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We all eat microbes: diet as reservoir of microorganisms that preserve the ecosystem services of the human gastrointestinal microbiota (the µbEat project)

Submission date
22/12/2025

Recruitment status
No longer recruiting

Registration date
26/01/2026

Overall study status
Ongoing

Last Edited
26/01/2026

Condition category
Digestive System

[_] 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
Modern diets often contain fewer live microorganisms because of food processing and hygiene practices. This may reduce exposure to microbes that could play a role in supporting gut health, immune function, and metabolic balance. The aim of this study is to evaluate whether consuming a diet rich in naturally occurring food-associated microorganisms, compared with a diet low in microorganisms, affects the gut microbiome, blood metabolites, immune markers, and metabolic status in healthy adults.

Who can participate?
Healthy adult volunteers aged between 18 and 60 years can participate. Individuals with gastrointestinal diseases, recent infections, recent antibiotic use, pregnancy or breastfeeding, or other conditions that could interfere with the study are excluded.

What does the study involve?
This is a randomized, controlled, open-label crossover dietary intervention. Participants will follow two different diets:
• a diet low in microorganisms, and
• a diet rich in naturally occurring food-associated microorganisms.
Each diet will be followed for 8 weeks, separated by an 8-week washout period, with the order randomized. During the study, participants will provide stool, blood, and saliva samples and will complete food diaries and questionnaires to monitor diet and bowel habits.

What are the possible benefits and risks of participating?
Participants may gain insight into their own dietary habits and gut microbiome profile. There is no direct guaranteed health benefit. Risks are minimal and mainly related to blood sampling (e. g. mild discomfort or bruising) and the effort required to follow specific dietary instructions.

Where is the study run from?
The study is coordinated by the University of Milano-Bicocca. Sample collection is carried out in collaboration with the Fondazione IRCCS San Gerardo dei Tintori (Monza), and laboratory analyses are performed at University of Milano-Bicocca facilities and collaborating academic laboratories.

When is the study starting and how long is it expected to run for?
The study is expected to start in mid-2024 and will run for approximately 18 months, including recruitment, intervention periods, and sample analyses.

Who is funding the study?
The study is funded by the Italian Ministry of University and Research through the PRIN 2022 project (code 2022TF9AHZ_001).

Who is the main contact?
The main contact and principal investigator is Prof. Simone Guglielmetti, University of Milano-Bicocca, simone.guglielmetti@unimib.it

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Evaluation of the effect of diet-associated microorganisms on the gut microbiome, blood metabolome, immune system, and metabolic status in healthy adult subjects: a randomized controlled crossover dietary intervention (μbEat-trial)

Acronym
μbEat

Study objectives

To assess whether the ingestion of naturally occurring food-associated microorganisms modulates gut microbiome biodiversity and is associated with changes in immune and metabolic markers in healthy adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/05/2024, Comitato Etico dell'Università degli Studi di Milano-Bicocca (Piazza dell' Ateneo Nuovo, 1, Milano, 20126, Italy; +39 02 6448 6581; comitatoetico@unimib.it), ref: Protocollo n. 835

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Prevention of low-grade chronic systemic inflammation and related non-communicable disease risk through modulation of the gut microbiome, immune function, and metabolic status in healthy adult subjects.

Interventions
Two dietary interventions:
1. Low microbial diet (LM): diet designed to minimize ingestion of live food-associated microorganisms.
2. Microbe-enriched diet (MR): diet allowing and promoting ingestion of foods naturally rich in live microorganisms.
Each intervention lasts 8 weeks, separated by an 8-week washout period, according to a randomized crossover design.

Treatment sequences were generated using computer-based randomization in Microsoft Excel (RAND function), with balanced allocation to the predefined cross-over sequences.

Intervention Type
Other

Primary outcome(s)
1. Alpha-diversity of the gut microbiome measured using Diversity Indexes using metagenomic data of fecal samples at end of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

Key secondary outcome(s))
1. Changes in gut microbiome composition measured using Taxonomic profiling and functional potential analysis of the fecal microbiome by metagenomic sequencing at End of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

2. Changes in microbial-derived metabolites in fecal samples measured using Quantification of short-chain fatty acids and other low-molecular-weight metabolites by UPLC-MS and or GC-MS at End of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

3. Changes in blood metabolome measured using Serum metabolomic profiling by ^{1}H-NMR and UPLC–ESI–QTOF mass spectrometry at End of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

4. Changes in immune, metabolic and inflammatory markers measured using Quantification of circulating immune, metabolic, and inflammatory markers by ELISA and standard clinical assays at End of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

5. Changes in bacterial DNAemia measured using Quantification of bacterial 16S rRNA gene copies in whole blood by quantitative PCR at End of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

6. Changes in oral microbiome composition measured using Taxonomic profiling and functional potential analysis of the oral microbiome by metagenomic sequencing at End of each dietary intervention period (after 8 weeks of LM diet and after 8 weeks of MR diet)

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Healthy adult subjects, without diagnosed acute or chronic diseases
2. Age between 18 and 60 years
3. Ability to provide written informed consent
4. Willingness and ability to comply with the dietary intervention, sample collection (feces, blood, saliva), and study procedures.

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit

18 years

Upper age limit
60 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Use of antibiotics within 1 month prior to study start
2. Use of antacids or gastrointestinal prokinetic drugs
3. Chronic inflammatory bowel diseases
4. Active irritable bowel syndrome (IBS)
5. Viral or bacterial enteritis within 2 months prior to enrollment
6. History of gastric or duodenal ulcers within the previous 5 years
7. Any severe disease that could interfere with the dietary intervention or study outcomes
8. Pregnancy or breastfeeding
9. Recent history or suspicion of alcohol or drug abuse
10. Poor reliability or conditions affecting compliance/adherence to the study protocol
11. Previous participation in this study

Date of first enrolment
09/09/2024

Date of final enrolment
09/01/2026

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
University of Milano-Bicocca

ROR
https://ror.org/01ynf4891

Funder(s)

Funder type

Funder Name
Ministero dell'Università e della Ricerca

Alternative Name(s)
Ministry for Universities and Research, Italy, MUR Ministero dell'Università e della Ricerca, Ministry for Universities and Research, Ministero Università e Ricerca, Italian Ministero Università e Ricerca, MUR, M.U.R.

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available