Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Name of organization / entity
Shiraz University of Medical Sciences
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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 hospitaliization 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

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

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Person responsible for updating data

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Full name of responsible person
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Position
Nursing Graduate Student

Other areas of specialty/work

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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