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Investigating whether a person's genes or sex affects the range of microbes in their gut when they eat a Mediterranean or Western diet

Submission date	Recruitment status	[ ] Prospectively registered
25/12/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/01/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/01/2023	Digestive System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The gut microbiome is the ecosystem of bacteria, fungi and other microorganisms that live in a person's gut. It is complex and highly individual. The variety of microbes present depends on some factors that cannot be changed, such as a person's genetic make-up, sex and age, as well as factors such as diet, illness and drug treatment. It is not currently known how to change the composition of the microbiome through diet.
This trial aims to investigate the gut microbiome in people who eat a Mediterranean diet and those who eat a Western, non-Mediterranean diet to explore whether there are any patterns or any genes that are associated with a healthy gut microbiome.

Who can participate?
Men and women aged 18-75 years who eat either a Mediterranean diet or a Western, non-Mediterranean diet

What does the study involve?
The participants will provide a stool sample and a blood sample before the start of the study. They will have some physical measurements taken (height, weight, waist circumference) and will also fill in questionnaires asking about their diet, physical activity, sleep etc.They will be asked to continue to eat a Mediterranean diet or a Western, non-Mediterranean diet for 8 months and will then provide the samples and measurements and fill out the questionnaires again.

What are the possible benefits and risks of participating?
In this study, no risks or benefits to participants are expected.

Where is the study run from?
University of Valencia (Spain) and FISABIO (Spain)

When is the study starting and how long is it expected to run for?
January 2019 to February 2022

Who is funding the study?
FISABIO (Spain) , University of Valencia (Spain), CIBEROBN (Spain) and CIBERESP (Spain)

Who is the main contact?
Professor Dolores Corella, dolores.corella@uv.es

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PCT4E-19

Study information

Scientific Title
Microbiome-Genome interaction in two dietary contexts with a gender perspective

Acronym
MicroGenDiet

Study objectives
The intestinal microbiome is a complex and dynamic ecosystem that has co-evolved with humans. However, its composition presents a great interindividual variability, being influenced by a series of intrinsic factors such as the age, sex and genotype of the individual and extrinsic factors such as diet, antibiotics or health status. Diet is the environmental factor that has the greatest effect on the composition of the intestinal microbiota. However, the interindividual variability makes it difficult to use diet as a modulating tool to correct the alteration of the microbiota associated with different pathologies since, in many cases, the response is specific to each individual. In our proposal we will address the problem of inter-individual variability of the microbiome by evaluating the effect of genetic determinants and sex on the composition and function of the microbiota in the framework of two types of diets, Mediterranean diet and Western diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2019, Ethics Committee of Human Research at the University of Valencia (Avenida Blasco Ibáñez, 13, Valencia 46010, Spain; +34 963864109; vicerec.investigacio@uv.es), ref: UV-INV_ETICA1206333

Study design
A longitudinal study will be carried out. Samples and data will be obtained at baseline and after 8-months of follow-up. Two groups of diets will be compared in an observational design. Mendelian randomization will be used for some analyses.

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Community

Study type(s)

Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied
Gut microbiome in people following two dietary patterns

Interventions
A longitudinal study will be carried out. Samples and data will be obtained at baseline and after 8 months of follow-up. Two groups of diets will be compared in an observational design. Mendelian randomization will be used for some analyses.
Two dietary patterns (high adherence to the Mediterranean diet group and low adherence to the Mediterranean diet group/Western dietary pattern) will be investigated.
A screening of compliance criteria for volunteers will be carried out. A validated Mediterranean diet adherence questionnaire will be administered and according to the score, the person will be included or not in the dietary groups. After this classification at baseline, subjects will receive advice to maintain their usual dietary pattern for 8 months of follow-up.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 03/01/2023:
1. Composition of bacteria and fungi in stool samples assessed using DNA sequencing at baseline and 6 months
2. Metabolic functions of the microbiota assessed using bioinformatic tools at baseline and 6 months
3. Host genomic profile assessed using a genome-wide genotyping array at baseline

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Previous primary outcome measures:
1. Composition of bacteria and fungi in stool samples assessed using DNA sequencing at baseline and 8 months
2. Metabolic functions of the microbiota assessed using bioinformatic tools at baseline and 8 months
3. Host genomic profile assessed using a genome-wide genotyping array at baseline

