

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effect of Home Care Educational Application on the Perceived Stress and Caregiving Burden in Parents of Children Undergoing Surgery for Congenital Heart Disease

Protocol summary

Study aim

To Determine the Effect of Home Care Educational Application on the Perceived Stress and Care Burden of Parents of Children Undergoing Surgery for Congenital Heart Disease.

Design

Phase III Randomized Clinical Trial with Two Groups, Pre-test and Post-test, without Blinding, 72 People Randomly Assigned Through PASS 11 Software

Settings and conduct

The location of the study is open heart surgery department in Imam Reza Hospital in Mashhad. The content of the educational application will be prepared based on the review of the texts and the opinion of experts. Before the intervention, the questionnaire of personal characteristics, the perceived stress questionnaire of Cohen and the care burden questionnaire of Zarit are completed in person by both groups. The intervention will last for a period of one month. Then, one month later, the questionnaires will be completed again in both groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Parents of Children with Congenital Heart Disease who have the Desire to Participate in Research and the Ability to use a Smartphone. Exclusion criteria: Parents' unwillingness, Child's death.

Intervention groups

In the intervention group, the home care educational application will be installed on the parents' mobile phones and how to use it will be taught. Offline parents can access the content of the application, which includes general information about the child's illness, complications of surgery and post-discharge care, necessary skills to reduce stress and other necessary measures, mostly written, audio, video and photo, for a month. The control group will receive training using pamphlets that are explained face-to-face by the

researcher.

Main outcome variables

Perceived Stress; caregiving burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231001059583N1**

Registration date: **2023-10-11, 1402/07/19**

Registration timing: **prospective**

Last update: **2023-10-11, 1402/07/19**

Update count: **0**

Registration date

2023-10-11, 1402/07/19

Registrant information

Name

Somaye Ostadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Home Care Educational Application on the Perceived Stress and Caregiving Burden in Parents of Children Undergoing Surgery for Congenital Heart Disease

Public title

Investigating the effect of home care educational application on perceived stress and care burden of parents

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents of children with congenital heart disease from one month to 11 years who undergo heart surgery for the first time Willingness to participate in research Ability to use a smartphone Not having a psychological problem and not taking psychoactive drugs There is no other child with this disease or any other chronic disease in the family that needs care

Exclusion criteria:

Parents' unwillingness to continue participating in the research The need for intervention or emergency operation again during research Death of a child during research Occurrence of severe stressful events during study for the family

Age

From **1 month** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done in such a way that people will be divided into two groups through the PASS 11 software using blocks of four. In this way, after determining the sequence, we put them in the envelopes and number them in order. One of the parents will take the envelope in the order of their entry into the study and will be placed in the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The content of the application includes: training in the field of post-operative care at home, which includes

information about the child's illness, post-operative care, including wound and operation site care, introduction of drugs, how to take and side effects of drugs, proper nutrition and the appropriate amount of activity for the child. With the age of the child (one month to one year old, 1 to 3 years old, 3 to 5 years old, 5 to 11 years old), the symptoms will need to see a doctor, follow up treatment, in addition, regarding the methods of dealing with stress, including: information about the sources of stress, training in deep breathing skills, listening to music, communicating with others to help reduce stress, as well as self-care as a caregiver (adequate sleep and rest, exercise and proper nutrition) will be provided. The mentioned content will be prepared based on the review of the texts and experts' opinions, then the educational application, which is an offline, Android, non-interactive and multimedia-based application, will be designed and piloted to the experts and children's parents, and their corrective comments will be applied. became.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Faculty of Nursing and Midwifery
- Mashhad University of Medical Sciences

Street address

Educational Complex of Shahid Dr. Kharazmi,
University Campus, east gate of Ferdowsi University
of Mashhad, Azadi Square, Mashhad, Khorasan Razavi

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Postal code

9137913199

Approval date

2023-08-15, 1402/05/24

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.078

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

Children undergoing surgery for congenital heart disease

ICD-10 code

Q20

ICD-10 code description

Congenital malformations of cardiac chambers and connections

Primary outcomes

1

Description

Perceived Stress

Timepoint

Measuring perceived stress at the beginning of the study (before the start of the intervention) and one month after using the educational application

Method of measurement

Cohen's Perceived Stress Questionnaire

2

Description

Caregiving Burden

Timepoint

Caregiving burden measurement at the beginning of the study (before the intervention) and one month after using the educational application

Method of measurement

Zarit Care Burden Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, one day before the child's discharge in the open heart surgery department, the home care educational application will be installed on the smartphone of the parents or a family member and will be taught how to use it.

Category

Prevention

2

Description

Control group: The control group will receive routine training, which currently involves the use of a training pamphlet that is explained face-to-face by the researcher.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, open heart surgery department

Full name of responsible person

Zahra Dalir

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Imam Reza Educational Research and Treatment Center, Imam Reza Hospital Square, Ibn Sina Ave, Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Research and Technology Vice-Chancellor of Mashhad University of Medical Sciences, Second Floor, Qureshi Building, Front of 16 University Ave, University Ave

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Dalir

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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

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

Title and more details about the data/document

All the data obtained from this research will be shared after completion.

When the data will become available and for how long

Access to the data will be possible 3 months after the results are published.

To whom data/document is available

These data will be used for researchers working in academic and scientific institutions, as well as for parents with children with congenital heart disease.

Under which criteria data/document could be used

The data obtained from this research can be used in other scientific studies.

From where data/document is obtainable

Copying (in any way) either from the full text or from the extracts is possible only with the coordination of the supervisor and the registered author and according to the instructions provided by the Central Library of Mashhad University of Medical Sciences. Details can be accessed through the relevant faculty library. The use of the thesis in articles or any scientific writing is subject to citing the source in compliance with the Mashhad University of Medical Sciences publishing regulations. Somaye Ostadi OstadiS971@mums.ac.ir

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

The applicant should send an email to the responsible author and register his request. After verifying the correctness of the information of the mentioned person, the required content will be provided to him by mentioning the source.

Comments

