

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of emotional intelligence component training in mothers on quality of life in their 2- 6 years old children with congenital heart disease

Protocol summary

Summary

(1) Objective: The effect of emotional intelligence component training in mothers on quality of life in their 2- 6 years old children with congenital heart disease .(2) Design: not blind clinical trial study .(3) Setting and conduct: this population consisted of mothers of children with Congenital heart disease is 2-6 years. 120 person for random sampling IS select and placed in two groups of 60 person and state in experimental and control groups. Before the start of training, quality of life questionnaires 2-6 years children with congenital heart disease of the mothers mind and Emotional Intelligence Bar-on Questionnaire for mothers and mother and children demographic information will be completed by the mothers in both groups. Then Education group will be receive, of emotional intelligence components for 90 minute section five over five weeks . But control group did not receive this training .then at the end of the last section and one month after intervention, both groups were given questionnaires for to complete. the control group receives education materials in the form of booklet after intervention .(4) Inclusion criteria: Children 6-2 years with congenital heart abnormality that by Shiraz University of Medical Sciences cardiologist confirms: the mother be primary caregiver! maternal age be 35-18 years :the minimum education level of mothers be diploma.(5) Exclusion criteria: death of the child or mother during the study! Mothers cut continue working on this research .(6) interventions: education by training interactive multimedia and educational booklet. (7) main outcome measures: changes in level of quality of life in their 2- 6 years old children with congenital heart disease .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016083029601N1**

Registration date: **2016-10-26, 1395/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-26, 1395/08/05

Registrant information

Name

Somayee Zare

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 4333 1538

Email address

stud2431409181@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2016-10-31, 1395/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotional intelligence component training in mothers on quality of life in their 2- 6 years old children with congenital heart disease

Public title

Effect of emotional intelligence component training on quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Children 6-2 years with congenital heart abnormality that by Shiraz University of Medical Sciences cardiologist confirme:the mother be primary caregiver: maternal age be 35-18 years :the minimum education level of mothers be diploma : Exclusion criteria: death of the child or mother during the study: Mothers cut continue working on this research

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

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

2016-05-29, 1395/03/09

Ethics committee reference number

ir.sums.rec.1395.33

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

Congenital malformations of cardiac septa

ICD-10 code

Q21

ICD-10 code description

Congenital malformations of cardiac septa

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

quality of life

Timepoint

Before the intervention, Immediately after the intervention and one month later

Method of measurement

Questionnaire

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

Emotional Intelligence

Timepoint

Before the intervention, after intervention and one month later

Method of measurement

Bar- on Emotional Intelligence questionnaire

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

The members of the intervention group had workshop for 5 section 90 minute duration 5 weeks. Also they completed Bar- on emotional ,ped quality of life questionnaires before, immediately after, and one month after the intervention.

Category

Other

2**Description**

The members of the control group completed Bar- on emotional intelligence,ped quality of life questionnaires before,after, and one month later, without any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Zohre Montasari

Street address

Namazi Square, Zand street Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Faghihi Shahidi Hospital affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Zohre Montasari

Street address

Namazi Square, Zand street Shiraz

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3

Recruitment center

Name of recruitment center

Emam reza Clinicl affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Zohre Montasari

Street address

Namazi Square, Zand street Shiraz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Science, Vice chancellor for research

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Vice chancellor for research, seventh floor, Shiraz University of Medical Science, next to the Red Crescent headquarters, Zand Ave., Shiraz

City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Science, Vice chancellor for research

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

Zohre Montasari

Position

Master Of Nursing

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Fatemeh Nursing and Midwifery college

Full name of responsible person

Somayee Zare

Position

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Other areas of specialty/work

Street address

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City

Shiraz

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