Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of the implemention of the care program on the continuous care model on activities of daily living and sleep quality of patients with epilepsy

Protocol summary

Study aim

General purpose: Determining the impact of the implementation of a care program based on the continuous care model on daily life activities and sleep quality of patients with epilepsy referred to Shahrekord medical centers in 1401-1402

Design

The clinical trial has two intervention and control groups, randomized and conducted on 62 patients.

Settings and conduct

Patients with grand mal epilepsy referred to Shahrekord medical centers affiliated to Shahrekord University of Medical Sciences were allocated to intervention and control groups by sampling method based on the purpose of selection and then by card selection method. In this study, the follow-up care model in patients with epilepsy is performed according to the following steps: The first stage is familiarization, which is to express the goals and explain the stages of the model to get to know the nurse, the patient and his family. The second stage is sensitization, which emphasizes the need for follow-up and continuity of care and its non-interruption, the third stage is follow-up and control, which follows how to continue care in order to improve health, the fourth stage is evaluation, which we check to what extent it meets the goals. We have achieved care and the effect of the trainings is carried out. During the intervention, only routine interventions are provided to the control group.

Participants/Inclusion and exclusion criteria

1- The diagnosis of grand mal epilepsy in patients based on clinical symptoms, the results of abnormal electroencephalogram (EEG) waves and the doctor's diagnosis. 2- The age range of patients is over 18 years old (58). 3-Having normal hearing, vision and mental strength to enable him to communicate.

Intervention groups

In this study, interventions are performed based on the continuous care model, which has four stages.

Main outcome variables

Activities of daily living and Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221220056879N1**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **retrospective**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Hamidreza Amirhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 041 7981

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

2023-05-22, 1402/03/01

Actual recruitment end date

2023-08-23, 1402/06/01

Trial completion date

empty

Scientific title

The effect of the implemention of the care program on the continuous care model on activities of daily living and sleep quality of patients with epilepsy

Public title

The effect of the implemention of the care program on the continuous care model on activities of daily living and sleep quality of patients with epilepsy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The diagnosis of grand mal epilepsy in patients based on clinical symptoms, the results of abnormal electroencephalogram (EEG) waves and the doctor's diagnosis. The age range of patients is over 18 years old. Having normal hearing, vision and mental strength to enable him to communicate. To have the ability and literacy to read and write.

Exclusion criteria:

patients who do not want to continue attending the study for any reason. Creating an acute and serious illness, problem or stress that somehow prevents them from continuing interventions during the intervention period. Absent more than one session in training sessions. Incompletely filling out questionnaires.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with grand mal epilepsy referred to Shahrekord medical centers affiliated to Shahrekord University of Medical Sciences are allocated to intervention and control groups by sampling method based on the purpose of selection and then by card selection method. In this way, 31 cards related to the intervention group and 31 cards related to the control group are placed in the envelope, and then the clients are asked to randomly pick one of them, and in this way, the client is assigned to the group listed on the card.

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

Ethics committee of Shahrekord University of Medical Sciences

Street address

No.55 , Salmane farsi Ave., Farhangian 3 Faz., Shahid rafiee pour street

City

Ramhormoz

Province

Khouzestan

Postal code

6381675178

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.SKUMS.REC.1401.213

Health conditions studied

1

Description of health condition studied

Epilepsy

ICD-10 code

G40.3

ICD-10 code description

Generalized idiopathic epilepsy and epileptic syndromes

Primary outcomes

1

Description

Score of activities of daily living in Barthel questionnaire

Timepoint

The score of activities of daily living in patients with epilepsy before, immediately and two months after the intervention.

Method of measurement

Questionnaire (score 0 to 100)

2

Description

Sleep quality score in the Petersburg questionnaire

Timepoint

Sleep quality score in patients with epilepsy before, immediately and two months after the intervention

Method of measurement

Questionnaire (score 0 to 21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Demographic data questionnaire, Persian version of Barthel's daily life activities questionnaire and Petersburg Sleep Quality Questionnaire (PSQI) whose validity and reliability have been proven in Iran are completed by both groups and the intervention work For the group, the test begins, which takes place in four steps, including familiarization, sensitization, follow-up, and evaluation, and is carried out for eight weeks. The content of the training program takes place in five sessions. Familiarization and sensitization stages are carried out for three weeks and control and evaluation stages for five weeks. Questionnaires are completed by the intervention group before, immediately after and two months after the intervention.

Category

Lifestyle

2

Description

Control group: they only receive routine training in the first phase of familiarization, and this includes how to deal with the patient and his family in an emergency when a seizure attack occurs, and questionnaires in the three phases before, immediately after the intervention and two months after The intervention is completed by the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital in Shahrekord

Full name of responsible person

Hamidreza Amirhosseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Raeesi

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Hamidreza Amirhosseini

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The release of raw data has no logical justification except for a data bank suitable for analysis.
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not 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
Part of the data, such as the information related to the main outcome, can be shared.
When the data will become available and for how long
The access starts 6 months after the results are printed.
To whom data/document is available
All researchers have permission to access the data.
Under which criteria data/document could be used
The data will be entered in SPSS version 19 statistical software and will be analyzed using descriptive and analytical statistical tests.
From where data/document is obtainable
Gmail address 1: h.r.amirhosseini@gmail.com Phone number: 09389411200 Hamidreza Amirhosseini Gmail address 2: shdavodvand@gmail.com Phone number: 09132313986 Shirmohammad davodvand
What processes are involved for a request to access data/document
1_ The applicant should apply 2_ Refer to the university's proposal and permits 3_ If we are allowed to release the documents, ask for his email address and phone number 4_ We will hand over the documents to him with an undertaking that he will not use the documents unethically.
Comments