Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of self-care programs on the quality of life of 6-18 year old children and adolescents with syncope

Protocol summary

Study aim
Determining the effect of self-care behaviors on the quality of life among children and adolescents with syncope

Design
An experimental, single blind, randomized study with 120 patients, with the control group, with parallel design

Settings and conduct
Participants will be selected from children and adolescents aged 6-18 years with syncope referred to Shahid Chamran Cardiovascular Hospital and Imam Hossein Children's Hospital in Isfahan, and then they will be divided into two groups of intervention and control. The participants will be kept blind to the received intervention. They will complete pre-test questionnaires and the intervention will be conducted on both groups. After the data is collected, self-care behavior programs will be explained for the children and adolescents and their parents through speech, question-answering, role-play, pamphlet, and booklet. Verbal persuasion will be done in two ways: Verbal encouragement during intervention and monthly follow-ups by telephone throughout the study. Six months after the intervention, the post-test self-report questionnaires will be completed by the participants.

Participants/Inclusion and exclusion criteria
Inclusion criterion: Children and adolescents aged 6-18 years with syncope Exclusion criteron: Patients with major chronic medical problems

Intervention groups
Intervention group: Receiving routine, common and standard syncope commands, Handgrip & Arm Tensing-Leg Crossing training, Tilting Training. Control group: Receiving routine, conventional and standard syncope commands, physical training for syncope control (Handgrip & Arm Tensing - Leg Crossing)

Main outcome variables
self-care behaviors and quality of life in patients with syncope; Prevention of syncope in children and adolescents

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150428021987N3**
Registration date: **2018-04-08, 1397/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-08, 1397/01/19**
Update count: **0**

Registration date
2018-04-08, 1397/01/19

Registrant information

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Name of organization / entity
medical university of isfahan

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-06, 1396/12/15

Expected recruitment end date
2018-09-06, 1397/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of self-care programs on the quality of life of 6-18 year old children and adolescents with syncope

Public title
The effect of Self-Care Behaviors on Quality Of Life
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of syncope disease by a specialist physician and having a positive Tilt test being at the age of 6-18 years The ability to perform physical maneuvers Written consent from parents
Exclusion criteria:
Patients with syncope due to structural heart disease Patients with Orthostatic Hypotension Patients with Vascular Steal Syndrome People with chronic diseases Not being volunteer to participate in the study
Age
From **6 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly assigned to two groups using the random numbers table
Blinding (investigator's opinion)
Single blinded
Blinding description
After receiving explanations about the study and receiving informed consent from parents, children and adolescents and their parents will be blind to the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences; Hezajarib Street
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Approval date
2018-01-23, 1396/11/03
Ethics committee reference number
IR.MUI.REC.1396.2.125

Health conditions studied

1

Description of health condition studied
Vasovagal syncope
ICD-10 code
R55
ICD-10 code description
Syncope and collapse

Primary outcomes

1

Description
Total Quality of Life Score
Timepoint
Baseline and 6 months after intervention
Method of measurement
Quality of Life questionnaire (PedsQL)

2

Description
Physical Health Score
Timepoint
Baseline and 6 months after intervention
Method of measurement
Quality of Life questionnaire (PedsQL)

3

Description
Emotional Functioning Score
Timepoint
Baseline and 6 months after intervention
Method of measurement
Quality of Life questionnaire (PedsQL)

4

Description
School Functioning Score
Timepoint
Baseline and 6 months after intervention
Method of measurement

Quality of Life questionnaire (PedsQL)

5

Description
Social Functioning Score
Timepoint
Baseline and 6 months after intervention
Method of measurement
Quality of Life questionnaire (PedsQL)

6

Description
Psychosocial Health Score
Timepoint
Baseline and 6 months after intervention
Method of measurement
Quality of Life questionnaire (PedsQL)

7

Description
Self-care questionnaire Score
Timepoint
Baseline and 6 months after intervention
Method of measurement
Researcher made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving routine, common, and standard syncope commands, including increased fluid intake and consuming more salt in foods and Physical maneuver training Including Handgrip & Arm Tensing - Leg Crossing and tilt training including Standing with back against a wall
Category
Prevention

2

Description
Control group: Receiving routine, common, and standard syncope commands, including increased fluid intake and consuming more salt in foods and Physical maneuver training Including Handgrip & Arm Tensing - Leg Crossing
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Heart Center
Full name of responsible person
Dr. Alireza Ahmadi
Street address
Pediatric Cardiovascular Research Center, Cardiovascular Research Institute, Third Moshtagh Ave, Isfahan, Iran
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2

Recruitment center
Name of recruitment center
Imam hossein chidren hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan Cardiovascular Research Institute
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Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, Moshtagh Sevom St.,
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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
Isfahan Cardiovascular Research Institute

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
Pediatric Cardiovascular Research Center, Cardiovascular Research Institute,

Full name of responsible person
Zohreh Sadat Navabi

Position
Expert at the Pediatric Cardiovascular Research Center

Latest degree
Master

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary	Not applicable