Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of MIND diet and propolis supplementation on metabolic syndrome indices and cognitive function and its areas in people with metabolic syndrome. Randomized controlled clinical trial.

Protocol summary

Study aim

Comparison of the effects of MIND diet and propolis supplementation on metabolic syndrome indices and cognitive function and its areas in people with metabolic syndrome.

Design

Randomized controlled clinical trial, with factorial groups, without blinding, phase 3 will be conducted on 84 patients with metabolic syndrome, random number table will be used for randomization.

Settings and conduct

This study will be conducted on people who visit the diabetes clinic. The people participating in the study will be divided into 3 groups and will be controlled for 12 weeks the two intervention groups will be given the usual food recommendations as well as the control group, and no calorie restriction will be considered for any of the three groups. At the beginning and end of the study, metabolic syndrome indices and cognitive function will be measured.

Participants/Inclusion and exclusion criteria

inclusion criteria: Having informed consent Adults (18-60 years old) have metabolic syndrome. Non-entry criteria: . Suffering from thyroid diseases, anemia, diabetes, neurological and psychiatric illnesses . Have a stroke or transient ischemic attack in the last 3 months. . History of brain damage, liver and kidney illnesses, HIV . Have been diagnosed with cancer in the last five years. . Obese people with a BMI higher than 40

Intervention groups

One intervention group will receive the MIND diet + placebo, the other group, which is also the intervention group, will receive the MIND diet + propolis supplement, and the next group, which is the control group, will receive microcrystalline cellulose placebo + usual dietary advice.

Main outcome variables

metabolic syndrome indices and cognitive function

General information

Reason for update

Acronym

MIND (Mediterranean-DASH Intervention for Neurodegenerative Delay diet)

IRCT registration information

IRCT registration number: **IRCT20230105057054N1**
Registration date: **2023-03-28, 1402/01/08**
Registration timing: **prospective**

Last update: **2023-03-28, 1402/01/08**
Update count: **0**

Registration date

2023-03-28, 1402/01/08

Registrant information

Name

zeinab gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3833 3591

Email address

zeinab.gh.nut@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-31, 1402/03/10

Expected recruitment end date

2023-09-01, 1402/06/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of MIND diet and propolis supplementation on metabolic syndrome indices and cognitive function and its areas in people with metabolic syndrome. Randomized controlled clinical trial.

Public title
Comparison of the effect of MIND diet and propolis supplement on metabolic syndrome and cognitive function
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants must provide informed consent prior to engaging in the study Adults (18-60 years old) have metabolic syndrome
Exclusion criteria:
Suffering from thyroid diseases, anemia, diabetes, neurological and psychiatric illnesses containing depression, Parkinson's disease, Alzheimer's disease, mental disorders and, a history of severe medical treatment. Have a stroke or transient ischemic attack in the last 3 months. Have a history of brain damage, liver and kidney disease, hepatitis C or HIV. have been diagnosed with cancer in the last five years. Obese people with a BMI higher than 40
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment to intervention and control groups. samples will be allocated to the intervention and control groups using a randomized block design. The randomization unit is the individual that will be used from the table of random numbers. Eligible people visiting the clinic enter in 28 blocks of three. The first 3 eligible subjects are placed in the first block, the second 3 in the second block, and the 28th 3 in the 28th block. For all three intervention and control groups codes A, B, and C are named. The subjects of each block are based on the table of random numbers, so that if the random number is 1-3, treatment A, if it is 4-6, treatment B, and if it is 7-9, treatment C (Random numbers generated by the computer can also be used for this purpose). Therefore, based on the received random number, the first person in the block is assigned to the treatment code corresponding to the random number. This process will continue until 28 blocks are completed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hazar Jerib Street, Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2023-02-05, 1401/11/16
Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.330

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

2

Description of health condition studied
cognitive function
ICD-10 code
R41
ICD-10 code description
Other symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description

