

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 31 3668 3295

##### Email address

alirezaahmadi@med.mui.ac.ir

##### 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**

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

#### **City**

Isfahan

#### **Province**

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#### **Postal code**

81465-1148

#### **Phone**

+98 31 3611 5212

#### **Email**

ahmadi\_cardio@yahoo.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Imam hossein children hospital

##### **Full name of responsible person**

Dr. Alireza Ahmadi

##### **Street address**

Isfahan, Imam Khomeini St, Imam hossein children  
hospital

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Isfahan Cardiovascular Research Institute

##### **Full name of responsible person**

Dr. Masomeh Sadeghi

##### **Street address**

Isfahan Cardiovascular Research Institute, Shahid  
Rahmani Alley, Moshtagh Sevom St.,

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crc@mui.ac.ir

#### **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****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Alireza Ahmadi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

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**Person responsible for updating data****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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**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

