Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of educational program on understanding the uncertainty of disease and anxiety in mothers of children with febrile convulsion in the paediatric ward of Imam Ali Hospital in Zahedan in 2017

Protocol summary

Study aim

The effect of educational program on understanding the uncertainty and anxiety of mothers in febrile seizure in pediatric ward of Imam Ali Hospital in Zahedan, Iran.

Design

Clinical trials with intervention and control group, with parallel groups, Not blind, randomized

Settings and conduct

Mothers of children with febrile seizure in the pediatric wards of Imam Ali Hospital in Zahedan participated in this study. Qualified individuals were classified into intervention and control groups. The intervention group received educational content, but the control group received routine care.

Participants/Inclusion and exclusion criteria

Entry requirements: 1. There is no other illness other than seizure associated with fever. 2. The mother is not a hospital staff. 3. Have a child admitted at the age of 6 months to 6 years of age with seizure. 4. The mother has no history of anxiety and depression disorders or the mother is not being treated with psychiatric drugs. 5. The first childhood admission. Non-arrival conditions: Did not attend more than one session.

Intervention groups

In this research, the samples were available from the mothers of children with febrile seizure in the pediatric wards of Zahedan hospitals who had the conditions to enter the study, then the first group as an intervention group and then the control group of the sample They were The intervention group received educational content during 3 sessions, but the control group received routine care.

Main outcome variables

1- The anxiety of mothers of seizure-induced febrile seizure in pediatric ward of Imam Ali Hospital in Zahedan city 2. Uncertainty of maternal diseases in children with febrile convulsion in the pediatric ward of Imam Ali Hospital in Zahedan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043028N1**
Registration date: **2019-05-13, 1398/02/23**
Registration timing: **retrospective**

Last update: **2019-05-13, 1398/02/23**
Update count: **0**

Registration date

2019-05-13, 1398/02/23

Registrant information

Name

Zeinab Hosseinrezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2018-10-23, 1397/08/01

Trial completion date
2018-10-23, 1397/08/01

Scientific title
The effect of educational program on understanding the uncertainty of disease and anxiety in mothers of children with febrile convulsion in the paediatric ward of Imam Ali Hospital in Zahedan in 2017

Public title
The effect of educational program on understanding the uncertainty of the disease and anxiety of mothers of children with seizure

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
There is no other illness other than seizure associated with fever. The mother is not a hospital staff. The mother is fluent in Persian. The mother will have read and write literacy. Samples will reside in Zahedan. Have a child admitted at the age of 6 months to 6 years old with seizure. There is no history of epilepsy in the child and the family. The mother has no history of anxiety and depression disorders or the mother is not being treated with psychiatric drugs. The first childhood admission.
Exclusion criteria:
Did not attend more than one session

Age
From **6 months** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simplistic randomisation available

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
Ethical Committee of Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Dr Hasabi Campus
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463

Approval date
2017-10-17, 1396/07/25

Ethics committee reference number
IR.ZAUMS.REC.1396,117

Health conditions studied

1

Description of health condition studied
The effect of educational program on understanding the uncertainty of the disease and the anxiety of mothers of children with seizure associated with fever

ICD-10 code
G40.901

ICD-10 code description
Epilepsy, unspecified

Primary outcomes

1

Description
Impact of educational program on understanding the uncertainty of the disease

Timepoint
Start of training sessions from the start of admission after admission. The training sessions were held in 3 sessions and one day apart.

Method of measurement
A three-part questionnaire including demographic information, Spielberg's apparent anxiety questionnaire and parents' perception of uncertainty questionnaire.

2

Description
The effect of educational program on the anxiety of mothers of children with seizure

Timepoint
A three-part questionnaire including demographic information, Spielberg's apparent anxiety questionnaire and parents' perception of uncertainty

Method of measurement
Spill bugger's Clear Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The onset of intervention begins at the time of admission and after admission. The training intervention will be designed to provide educational content based on educational objectives and with the use of a pediatric pediatric neurologist, which includes a simple definition of febrile seizure, causes, prevalence, symptoms, probability Recurrence, prognosis and treatment and drug therapy, prevention methods, diagnostic methods, methods for controlling fever, feeding and educating the mother when discharge is an anxiety control way. The intervention includes: Individual training and providing a training booklet and providing a training CD for seizure control and a practical demonstration of the child's body temperature with a thermometer and a practical demonstration of spitting. And the duration of the training will be given to the mothers for at least 30 minutes to 45 minutes, individually and face-to-face with questions and answers within the department. The number of sessions in this section will be based on the patient's requirements and conditions three times a day and one Meanwhile, three sessions were considered in one week. The time of the session is after admission. The place of intervention in theoretical debates in the classroom and in practical discussions on the patient's bedside (in the condition of a mother's relaxation and admission conditions). The educator will be a researcher. The researcher also provided the intervention group's mothers with their telephone number to contact the researcher if they had a question and the researcher would follow them up for a month. The questionnaires will be filled in by the mothers before and after the intervention in both intervention and control groups and immediately after the intervention and after one month follow up after discharge (by telephone and coordination with the mother). Training sessions are as follows: Session 1: Introducing the researcher, providing a simple definition of febrile seizure, causes, prevalence, symptoms, relapse, prognosis and treatment, and drug therapy. Session 2: Prevention Methods, Diagnostic Methods, Fever Control Methods, Maternal Education When Dispensing. Session Three: Anxiety Control Ways

Category

Other

2

Description

Control group: In the control group only routine care was provided

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital in Zahedan

Full name of responsible person

Zeinab Rezaei

Street address

Imam Ali Hospital, Imam Khomeini Mosque, Persian Gulf Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshani

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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

Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Zeinab Rezaei
Position
Student Master
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The total potential data after being unidentifiable are those that can be shared
When the data will become available and for how long
Start the access period after printing the results
To whom data/document is available
Researchers working in academia, academia and industry
Under which criteria data/document could be used
Data can be used to conduct further research with the mention of the portal
From where data/document is obtainable
Zeinab Rezaei zeinabrezaei2711@gmail.com
What processes are involved for a request to access data/document
After reviewing the request, data is sent within 1 month.
Comments