fasting blood sugar

Timepoint

Before and after study

Method of measurement

blood sample

2

Description

Triglyceride

Timepoint

Before and after study

Method of measurement

blood sample

3

Description

High density lipoprotein cholesterol

Timepoint

Before and after study

Method of measurement

blood sample

4

Description

blood pressure

Timepoint

Before and after study

Method of measurement

sphygmomanometer

5

Description

cognitive function

Timepoint

Before and after study

Method of measurement

Neuropsychiatry Unit Cognitive Assessment

6

Description

waist

Timepoint

Before and after study

Method of measurement

inflexible meter

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: MIND diet and placebo. The counseling plan for the intervention diet group will include instructions on what foods to include in the diet, the paths to provide these foods. The dietary regimen being employed in this study is the MIND diet, as outlined by Morris et al in its expanded form. Participants in the MIND diet group will receive instructions to modify their dietary content, emphasizing natural and plant-based foods and consuming berries and green leafy vegetables, whole grains, fish, nuts, and olive oil and with restricted consume of animal's food and high saturated fat is recommended. According to Islamic customs and culture, the people of Iran are bound not to consume alcoholic beverages, so, we persuade our patients to use grapes, grape juice, and raisins for correcting. For each person, the MIND diet will be provided specifically for seven days a week along with counseling for at least 30 minutes, and continue for 3 monthsو and people will be asked to visit the relevant center for three days (days 7, 45, and 80 of the study). and the minimum time for each person in each meeting will be 15 minutes for counseling and checking compliance with the diet. In addition, routine dietary advice will be used, which will include verbal and written general data about healthy food selections according to the healthy food plate (50-60% carbohydrates, 5-20% protein, and 30% fat). All participants will get acquainted with the principles of food recommendations, which are as follows: Eat slowly and chew your food completely and with pleasure. Instead of frying foods, use steamed, boiled, and grilled foods. take off any excess fat and skin from your chicken or meat before cooking. use whole-meal bread and mixed oats and rice instead of simple rice and pasta. refrain from removing any meals. Eat frequent but small meals. Try to limit your intake of sugary and fatty foods. This combination is more similar to the food pattern of Iranians. Microcrystalline cellulose placebo will also be used in this group, the drug and placebo will be completely similar which will be prepared in the Department of Pharmacology of Mashhad University of Medical Sciences and none of the participants and researchers will know about them until the end of the study.

Category

Treatment - Other

2

Description

Second intervention group: MIND diet and propolis supplementation. The counseling plan for the intervention diet group will include instructions on what foods to include in the diet, the paths to provide these foods. The dietary regimen being employed in this study is the MIND diet, as outlined by Morris et al in its expanded form. Participants in the MIND diet group will receive instructions to modify their dietary content, emphasizing natural and plant-based foods and consuming berries and green leafy vegetables, whole grains, fish, nuts, and olive oil and with restricted consume of animal's food and high saturated fat is recommended. According to Islamic customs and culture, the people of Iran are bound not to consume alcoholic beverages, so, we persuade our patients to use grapes, grape juice, and raisins for correcting. For each person, the MIND diet will be provided specifically for seven days

a week along with counseling for at least 30 minutes, and continue for 3 months و and people will be asked to visit the relevant center for three days (days 7, 45, and 80 of the study). and the minimum time for each person in each meeting will be 15 minutes for counseling and checking compliance with the diet. In addition, routine dietary advice will be used, which will include verbal and written general data about healthy food selections according to the healthy food plate (50-60% carbohydrates, 5-20% protein, and 30% fat). All participants will get acquainted with the principles of food recommendations, which are as follows: Eat slowly and chew your food completely and with pleasure. Instead of frying foods, use steamed, boiled, and grilled foods. take off any excess fat and skin from your chicken or meat before cooking. use whole-meal bread and mixed oats and rice instead of simple rice and pasta. refrain from removing any meals. Eat frequent but small meals. Try to limit your intake of sugary and fatty foods. This combination is more similar to the food pattern of Iranians. Also it will be recommended to take a propolis supplement which will be prepared in the Department of Pharmacology of Mashhad University of Medical Sciences (Take 450 mg twice daily before lunch and dinner) for 3 months.

Category

Treatment - Other

3

Description

Control group: microcrystalline cellulose placebo. For these individuals, routine dietary advice will be used, which will include verbal and written general data about to ensure your diet is balanced, aim for healthy food choices that follow the guidelines of the healthy food plate. This means consuming around 50-60% carbohydrates, 5-20% protein, and 30% fat. In this case, none of participants will receive food menus and will get acquainted with the principles of food recommendations, as follows: Eat slowly and chew your food completely and with pleasure. Instead of frying foods, use steamed, boiled, and grilled foods. take off any excess fat and skin from your chicken or meat before cooking. use whole-meal bread and mixed oats and rice instead of simple rice and pasta. refrain from removing any meals. Eat frequent but small meals. Try to limit your intake of sugary and fatty foods. In addition to the usual food recommendations, the microcrystalline cellulose placebo will be used. The drug and the placebo will be completely similar which will be prepared in the Department of Pharmacology of Mashhad University of Medical Sciences and none of the participants and researchers will know about them until the end of the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Health

Full name of responsible person

Dr Galehdari

Street address

Ebnesina street

City

isfehan

Province

Isfehan

Postal code

8148653374

Phone

+98 31 3447 6060

Email

Health@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Asgari

Street address

Hezar jerib

City

Isfehan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person
Dr Zamzam Paknahad
Position
professer
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Postal code
81746-73461
Phone
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Email
paknahad@hlth.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Zamzam paknahad
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
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paknahad@hlth.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Zeinab Gholami
Position
PhD student
Latest degree
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Other areas of specialty/work
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81746-73461
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+98 31 3792 3166
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zeinab.gh.nut@gmail.com

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data will be available upon reasonable request from Prof. Zamzam Paknahad
When the data will become available and for how long
12 months after publication of results
To whom data/document is available
Academic users
Under which criteria data/document could be used
Academic purposes
From where data/document is obtainable
paknahad@hlth.mui.ac.ir
What processes are involved for a request to access data/document
Upon receipt of the request, the data will be sent as soon as possible.
Comments