

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of Dietary Approaches to Stop Hypertension (DASH) diet on mental health, sleep, sexual hormones and advanced glycated end products (AGEs) serum levels among type 2 diabetic women: A clinical trial study

Protocol summary

Study aim

Effect of Dietary Approaches to Stop Hypertension (DASH) diet on psychological and sleep status, sexual hormones, and AGEs levels

Design

This study is a parallel clinical trial in 60 postmenopause and diabetic patients. These subjects divided into intervention and control groups as follows: Intervention group and the usual diet as Control group. The tendency to participate in the study, patients with type 2 diabetes and who are postmenopause and don't adhere to a specific diet are inclusion criteria. The exclusion criteria are as follows: cancer, kidney, liver, heart, psychological disorders, and other diseases, any new events which impact patients' mood, consumption of OCPs, hormonal drugs, and hormone therapy. estrogen therapy for 3 last months. smoking. Insulin therapy and consumption of any supplement and vitamin during 2 last months.

Settings and conduct

Sampling will be done in the diabetes clinic of TUMS. Characteristics information, physical activity, food records, PSQI, DASS-21 questionnaire, and blood samples will be filled before and at the end of the trial. 2 groups (n=30) of participants will receive a DASH or usual diet for 12 weeks. The intervention is a diet, there is no concealing.

Participants/Inclusion and exclusion criteria

The tendency to participate in the study, patients with type 2 diabetes and who are postmenopause and don't adhere to a specific diet are inclusion criteria. The exclusion criteria are as follows: cancer, kidney, liver, heart, psychological disorders, and other diseases, any new events which impact on patients mood

Intervention groups

Intervention group: 30 postmenopause women with type 2 diabetes in DASH diet Control group: 30

postmenopause women with type 2 diabetes in the usual diet

Main outcome variables

Stress, Anxiety, and depression, Sleep status, Sexual hormones, Advanced Glycated End Products in serum

General information

Reason for update

Sodium and potassium urine tests changed to serum vitamin C testing. Because it is not possible to store urine for 24 hours in a university laboratory. Patients also do not cooperate.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180312039055N1**
Registration date: **2018-05-20, 1397/02/30**
Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**

Update count: **1**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

Elnaz Daneshzad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Dietary Approaches to Stop Hypertension (DASH) diet on mental health, sleep, sexual hormones and advanced glycated end products (AGEs) serum levels among type 2 diabetic women: A clinical trial study

Public title

DASH diet in diabetes complications

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Tendency to participate in the study Patients with type 2 diabetes Postmenopause individuals (who don't have the period cycle for 12 months) Persons who dont adhere special diets

Exclusion criteria:

Patients with cancer, kidney, liver, heart and other specific diseases, patients with depression and other psychological diseases, New events which impact on patients mood Consumption of OCPs, hormonal supplements and hormone therapy Esterogen therapy during 3 last months Smoking Insulin therapy Consumption of supplements and vitamins during 2 last months Patients with depression and other psychological diseases, New events which impact on patients mood

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Participants divide into control (n= 30) and intervention (n= 30) groups using randomized number table by permuted-block randomization method . Then, individuals block according to age and body mass index (normal, overweight and obese). This study is diet therapy and doesn't have concealing processing.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

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Tehran University of Medical Sciences Research Center, Qods Ave, Keshavarz Blv

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Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.TUMS.VCR.REC.1397.158

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Diabetes

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

sleep

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Luteinizing Hormone (LH)

Timepoint

Before and after intervention (12wk)

Method of measurement

Serum levels by ELISA

2**Description**

Follicle Stimulating Hormone (FSH)

Timepoint

Before and after intervention (12wk)

Method of measurement

Serum levels by ELISA

3**Description**

Sex Hormone Binding Globulin (SHBG)

Timepoint

Before and after intervention (12wk)

Method of measurement

Serum levels by ELISA

4**Description**

Testosterone

Timepoint

Before and after intervention (12wk)

Method of measurement

Serum levels by ELISA

5**Description**

Advanced Glycation End products (AGEs)

Timepoint

Before and after intervention (12wk)

Method of measurement

Serum levels by ELISA

6**Description**

depression

Timepoint

Before and after intervention (12wk)

Method of measurement

DASS-21 item questionnaire

7**Description**

Sleep status

Timepoint

Before and after intervention (12wk)

Method of measurement

Pittsburgh sleep questionnaire index (PSQI)

8**Description**

anxiety

Timepoint

Before and after intervention (12 wk)

Method of measurement

DASS-21 item questionnaire

9**Description**

Stress

Timepoint

Before and after intervention (12 wk)

Method of measurement

DASS-21 item questionnaire

Secondary outcomes**1****Description**

Weight

Timepoint

Before and after intervention (12 wk)

Method of measurement

Scale

2**Description**

Waist circumference

Timepoint

Before and after intervention (12 wk)

Method of measurement

inflexible meter

3**Description**

Blood pressure

Timepoint

Before and after intervention (12 wk)

Method of measurement

Digital Sphygmomanometer

4**Description**

Body Mass Index (BMI)

Timepoint

Before and after intervention (12 wk)

Method of measurement

Weight in kilogram divided to square of height in meter

Intervention groups**1****Description**

Intervention group: Postmenopausal diabetic patients who adhere to the DASH diet. Intervention in this group of people receiving the DASH diet as a diet rich in antioxidants for three months in which it is recommended to receive vegetables, fruits, nuts and nuts, fish, legumes and low-fat dairy products. In this diet, it is recommended to reduce the consumption of red meat, salt, and salts, as well as sweets. No

intervention is given in the medication regimen. People are advised not to change their physical activity before studying.

Category

Treatment - Other

2**Description**

Control group: Postmenopausal diabetic patients who adhere usual diet. The intervention in this group of people is to receive the usual daily diet and receive the usual recommendations for three months. The amount of calories and nutrients is the same as the intervention group, but differs from the intervention group in terms of the number of food group units. No intervention is given in the medication regimen. People are advised not to change their physical activity before studying.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrine & Metabolism Research Institute

Full name of responsible person

Bagher Larijani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Leila Azadbakht

Position

PhD in Nutrition, Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Full name of responsible person

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of privacy and ethics committee, we can not distribute their information.

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable