Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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

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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