

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 questionnairesr

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

City

shahrekord

Postal code

Phone

+98 383335654

Fax

Email

heidari93_m@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Medical Sciences shahrekord

Full name of responsible person

shahram eatamadifar

Position

nursing PH .D

Other areas of specialty/work

Street address

University of Medical Sciences

City
University of Medical Sciences Shahr e Kord
Postal code
Phone
+98 383335654
Fax
Email
sh_etemadifar@yahoo.com
Web page address

Postal code
Phone
+98 38 3344 7394
Fax
Email
heidari93_m@yahoo.com
Web page address

Sharing plan

Person responsible for updating data

Contact
Name of organization / entity
University of Medical Sciences
Full name of responsible person
maryam heidari
Position
Nursing Graduate Student
Other areas of specialty/work
Street address
Shahr e Kord
City
Shahr e Kord

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