

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of discharge plan implementation on knowledge of care and quality of life in mothers of children with congenital heart diseases undergoing surgery

Protocol summary

Study aim

The effect of discharge planning on knowledge of care and quality of life in mothers of children with congenital heart diseases undergoing surgery

Design

clinical trial with Control group

Settings and conduct

Intervention in this study is the implementation of the discharge plan that will be carried out in children with congenital heart disease undergoing surgery in Shahid Rajaei Heart Hospital of Tehran. The discharge plan includes education at admission, hospitalized days to the ward, during discharge and follow up after discharge that provided by the researcher to the mothers of children with congenital heart disease. According to the nature of the study, no blinding has been done.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Mother's understanding and mastery of Persian language Mother's education is at reading and writing, The mother has not physical, psychological and cognitive disease, The child has undergone cardiac surgery for the first time, The length of the child's admission is more than 3 days. Exclusion Criteria: Mother's education is in the medical field, The presence of another child with chronic illness in the family.

Intervention groups

The intervention group: The intervention involves education for 6 sessions of 30 minutes at admission, hospitalized days to the ward and during discharge to the mothers and follow up after discharge at 2 months. Individual education and small groups are conducted using an instruction booklet. The educational content includes: explanations of the structure of the normal and abnormal heart, physical activity, child nutrition, bathing, preventing infection, caring for surgical scar, benefits and side effects of drugs and the treatment of fever and diarrhea. The control group: Mothers in this group

receive routine hospital care.

Main outcome variables

Knowledge of care : Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180501039489N3**

Registration date: **2019-06-24, 1398/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-24, 1398/04/03**

Update count: **0**

Registration date

2019-06-24, 1398/04/03

Registrant information

Name

Fahimeh Sabeti

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8888 2885

Email address

sabeti.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of discharge plan implementation on knowledge of care and quality of life in mothers of children with congenital heart diseases undergoing surgery

Public title

The effect of discharge plan on knowledge and quality of life in mothers of children with congenital heart diseases

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Mother's understanding and mastery of Persian language
 Mother's education is at reading and writing
 The mother has not physical, psychological and cognitive disease
 The child has undergone cardiac surgery for the first time
 The length of the child's admission is more than 3 days.

Exclusion criteria:

Mother's education is in the medical field
 The presence of another child with chronic illness in the family

Age

From **1 day** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not 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 Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat

Highway, Tehran1449614535, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-04-07, 1398/01/18

Ethics committee reference number

IR.IUMS.REC.1398.217

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

Congenital malformations of cardiac chambers and connections

ICD-10 code

Q20

ICD-10 code description

Congenital malformations of cardiac chambers and connections

2**Description of health condition studied**

Congenital malformations of cardiac septa

ICD-10 code

Q21

ICD-10 code description

Congenital malformations of cardiac septa

3**Description of health condition studied**

Congenital malformations of pulmonary and tricuspid valves

ICD-10 code

Q22

ICD-10 code description

Congenital malformations of pulmonary and tricuspid valves

4**Description of health condition studied**

Congenital malformations of aortic and mitral valves

ICD-10 code

Q23

ICD-10 code description

Congenital malformations of aortic and mitral valves

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

knowledge of care

Timepoint

Before intervention, Discharge time, 2 month after

intervention
Method of measurement
Knowledge of care questionnair

2

Description
Quality of life
Timepoint
Before intervention ,2 month after intervention
Method of measurement
Quality of life questionnair

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group at first, Demographic questionnaire, knowlege of care and quality of life questionnaire were completed before the intervention by mothers. Then, in the first stage of intervention, the education includes 6 sessions of 30 minutes at admission, hospitalized days and discharge time individually and small groups using a booklet for mothers. The educational content includes: explanations of the natural and abnormal heart structure, surgical treatment, physical activity, child nutrition post-surgery, baby bathing, infection prevention, surgical scar treatment, medication usage, benefits and side effects of medications and Treatment of fever and diarrhea. The second stage of the intervention involves post discharge follow-up. At this stage, the researcher will call with the mothers, one week, two weeks, one month, and two months after the discharge , asking for the child's condition and, if necessary, giving them the necessary education.
Category
Rehabilitation

2

Description
Control group: this group completes the relevant questionnaires and receives only the usual care and training of the hospital.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Heart Hospital
Full name of responsible person
Masomeh Safarkhanlo

Street address
Shahid Rajaei Hospital, Next to Mellat Park, Valiasr Ave Tehran, IRAN
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Fax
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Phone
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malakoutik@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fahime Sabeti

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Fahime Sabeti

Position

Faculty Member

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available