

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of educational intervention based Adult Learning Theory- with and without telephone follow up by nurse(telenursing) on self-management in adult with Epilepsy

Protocol summary

Summary

This Randomized Controlled Trial (RCT) was conducted to compare the effectiveness of educational intervention based on Adult Learning Theory with and without telephone follow up by nurse (Telenursing) on self-management in adult with Epilepsy. Epileptic patients who had 18 years old and older and met other inclusion criteria from Isfahan Society of Epilepsy were recruited. 120 adults with epilepsy were recruited then were randomly assigned to the 3 groups: 1) Those in the education group received a four-session education based on Adult Learning Theory, 2) Those in the education & Telephone follow up group received a four-session education based on Adult Learning Theory plus 6-session telephone follow up by nurse, and 3) Those in the control group received no intervention. Education sessions based on the principle of Adult Learning Theory were held for groups 1 and 2 (1-hour once per week for 4 consecutive weeks). After the training sessions, nurses called with the participants in the second group in the certain intervals (total 6 phone contacts). For all participants, the Epilepsy Self-Management Scale and demographic information at the baseline and 4 months after by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121511758N1**

Registration date: **2013-01-05, 1391/10/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-05, 1391/10/16

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Tehran University of Medical Science

Expected recruitment start date

2012-07-29, 1391/05/08

Expected recruitment end date

2012-08-29, 1391/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of educational intervention based Adult Learning Theory- with and without telephone follow up by nurse(telenursing) on self-management in adult with Epilepsy

Public title

Comparison effectiveness of education and telenursing on self-management in adult with Epilepsy

Purpose

Supportive

Inclusion/Exclusion criteria

Individuals were eligible if they had been diagnosed of epilepsy by a neurologist, diagnosed with epilepsy for at least 6 months; were receiving antiepileptic drugs (AEDs); were 18 years old and elder ; were able to understand and speak Persian ; had a telephone (or access to one).Residents in Isfahan and its surrounding. Exclusion criteria: Unwilling to participate in Clinical Trial Hospitalized for any reason during the training sessions Non participate in any of education session (in education and education plus telephone follow up groups) - No answer to 2 or more phone contacts(in education plus telephone follow up group)

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Science

Street address

Tehran University of Medical Science, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-07-29, 1391/05/08

Ethics committee reference number

1008/130/91/ص

Health conditions studied

1

Description of health condition studied

Localization-related (focal)(partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset

ICD-10 code

G40.0

ICD-10 code description

Incl.: Benign childhood epilepsy with centrotemporal EEG spikes- Childhood epilepsy with occipital EEG paroxysms

2

Description of health condition studied

Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures

ICD-10 code

G40.1

ICD-10 code description

Incl.: Attacks without alteration of consciousness- Simple partial seizures developing into secondarily generalized seizures

3

Description of health condition studied

Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures

ICD-10 code

G40.2

ICD-10 code description

Incl.: Attacks with alteration of consciousness, often with automatisms- Complex partial seizures developing into secondarily generalized seizures

4

Description of health condition studied

Generalized idiopathic epilepsy and epileptic syndromes

ICD-10 code

G40.3

ICD-10 code description

Incl.:Benign: myoclonic epilepsy in infancy- neonatal convulsions (familial)- Childhood absence epilepsy [pyknolepsy]- Epilepsy with grand mal seizures on awakening- Juvenile: absence epilepsy- myoclonic epilepsy [impulsive petit mal]- Nonspecific epilept

5

Description of health condition studied

Other generalized epilepsy and epileptic syndromes

ICD-10 code

G40.4

ICD-10 code description

Incl.:Epilepsy with: myoclonic absences- myoclonic-astatic seizures- Infantile spasms- Lennox-Gastaut syndrome-Salaam attacks- Symptomatic early myoclonic encephalopathy- West syndrome

6

Description of health condition studied

Special epileptic syndromes

ICD-10 code

G40.5

ICD-10 code description

Incl.: Epilepsia partialis continua [Kozhevnikof]- Epileptic seizures related to: alcohol, drugs, hormonal changes, sleep deprivation, stress

7

Description of health condition studied

Grand mal seizures, unspecified (with or without petit mal)

ICD-10 code

G40.6

ICD-10 code description

8

Description of health condition studied

Petit mal, unspecified, without grand mal seizures

ICD-10 code

G40.7

ICD-10 code description

9

Description of health condition studied

Other epilepsy

ICD-10 code

G40.8

ICD-10 code description

Incl.: Epilepsies and epileptic syndromes undetermined as to whether they are focal or generalized

