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Effect of walnut consumption on inflammation and oxidative stress in middle-aged and elderly people

Submission date
25/09/2024

Recruitment status
No longer recruiting

Registration date
26/09/2024

Overall study status
Completed

Last Edited
01/09/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to evaluate how eating walnuts affects antioxidant levels, inflammation, and heart health in middle-aged adults (40-65 years). Researchers want to see if walnuts can improve these health markers.

Who can participate?
Caucasian adults aged 40-65 years with no known allergy to walnuts can participate. They must provide informed consent and be at risk for metabolic syndrome, which includes conditions like abdominal obesity, high blood pressure, high triglycerides, low HDL cholesterol, or high fasting blood glucose.

What does the study involve?
Participants will be randomly assigned to one of two groups: one group will consume 45 grams of walnuts daily, while the other group will not consume any nuts. The study will have two 28-day sessions with a one-month break in between.

What are the possible benefits and risks of participating?
No personal benefit was expected from this study for the participants, but their involvement was necessary to help us answer the research questions.
Participants were informed in advance regarding the potential predictable risks associated with the study procedures (e.g. venipuncture which may be accompanied by pain/ hematoma/ heamedema/ amnesia/ lipoptysis/ etc, possible allergic reactions). No unpredictable risks were anticipated.

Where is the study run from?
Iuliu Hatieganu University of Medicine and Pharmacy in Romania.

When is the study starting and how long is it expected to run for?
November 2022 to December 2023

Who is funding the study?
Iuliu Hatieganu University of Medicine and Pharmacy in Romania.

Who is the main contact?
Letitia Mates

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Letitia Mates

ORCID ID
https://orcid.org/0000-0001-9983-0642

Contact details
Cezar Baltag 18
Cluj-Napoca
Romania
400688

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AVZ 79/12.05.2023, Funding 771/42/11

Study information

Scientific Title
Effect of walnut (juglans regia L.) consumption on biomarkers of inflammation and oxidative stress in middle-aged and elderly people: a randomized controlled trial

Acronym
WALINOX

Study objectives
Walnuts are correlated with decreased biomarkers of inflammation and oxidative stress in participants of different ages. Regular walnuts consumption have the potential to reduce cardiometabolic risk and anti-aging benefits in middle-aged and elderly individuals.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 12/05/2023, Scientific Research Ethics Committee of Iuliu Hatieganu University of Medicine and Pharmacy, Cluj-Napoca, Romania (Victor Babes 8, Cluj-Napoca, 400012, Romania; +40-264-597256; etica.cercetare@umfcluj.ro), ref: AVZ 79/12.05.2023

Study design
Interventional randomized controlled crossover trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of metabolic syndrome and anti-aging potential of walnut in middle-aged and elderly people.

Interventions
Two intervention periods of 28 days each, separated by a one-month (31 days) washout period. Participants were randomly assigned to receive either a daily serving of walnut kernels (45 g per day) or habitual diet without walnut (control) in the first period, followed by the opposite treatment in the second period.

The total duration of treatment and follow-up for the two arms of the study was three months. Participants were randomly assigned to the intervention or control group using a computer-generated randomization program.

Intervention Type
Behavioural

Primary outcome(s)
Assessment of blood vascular cell adhesion molecule (s-VCAM) levels using Elisa Kit at baseline and at the end of each intervention period.

