

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

To compare the effectiveness of self-care education in two methods, face to face and video educational, on the self-efficacy and quality of life in adolescents with congenital heart disease

Protocol summary

Study aim

Determining the effect of Self-care education on Face-to-Face and Videoclip on self-efficacy and quality of life in adolescents with congenital heart disease

Design

Semi-experimental study with three groups (two groups of intervention and control group), with parallel groups, randomized, design of 111 patients

Settings and conduct

The total number of samples will be 111 (37 individuals each), which will be included in the sampling among adolescents with heart disease in the selected hospital (Shahid Rajaee Cardiology Hospital). In the control group, the education group Face-to-face and training group will be clipped with video. The way of work is that before the implementation of educational methods, the pre-test will be taken from all three groups and two months after implementation of the training methods in the two intervention groups, the post-test will be taken from all three groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-21 year-old adolescents with congenital heart disease; Having Satisfaction; Have at least the ability to read and write; A home theater display device to see the educational video; Has not participated in similar educational programs. exclusion criteria: Cases of other chronic diseases.

Intervention groups

Intervention group1(Face-to-face education group): Face-to-face self-care education is one for each person in two sessions of 35 to 45 minutes and one week apart.
Intervention group2 (Educational video clip group): Educational video clip The study included a compact disc made by a researcher and media consultant. Control group: receive routine hospital training.

Main outcome variables

Self-efficacy; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180417039341N1**

Registration date: **2018-06-13, 1397/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-21, 1399/04/01**

Update count: **1**

Registration date

2018-06-13, 1397/03/23

Registrant information

Name

Parisa Hasannezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2392 2477

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the effectiveness of self-care education in two methods, face to face and video educational, on the self-efficacy and quality of life in adolescents with congenital heart disease

Public title

Evaluation of self-care education on self-efficacy and quality of life in adolescents with congenital heart disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

18-21 year-old adolescents with congenital heart disease who have come to the clinic at least once a year. The adolescents has the consent to participate in the study. Have at least the ability to read and write. At least 6 months have passed since the initial diagnosis of their illness. A home theater display device to see the educational video. Has not participated in similar educational programs (with the exception of the routine program) over the past year.

Exclusion criteria:

Hearing and vision impairment, and other chronic diseases.

Age

From **18 years** old to **21 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **111**

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, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-06, 1396/08/15

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9311687003

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

Self-efficacy score in SHERER questionnaire

Timepoint

Measurement of self-efficacy at the beginning of the study (before intervention) and 2 months after face-to-face training and educational video clip

Method of measurement

SHERER Self-efficacy questionnaire

2

Description

Quality of Life Score in the WHO Quality of Life-BREF Questionnaire

Timepoint

Measurement of quality of life at the beginning of the study (before intervention) and 2 months after face-to-face training and video clip training

Method of measurement

WHO Quality of Life-BREF Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Face to face education individually per person in two sessions of 35 to 45 minutes, intervals of one week about 1- Description of heart defect and treatment 2- Prevention of complications 3- Physical activities 4. Fertility and

genetic health 5 Prevention and Pregnancy Program.

Category

Rehabilitation

2

Description

Second intervention group: Educational video clip In this study, a compact disc was developed by a researcher and assisted by a media consultant, which included educational content: a description of congenital heart disease and treatment in summary and simple language, along with moving pictures, teaching common complications And prevention of them in the form of lectures, the scope of physical activity in different patients, the education of reproductive health and appropriate prevention methods in the form of lectures

Category

Rehabilitation

3

Description

Control group: Get a routine hospital training program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Rajaei Cardiovascular Medical and Research Center

Full name of responsible person

Parisa Hassannezhad

Street address

Shaheed Rajaei Cardiovascular Medical and Research Center., Valiasr Ave., Niayesh Intersection., Tehran., Iran

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hassannejad.p@tak.iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malekoti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, Iran

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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

Parisa Hasannezhad

Position

Masters Student of Pediatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St., Tehran, 1996713883, IRAN

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Individual data of the participants as well as the final results of self-efficacy and their quality of life in the study after unidentifiable individuals can be shared.

When the data will become available and for how long

Start the 6 month period after the results are printed

To whom data/document is available

All individuals can use the results of this research if necessary.

Under which criteria data/document could be used

Using the results of the research to raise the level of science and also use its results in conducting other research.

From where data/document is obtainable

Parisa hasannezhad: Email:
parisa.hasannezhad@yahoo.com Address: Shaheed
Rajaei Cardiovascular Medical and Research Center.,
Valiasr Ave., Niayesh Intersection., Tehran., Iran

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

After registering the data, the applicant, upon request, sends the email to the researcher, and the purpose of the request is to explain the results and the results, and will be sent to them by email within the shortest possible time after the review by the researcher.

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

Iran University of Medical Sciences

Full name of responsible person

Parisa Hasannezhad

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Latest degree

Bachelor

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