

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 criterion: 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

Name

alireza ahmadi

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

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Isfahan

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Isfahan

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 children hospital

Full name of responsible person

Dr. Alireza Ahmadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan Cardiovascular Research Institute

Full name of responsible person

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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,
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Full name of responsible person
Zohreh Sadat Navabi
Position
Expert at the Pediatric Cardiovascular Research Center
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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

