

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of intervention based on Orem self-care model on anxiety of mothers with children with febrile seizures

Protocol summary

Study aim

Determining the effect of intervention based on Orem self-care model on anxiety of mothers with children with febrile seizures

Design

A randomized, single-blind, placebo uncontrolled clinical trial to be performed on 70 participants. The block method will be used for randomization.

Settings and conduct

This study will be performed in Amir Kabir Hospital in Arak on mothers who have children with febrile seizures. Participants are randomly divided into intervention and control groups and data analyzer willn't know about the assignment of individuals in the intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study; fluency in Persian; reading and writing skills; access to smart phones, internet and cyberspace; not having addiction of mothers to drugs; not having history of sedative drugs consumption among mothers. Exclusion criteria: Diagnosis of a disease other than febrile seizures in the child.

Intervention groups

Intervention group: At first, the level of information and ability of each mother (individually) about the disease and proper care in case of fever and seizures will be assessed through a written test and a simulation model. Then, based on the level of information, the intervention will begin. Each mother will be individually trained on anxiety management skills for 60 to 90 minutes for three days. In order to ensure the improvement of the mother's performance and the consolidation of the education, the content will be sent to the mothers in the form of videos, photos, SMS and voice messages again through WhatsApp messenger for three weeks. Control group: The control group will not receive any intervention.

Main outcome variables

Level of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200529047593N1**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

Elham Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 6730

Email address

e.mohammadi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-11-30, 1399/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of intervention based on Orem self-care model on anxiety of mothers with children with febrile seizures

Public title
The effect of intervention based on self-care model on anxiety of mothers with children with febrile seizures

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Fluency in Persian Reading and writing skills Access to smart phones, internet and cyberspace Not having addiction of mothers to drugs Not having history of sedative drugs consumption among mothers
Exclusion criteria:
Diagnosis of a disease other than febrile seizures in the child

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, the samples were selected using convenience sampling and then randomly assigned to intervention and control groups using block randomization. Initially, 6 blocks will made (ABAB, ABBA, BBAA, BABA, BAAB, AABBB). Then these blocks are arranged using a table of random numbers and people are divided into two groups according to the letters of A (intervention group) and B (control group).

Blinding (investigator's opinion)
Single blinded

Blinding description
Data analyzer willn't know about the assignment of individuals in the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij Sq., Sardasht Region
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2020-02-16, 1398/11/27
Ethics committee reference number
IR.ARAKMU.REC.1398.321

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety score in Spielberger inventory
Timepoint
In the pre-test stage (before the intervention), 3 and 21 days (three weeks) after the intervention.
Method of measurement
The Spielberger state-trait anxiety inventory

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: At first, the level of information and ability of each mother (individually) about the disease and proper care in case of fever and seizures will be assessed through a written test and a simulation model. Then, based on the level of information, the intervention will begin. Each mother will be individually trained on anxiety management skills for 60 to 90 minutes for three days. In order to ensure the improvement of the mother's performance and the consolidation of the education, the content will be sent to the mothers in the

form of videos, photos, SMS and voice messages again through WhatsApp messenger for three weeks.

Category

Behavior

2

Description

Control group: routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Kabir Hospital

Full name of responsible person

Esmail Moshiri

Street address

Amir-Kabir Hospital, Parastar Sq., Rah-ahan Sq.,
Shiroodi St.

City

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3819693345

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+98 86 3313 4715

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info@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Elham Mohammadi

Position

Nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Elham Mohammadi

Position

Nursing student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Elham Mohammadi
Position
Nursing student
Latest degree
Bachelor
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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the main outcome and the final result
can be shared.

When the data will become available and for how long

24 months after the publishing of the results.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

Scientific purposes.

From where data/document is obtainable

Elham mohammadi elham.mohammadi1364@yahoo.com

What processes are involved for a request to access data/document

Upon receipt of the request, the information will be sent
within 2 to 3 working days.

Comments