

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

The effect of MIND (Mediterranean-DASH Intervention for Neurodegenerative Delay) diet pattern on sleep status, anxiety, depression, and cardiometabolic indices in overweight or obese diabetic women with insomnia: A randomized controlled clinical trial

Protocol summary

Study aim

The effect of MIND diet pattern on sleep status, anxiety, depression, and cardiometabolic indices in overweight or obese diabetic women with insomnia

Design

Randomized controlled trial with 2 parallel groups (22 in each group), the random block was used for randomization.

Settings and conduct

44 diabetic women with insomnia referred to Kurdistan University of Medical Sciences will be selected. Then the subjects will be divided into two groups: a control group and an intervention group. The required energy will be calculated based on the World Health Organisation equations, and 500 kcal will be subtracted in both groups for weight loss. A low-calorie mind diet will be followed in the intervention group and a low-calorie diet will be followed in the control group. After 3 months of intervention, the results will be compared in both groups. For this study, there is no possibility of blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with type 2 diabetes, desire to participate in the study, age range from 30 to 65 years old, body mass index between 25 and 35 kg/m², suffering from insomnia disorder
Exclusion criteria: Insulin use, pregnancy and lactation, alcohol and smoking, sleep apnea, shift work, Special diets and medications for weight loss in the last 3 months, suffering from other endocrine, metabolic, kidney and neurological diseases, taking any medicine with the exception of blood glucose, lipid and blood pressure lowering medications

Intervention groups

The subjects divided into 2 groups: Group 1: receiving low calorie mind diet 2: receiving low calorie diet

Main outcome variables

Fasting blood sugar; HbA1C; insulin; triglyceride; total cholesterol; HDL-C; hs-CRP; BDNF; cortisol; TAC; TOC; GSH-Px; catalase; SOD; MDA; body mass index; quality of life; anxiety and depression status; sleep quality; insomnia; blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041611N8**

Registration date: **2023-08-07, 1402/05/16**

Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**

Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Mehnoosh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2009

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mehnoosh_samadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-19, 1402/05/28

Expected recruitment end date

2024-01-18, 1402/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of MIND (Mediterranean-DASH Intervention for Neurodegenerative Delay) diet pattern on sleep status, anxiety, depression, and cardiometabolic indices in overweight or obese diabetic women with insomnia: A randomized controlled clinical trial

Public title

The effect of MIND diet in diabetic patients with insomnia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with type 2 diabetes Desire to participate in the study Age range from 30 to 65 years old Body mass index between 25 and 35 kg/m2 Suffering from insomnia disorder, based on the Insomnia Severity Index (ISI) questionnaire, with scores above 7

Exclusion criteria:

Insulin use Pregnancy and lactation Alcohol and smoking Sleep apnea Shift work Special diets and medications for weight loss in the last 3 months Suffering from other endocrine, metabolic, kidney and neurological diseases Taking medications (sedatives, painkillers, sleeping pills, etc.) other than blood sugar, lipid, and blood pressure lowering medications

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The random sequence is generated using the random block method. For random allocation of people, 11 blocks with 4 permutations will be created. The person collecting the information does not know anything about how the samples are assigned to the study groups. In performing the random assignment, the following points are considered: a) Each group is assigned an English letter: A to the low calorie MIND diet group, B to the normal low calorie diet group b) An order for sample size 44 is prepared. c) For the concealment procedure of random assignment, 44 opaque envelopes and 44 cards are prepared. In each envelope, 4 cards are placed in order in each block. The block numbers are written on each envelope. The name of the desired group is written

on each card in turn.

