

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the effect of MIND diet on physical fitness and anthropometric indices in female high school students: a cluster randomized controlled trial

Protocol summary

Study aim

The purpose of this study is to determine the effect of MIND diet on physical fitness and anthropometric factors among female high school students.

Design

This study is a cluster randomized controlled trial

Settings and conduct

In this study, 6 eligible schools will be randomly assigned to one of the intervention and control arms and two types of MIND and control diets will be studied. people will be followed up for 3 months

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. High school girls aged 15 to 17 years
2. Informed consent of participants and their parents
Exclusion criteria: 1) Cardiovascular diseases. 2) History of liver disease (alanine aminotransferase (ALT) and aspartate transaminase (AST) more than three times the normal values) and kidney disease (BUN and creatinine values higher than normal). 3) Suffering from cancer or a history of it. 4) suffering from a known cardiovascular disease (coronary artery disease, stroke, congestive heart disease) or a history of heart surgery. 5) having type 2 diabetes (fasting blood sugar above 126) or type 1 diabetes 6) receiving a special diet 7) having any underlying disease 8) people who do professional sports or are athletes 9) Allergy to any of the MIND diet components 10) Obese people (above 97th percentile)

Intervention groups

The MIND diet is a combination of the Mediterranean diet and DASH, which will be adjusted according to the ratio of macronutrients: 50-60% carbohydrates, 25-30% fat, and 15-20% protein for the intervention group and the diet of the control group is similar to the typical Iranian diet with a combination of macronutrients. 50 - 60% carbohydrates, 25-30% fat and 15-20% protein

Main outcome variables

Weight, body mass index, waist circumference , body fat

percentage, skeletal muscle percentage, cardiorespiratory fitness, anaerobic strength and Handgrip strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130223012571N9**

Registration date: **2023-10-13, 1402/07/21**

Registration timing: **prospective**

Last update: **2023-10-13, 1402/07/21**

Update count: **0**

Registration date

2023-10-13, 1402/07/21

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

Expected recruitment start date

2023-11-06, 1402/08/15

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of MIND diet on physical fitness and anthropometric indices in female high school students: a cluster randomized controlled trial

Public title
The effect of MIND diet on physical fitness

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

High school girls aged 15 to 17 years Informed consent of participants and their parents Having regular menstruation

Exclusion criteria:

cardiovascular diseases History of liver and kidney disease Suffering from cancer or a history of cancer Having a known cardiovascular disease or a history of heart surgery Having type 2 diabetes (fasting blood sugar above 126) or type 1 diabetes Recipient of a special diet Having any underlying disease People who do professional sports or are athletes Allergy to any of the components of the MIND diet Obese people (over 97th percentile) History of women's diseases and use of hormonal drugs

Age
From **15 years** old to **17 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Among the high school girls' schools in Yazd that are eligible to enter the study, 6 schools are randomly selected using SPSS software. 6 envelopes containing intervention or control codes prepared in advance are provided to the investigators. After opening each envelope, the investigators identify each school. In each school, according to the assigned group, 50 students are randomly selected (by generating 50 random numbers and choosing from the list of students of each school) and enter the study.

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

Faculty of Public Health, Shahid Sadughi University of Medical Sciences, Alem Square, Yazd, Iran.

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2023-09-11, 1402/06/20

Ethics committee reference number

IR.SSU.SPH.REC.1402.062

Health conditions studied

1

Description of health condition studied

High school girl students

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Weight

Timepoint

The beginning and end of the study (after three months)

Method of measurement

A scale with an accuracy of 100 grams

2

Description

waist circumference

Timepoint

The beginning and end of the study (after three months)

Method of measurement

tape measure with an accuracy of 0.5 cm

3

Description

Body mass index

Timepoint

The beginning and end of the study (after three months)

Method of measurement

The ratio of weight to the square of height

4

Description

Percentage of fat mass

Timepoint

The beginning and end of the study (after three months)

Method of measurement

body composition analyzer (Omron)

5

Description

Skeletal muscle percentage

Timepoint

The beginning and end of the study (after three months)

Method of measurement

body composition analyzer (Omron)

6

Description

Cardiorespiratory fitness

Timepoint

The beginning and end of the study (after three months)

Method of measurement

20 m shuttle run test

7

Description

Handgrip strength

Timepoint

The beginning and end of the study (after three months)

Method of measurement

Handgrip

8

Description

Anaerobic power

Timepoint

The beginning and end of the study (after three months)

Method of measurement

Standing broad jump

Secondary outcomes

1

Description

Depression score

Timepoint

The beginning and end of the study (after three months)

Method of measurement

PHQ-9 and DASS-21 questionnaires

2

Description

Anxiety score

Timepoint

The beginning and end of the study (after three months)

Method of measurement

GAD-7 and DASS-21 questionnaires

3

Description

Stress score

Timepoint

The beginning and end of the study (after three months)

Method of measurement

DASS-21 questionnaire

4

Description

Overall health score

Timepoint

The beginning and end of the study (after three months)

Method of measurement

GHQ questionnaire

5

Description

The obtained score of premenstrual syndrome symptoms

Timepoint

The beginning and end of the study (after three months)

Method of measurement

PSST questionnaire

6

Description

The obtained score of menstrual distress

Timepoint

The beginning and end of the study (after three months)

Method of measurement

MMDQ questionnaire

7

Description

sleep quality and quantity

Timepoint

The beginning and end of the study (after three months)

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

8

Description

mental health

Timepoint

The beginning and end of the study (after three months)

Method of measurement

SDQ questionnaire

9

Description

health-related quality of life

Timepoint

The beginning and end of the study (after three months)

Method of measurement

SF-36 questionnaire

Intervention groups

1

Description

Intervention group: Mediterranean-DASH Diet
Intervention for Neurodegenerative Delay The MIND diet is a combination of the Mediterranean diet and DASH, which will be adjusted according to the ratio of macronutrients: 50-60% carbohydrates, 25-30% fat, and 15-20% protein for the intervention group. The MIND diet contains high amounts of green leafy vegetables and other vegetables, berries, nuts, olive oil, whole grains, fish, legumes, and poultry.

Category

Lifestyle

2

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% of proteins.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

High schools for girls in Yazd city

Full name of responsible person

Fatemeh Moghtaderi

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Department of Nutrition, Faculty of Public Health,
Shahid Sadoughi University of Medical Sciences, Alem
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amin Salehi-Abargouei

Street address

Chancellery for research, Central Building of Shahid
Sadoughi University of Medical Sciences, Bahonar
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Email

abargouei@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

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Moghtaderi

Position

PhD student of nutrition sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

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Department of Nutrition, Faculty of Public Health,
Shahid Sadoughi University of Medical Sciences, Alem
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moghtaderi.fatemeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amin Salehi-Abargouei

Position

PhD in Nutrition Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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Email

moghtaderi.fatemeh@gmail.com

Web page address

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

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

Informed Consent Form

Yes - There is 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

The general characteristics of the participants (without mentioning names and personal information) as well as the data for baseline and post-intervention values for primary and secondary outcomes will be made available to those interested after submitting the researchers' request and reviewing the principal investigators.

When the data will become available and for how long

The data will be available to the researchers when the related articles are 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 Shahid 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, Shahid Sadoughi University of Medical Sciences (the sponsor) and the data will be sent by the principal investigator if the sponsor confirms the cooperation.

Comments