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 Khayyatzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3820 9100
Email address
khayyatzadeh@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 Khayyatzadeh
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
khayyatzadeh@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 Khayyatzadeh

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 Sadughi 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 Sadughi 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 Khayyatzadeh Assistant professor of nutrition in Shahid Sadoughi university of medical sciences Khayyatzadeh@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