

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of the DASH diet on the severity of attention deficit and hyperactivity disorder (ADHD) symptoms in children

Protocol summary

Study aim

The purpose of the study is to assess the effect of the dietary approaches to stop hypertension (DASH) diet on the severity of the ADHD compared to the usual diet.

Design

This study will be a randomized controlled clinical trial on 60 children with attention deficit hyperactivity disorder (ADHD) referred to Shahid Sadoughi University of Medical Sciences' clinics, Yazd, Iran. The study participants will be followed for 3 months. After the diagnosis of ADHD, children will be entered into the study according to the eligibility criteria. Verbal and written information about the study protocol will be provided for the parents, and then they will sign an informed consent. Eligible individuals will be randomly assigned to the DASH diet or the control diet group.

Settings and conduct

Both diets will be designed based on the calculated energy requirements of the participants. Participants are asked to visit the center for each month, in order to determine the severity of ADHD based on Abbreviated ten item Conner's Scale (ACS), Swanson, Nolan and Pelham Questionnaire (SNAP) and Strengths and Difficulties Questionnaire (SDQ) questionnaires, and assess the anthropometric indices, physical activity and dietary compliance rates. This process will be carried out for three times up to the end of the third month of follow-up.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Children aged 7-12 years; 2) Diagnosed with ADHD according to DSM-IV criteria
Exclusion criteria: 1) A sudden change in the diet; 2) Intending not to follow the diet by participants; 3) Use of medication during the intervention period; 4) Unwillingness to continue participating in the study for any reason.

Intervention groups

Intervention group: The Dietary Approaches to Stop Hypertension (DASH) diet, which is characterized by high

intake of fruits, vegetables, low-fat dairy products, whole grains, poultry, fish, nuts and legumes and low intake of saturated fat, red meat, sweets, food colors, and sweetened beverages. The macro-nutrient composition of the diet will be 60-50% of carbohydrates, 25-30% of fats and 15-20% of proteins. Control group: The usual diet which is similar to the usual Iranian diet with a macro-nutrient composition of 60-50% of carbohydrates, 25-30% of fats and 15-20% of proteins.

Main outcome variables

Participants will be visited each month, in order to determine the severity of ADHD based on Abbreviated ten item Conner's Scale (ACS), Swanson, Nolan and Pelham Questionnaire (SNAP) and Strengths and Difficulties Questionnaire (SDQ), and to assess the anthropometric indices, physical activity, and dietary compliance rates. This process will be carried out each month up to the end of the third month of follow-up. The assessment of ADHD severity will be done by using three questionnaires including Abbreviated ten item Conner's scale (ACS), Swanson, Nolan and Pelham Questionnaire (SNAP) and Strengths and Difficulties Questionnaire (SDQ). Anthropometric measurements will be done three times during each visit and their mean will be recorded as the final value. The physical activity will be assessed using three-day physical activity record which will be filled by parents before each visit. Furthermore, the parents will provide three-day dietary records each month to assess the compliance of the children with the intervention diets.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130223012571N6**

Registration date: **2018-01-08, 1396/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-08, 1396/10/18**

Update count: **0**

Registration date

2018-01-08, 1396/10/18

Registrant information

Name

Amin Salehi-Abargouei

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

abargouei@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutrition and Food security research center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2018-02-21, 1396/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the DASH diet on the severity of attention deficit and hyperactivity disorder (ADHD) symptoms in children

Public title

The effect of DASH diet on attention deficit and hyperactivity disorder (ADHD) in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 7-12 years; Diagnosis of ADHD according to DSM-IV criteria

Exclusion criteria:

A sudden change in the diet; Intending not to follow the diet by participants; Use of medication during the intervention period; Unwillingness to continue participating in the study for any reason

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The first 60 participants will be randomized to DASH or control diet (30 participants in each group) using simple randomization method by SPSS software. When the 60th participant entered to the study, the participants will be included in the trial using block randomization with the block size of 10. The allocation concealment was done by putting the randomized groups in sealed opaque envelopes, therefore the investigator could not predict the intervention group of invited participants before opening the envelopes.

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 Shahid Sadoughi University of Medical Sciences Yazd

Street address

Yazd, Bahonar Square, Research Deputy

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2016-11-05, 1395/08/15

Ethics committee reference number

IR.SSU.SPH.REC.1395.106

Health conditions studied

1

Description of health condition studied

Attention deficit hyperactivity disorder

ICD-10 code

F90

ICD-10 code description

Attention-deficit hyperactivity disorders

Primary outcomes

1

Description

Inattention

Timepoint

Before the study. One , two and three months after the start of the study.

