

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-centered care on the burden of care and anxiety in parents of children after heart transplantation

Protocol summary

Study aim

The effect of family-centered care on parental care burden and anxiety of children after heart transplantation

Design

Family-centered, in four stages of perceived threat, self-efficacy, educational participation and evaluation are performed in four sessions of 20 to 40 minutes for the intervention group; The control group receives only routine ward care .Randomization and blinding are not done

Settings and conduct

Research environment of Shahid Rajaei Hospital

Participants/Inclusion and exclusion criteria

Self-declaration of non-parental mental illness Awareness of the type of child disease - No stressful events other than the child's illness during the past year - Not attending similar training sessions and classes - Hospitalization and presence of the child for at least 5 days in the ward Lack of care for another patient at home

Intervention groups

First, by obtaining the necessary permits, they were randomly selected into two experimental and control groups. 56 parents of children will be selected after heart transplantation. While the control group receives routine care, after completing the training, the anxiety and care questionnaires are distributed to the experimental and control groups and a month later. Finally, the data obtained from the questionnaires are collected and analyzed.

Main outcome variables

Education and application of family-centered care reduces the burden of care and anxiety of parents of children after heart transplantation

General information

Reason for update

Acronym

پیوند قلب

IRCT registration information

IRCT registration number: **IRCT20141216020344N2**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Hamidreza Khoshnezhad Ebrahimi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7787 2189

Email address

khoshnezhad.hr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-29, 1399/09/09

Expected recruitment end date

2021-08-28, 1400/06/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-centered care on the burden of care

and anxiety in parents of children after heart transplantation

Public title

The effect of family-centered care on the burden of care and anxiety in parents of children after heart transplantation

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of heart transplant children 7-15 years Self-reported non-parental mental illness Awareness of the type of child disease No stressful events other than the child's illness during the past year Absence from attending similar training sessions and classes- Hospitalization and presence of the child for at least 5 days in the ward Lack of care for another patient at home

Exclusion criteria:

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

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

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.IUMS.REC.1399.930

2

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2020-11-30, 1399/09/10

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Health conditions studied

1

Description of health condition studied

Heart transplantation in children

ICD-10 code

i160-i169

ICD-10 code description

بیماری قلب عروقی

Primary outcomes

1

Description

burden of care

Timepoint

Before intervention and immediately after intervention and one month after intervention

Method of measurement

Zarit Care Questionnaire

2

Description

Anxiety

Timepoint

Before intervention and immediately after intervention and one month after intervention

Method of measurement

Beck Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family-oriented, in four stages of perceived threat, self-efficacy, educational participation and evaluation are performed in four sessions of 20 to 40 minutes for the intervention group.

Category

N/A

2

Description

Control group: in the control group, routine care is performed and family-centered interventions are not performed

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Heart Hospital, Tehran

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Street address

Tehran - Vali Asr St. (AS) - next to Mellat Park - corner of Niayesh Shahid Rajaei Cardiovascular Training, Research and Treatment Center

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Email

khoshnezhad.hr@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Email

admins@iums.ac.ir

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

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Tehran, Modares Highway, after Mirdamad Bridge, Shahid Dastgerdi St. (Zafar), Hazrat Ali Asghar Children's Hospital

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2045

Email

khoshnezhad.hr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data is encrypted in order to make the identities of
individuals unidentifiable and confidential

When the data will become available and for how long

From the end of sampling to 6 months after the
publication of the article

To whom data/document is available

University Ethics Committee, Project Arbitration
Committee, Article Arbitration Committee and other
researchers

Under which criteria data/document could be used

Perform systematic review or meta-analysis by
mentioning the document

From where data/document is obtainable

Dr Hamidreza Khoshnezhad Ebrahimi

What processes are involved for a request to access data/document

After submitting the application via academic email, we
will provide information files to individuals within a
maximum of one week

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Hamidreza Khoshnezhad Ebrahimi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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