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 Kermanshah University of Medical Sciences

Street address

Building No.2, Research Council of Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard, Kermanshah, Iran

City

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Province

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Postal code

6719851351

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.KUMS.REC.1402.170

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

Type 2 diabetes

ICD-10 code

E11.6

ICD-10 code description

Type 2 diabetes mellitus with other specified complications

Primary outcomes**1****Description**

Sleep quality

Timepoint

Baseline and End-of-trial

Method of measurement

The Pittsburgh Sleep Quality Index

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic method

2

Description

HbA1C

Timepoint

Baseline and End-of-trial

Method of measurement

Photometric method

3

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

4

Description

Triglyceride

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic method

5

Description

Total cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic method

6

Description

HDL Cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic method

7

Description

Brain-derived neurotrophic factor

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

8

Description

hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

9

Description

Cortisol

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa

10

Description

Total Antioxidant Capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Calorimetric method

11

Description

Total oxidant capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Calorimetric method

12

Description

GSH-Px

Timepoint

Baseline and End-of-trial

Method of measurement

Calorimetric method

13

Description

Catalase

Timepoint

Baseline and End-of-trial

Method of measurement

Calorimetric method

14

Description

SOD

Timepoint

Baseline and End-of-trial

Method of measurement

Calorimetric method

15

Description

MDA

Timepoint

Baseline and End-of-trial

Method of measurement

Calorimetric method

16

Description

Quality of life

Timepoint

Baseline and End-of-trial

Method of measurement

36-Item Short Form Survey

17

Description

Depression-anxiety-stress

Timepoint

Baseline and End-of-trial

Method of measurement

Depression Anxiety and Stress Scale-21 questionnaire

18

Description

LDL Cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Friedewald

19

Description

Blood pressure

Timepoint

Baseline and End-of-trial

Method of measurement

Sphygmomanometer

20

Description

Weight

Timepoint

Baseline and End-of-trial

Method of measurement

Digital scale

21

Description

Body mass index

Timepoint

Baseline and End-of-trial

Method of measurement

Dividing weight (in kilograms) by the square of height (in meters)

22

Description

Waist circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Tape measure

23

Description

Hip circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Tape measure

24

Description

Waist to hip ratio

Timepoint

Baseline and End-of-trial

Method of measurement

Dividing waist circumference (in centimeters) by the hip circumference (in centimeters)

25

Description

Height

Timepoint

Baseline and End-of-trial

Method of measurement

Stadiometer

26

Description

Waist to height ratio

Timepoint

Baseline and End-of-trial

Method of measurement

Dividing waist circumference (in centimeters) by the height (in centimeters)

27

Description

Insomnia

Timepoint

Baseline and End-of-trial

Method of measurement

Insomnia Severity Index

28

Description

Insulin sensitivity

Timepoint

Baseline and End-of-trial

Method of measurement

QUICKI formula

29

Description

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

HOMA-IR formula

30

Description

Pancreatic beta cell function

Timepoint

Baseline and End-of-trial

Method of measurement

HOMA-IR formula

Intervention groups

1

Description

Intervention group: Receive a low-calorie MIND diet for 3 months. The required energy will be calculated based on the World Health Organization equations and 500 kcal will be deducted from the calculated energy amount. 50-55% of calories come from carbohydrates, 30% from fat and 15-20% from protein, which will be included in 3 meals and 3 snacks. In this dietary pattern, the consumption of green leafy vegetables, other vegetables, berries, nuts, whole grains, fish, beans, chicken and poultry, and olive oil is recommended, while the consumption of butter and stick margarine, cheese, red meat, fried and fast foods, and pastries and sweets is restricted. In this study, due to the ban on wine, it will be recommended to consume raisins and currants in calculated amounts.

Category

Other

2

Description

Control group: Receive a low-calorie MIND diet for 3 months. The required energy will be calculated based on the World Health Organization equations and 500 kcal will be deducted from the calculated energy amount. 50-55% of calories come from carbohydrates, 30% from fat and 15-20% from protein, which will be included in 3 meals and 3 snacks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Lotfollah Saed, subspecialist in endocrine and metabolic disease

Full name of responsible person

Dr. Lotfollah Saed

Street address

Diamond Doctors Building, Shahid Tarif St

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Ramin Ghasemi

Street address

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Sayed Mostafa Nachvak

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Seyed Mostafa Nachvak

Position

Associate professor

Latest degree

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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

There is no further 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

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