Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 of111 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

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Iran (Islamic Republic of)

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Seyed 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

Parisa Hasannezhad

Position

Masters Student of Pediatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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