

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the effect of Dietary Approaches to Stop Hypertension diet on stress, depression, quality of life and sleep status of students and their families: A randomized clinical trial

Protocol summary

Study aim

This study aimed to investigate the effect of DASH diet prescription compared with standard diet on levels of depression, anxiety, stress, quality of life, sleep quantity and quality among students and their families

Design

A two-arm, randomized parallel controlled clinical trial. A total of 400 eligible participants will be assigned to two intervention groups (n=200) using simple randomization.

Settings and conduct

This study will be conducted in the Nutrition and Food Security research center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran. A total of 400 eligible individuals will be randomly assigned to two groups (n=200) in which they will receive recommendations of DASH or standard diets for six months. Depression, stress, anxiety, quality of life, adherence to diet, sleep quantity and quality will be assessed at baseline and 6 month later

Participants/Inclusion and exclusion criteria

Inclusion criteria: undergraduate nutrition students and their families (over 12 years old) which give consent to enter the study Exclusion criteria: past history of cancer, autoimmune diseases, inflammatory bowel disease, chronic or acute renal disease (creatinine ≥ 1.4 mg / dL for men or 1.3 for women or proteinuria) and anti-psychotic drugs use in past 6 months

Intervention groups

Intervention group: the individuals will receive DASH diet. The participants will be trained DASH diet in four online sessions. They will receive dietary recommendations during intervention period. Control group: the individuals will receive standard diet. The study participants will be trained standard diet recommendations in four online sessions. They will receive dietary recommendations during intervention period. The duration of the intervention and study will be

6 months

Main outcome variables

Depression, Anxiety, Stress, Sleep Quality, Sleep quantity, Quality of Life, Adherence to diet

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210427051098N1**

Registration date: **2021-10-10, 1400/07/18**

Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**

Update count: **0**

Registration date

2021-10-10, 1400/07/18

Registrant information

Name

Sayyed Saeid Khayyatadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

khayyatadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Dietary Approaches to Stop Hypertension diet on stress, depression, quality of life and sleep status of students and their families: A randomized clinical trial

Public title
The effect of Dietary Approaches to Stop Hypertension diet on mental health

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Undergraduate nutrition students and their families (over 12 years old) Completion of informed consent
Exclusion criteria:
Pregnancy and lactation Suffering from cancer Suffering from autoimmune diseases Suffering from inflammatory bowel disease Chronic or acute kidney disease (creatinine ≥ 1.4 mg / dL for men or ≥ 1.3 for women or proteinuria) Hospitalization for more than 2 weeks

Age
From 12 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 400

Randomization (investigator's opinion)
Randomized

Randomization description
After determining the eligible people and obtaining their consent, the participants will be divided into two groups [intervention (DASH diet) or control (standard diet)] by random allocation method. Firstly, each individual will receive a specific code number. Then all code numbers will be entered to random allocation software. Software inputs will include the total number of samples and the number of treatment groups (intervention and control). The software output will include random numbers assigned to two groups. The allocation ratio will be 1:1. Each participant will have an equal chance of being in each group, and participants in the study will not be able to predict the type of intervention they receive.

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

Central Building of Shahid Sadoughi University of Medical Sciences, Yazd, Bahonar Square, Shahid Sadoughi Blvd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2021-02-03, 1399/11/15

Ethics committee reference number

IR.SSU.SPH.REC.1399.244

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

3

Description of health condition studied

Sleep disorders

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

4

Description of health condition studied

Dyspepsia

ICD-10 code

K30
ICD-10 code description
Functional dyspepsia

5
Description of health condition studied
Irritable bowel syndrome

ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

6
Description of health condition studied
Stress
ICD-10 code
F54
ICD-10 code description
Psychological and behavioral factors associated with disorders or diseases classified elsewhere

7
Description of health condition studied
Quality of life
ICD-10 code
F54
ICD-10 code description
Psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes

1
Description
Anxiety
Timepoint
Before the intervention, 6 months after the intervention
Method of measurement
DASS-21 validated questionnaire

2
Description
depression
Timepoint
Before the intervention, 6 months after the intervention
Method of measurement
Beck and DASS-21 validated questionnaires

3
Description
Sleep quality
Timepoint
Before the intervention, 6 months after the intervention
Method of measurement
Pittsburgh Validated Questionnaire

4
Description
Stress
Timepoint
Before the intervention, 6 and 12 months after the intervention
Method of measurement
DASS-21 validated questionnaire

5
Description
Quality of life
Timepoint
Before the intervention, 6 and 12 months after the intervention
Method of measurement
SF-12 validated questionnaire

