

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of peri operative education on anxiety and self-efficacy in mothers of 1-3-year-old children under Cochlear Implant surgery

Protocol summary

Summary

Objectives: Determining the effect of education on anxiety and self-efficacy in mothers of 1-3 -year- old children under Cochlear Implant surgery. Design: Single-blind randomized clinical trial. Setting and conduct: This study is conducted on 70 mothers of 1-3 -year- old children admitted in the pediatric ear surgery department at Shiraz Khalili Hospital who are eligible for the study. Subjects are first selected through purposive sampling method to achieve the desired sample size, and then they are divided in to two experimental (n=35) and control groups (n=35). They are randomly chosen using the table of random numbers and simple randomized sampling allocation, through RA software. Educational interventions are held for the experimental group during four training sessions, with one week interval, regarding the illness, recovery process and necessary post-surgery care for children. There are no interventions for the control group. The level of anxiety and self-efficacy in the mothers is measured by having them fill out the Spielberger state-trait anxiety inventory questionnaire and the Sherer self-efficacy questionnaire during the admission and after the surgery by the two experimental and control groups and the results are compared. The inclusion criteria: No history of hospitalization in the child; the patient being the first child in the family; no mental problem in the mothers; no record of mother's participation in the respective courses. The exclusion criteria: The mother's unwillingness to participate in the study. The main outcome measures variables are mother's anxiety and self-efficacy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708072432N5**

Registration date: **2017-09-25, 1396/07/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-25, 1396/07/03

Registrant information

Name

Azadeh Amiri

Name of organization / entity

Shiraz University Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4254

Email address

amiriea@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-06, 1396/05/15

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peri operative education on anxiety and self-efficacy in mothers of 1-3-year-old children under Cochlear Implant surgery

Public title

Examining the effect of peri operative education on anxiety and self-efficacy in mothers of children under Cochlear Implant surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: No history of hospitalization in the child; the patient being the first child in the family; no mental problem in the mothers; and no record of mother's participation in the respective courses.
Exclusion Criteria: Mother's unwillingness to cooperate in the study.

Age

From **1 year** old to **3 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

none

Secondary Ids**1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences,Zand Street, Shiraz

City

Shiraz

Postal code

7193613119

Approval date

2017-08-05, 1396/05/14

Ethics committee reference number

IR.SUMS.REC.1396.87

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Anxiety

Timepoint

Before intervention during admission and after intervention following surgery

Method of measurement

Spielberger state-trait anxiety inventory questionnaire

Secondary outcomes**1****Description**

Self-efficacy

Timepoint

Before intervention during admission and after intervention following surgery

Method of measurement

Sherer self-efficacy questionnaire

Intervention groups**1****Description**

In the intervention group, educational interventions are held during four training sessions regarding the illness, recovery process and necessary post-surgery care for children.

Category

Lifestyle

2**Description**

The control group receives routine care.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital affiliated to Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Azadeh Amiri

Street address

Namazi Square, Zand Street, Shiraz

City

Shiraz

Street address

School of Nursing and Midwifery, Namazi Square, Zand Street, Shiraz

City

Shiraz

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

+98 71 3647 4252

Email

amiriea@sums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

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, Shiraz University of Medical Sciences

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

Name of organization / entity

School of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Azadeh Amiri

Position

Master of Science In Nursing, Faculty member of School of Nursing and Midwifery, Shiraz University o

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Azadeh Amiri

Position

Master of Science In Nursing, Faculty member of School of Nursing and Midwifery, Shiraz University o

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Namazi Square, Zand Street, Shiraz

City

Shiraz

Postal code

7193613119

Phone

+98 71 3647 4258

Fax

+98 71 3647 4252

Email

amiriea@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery, Shiraz University of Medical Sciences

Full name of responsible person

Azadeh Amiri

Position

Master of Science In Nursing, Faculty member of School of Nursing and Midwifery, Shiraz University o

Other areas of specialty/work**Street address**

School of Nursing and Midwifery, Namazi Square, Zand Street, Shiraz

City

Shiraz

Postal code

7193613119

Phone
+98 71 3647 4258
Fax
+98 71 3647 4252
Email
amirlea@sums.ac.ir
Web page address

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