Secondary outcome measures
Current primary outcome measures as of 03/01/2023:
1. Host genome-wide determinations assessed by microarray at baseline
2. Blood pressure measured using standard methods at baseline and longitudinally at 6 months
3. Weight measured using validated scales and bioimpedance at baseline and 6 months
4. Height measured using standard methods at baseline and 6 months
5. Waist circumference measured using standard methods at baseline and 6 months
6. Body composition measured by bioimpedance at baseline and 6 months
7. Food intake and adherence to the Mediterranean diet will be measured using the 14-item Mediterranean diet adherence PREDIMED score at baseline and 6 months
8. Dietary intake assessed using dietary questionnaires (24-h recalls and food frequency

questionnaires) at baseline and 6 months
9. Physical activity measured using the short form of the Minnesota physical activity questionnaire at baseline and 6 months
10. Sleep characteristics measured using the Pittsburgh Sleep Quality Index questionnaire at baseline and after 6 months
11. Chronotype (i.e. morning or evening person) measured using the Horne and Östberg questionnaire at baseline
12. Cognitive function measured using the TMT-A, TMT-B, COWAT and Wechsler Adult Intelligence Scale-III tests at baseline and after 6 months
13. Plasma lipids measured using standard methods at baseline and after 6 months
14. Fasting glucose measured using colorimetric methods at baseline and after 6 months
15. Bilirubin measured using colorimetric methods at baseline and after 6 months
16. Blood counts measured using standard methods at baseline and after 6 months

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Previous secondary outcome measures:
1. Host genome-wide determinations assessed by microarray at baseline
2. Blood pressure measured using standard methods at baseline and longitudinally at 8 months
3. Weight measured using validated scales and bioimpedance at baseline and 8 months
4. Height measured using standard methods at baseline and 8 months
5. Waist circumference measured using standard methods at baseline and 8 months
6. Body composition measured by bioimpedance at baseline and 8 months
7. Food intake and adherence to the Mediterranean diet will be measured using the 14-item Mediterranean diet adherence PREDIMED score at baseline and 8 months
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12. Cognitive function measured using the TMT-A, TMT-B, COWAT and Wechsler Adult Intelligence Scale-III tests at baseline and after 8 months
13. Plasma lipids measured using standard methods at baseline and after 8 months
14. Fasting glucose measured using colorimetric methods at baseline and after 8 months
15. Bilirubin measured using colorimetric methods at baseline and after 8 months
16. Blood counts measured using standard methods at baseline and after 8 months

Overall study start date
27/01/2019

Completion date
15/02/2022

Eligibility

Key inclusion criteria
1. Aged 18-75 years with 50% females
2. Has a dietary profile (Mediterranean diet or Western diet)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
100 participants (50 in each dietary group)

Total final enrolment
102

Key exclusion criteria
1. Received antibiotics or prebiotics or probiotics in the last 6 months
2. Diseased
3. Immunodeficient or HIV-positive
4. Liver cirrhosis or chronic renal failure
5. Serious psychiatric disorders: schizophrenia, bipolar disease, eating disorders, depression, etc
6. Any severe co-morbid condition
7. Alcohol abuse or addiction
8. History of major organ transplantation
9. Concurrent therapy with immunosuppressive drugs or cytotoxic agents
10. Current treatment with systemic corticosteroids
11. Current use of weight loss medication
12. Patients with an acute infection or inflammation
13. Pregnant or breastfeeding women
14. Any other condition that may interfere with the completion of the study protocol

Date of first enrolment
30/12/2019

Date of final enrolment
01/07/2021

Locations

Countries of recruitment
Spain

Study participating centre

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Study participating centre
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Sponsor type
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Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública

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Sponsor type
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Funder(s)

Funder type
Research organisation

Funder Name
Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO)

Funder Name
University of Valencia

Funder Name
CIBEROBN

Funder Name
Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública (CIBERESP)

Results and Publications

Publication and dissemination plan
Results will be presented in scientific meetings and published in international journals.

Intention to publish date
15/07/2023

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 restrictions in the informed consent. Participants did not consent to share data.

IPD sharing plan summary

Not expected to be made available