

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The comparison of the quality of life and self-efficacy of the mothers of infant with congenital heart disease in two educational program and control groups.

Protocol summary

Summary

This study aimed to assess the effect of an educational program on the quality of life and self efficacy of mothers of infants with congenital heart disease. The present clinical trial study was conducted on 60 mothers (30 in the control and 30 in the intervention group) referring to Emam Reza affiliated to Shiraz University of Medical Sciences. The inclusion criteria were the infants suffering from Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD), and Patent Ductus Arteriosus (PDA). Moreover, the children did not have other chronic diseases. The exclusion criteria of the study were the infants hospitalization during the intervention period. The intervention group received the educational program through four 90 - minute sessions in 4 weeks and the control group received routine care. The mothers' quality of life and self efficacy were assessed using SF-36 and Sherer general self efficacy questionnaire before, immediately and 2 months after the training.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012080410489N1**

Registration date: **2013-10-09, 1392/07/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-09, 1392/07/17

Registrant information

Name

Mozhgan Kamali

Name of organization / entity

Shiraz University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 917 562 8900

Email address

kamalimo@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2012-07-31, 1391/05/10

Expected recruitment end date

2012-10-31, 1391/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the quality of life and self-efficacy of the mothers of infant with congenital heart disease in two educational program and control groups.

Public title

Effect of an education program on congenital heart disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:1. The children suffering from ASD, VSD, PDA 2. The children not suffering from other chronic diseases 3. Being less than 12 months 4. The family having no other children with congenital heart disease 5. The children not having under gone heart surgery.

Exclusion criteria: 1. The children death 2. Unwillingness to cooperate in the study 3. The children hospitalization during the intervention

Age

No age limit

Gender

Female

Phase

1

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, Shiraz, Iran

Street address

Shiraz University Of Medical Sciences, Zand Ave. , Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2012-07-30, 1391/05/09

Ethics committee reference number

CT - 91- 6107

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

congenital heart disease

ICD-10 code

Q21.0, Q21

ICD-10 code description

ventricular septal defect, Atrial septal defect, patent ductus arterios

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

quality of life

Timepoint

Before intervention, immediately after, and 2 months after the last educational session

Method of measurement

SF_36 Questionnaire

2**Description**

Self - efficacy

Timepoint

Before intervention, immediately after, and 2 months after the last educational session

Method of measurement

Sherer General Self Efficacy questionnaire

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

Mental Health

Timepoint

Before intervention, immediately and 2 months after last training session

Method of measurement

GHQ-28 Questionnaire

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

The experimental group were received the educational program through four 90 - minute sessions in 4 weeks. This program was presented through power point and included information about the disease, type of disease, causes, symptoms, diagnostics tests, treatment, its effect on the infant and family, coping methods, taking care of such infants at home, nutrition, preventing infection, vaccination, and medication.

Category

Lifestyle

2**Description**

The control group was received routine care.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza poly clinic

Full name of responsible person

Mitra Edraki

Street address

Imam Reza Poly Clinic, Namazi Square, Shiraz, Iran

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

Gholamreza Hatam

Street address

Shiraz University Of Medical Sciences, Zand St., Shiraz, Iran

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

Full name of responsible person

Mitra Edraki

Position

Master of nursing/Faculty member

Other areas of specialty/work

Street address

School Of Nursing and Midwifery, Namazi Square, Shiraz, Iran

City

Shiraz

Postal code

71936-13119

Phone

+98 711647425458

Fax

+98 71 1647 4259

Email

mitraedraki@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School Of Nursing and Midwifery

Full name of responsible person

Mitra Edraki

Position

Master of nursing

Other areas of specialty/work

Street address

School Of Nursing and Midwifery, Namazi Square, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 711647425458

Fax

Email

mitraedraki@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School Of Nursing and Midwifery

Full name of responsible person

Mozhgan Kamali

Position

Graduate student

Other areas of specialty/work

Street address

School Of Nursing and Midwifery , Namazi Square, Shiraz, Iran

City

Shiraz

Postal code

Phone

Fax

Email

kamalimo@sums.ac.ir; mitraedraki@yahoo.com

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