

# 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 Montaseri

**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 Montaseri

**Street address**

Namazi Square, Zand street Shiraz

**City**

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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 Montaseri

**Street address**

Namazi Square, Zand street Shiraz

**City**

Shiraz

## 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**

Shiraz

**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 Montaseri

**Position**

Master Of Nursing

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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

**Contact**

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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**

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Namazi Square, Shiraz

**City**

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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*