caregiver, sources of support, educational package includes a manual and CD, is provided by a steady group of neurologist doctors and nurses and psychiatric nursing. Before and after and two months after the intervention was completed questionnaires

##### Category

Other

#### 2

##### Description

Control group: no intervention on control group . questionnaires (before, after and two months after the intervention on intervention groups) are completed.

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Ayatollah Kashani shahrekord Hospital/Neurological ward

###### Full name of responsible person

maryam heidari soureshjani

###### Street address

shahrekord

###### City

shahrekord

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice chancellor for research,Shahrekord University of Medical Sciences

###### Full name of responsible person

Doctor Shahram Etemadifar

###### Street address

Street Kashani

###### City

Shahrekord

###### Grant name

###### Grant code / Reference number

###### Is the source of funding the same sponsor organization/entity?

Yes

###### Title of funding source

Vice chancellor for research,Shahrekord 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

##### Contact

###### Name of organization / entity

shahrekord University of Medical Sciences

###### Full name of responsible person

maryam heidari soureshjani

###### Position

Nursing Graduate Student

###### Other areas of specialty/work

###### Street address

shahrekord Street Kashani

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### Person responsible for scientific inquiries

##### Contact

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University of Medical Sciences shahrekord

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###### Position

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Nursing Graduate Student

**Other areas of specialty/work****Street address**

Shahr e Kord

**City**

Shahr e Kord

**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*