

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of educational program on the knowledge and care performance of parents of children with congenital heart disorders

Protocol summary

Study aim

Determining the effect of the educational program on the knowledge and care performance of parents of children with congenital heart defects

Design

The clinical trial has a control group, with parallel groups, the samples will be randomly divided into two groups test (N=43) and control (N=43) using a random replacement blocks.

Settings and conduct

The research sample in this study includes 86 parents (fathers or mothers) of children with congenital heart abnormalities. The research environment is hospitals affiliated to Jundishapur University of Medical Sciences in Ahvaz. For the test group (43 people), combined educational intervention (face-to-face and showing an educational film approved by the doctor and performing physical activities in a practical way under the supervision of the researcher) by the researcher during 6 sessions of 45 minutes (one session per week) will be executed. No educational intervention will be done for the control group.

Participants/Inclusion and exclusion criteria

Registration and certainty of the diagnosis of congenital heart abnormality in the child's medical record: Children in the age group of one month to twelve years! Parents have not participated in educational groups before! Parents should have mental and intellectual skills to complete the questionnaire and participate in the educational program.

Intervention groups

For the test group (43 people), combined educational intervention by the researcher during 6 sessions of 45 minutes (one session per week) will be executed. No educational intervention will be done for the control group.

Main outcome variables

Parental Knowledge: Parental care performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220912055950N1**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **prospective**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Najmeh Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3334 1728

Email address

hoseiny.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2022-12-01, 1401/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational program on the knowledge and care performance of parents of children with congenital heart disorders

Public title

The effect of educational program on the knowledge and care performance of parents of children with congenital heart disorders

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Registration and certainty of diagnosis of congenital heart abnormality in the child's medical record. Parents of children from one month to twelve years old. Parents have not participated in educational groups before. Parents must have the mental and intellectual ability to complete the questionnaire and participate in the educational program.

Exclusion criteria:

Absence of more than one session in training classes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 86

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be randomly divided into two intervention and control groups using the random permutation block method (using the table of random permutation blocks).

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 committees of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences., Golestan St., Ahvaz., Iran

City

Ahvaz

Province

Khouzestan

Postal code

6136939305

Approval date

2022-09-10, 1401/06/19

Ethics committee reference number

IR.AJUMS.REC.1401.251

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

Congenital heart disorders

ICD-10 code

XIII

ICD-10 code description

Congenital malformations, deformations and chromosomal abnormalities

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

The level of knowledge and care performance of parents with children with congenital heart disorders

Timepoint

Before the start of the intervention and 3 months after the intervention

Method of measurement

Researcher-made questionnaire (measurement of knowledge and care performance)

Secondary outcomes

empty

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

Intervention group: For the intervention group, the combined educational program (face-to-face and educational film screening approved by the doctor and practical physical activities under the supervision of the researcher) will be implemented by the researcher during 6 45-minute sessions (one session per week).

Category

N/A

2**Description**

Control group: No educational intervention will be done for the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

AshrafalSadat Hakim

Street address

Golestan Hospital, Farvardin St., Golestan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Ahvaz Jundishapur University of Medical Sciences,
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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

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ashrafalsadat Hakim

Position

Assistant professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available