# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Examining the effect of education on anxiety and self-efficacy in mothers of 1-3-year-old children under glaucoma surgery

## Protocol summary

**Summary**

Objectives: Determining the effect of education on anxiety and self-efficacy in mothers of 1-3-year-old children under glaucoma surgery. Design: Randomized clinical trial. Setting and conduct: This study is conducted on 60 mothers of 1-3-year-old children admitted in the pediatric eye 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 = 30) and control groups (n = 30) using simple randomized sampling allocation, through RA software. Educational interventions are held for the experimental group during two 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 together. 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 cooperate in the study. The main outcome measures (variables): mother’s anxiety and self-efficacy

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201704032432N4**
Registration date: **2017-07-12, 1396/04/21**
Registration timing: **retrospective**
Last update:
Update count: **0**

**Registration date**

2017-07-12, 1396/04/21

**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**

2017-02-19, 1395/12/01

**Expected recruitment end date**

2017-06-22, 1396/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Examining the effect of education on anxiety and self-efficacy in mothers of 1-3-year-old children under glaucoma surgery

**Public title**

The impact of education on anxiety and self-efficacy in mothers of children under glaucoma 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**
No age limit
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**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**
Ethics committee of Shiraz University of Medical Sciences
**Street address**
Shiraz University of Medical Sciences,Zand Street, Shiraz
**City**
Shiraz
**Postal code**
**Approval date**
2017-05-02, 1396/02/12
**Ethics committee reference number**
IR.SUMS.REC.1396.17

## Health conditions studied

**1**

**Description of health condition studied**
Glaucoma
**ICD-10 code**
Q15.0
**ICD-10 code description**
Congenital glaucoma

**2**

**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**
The control group receives routine care.
**Category**
Other

**2**

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

## 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

## 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**
**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 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**
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## 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
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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*