Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of group education of parents on controlling the recurrence of seizure attacks in children 6 months to 5 years

Protocol summary

Study aim

Determining the effect of group training of parents on controlling the recurrence of convulsive attacks in children

Design

Sampling will be done by random sampling method. The clinical trial has a control group, with parallel groups, not blinded, a study on 72 patients, and the samples will be randomly placed in two control groups (N=36) and test group (N=36) by permutation method. The design of this plan is parallel.

Settings and conduct

The research sample includes 72 children from 6 months to 5 years with seizures. The research environment is teaching hospitals affiliated to Ahvaz University of Medical Sciences. For the test group the educational intervention will be conducted in face-to-face and showing an educational film approved by the doctor and presentation of an educational pamphlet by the researcher during 10 sessions of 45 minutes one session per week.For the control group No educational intervention will be done.

Participants/Inclusion and exclusion criteria

The conditions for entering the study include:1.Children with seizures must be between six months and five years old 2.parents must have minimum reading and writing literacy or the mental and intellectual ability to participate in educational programs and complete the questionnaire؛The conditions for leaving study include:1.parents' unwillingness to participate in the research 2.parents suffering from physical or mental disorders based on self-report 3.parents' non-participation in 2 training sessions

Intervention groups

For the test group , the educational intervention will be conducted in face-to-face and showing an educational film approved by the doctor and presentation of an educational pamphlet by the researcher during10 sessions of 45 minutes one session per week.For the control group No educational intervention will be done.

Main outcome variables

Seizure control rate in children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230709058732N1**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-24, 1402/05/02**
Update count: **0**

Registration date

2023-07-24, 1402/05/02

Registrant information

Name

Niloofar Eskandari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group education of parents on controlling the recurrence of seizure attacks in children 6 months to 5 years

Public title

The effect of group education on controlling of seizure attacks in children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The main conditions for entering the study before randomization include: 1. Having an age of six months to five years for children with seizures 2. Parents must have minimum reading and writing literacy or mental and intellectual ability to participate in educational programs and complete the questionnaire

Exclusion criteria:

Parents' unwillingness to participate in the research Parents suffering from physical or mental disorders based on self-report Parents' non-participation in 2 training sessions.

Age

From **6 months** old to **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **36**

36 people in the control group and 36 people in the test group

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were first selected from the research community based on the inclusion criteria. The random assignment of the research sample to two intervention and control groups will be done based on permutation blocks of four (using the table related to random blocks). In this method, the people assigned to each group are equal. The blocks are formed based on the desired variables and half of the people in each block are included as intervention and half as control. The main goal is to balance the number of participants in each group.

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

Jundishapur University of Medical Sciences., Ahvaz

Street address

University of Medical Science., Esfand Street., Golestan Blvd

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Ahvaz

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Postal code

6135715794

Approval date

2023-07-01, 1402/04/10

Ethics committee reference number

IR.AJUMS.REC.1402.215

Health conditions studied

1

Description of health condition studied

Seizure (convulsive)

ICD-10 code

R56.8

ICD-10 code description

Seizure (convulsive) NOS

Primary outcomes

1

Description

Seizure (convulsive)

Timepoint

Before the start of the intervention and one month after the intervention

Method of measurement

A combined questionnaire including a researcher-made questionnaire and an original questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the test group, educational intervention in the form of (face-to-face and showing

educational videos and educational sessions approved by the doctor) will be carried out by the researcher during 10 sessions of 45 minutes, 1 session per week. In order to apply the educational method, the educational content is prepared based on the educational goals and by using authentic books and consultation with a doctor specializing in seizures. Educational content will be presented to parents first through face-to-face method and then through videos and other educational methods during training sessions.The educational content includes the definition of seizures, classification and types of seizures (simple, complex), duration of each type of seizure, symptoms of seizures, probability of recurrence, causes and risk factors of seizures, complications caused by seizures, treatment methods, drugs and methods Taking medicines, feeding the child, in case of fever, fever control methods, the correct method of application, ways to prevent convulsions and education about convulsion-accelerating factors (flashing light, lack of sleep, excessive activity, exercise, physical factors).Among other things, teaching precautions at home, interventions during seizures (the correct position of the child during an attack, removing tight and restricting clothes, giving the opportunity to perform spontaneous convulsive movements, not putting anything in the child's mouth, not trying to restrict sedating the child, using suppositories, calling the emergency center if the seizure lasts more than five minutes or repeats the attacks or the child's lack of consciousness after stopping the convulsive movements. After the intervention, a checklist will be provided to parents to check their performance at home to control children's seizures within a month.

Category

Behavior

2

Description

Control group: No educational intervention will be done for the control group, but in order to comply with the ethical points, pamphlets and educational booklets will be provided to the control group after the analysis of the study results.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu Dhar Hospital

Full name of responsible person

Ashraf al-Sadat Hakim

Street address

Abu Dhar Hospital., Nurse Street., Pasdaran Blvd., Zeitun Karmani., Ahvaz City

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2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology, Dr. Mehrnoosh Zakirkish

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Jundishapur University., Esfand Street., Golestan Blvd., Ahvaz

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ashraf al-Sadat Hakim

Position

Assistant professor, faculty member

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Position

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available