6
Description
Excessive daytime sleepiness
Timepoint
Before the intervention, 6 and 12 months after the intervention
Method of measurement
Epworth Sleepiness Scale validated questionnaire

7
Description
dyspepsia
Timepoint
Before the intervention, 6 and 12 months after the intervention
Method of measurement
Rome IV questionnaire

8
Description
Irritable bowel syndrome
Timepoint
Before the intervention, 6 and 12 months after the intervention
Method of measurement
Rome IV questionnaire

Secondary outcomes

1
Description
Weight
Timepoint
Before the intervention, 6 and 12 months after the intervention
Method of measurement
Weighting scale

2

Description

Body mass index (BMI)

Timepoint

Before the intervention, 6 and 12 months after the intervention

Method of measurement

Ratio of weight to height squared

Intervention groups

1

Description

Intervention group: in this group, the individuals will receive dietary approach to stop hypertension (DASH) diet which including 18% protein, 27% fat and 55% carbohydrate. At first, the study participants will be trained DASH diet recommendations in four online sessions of 2 hour each. Then, the individuals will weekly receive DASH recommendations through communication software during intervention. The individuals will be encouraged to consume more amount of whole grains, low-fat foods, fish, chicken, lean beef and eggs (to reduce the intake of saturated fat and cholesterol), low-fat dairy products, seeds and nuts, fruits and vegetables high in potassium (with emphasis on sources of key nutrients in the DASH diet). We will recommend individuals to limit intake of processed foods, which have high calorie density and are rich in fats, sugars and sodium. Sodium intake will be limited to 2,400-3,000 mg/day. The required energy of each person will be determined based on Harris Benedict formula. If a person is overweight or obese, the patient's calculated energy will be reduced by 500 kcal. The dietary plan will prescribe individually. The duration of the study and intervention will be 6 months. Training sessions will be held once a week in the first month. Contents of the first session: Principles of DASH diet and calculation of calorie intake, Session 2: Carbohydrate sources of DASH diet, Session 3: Protein sources of DASH diet, Fourth session: Fat sources of DASH diet and sodium and sugar restriction of diet.

Category

Behavior

2

Description

Control group: In this group, the individuals will receive standard diet which including 15% protein, 30% fat and 55% carbohydrate. At first, the study participants will be trained standard diet recommendations in four online sessions of 2 hour each. Then, the individuals will weekly receive standard diet recommendations through communication software during intervention. The amount of calories is the same as the intervention group, but differs from the intervention group in terms of the number of food group units. Diet low in sugar and fat will be recommended. We will not have any recommendation about sodium or potassium intakes. The required energy of each person will be determined based on Harris

Benedict formula. If a person is overweight or obese, the patient's calculated energy will be reduced by 500 kcal. The dietary plan will prescribe individually. Contents of the first session: Food groups and calculation of calorie intake, Session 2: Importance of cereals, legumes and sugar in diet, Session 3: the role of dairy products, meat and oil in human health, Fourth session: importance of fruits and vegetables in human health.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Sayyed Saeid Khayyatadeh

Street address

Shahid Sadoughi university of medical sciences,
Shohadaye gomnam Blvd, Alem square,

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9100

Email

khayyatadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Shahid Sadoughi University of Medical Sciences,
Bahonar Square.

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3146 2136

Email

mmirzaei@ssu.ac.ir

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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Sayyed Saeid Khayatzadeh

Position

Assistant professor in nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shahid Sadoughi University of Medical Sciences, Alem Square.

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9100

Email

khayyatzadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Seyed Saeed Khayatzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Public Health, Shahid Sadoughi University of Medical Sciences, Alem Square.

City

yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9100

Email

khayyatzadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Seyed Saeed Khayatzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Public Health, Shahid Sadoughi University of Medical Sciences, Alem Square.

City

yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3820 9100

Email

khayyatzadeh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

No - There is not 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

primary outcome will be available at the end of study

When the data will become available and for how long

From January 2023

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Academic institutes can send their official request to the email of the scientific director of the project. the data will be sent after confirmation of ethics committee of shahid

sadoughi university of medical sciences. It is not possible to perform statistical analysis on the data.

From where data/document is obtainable

Sayyed Saeid Khayyat-zadeh Assistant professor of nutrition in Shahid Sadoughi university of medical sciences Khayyat-zadeh@yahoo.com 00983538209100

What processes are involved for a request to access

data/document

Academic institutes can send their official request to the email of the scientific director of the project. The data will be sent after confirmation of ethics committee of Shahid Sadoughi university of medical sciences

Comments