Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Rajaee 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
Inclousion 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. Exclousion 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
Knowleg 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

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Iran (Islamic Republic of)

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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 Rajaee Heart Hospital
Full name of responsible person
Masomeh Safarkhanlo
Street address
Shahid Rajaee Hospital, Next to Mellat Park,Valiasr Ave Tehran,IRAN
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Seyyed Kazem Malekoti
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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
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
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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