10

Description of health condition studied

Epilepsy, unspecified

ICD-10 code

G40.9

ICD-10 code description

Incl.: Epileptic: convulsions NOS- fits NOS- seizures NOS

Primary outcomes

1

Description

Epilepsy self-management

Timepoint

At baseline - 4months after

Method of measurement

Epilepsy Self-Management Scale(ESMS)

Secondary outcomes

1

Description

Age

Timepoint

At baseline

Method of measurement

Demographic information

2

Description

Gender

Timepoint

At baseline

Method of measurement

Demographic information

3

Description

Education level

Timepoint

At baseline

Method of measurement

Demographic information

4

Description

Marital status

Timepoint

At baseline

Method of measurement

Demographic information

5

Description

Occupation

Timepoint

At baseline

Method of measurement

Demographic information

6

Description

Economic status

Timepoint

At baseline

Method of measurement

Demographic information

7

Description

Insurance

Timepoint

At baseline

Method of measurement

Demographic information

8

Description

Duration of disease

Timepoint

At baseline

Method of measurement

Demographic information

9

Description

Type of seizure

Timepoint

At baseline

Method of measurement

Demographic information

10

Description

Number of Antiepileptic Drugs

Timepoint

At baseline

Method of measurement

Demographic information

11

Description

Frequency of seizure

Timepoint

At baseline

Method of measurement

Demographic information

12

Description

Other disease

Timepoint

At baseline

Method of measurement

Demographic information

Intervention groups

1

Description

Education based on Adult Learning Theory - The education program was developed to be delivered in a group discussion for approximately 10–12 individuals, meeting for a 1-hour once per week for 4 consecutive .The curriculum included a mixture of psychosocial and medical information topics framed in the self-management activities.The overriding theme of self-management was built into all sessions, session materials, and session discussions. For example, meeting 1 focused on information management, Topics that were discussed in detail focused on definition of epilepsy, type of seizure, diagnosis and treatment. Other discussed topic was medication management (such as maintaining blood levels of medications, side effects, drug toxicity identification), seizure triggers and life style management, including sleep, exercise, stress, smoking and other risky behaviors, safety management, psychosocial factors such as depression, stigma, occupation, marriage, social interaction and etc. We also solicited input from the group participants on each topic throughout the discussion and encouraged sharing of personal histories, experiences, perspectives, and

approaches to self-management. Group leaders helped to identify the self-management strategies used by participants in real-life scenarios.

Category

Other

2

Description

Education based on Adult Learning Theory plus Telephone Follow up by Nurse - The education program was developed to be de 1-hourblock of time once per week for 4 consecutive weeks. The curriculum included a mixture of psychosocial and medical information topics framed in the self-management activities.The overriding theme of self-management was built into all sessions, session materials, and session discussions. For example, meeting 1 focused on information management. Topics that were discussed in detail focused on definition of epilepsy, type of seizure, diagnosis and treatment. Other discussed topic was medication management (such as maintaining blood levels of medications, side effects, drug toxicity identification), seizure triggers and life style management, including sleep, exercise, stress, smoking and other risky behaviors, safety management, psychosocial factors such as depression, stigma, occupation, marriage, social interaction and etc. We also solicited input from the group participants on each topic throughout the discussion and encouraged sharing of personal histories, experiences, perspectives, and approaches to self-management. Group leaders helped to identify the self-managementsstrategies used by participants in real-life scenarios. This session was followed by six telephone- based on sessions content over the next 2 months (first month weekly and second month every 2 week) aimed at enhancing self-management practices in thefollowing areas: medication, information, seizure, safety, and lifestyle. For each of the phone contact, the nurses first discussed medication management with the participant.The nurse began by asking a general question about medication-taking practices. Participants who were taking medications as prescribed and had no difficulties were encouraged to continue with their regimen. Those who reported problems with medications(e.g., nonadherence or side effects) were provided supportin weighing the costs and benefits of adherence, eliciting barriersto adherence and supporting efforts to solve the barriers to adherence. Following the discussion of medications, the nurse asked the participant to select one or two other self-management components that were important to him or her. The subsequent discussion was directed toward identifying barriers and facilitators of desired behaviors(e.g., reducing stress). Participants were encouraged to develop their own solutions and devise an action plan.

Category

Other

3

Description

The participants enrolled in the control group received no

intervention.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Society of Epilepsy
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellor for Research of Tehran University of Medical Science
Full name of responsible person
Dr Masud Yunesian
Street address
Sixth Floor, Central Organization of TUMS, Keshavarz Blvd, Tehran, Iran
City
Tehran
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 of Tehran University of Medical Science
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

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Person responsible for scientific inquiries

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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