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The future of eating: how the MED_EAT-IT diet can improve health and contribute to sustainability

Submission date
07/08/2024

Recruitment status
Recruiting

Registration date
31/01/2025

Overall study status
Ongoing

Last Edited
31/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Defining healthy and sustainable diets is nowadays considered a critical task, as it addresses the dual challenges of preventing chronic diseases and malnutrition while minimizing the environmental impact of food systems. The EAT-Lancet Commission has recently proposed the "Planetary Health Diet," which can be adapted to various food contexts. Building on several evaluations conducted in previous years, we have developed an adaptation of this dietary pattern for the Italian-Mediterranean context, optimizing for potential issues related to nutritional adequacy, acceptability, and cultural aspects (the MED_EAT-IT dietary pattern). This study aims to evaluate the effects of adopting the MED_EAT-IT dietary pattern, identifying the actual benefits and possible risks associated with sustainable, plant-based diets across different target population groups.

Who can participate?
Healthy adult volunteers (aged over 18 years)

What does the study involve?
Participants are requested to follow two different diets for 8 weeks, separated by a washout period in which the individual diet without specific recommendations will be followed. The first diet is called MED_EAT-IT and includes three main meals (breakfast, lunch, and dinner), plus one snack based on nuts. Breakfast comprises a portion of dairy products, whole grains (wholegrain bread, wholegrain rusks, oats, or cornflakes), and a portion of jam or fruit juice. Lunch and dinner feature whole grains (wholegrain rice or pasta, spelt, wholegrain bread, etc) or potatoes, protein sources (beef, pork, lamb, poultry, eggs, fish, or legumes) according to appropriate consumption frequency, vegetables, oil, and fruits. The diet is also personalized based on individual needs and eating behavior. The second diet is based on the Italian dietary recommendations. The overall study duration will be about 6 months. Volunteers will be asked to complete three separate 7-day weighted food records and questionnaires to assess acceptability and dietary behaviors. In addition, blood, 24-hour urine, and fecal samples will be collected.

What are the possible benefits and risks of participating?
Since the MED-EAT-IT dietary pattern has undergone various evaluations to ensure it meets nutritional requirements, the diet can be considered beneficial from a nutritional point of view. While there are no relevant foreseeable risks associated with these dietary interventions, participants with a low habitual intake of legumes and fiber may eventually experience gastrointestinal discomfort during the first 1 to 2 weeks of the intervention and can withdraw from the study at any time.

Where is the study run from?
University of Milan (Italy)

When is the study starting and how long is it expected to run for?
June 2022 to December 2026

Who is funding the study?
Project funded under the National Recovery and Resilience Plan (NRRP), Mission 4 Component 2 Investment 1.3 - Call for tender No. 341 of 15 March 2022 of Italian Ministry of University and Research funded by the European Union – NextGenerationEU;
Award Number: Project code PE00000003, Concession Decree No. 1550 of 11 October 2022 adopted by the Italian Ministry of University and Research, CUP D93C22000890001, Project title "ON Foods - Research and innovation network on food and nutrition Sustainability, Safety and Security – Working ON Foods".

Who is the main contact?
Prof. Patrizia Riso
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Study website
https://www.onfoods.it/research-projects/evaluation-individual-response-targeted-plant-based-sustainable-diets-feasibility

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Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the acceptability, metabolic effect and impact on the nutritional status of a sustainable dietary pattern (MED_EAT-IT) based on the Planetary Health Diet and adapted to the Italian-Mediterranean food context

Acronym
EASE MED_EAT-IT

Study objectives
Is it possible to develop and validate a healthy and sustainable dietary pattern at a national level? The hypothesis is that the MED_EAT-IT dietary pattern specifically developed can be acceptable and can ensure adoption in a target group of the Italian population; it can be personalized based on individual characteristics and long-term intake can influence nutritional status and environmental sustainability, also promoting a favorable impact on metabolic and health-related markers. Such a diet can also improve the microbial ecosystem with an increase in short-chain fatty acids. Finally, it is hypothesized that effects could be different depending on specific target groups of the general population, which could be evaluated subsequently to the initial general analysis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/07/2022, Ethics Committee of the University of Milan (Via Festa del Perdono 7, Milan, 20122, Italy; +39 (0)250312667; lidia.mantia@unimi.it), ref: 68.22 parere RISO_21.07.22 _signed

Study design
Randomized controlled cross over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Prevention, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Apparently adult healthy subjects with possible metabolic risk factors

