

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

<b>Submission date</b> 25/12/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/01/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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## Additional identifiers

**Protocol serial number**  
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

## Study type(s)

Prevention

## 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(s)**

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

## **Key secondary outcome(s)**

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:

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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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**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

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**University of Valencia**

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**Sponsor information****Organisation**

Fisabio

**Organisation**

University of Valencia

**Organisation**

CIBEROBN

**Organisation**

Centro de Investigación Biomédica en Red de Epidemiología y Salud Pública

**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**

**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