

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of lifestyle change and stress management training on hypertensive children and adolescents compared to routine care on blood pressure, blood sugar and lipid profiles control

Protocol summary

Study aim

Determine the impact of stress management lifestyle training exercises on hypertensive children and adolescents compared to routine care on blood pressure control, glucose and lipid profile

Design

This study is a randomized controlled clinical trial with three arms performed in parallel groups. Individuals are assigned to groups using a simple randomization method and a random number table. This is a single-blind study. 144 children and adolescents are randomly selected.

Settings and conduct

This study was performed in three times at Shahid Sadoughi University of Medical Sciences in Yazd: time before intervention, time immediately after intervention, time 6 months after intervention. The analyser does not know where people are in groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Children and adolescents diagnosed with re-evaluation of hypertension (Stage I), - If the consent for entry is completed by parents (for children under 15 years) or adolescents (for adolescents over 15 years). Exclusion criteria: - Children and adolescents taking hypertension medication, - Children and adolescents who do not qualify for a class (with mental or physical disabilities that make it difficult for them to attend class).

Intervention groups

Groups are defined as group A (lifestyle improvement training group including nutrition modification and physical activity), group B (stress management training group) and group C (usual care group). People in group A are invited to 4 sessions (2 sessions of proper nutrition training and 2 sessions of physical activity training), people in group B receive 8 sessions of stress management training, and those in group C are also two question and answer session by a psychologist and a

physician, are invited.

Main outcome variables

Blood pressure, glucose and blood lipid profiles

General information

Reason for update

Acronym

HCA

IRCT registration information

IRCT registration number: **IRCT20191109045367N1**

Registration date: **2019-12-14, 1398/09/23**

Registration timing: **prospective**

Last update: **2019-12-14, 1398/09/23**

Update count: **0**

Registration date

2019-12-14, 1398/09/23

Registrant information

Name

Nastaran Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3525 4068

Email address

ahmadi.psy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-05-04, 1399/02/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of lifestyle change and stress management training on hypertensive children and adolescents compared to routine care on blood pressure, blood sugar and lipid profiles control

Public title
Effect of lifestyle change and stress management training on hypertensive children and adolescents compared to routine care on blood pressure, blood sugar and lipid profiles control

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Children and adolescents diagnosed with re-evaluation of hypertension (Stage I) If the consent for entry is completed by parents (for children under 15 years) or adolescents (for adolescents over 15 years).
Exclusion criteria:
 Children and adolescents taking hypertension medication
 Children and adolescents who do not qualify for a class (with mental or physical disabilities that make it difficult for them to attend class).

Age
From **9 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals are assigned to groups using a simple randomization method and a random number table.

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyser does not know where people are in groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Yazd Cardiovascular Research Center, Afshar Hospital, Jomhuri Boulevard, Yazd, Iran.

City

Yazd

Province

Yazd

Postal code

8917945556

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.SSU.REC.1398.128

Health conditions studied

1

Description of health condition studied

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

hypertension stage I

Timepoint

- Time 1: Time before intervention - Time 2: Time immediately after intervention Time 3: Time 6 months after intervention

Method of measurement

Blood pressure between 95 and 99 percentile

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lifestyle improvement training group includes nutrition modification and physical activity

Category

Lifestyle

2

Description

Intervention group: Stress Management Training

Category

Behavior

3

Description

Control group: Routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Nastaran Ahmadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

Street address

Yazd Cardiovascular Research Center, Afshar Hospital, Jomhouri Boulevard, Yazd, 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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Nastaran Ahmadi

Position

Associate

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Clinical study report

When the data will become available and for how long

Start of access period 6 months after publishing results

To whom data/document is available

Scientific people

Under which criteria data/document could be used

publish article

From where data/document is obtainable

نسترن احمدی

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

The clinical study report will be sent within three weeks after receiving the request.

Comments

Person responsible for updating data

Contact

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