Interventions
A healthy and sustainable dietary pattern called MED_EAT-IT has been developed also considering the possibility to make it tailored to individual characteristics (see https://doi.org/10.1016/j.crfs.2024.100765). The MED_EAT-IT dietary pattern is developed based on the recommendation of the EAT-Lancet Commission on Healthy Diets from Sustainable Food Systems, and is designed to be both healthy and environmentally sustainable, allowing the fulfillment of nutritional needs for adult subjects. To match Italian dietary habits, the pattern is structured to include three main meals (breakfast, lunch, and dinner) plus one snack of nuts. Breakfast comprises dairy, whole grains, and a portion of jam or fruit juice. Lunch and dinner include whole grains or potatoes, protein sources (meat, poultry, eggs, fish, or legumes), vegetables, oil, and fruit.

Based on a computer randomization plan, subjects are divided into two groups and receive dietary instructions to follow for an eight-week intervention period either the MED_EAT-IT dietary pattern or a control diet. The control diet is based on the Italian Food-Based Dietary Guidelines and provide the same amount of energy as the MED_EAT-IT diet. After the first eight-week intervention, participants have a six-week wash-out period before switching to the subsequent intervention.

Intervention Type
Other

Primary outcome measure
The level of short-chain fatty acids (SCFA) in biological samples measured by mass spectrometry at the beginning and at the end of each intervention arm

Secondary outcome measures
1. Dietary habits are recorded using a 7-day weighted food diary at the beginning, after 4 weeks, and after 8 weeks of each intervention
2. Anthropometric measures and body composition are evaluated using reference methods for height, weight, waist circumferences, and Body Impendence Assessment (BIA) for body composition, at the beginning and at the end of each intervention
3. Markers of nutritional status (e.g., vitamins, minerals, and bioactive compounds) will be evaluated in serum through standardized analytical methods at the beginning and at the end of each intervention
4. Markers of glucose metabolism (e.g., fasting glucose, insulin, HOMA-IR) will be evaluated in serum through standardized analytical methods at the beginning and at the end of each intervention
5. Markers of lipid profile (e.g., total cholesterol, LDL, HDL, triglycerides) will be evaluated in

serum through standardized analytical methods at the beginning and at the end of each intervention
6. Markers of inflammatory status (e.g., TNF-α, IL-6, CRP) and oxidative stress (e.g., ox-LDL, DNA damage by Comet assay) will be evaluated in serum, using ELISA kits, at the beginning and at the end of each intervention
7. Microbiota composition in fecal samples will be evaluated through 16S rRNA sequencing methods at the beginning and at the end of each intervention
8. Metabolomic analyses performed on urine samples by mass spectrometry at the beginning and at the end of each intervention
9. Environmental impact, including carbon and water footprints, are assessed based on food intake data collected at the beginning and at the end of each intervention arms using a multilevel database from the EU SU-EATABLE LIFE project
10. The acceptability and feasibility of the MED_EAT-IT dietary pattern are evaluated through validated questionnaires at the end of the treatment

Overall study start date
01/06/2022

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Healthy adult volunteers (aged >18 years)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Pharmacological therapies that may interfere in the analysis of the results (e.g., antibiotics)
2. Presence of pathologies that may contraindicate adherence to the dietary pattern (e.g., celiac disease, food allergies related to nuts, inflammatory bowel diseases). In case of doubt, the eligibility of the subject will be left to the decision of the medical staff involved in the research
3. Severe obesity or specific diets (e.g., vegetarian, vegan), diets for specific pathologies (e.g. gluten-free diet, low FODMAP diet)
4. Regular use of food supplements
5. Pregnancy or breastfeeding

Date of first enrolment
01/09/2023

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
Italy

Study participating centre
ICANS-DIS International Center for the Assessment of Nutritional Status and development of Dietary Intervention Strategies
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University/education

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ROR
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Funder(s)

Funder type
Government

Funder Name
National Recovery and Resilience Plan (NRRP), Mission 4 Component 2 Investment 1.3 - Call for tender No. 341 of March 15, 2022 of Italian Ministry of University and Research funded by the European Union – NextGenerationEU Project code PE00000003, Concession Decree No. 1550 of October 11, 2022 adopted by the Italian Ministry of University and Research, CUP D93C22000890001, Project title “ON Foods - Research and innovation network on food and nutrition Sustainability, Safety and Security – Working ON Foods”.

Results and Publications

Publication and dissemination plan
Planned publications in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Patrizia Riso (patrizia.riso@unimi.it)

IPD sharing plan summary
Available on request