Key secondary outcome(s))
1. Blood biomarkers of oxidative stress (CAT, GPx, TAC) measured at baseline and at the other three-monthly scheduled clinic visits using ELISA kits.
2. Blood biomarkers of inflammation (IL-6, IL-8, IL-1, TNF-alpha) measured at baseline and at the other three-monthly scheduled clinic visits using ELISA kits.
3. Blood pressure values (SBP, DBP) measured at baseline and at the other three-monthly scheduled clinic visits using a professional automated sphygmomanometer.
4. Blood lipid profile markers (TG, TC, HDL-C, LDL-C) measured at baseline and at the other three-monthly scheduled clinic visits using standard laboratory methods.
5. Blood glucose profile (basal blood glucose, HbA1c) measured at baseline and at the other scheduled three-monthly clinic visits using standard laboratory methods.
6. Anthropometric parameters: body height (BH), waist circumference (WC), hip circumference

(HC), waist-to-hip circumference ratio (WHR), body weight (BW), body mass index (BMI), body fat mass (BFM), and body water (BW), measured at baseline and at the other three-monthly scheduled clinic visits using a professional segmental body composition scale and a taliometer.

Completion date
22/12/2023

Eligibility

Key inclusion criteria
1. Caucasian adults, women and men aged 40-65 years
2. With no known allergy to walnuts
3. Provide informed consent
4. Clinical characteristics: healthy individuals at MetS risk with at least one of the specific parameters present, including:
4.1. Abdominal obesity: waist circumference (WC) ≥ 102 cm and ≥ 88 cm for European men and women, respectively
4.2. Hypertension: systolic blood pressure (SBP) ≥ 130 mmHg or/and diastolic blood pressure (DBP) ≥ 85 mmHg
4.3. Dyslipidemia: TG ≥ 150 mg/dL and high-density lipoprotein cholesterol (HDL-c) < 40 mg/dL in men or < 50 mg/dL in women
4.4. Dysglycemia: fasting blood glucose (FBG) ≥ 100 mg/dL

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
65 years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Individuals with allergies to walnuts, other tree nuts, and peanuts or following restric-tive diets for food allergies, food intolerances (lactose, fructose, gluten)
2. Diets for chronic gastrointestinal or kidney disease, vegetarians, or other types of diet that could interfere with study results, as well as those with current or recent eating disorders (last 6 months prior to the start of the study). 3. Individuals with current chronic diseases: chronic

intestinal diseases (ulcerative colitis, Crohn's disease), chronic renal disease, CVD, pulmonary disease, Type 1 or 2 diabetes, cancer, neurodegenerative diseases (Alzheimer's disease, Parkinson's disease), gallbladder disorders (gallbladder lithiasis, biliary dyskinesia, and acute or chronic cholecystitis)
4. Drug treatments (insulin therapy, hypoglycemic and/or hypolipidemic treatments, chronic treatment with non-steroidal and/or steroidal an-ti-inflammatory drugs)
5. Concomitant use or at least two weeks prior to the start of the study of dietary supplements (vitamins or minerals, anti-inflammatory and/or antiox-idant compounds, including fish oil, omega-3 fatty acids, resveratrol, curcumin, vita-min C, selenium, zinc, as well as dietary fiber, probiotics, symbiotics).
6. Pregnancy
7. Smoking
8. Chronic alcohol consumption

Date of first enrolment
01/08/2023

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
Romania

Study participating centre
Iuliu Hatieganu University of Medicine and Pharmacy
Victor Babes 8
Cluj-Napoca
Romania
400012

Sponsor information

Organisation
University of Medicine and Pharmacy "Iuliu Haţieganu" Cluj-Napoca

Funder(s)

Funder type
University/education

Funder Name
Universitatea de Medicină şi Farmacie Iuliu Haţieganu Cluj-Napoca

Alternative Name(s)
University of Medicine and Pharmacy Cluj-Napoca, Iuliu Haţieganu University of Medicine and Pharmacy, University of Medicine and Pharmacy "Iuliu Haţieganu" Cluj-Napoca, “Iuliu Hatieganu” University of Medicine and Pharmacy Cluj-Napoca, Universitatea de Medicină și Farmacie “Iuliu Hațieganu”, UMF Iuliu Hațieganu Cluj-Napoca, UMF Cluj, UMF Cluj-Napoca, UMFCLUJ, UMF

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Romania

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality reasons.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/06/2025	07/07/2025	Yes	No
Results article		30/08/2025	01/09/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes