

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Survey the effect of "Creating Opportunities for Parents Empowerment" Program on anxiety and depression of parents of children with epilepsy and other Chronic Neurological conditions with epileptic attacks

Protocol summary

Summary

This is a quasi-experimental research. Research samples include 64 mothers of children with epilepsy and other chronic neurological conditions with epileptic attack selected by the gradual sampling method and placed in control and experimental groups. At first, control group will be select and receives usual care. Then, the experimental group will be select and receives "Creating Opportunities for Parents Empowerment" Program. The first Phase of the C.O.P.E program begins within 24 hours of admission of child in the hospital and included written and audio information regarding children's expected responses to illness and how caregivers can facilitate the child's adjustment to the experiences associated with the hospitalization. The second Phase of the C.O.P.E intervention consists of a call, 3 days after discharge from the hospital to reinforce information provided during first phase. At this phase, the control group also receives a call about their satisfaction with hospitalization and discharge processes. The third Phase of the C.O.P.E intervention will be four weeks after the discharge, including present a parent-child activity workbook which teaches mothers how to use play to help the child to cope with medical procedures and hospitalization. The questionnaires will be completed in three phase, before intervention, one week after discharge from hospital and eight weeks after discharge. Expected outcomes will be reduce the anxiety and depression of parents of children with epilepsy and other chronic neurological conditions with epileptic attack under C.O.P.E intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017110712990N9**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Minoo Mitra Cherhzad

Name of organization / entity

Guilan University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology, Guilan University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of "Creating Opportunities for Parents Empowerment" Program on anxiety and depression of parents of children with epilepsy and other Chronic Neurological conditions with epileptic attacks

Public title

The effect of "Creating Opportunities for Parents Empowerment" Program on anxiety and depression of parents of children with epilepsy and other chronic neurological conditions with epileptic attacks

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: mothers of children between 3 and 12 years old with epilepsy and other chronic neurological condition, tendency to participate in the study, doesn't work in health system, absence of a special incident that affects mother's mode such as death of relatives or a financial crisis, ability to read and complete the questionnaire, daily care of the child and telephone access. Exclusion criteria: Disinclination to continuation at each stage of the research, training related to empowerment programs in other way, use of psychological drugs.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Samples of the control and experimental groups will be homogenized in some personal characteristics such as mother's age, marital status, mother's education and family's income.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences Ethics Committee

Street address

Opposite the 17 Shahrivar Hospital. Shahid Siadati Street, Namjoo Street

City

Rasht

Postal code

4193893345

Approval date

2017-11-04, 1396/08/13

Ethics committee reference number

IR.GUMS.REC.1396.302

Health conditions studied

1

Description of health condition studied

anxiety and depression on parents of children with epilepsy and other chronic neurologic conditions

ICD-10 code

F41.9, F3

ICD-10 code description

Mental and behavioural disorders

Primary outcomes

1

Description

anxiety

Timepoint

Before intervention, one week after discharge from hospital, eight weeks after discharge from hospital

Method of measurement

Speilberger state-trait anxiety inventory

2

Description

depression

Timepoint

Before intervention, one week after discharge from hospital, eight weeks after discharge from hospital

Method of measurement

Beck Depression Inventory II (BDI-II)

Secondary outcomes

empty

Intervention groups

1

Description

The experiment group receives "Creating Opportunities for Parents Empowerment" Program in three phases. The first Phase of the C.O.P.E intervention begins in the first 24 hours of admission (written and audio information), second Phase of the COPE intervention, one week after the discharge (telephone call) and The third Phase of the C.O.P.E intervention, four weeks after the discharge

(child-parent work book).

Category

Behavior

2

Description

The control group receives usual care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

17 Shahrivar pediatric Educational and therapeutic Center

Full name of responsible person

Maryam Jahri Sheijani

Street address

Navab Safavi Street, Golsar Square

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Guilan University of Medical Sciences

Full name of responsible person

Doctor Shadman Nemati

Street address

Opposite the 17 Shahrivar Hospital. Shahid Siadati Street, Namjoo Street

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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

Deputy of Research and Technology, Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Maryam Jahri Sheijani

Position

Bachelor's Degree in Nursing / Nurse

Other areas of specialty/work

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Person responsible for updating data

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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