Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 cholestrol; 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

Email address

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
Kermanshah
Province
Kermanshah
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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Province
Kurdistan
Postal code
6617658431
Phone
+98 939 634 8062
Email
Lotfollahsaed@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ramin Ghasemi
Street address
Kermanshah Medical Sciences Central Building, Shahid Beheshti Boulevard
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Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3835 8239
Email
sdrc@kums.ac.ir
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
Seyed Mostafa Nachvak

Position
Associate professor
Latest degree
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Person responsible for scientific inquiries

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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
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