# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jun 2026

## The effect of combination of individual and multimedia education on quality of life of school-aged children with congenital heart defects

### Protocol summary

**Study aim**
Determine the effect of combination of individual and multimedia education on quality of life of school-aged children with congenital heart defects.

**Design**
Clinical trial with control group, with parallel groups, randomized

**Settings and conduct**
Sixty patients referred to the pediatric cardiology clinic of Imam Reza Hospital in Mashhad, based on inclusion criteria, will be randomly assigned (blocking) to the intervention or control group without the knowledge in which group they are in. Quality of life questionnaire of a child with congenital heart disease will complted for both group before and two months after the intervention.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: willingness of the child to participate in the research and permission of his parent; age of the child between 8-12 years old; the child's ability to read and speak Persian; diagnosis of congenital heart disease at a younger age; not mentally retarded; child with congenital heart disease (cyanotic and non-cyanotic); age of diagnosis in preschool child (from infancy to toddler); having a smartphone; no diagnosis of other heart diseases. Exclusion criteria: child and parent withdrawal from cooperation; event in the patient's individual or family life during intervention that affects the quality of life, such as the death of a parent.

**Intervention groups**
In intervention group, first, an 80-minute face-to-face education session will be held in the presence of parents and children. After that educational package that includes short videos which played in in a face-to-face session will be available for patients. In control group, participants will receive routine hospital training in the form of an educational pamphlet that includes explanations of illness, treatment, and nutrition.

**Main outcome variables**
Quality of life score in the quality of life questionnaire of a child with congenital heart disease

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20211017052789N1**
Registration date: **2021-11-11, 1400/08/20**
Registration timing: **prospective**

Last update: **2021-11-11, 1400/08/20**
Update count: **0**

**Registration date**
2021-11-11, 1400/08/20

**Registrant information**

**Name**
Atousa Dezhraftar

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-12-11, 1400/09/20

**Expected recruitment end date**
2022-03-20, 1400/12/29

**Actual recruitment start date**
2021-12-16, 1400/09/25

**Actual recruitment end date**
2022-03-21, 1401/01/01

**Trial completion date**

2022-04-19, 1401/01/30

**Scientific title**
The effect of combination of individual and multimedia education on quality of life of school-aged children with congenital heart defects

**Public title**
The effect of combination of individual and multimedia education on quality of life of school-aged children with congenital heart defects

**Purpose**
Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Willingness of the child to participate in the research and permission of his parent Age of the child between 8-12 years old The child's ability to read and speak Persian Diagnosis of congenital heart disease at a younger age Not mentally retarded Child with congenital heart disease (cyanotic and non-cyanotic) Age of diagnosis in preschool child (from infancy to toddler) Having a smartphone No diagnosis of other heart diseases

**Exclusion criteria:**
Child and parent withdrawal from cooperation An event in the patient's individual or family life during intervention that affects the quality of life, such as the death of a parent

**Age**
From **8 years** old to **12 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **60**
Actual sample size reached: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
In this way, the allocation of samples to test or control groups will be done by random allocation (using blocking). The use of blocking will be done on different days due to the allocation of samples. In this method, the groups are first identified by giving the code to the groups that will be group A: intervention and B: control. 5 blocks of 6 are specified: 1- AABBAB, 2- BBAABA, 3- AABABB, 4-BABABA, 5-BBBAAA, 6- AAABBB. Finally, they are included in the study and placed in the intervention and control groups, respectively. After completing the first 5 blocks, the second block will be sampled.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
Participants will not be informed about which group they will be in.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Ethics Committees of School of Nursing & Midwifery, Mashhad University of Medical Sciences

**Street address**
Nursing and Midwifery school, Ibn Sina St

**City**
Mashhad

**Province**
Razavi Khorasan

**Postal code**
9177948959

**Approval date**
2021-05-18, 1400/02/28

**Ethics committee reference number**
IR.MUMS.NURSE.REC.1400.024

## 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**
Quality of life score in the quality of life questionnaire of a child with congenital heart disease

**Timepoint**
Before the intervention and at the end of the second month

**Method of measurement**
The quality of life questionnaire of a child with congenital heart disease

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

First, an 80-minute face-to-face training session based on dimensions affecting quality of life (medication use, nutrition, communication with friends, cognitive problems, familiarity with congenital heart problems, and physical appearance) will be held in the presence of parents and children. The educational materials have been obtained by reviewing the texts and opinions of cardiologists and the cooperation of professors and nursing experts, and will be provided by animator expert in the form of multimedia and understandable form for the child and playable on mobile phones which produced by Softwares such as Perezi, After that educational package that includes short videos which played in in a face-to-face session (5 minutes for each quality of life aspects) using a micro e-learning and combination of videos with motion graphics will be available for patients. It should be noted that the motion graphics are extracted from the YouTube site and will be recorded in the sound recording studio of the School of Health.

**Category**

N/A

**2**

**Description**

Control group: this group will receive routine hospital training in the form of an educational pamphlet that includes explanations of illness, treatment, and nutrition.

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Pediatric Cardiology Clinic of Imam Reza Hospital, Mashhad

**Full name of responsible person**

Dr.Tahereh Sadeghi

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School of midwifery and nursing, Ibn sina St

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Robabeh Latifnezhad

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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**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr.Tahereh Sadeghi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

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Bachelor

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

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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