

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of MIND diet with modified calories compared to low calorie diet on anxiety, depression, hormonal and metabolic status of obese or overweight women with polycystic ovary syndrome: A clinical trial.

Protocol summary

Study aim

Determining the effect of Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND) diet with modified calories compared to low calorie diet on anxiety, depression, hormonal and metabolic status of obese or overweight women with polycystic ovary syndrome (PCOS)

Design

A randomized controlled trial with 2 parallel groups (26 in each group). The random block was used for randomization.

Settings and conduct

52 patients with PCOS with the diagnosis of gynecologist, obstetric referred to Faculty of Nutrition Sciences will be selected. Then the subjects will be divided into two groups by permuted block randomization. The required energy will be calculated based on Mifflin-St Jeor formula, and in both groups the rate of 500-750 kcal will be deducted. In the intervention group, the diet will be determined based on the MIND dietary pattern and in the control group units of each food groups will be determined based on a regular diet. After 2 months of intervention, all groups will be compared. There is no possibility of blinding for dietary presentation.

Participants/inclusion and exclusion criteria

Inclusion criteria: Aged 18 to 45 years old, body mass index equal to or higher than 25 kg/m², and no recent weight loss during the previous 3 months Exclusion criteria: Having known metabolic, liver and neurological diseases, history of diagnosis of depression during the previous 1 year, and taking antidepressants and medications that affect appetite and body weight

Intervention groups

The subjects divide into 2 groups, Group 1: receiving MIND diet with modified calorie. Group 2: receiving low calorie diet with usual dietary recommendations.

Main outcome variables

Anxiety and depression status; quality of life status; fasting blood sugar; LH; FSH; hirsutism; weight; waist circumference; hip circumference; body mass index; waist to hip ratio; blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180712040438N8**

Registration date: **2023-01-18, 1401/10/28**

Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**

Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Jalal Moludi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 2148

Email address

jmoludi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of MIND diet with modified calories compared to low calorie diet on anxiety, depression, hormonal and metabolic status of obese or overweight women with polycystic ovary syndrome: A clinical trial.

Public title

Effect of diet therapy in treatment of polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with PCOS based on the Rotterdam diagnostic criteria Age range from 18 to 45 years old Desire to cooperate Body mass index equal to or higher than 25 kg/m² No recent weight loss during the previous 3 months Failure to follow a specific diet

Exclusion criteria:

Having known metabolic diseases Having known neurological disease Having major systemic diseases such as malignancies Having known liver disease Taking Antidepressants or history of diagnosis of depression during the previous one year Taking medications that affect appetite and body weight, such as corticosteroids or other supplements

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study is block randomization, the random sequence is generated by a statistical consultant. The registration of people is done by the project manager. Allocating people to groups is done by the statistics consultant. The team leader is different from the outcome assessor, and the team leader is not involved in the process of collecting information and evaluating the outcome, and this work will be done by trained evaluators. For random allocation of people, 13 blocks with 4 permutations will be created. Then, based on the numbers in the random table, a number will be chosen randomly, and based on the last digit on the right, one of the groups will be used to determine the sequence of randomization. It should be noted that if the number on the right side is zero or 7 to 9 when choosing a random number, that number will not be considered and a random number will be selected

again. This work will continue until all 52 people are assigned to two groups. It should be noted that this method will prevent the unbalance of the two groups as well as the identification of the randomization sequence, and the ratio of 1:1 will be observed in the two groups. It is registered and the cards are placed in the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lids of the envelopes are glued and placed in a box respectively. At the time of starting the registration of participants, based on the order in which eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

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

Faculty of Nutritional Sciences and Food Industry, next to Farabi hospital, Isar square, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2023-01-03, 1401/10/13

Ethics committee reference number

IR.KUMS.REC.1401.427

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Depression score

Timepoint

Baseline and End-of-trial

Method of measurement

Depression Anxiety and Stress Scale-21 Questionnaire

2

Description

Anxiety score

Timepoint

Baseline and End-of-trial

Method of measurement

Depression Anxiety and Stress Scale-21 Questionnaire

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Glucose oxidase assay

2

Description

LH

Timepoint

Baseline and End-of-trial

Method of measurement

Chemiluminescence immunoassay (CLIA)

3

Description

FSH

Timepoint

Baseline and End-of-trial

Method of measurement

Chemiluminescence immunoassay (CLIA)

4

Description

Hirsutism

Timepoint

Baseline and End-of-trial

Method of measurement

Ferriman-Gallway scoring system

5

Description

Quality of life score

Timepoint

Baseline and End-of-trial

Method of measurement

Polycystic Ovary Syndrome Questionnaire

6

Description

Weight

Timepoint

Baseline and End-of-trial

Method of measurement

Digital scale

7

Description

Body mass index

Timepoint

Baseline and End-of-trial

Method of measurement

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

8

Description

Waist circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Tape measure

9

Description

Hip circumference

Timepoint

Baseline and End-of-trial

Method of measurement

Tape measure

10

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)

11

Description

Systolic blood pressure

Timepoint

Baseline and End-of-trial

Method of measurement

Sphygmomanometer

12

Description

Diastolic blood pressure

Timepoint

Baseline and End-of-trial

Method of measurement

Sphygmomanometer

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

Intervention group: Receiving MIND diet with modified calorie for 2 months. In this group, the required energy of each person will be determined based on Mifflin-St Jeor formula, the rate of 500-750 kcal will be deducted. The distribution percentage of macronutrients will include 50-55% carbohydrates, 30% fat, and 15-20% protein. The MIND diet with an emphasis on ten brain-healthy components will include green leafy vegetables, other vegetables, nuts, berries, legumes especially beans, whole grains, fish, poultry, olive oil, and wine. five unhealthy components include red meats, butter and stick margarine, cheese, pastries and sweets, and fried or fast foods will be restricted in this diet. In this study, wine consumption will not be considered because its usage is forbidden in Iran, instead it is recommended to consume raisins and currants.

Category

Treatment - Other

2**Description**

Control group: Receiving hypocaloric diet for 2 months. In this group, the required energy of each person will be determined based on Mifflin-St Jeor formula, the rate of 500-750 kcal will be deducted. The distribution percentage of macronutrients will include 50-55% carbohydrates, 30% fat, and 15-20% protein, then units of each food groups will be determined based on a regular diet. The control group will also receive general oral and written advice about healthy food choices due to ethical concerns. Participants in both groups will receive 3 main meals and 3 snacks.

Category

Placebo

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

Faculty of Nutritional Sciences and Food Industry, Isar square, Kermanshah

Full name of responsible person

Jalal Moludi

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

Kermanshah University of Medical Sciences

Full name of responsible person

Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research No 2 Central Building, Kermanshah

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2589631478

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Email

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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

Jalal Moludi

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

Jalal Moludi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Full name of responsible person

Jalal Moludi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isar St

City

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Title and more details about the data/document

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

Accessibility to data is possible 8 months after publication.

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta analysis.

From where data/document is obtainable

Dr Jalal Moludi, Faculty of Nutrition Sciences and Food Technology, Kermanshah University of Medical Sciences, +989399516766, j.moloudi@yahoo.com

What processes are involved for a request to access data/document

Any one who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All these steps will not take more than 10 days.

Comments