

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Survey of the effect of post transfer to ward care training on anxiety and self efficacy in mothers of hospitalized 1 to 3 years old children in a pediatric cardiac surgery intensive care unit ward

#### Protocol summary

##### Summary

(1) Objective: survey of the effect of post transfer to ward care training on anxiety and self efficacy in mothers of hospitalized 1 to 3 years old children in a pediatric cardiac surgery intensive care unit. (2) Design: A randomized controlled trial by Using the method of permuted blocks. (3) intervention: forty mothers of hospitalized children in the intensive cardiac surgery randomly divided in two groups of control and intervention then take pre test of sherer self-efficacy scale(GSES) and Spielberger state and trait anxiety inventory(STAI) in both groups before the intervention. then the intervention group will be trained. motrally after completing the questionnaires the educational booklet provided to the control group . final test will be completed in two groups when children are transfered to cardiac surgery ward. (4)Inclusion criteria: The first of hospitalized in pediatric cardiac surgery intensive care unit; physical and mental health; Mothers in the study do not have the same training program; other children in the family don't have any history of hospitalization. (5) Exclusion criteria: the child's death; transfer the child to another hospital; lack of participation in training meeting even once. (6) interventions: education by training educational booklet. (7) main outcome measures: Changes in the level of anxiety and self-efficacy of mothers

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016110730771N1**  
Registration date: **2017-07-05, 1396/04/14**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-05, 1396/04/14

##### Registrant information

###### Name

parvin Sajadian

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3651 1056

###### Email address

stud2431926613@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Shiraz University of Medical Science

##### Expected recruitment start date

2017-01-19, 1395/10/30

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Survey of the effect of post transfer to ward care training on anxiety and self efficacy in mothers of hospitalized 1 to 3 years old children in a pediatric cardiac surgery intensive care unit ward

##### Public title

The effect of Child Care Training on anxiety and self efficacy in mothers of hospitalized children

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: The first hospitalization of child in pediatric cardiac surgery intensive care unit; physical and mental health; Mothers in the study do not have the same training program; other children in the family don't have any history of hospitalization. Exclusion criteria: the child's death; transfer the child to another hospital; lack of participation in training meetings even once.

### **Age**

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

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

in this study the samples allocated by permutation blocks in the intervention and control groups

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

##### **Street address**

Ethics Committee, seventh floor, Shiraz University of Medical Sciences, next to the Red Crescent headquarters, Zand Ave., Shiraz.

##### **City**

Shiraz

##### **Postal code**

71348-14336

#### **Approval date**

2016-05-15, 1395/02/26

#### **Ethics committee reference number**

ir.sums.rec.1395.28

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Congenital Heart Disease

#### **ICD-10 code**

q24.9

#### **ICD-10 code description**

Congenital malformation of heart, unspecified

## **Primary outcomes**

### 1

#### **Description**

Self efficacy of child care

#### **Timepoint**

Before intervention, 4 to 5 days after intervention

#### **Method of measurement**

Shere Self -Efficacy scale

### 2

#### **Description**

Anxiety of child care

#### **Timepoint**

Before intervention, 4 to 5 days after intervention

#### **Method of measurement**

Spielberger state and trait anxiety inventory

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

intervention group: face to face education given according to the educational booklet to mothers of hospitalized children two days after cardiac surgery

#### **Category**

Behavior

### 2

#### **Description**

control group: after completing the questionnaires the educational booklet provided to the control group

#### **Category**

Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Faghihi Hospital

##### **Full name of responsible person**

Mitra Edraki  
**Street address**  
Zand Avenue, Shiraz, Iran  
**City**  
Shiraz

**Fax**  
+98 71336474252  
**Email**  
mitraedraki@yahoo.com  
**Web page address**  
nurs-midwif.sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Shiraz University of Medical Science  
**Full name of responsible person**  
Dr. Seyed Basir Hashemi  
**Street address**  
Vice chancellor for research, seventh floor, Shiraz University of Medical Sciences, next to the Red Crescent headquarters, Zand Ave, Shiraz  
**City**  
Fars  
**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 Science  
**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**  
Shiraz University of Medical Science, Shiraz Hazrate Fatemeh Nursing and Midwifery college  
**Full name of responsible person**  
Mitra Edraki  
**Position**  
Master Of Nursing  
**Other areas of specialty/work**  
**Street address**  
Hazrate Fatemeh Nursing and Midwifery college, Namazi Square, Shiraz  
**City**  
Shiraz  
**Postal code**  
71936-13119  
**Phone**  
+98 71 3647 4286

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shiraz University of Medical Science, Shiraz Hazrate Fatemeh Nursing and Midwifery college  
**Full name of responsible person**  
Mitra Edraki  
**Position**  
Master Of Nursing  
**Other areas of specialty/work**  
**Street address**  
Hazrate Fatemeh Nursing and Midwifery college, Namazi Square, Shiraz  
**City**  
Shiraz  
**Postal code**  
71936 -13119  
**Phone**  
+98 71 3647 4255  
**Fax**  
+98 71 3647 4252  
**Email**  
mitraedraki@yahoo.com  
**Web page address**  
nurs-midwif.sums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shiraz University of Medical Science, Shiraz Hazrate Fatemeh Nursing and Midwifery college  
**Full name of responsible person**  
parvin Sajadian  
**Position**  
Nursing Graduate Student  
**Other areas of specialty/work**  
**Street address**  
Hazrate Fatemeh Nursing and Midwifery college, Namazi Square, Shiraz  
**City**  
Shiraz  
**Postal code**  
71936-13119  
**Phone**  
+98 71 3651 1369  
**Fax**  
+98 71 3647 4252  
**Email**  
stud2431926613@sums.ac.ir;  
mitraedraki@yahoo.com  
**Web page address**  
nurs-midwif.sums.ac.ir

## **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*