

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Design, implementation and evaluation of an educational application for home care after surgery of pediatrics with congenital heart disease

#### Protocol summary

##### Study aim

Investigating the effect of using the home care training application on the quality of life and adherence to treatment of mothers of children with congenital heart diseases

##### Design

A randomized clinical trial with a control group, parallel groups, Examining the outcomes in 72 mothers, double-blind (principal researcher and statistical analyst), block randomization method will be used.

##### Settings and conduct

The samples are randomly distributed into two control and intervention groups. Data collection before and one month after the intervention will be done by two different people and the type of group is coded in the data. The intervention group will receive the educational application and the control group will receive routine interventions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Parents having access to a mobile phone with the Android operating system, parents having literacy and the ability to work with a mobile phone, the child being zero to six years old, the child having a confirmed diagnosis of heart disease, the child for the first time under Heart surgery has been performed, mothers have not received post-surgery training before, and the child does not have underlying problems or other chronic diseases. Exclusion criteria: Mothers' unwillingness to continue cooperation in each of the stages of the study, the occurrence of any reason that makes it impossible for mothers to use the educational application, re-hospitalization or death of the child.

##### Intervention groups

Intervention group: In addition to routine care such as education during discharge, they will also receive home care training applications. Phone calls and follow-ups for samples will be made within a month. The control group will receive routine care during discharge. Telephone

follow-up of the samples is done during the research.

##### Main outcome variables

Quality of Life; Adherence to treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230816059164N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

##### Registration date

2023-08-21, 1402/05/30

##### Registrant information

##### Name

Mohammad Mehdi Rajabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 939 811 2685

##### Email address

mmehdirajabi1379@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-05-21, 1403/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Design, implementation and evaluation of an educational application for home care after surgery of pediatrics with congenital heart disease

**Public title**  
Design, implementation and evaluation of an educational application for home care after surgery of pediatrics with congenital heart disease

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Mothers should have Informed consent to participate in research Mothers should be literate and have the ability to work with mobile phones Having access to a mobile phone with Android operating system The child must have a confirmed diagnosis of congenital heart disease The child should be zero to six years old Mothers should have not received post-surgery training before  
**Exclusion criteria:**  
The child has undergone surgery before In addition to heart disease, the child has other underlying problems

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **72**

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

**Randomization description**  
In this research, the block randomization method will be used to determine the control and intervention groups. For this purpose, all blocks of 4 contain two letters A and two letters B, the total number of which is 6 (including AABB, ABAB, BABA, ABBA, BBAA, ABBA). Then 18 blocks are selected using a table of random numbers. These blocks form a sequence of 72 numbers of letters A and B, where the letter A is the symbol of the control group and the letter B is the symbol of the intervention group, and they specify how the samples are placed in the groups.

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

**Blinding description**  
Data collection before and after the intervention will be done by two different people. The assistant researcher will specify the type of group in which the research samples are located with the letters A and B. After collecting the data, both people will send them separately to the statistical analyst. This method of collecting information makes the main researcher and

the statistical analyst not aware of the group in which the research samples are located. Also, the assistant researcher will not be aware of the final result and the effectiveness of the application. In this way, the research result is blinded from the point of view of the main researcher and the statistical analyst. The assistant researcher will follow up the samples by phone.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Children's Medical Center, Tehran University of Medical Sciences

##### Street address

No. 62, Next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., At the end of Keshavarz Blvd, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733151

#### Approval date

2023-08-16, 1402/05/25

#### Ethics committee reference number

IR.TUMS.CHMC.REC.1402.085

## 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

#### Timepoint

Before and one month after the intervention

#### Method of measurement

Quality of Life Questionnaire The 36-Item Short Form Survey (SF-36)

## Secondary outcomes

### 1

#### Description

Adherence to treatment

#### Timepoint

Before and one month after the intervention

#### Method of measurement

Modanlo et al.'s adherence to treatment questionnaire

## Intervention groups

### 1

#### Description

Intervention group: The intervention group will receive the home care education application, which is a guide for the care of children with congenital heart diseases after surgery. The educational content of this application, which will be approved by experts, will include information about how to take medicines, high-risk symptoms, how to perform chest physiotherapy, and other essential information needed by mothers. Quality of life and adherence to treatment of mothers before and one month after the intervention will be measured and compared. ADDIE standard application development protocol will be used to design the application. Educational applications will be developed for mobile phones with the Android operating system. During the research, the samples will be monitored through telephone follow-up.

#### Category

Other

### 2

#### Description

Control group: For the members of the control group, routine interventions including training during discharge and phone follow-up of the samples will be done and they will not receive any new intervention. Quality of life and adherence to treatment will be measured and compared before and one month after the intervention.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Children's Medical Center

##### Full name of responsible person

Reza Shervin Badv

##### Street address

No. 62, Dr. Mohammad Gharib St., Next to Imam Khomeini Hospital, At the end of Keshavarz Blvd, Tehran

##### City

Tehran

#### Province

Tehran

#### Postal code

1419733151

#### Phone

+98 21 6147 2917

#### Email

cmc.tums@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Reza Negarande

##### Street address

Nursing and Midwifery Care Research Center, School of Nursing and Midwifery, Tehran University of Medical Sciences, Nusrat Sharghi Street, Tohid Square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733171

##### Phone

+98 21 6642 1685

##### Email

negarandeh@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Mehdi Rajabi

##### Position

Master's student in pediatric nursing

##### Latest degree

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Tehran University of Medical Sciences, Nusrat Sharghi Street, Tohid Square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733171

**Phone**

+98 21 6105 4424

**Email**

mmehdirajabi1379@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Mehdi Rajabi

**Position**

Master's student in pediatric nursing

**Latest degree**

Bachelor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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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