Method of measurement

Swanson, Nolan and Pelham (SNAP) Questionnaire

2

Description

Hyperactivity

Timepoint

Before the study. One , two and three months after the start of the study.

Method of measurement

Swanson, Nolan and Pelham (SNAP) Questionnaire

3

Description

Inattention with Hyperactivity

Timepoint

Before the study. One , two and three months after the start of the study.

Method of measurement

Abbreviated ten item Conner's scale(ACS), Strengths and Difficulties Questionnaire (SDQ) and Swanson, and Nolan and Pelham (SNAP) Questionnaire

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before starting the study. One, two and three months after the start of the study

Method of measurement

Sphygmomanometer

2

Description

Weight

Timepoint

Before starting the study. One, two and three months after the start of the study

Method of measurement

Scales

3

Description

Height

Timepoint

Before starting the study. One, two and three months after the start of the study

Method of measurement

Meter

Intervention groups

1

Description

Control group: The usual diet which is similar to the usual Iranian diet with a macro-nutrient composition of 60-50% of carbohydrates, 25-30% of fats and 15-20% or proteins.

Category

Lifestyle

2

Description

Intervention group: The Dietary Approaches to Stop Hypertension (DASH) diet, which is characterized by high intake of fruits, vegetables, low-fat dairy products, whole grains, poultry, fish, nuts and legumes and low intake of saturated fat, red meat, sweets, food colors, and sweetened beverages. The macro-nutrient composition of the diet will be 60-50% of carbohydrates, 25-30% of fats and 15-20% or proteins.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali clinic, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Full name of responsible person

Yadollah Khoshbakht

Street address

Bahonar Square, Vice chancellery for research, Shahid Sadoughi University of Medical Sciences

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2229

Email

abargouei@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amirhushang Mehrparvar

Street address

Chancellery for research, Central Building of Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran

City
Yazd

Province
Yazd

Postal code
8915173160

Phone
+98 35 3149 2229

Email
ah.mehrparvar@gmail.com

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
Nutrition and Food Security Research Center, Shahid Sadughi University of medical Sciences, Yazd, Ir

Full name of responsible person
Yadollah khoshtakht

Position
MSc student of Health Sciences in Nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.

City
Yazd

Province
Yazd

Postal code
8915173160

Phone
+98 35 3820 9100

Fax

Email
Y.khoshtakht1369@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Nutrition and Food Security Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, I

Full name of responsible person
Amin Salehi-Abargouei

Position
PhD in Nutrition Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.

City
Yazd

Province
Yazd

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8915173160

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+98 35 3820 9100

Fax

Email
abargouei@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Nutrition and Food Security Research Center, Shahid Sadughi University of medical Sciences, Yazd, Ir

Full name of responsible person
Yadollah Khoshtakht

Position
MSc student of Health Sciences in Nutrition

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Fax

Email
Y.khoshtakht1369@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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

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

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

Data Dictionary

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

Title and more details about the data/document

Data on the baseline and after treatment values of primary and secondary outcome variables will be available for researchers.

When the data will become available and for how long

Data will be available after the summary data become

published.

To whom data/document is available

The data will be available for all researchers interested in the subject.

Under which criteria data/document could be used

Data will be available if the interested researcher(s) fills the proposal for a joint project and the sponsor of the study (Shahid Sadoughi University of Medical Sciences) confirms the protocol of the project.

From where data/document is obtainable

The data can be obtained from: Dr. Amin Salehi-Abargouei, Ph.D. in Nutrition Department of Nutrition Faculty of Public Health Sahid Sadoughi University of Medical Sciences Yazd, PO Code 8915173160 Iran
Tel:+98-35-31492229 Fax:+98-35-38209119 Email: abargouei@ssu.ac.ir Alternate email: abargouei@gmail.com

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

The interested investigators should provide a brief description of the data needed and their reason for asking the data by contacting the principal investigator. The principal investigator will assess the possibility of sharing the data and if applicable will ask for a joint proposal. The joint proposal will be sent to the vice chancellery for research, ShahidSadoughi University of Medical Sciences (the sponsor) and the data will be sent by the principal investigator if the sponsor confirms the cooperation.

Comments