

# Personalised nutritional advice to aid weight loss

<b>Submission date</b> 19/10/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/06/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Being obese is known to increase the chance of developing several health problems, including heart disease, type 2 diabetes, fatty liver disease, and some cancers. It results from the interactions of different factors, including genes, metabolism, behaviour, and environment. The latter factors include people's eating habits and how much exercise they do. However, both gaining and losing weight are complex because it is not known how the different factors interact.

This study aims to improve the health of obese people by developing personalized eating plans. In order to assess and characterize the patient's health status before and after dietary intervention, the project will measure various metabolic biomarkers. The aim of the study is to compare the effects of personalized dietary advice based on Preventomics software with general dietary recommendations on weight loss and improvement in metabolic health status.

### Who can participate?

Healthy volunteers aged 18 to 65 years old with a BMI between 25-40 kg/m<sup>2</sup> with abdominal obesity.

### What does the study involve?

Volunteers will be allocated in one of three groups: a control group, in which volunteers will receive general advice from a dietitian about how to improve their diet; a personalised nutrition group, in which participants will use MetaDieta app and the PREVENTOMICS' app; and the personalised plan group, in which, in addition to a personalised diet through the use MetaDieta and PREVENTOMICS' app, will also receive prompts to help change food and lifestyle choices. The intervention will last 4 months. Before and after the intervention, each participant will have blood, urine, saliva, and faeces samples taken for laboratory tests.

### What are the possible benefits and risks of participating?

Participants may benefit from losing weight and receiving laboratory test results as well as scientific advice on how to improve diet and lifestyle. Dietary intervention is unlikely to lead to undesirable effects and complications. The only side effects of the test may result from venous blood collection, such as bruising and feeling weak.

Where is the study run from?  
Jagiellonian University Medical College (Poland)

When is the study starting and how long is it expected to run for?  
From September 2018 to April 2022

Who is funding the study?  
The European Union's Horizon 2020 research and innovation programme (Belgium)

Who is the main contact?  
Prof. Malgorzata Malczewska-Malec  
m.malczewska-malec@uj.edu.pl

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Małgorzata Malczewska-Malec

**ORCID ID**  
<https://orcid.org/0000-0002-3522-0711>

**Contact details**  
Jagiellonian University Medical College  
Department of Clinical Biochemistry  
15A Kopernika Street  
Kraków  
Poland  
31-501  
+48 12 4214006  
m.malczewska-malec@uj.edu.pl

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
Z/H20/00030

## Study information

**Scientific Title**  
The effect of personalized nutritional advice based on weight loss and health status of subjects with abdominal obesity: empowering consumers to prevent diet-related diseases

## **Study objectives**

Personalized dietary advice based on omics science and Preventomics software is more effective at reducing weight and improving metabolic health status than general dietary recommendations in people with abdominal obesity.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 28/03/2019, Bioethics Committee of the Jagiellonian University (ul. Grzegórzecka 20, 31-531 Kraków, Poland; +48 12 433 27 39; kbet@cm-uj.krakow.pl), ref: 1072.6120.85.2019

## **Study design**

Single-centre interventional single-blinded randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Abdominal obesity

## **Interventions**

Randomisation will take place once anthropometry is completed using an independent online computerized randomisation system by a member of the study team. Randomisation will be conducted at the level of the individual and will be stratified by sex, age, and waist circumference. Volunteers will be randomly allocated to one of the three groups:

1. Control group, in which volunteers will receive general advice from a dietitian about how to improve their diet
2. Personalised nutrition group, in which participants will use the PREVENTOMICS' mobile application alongside a dietitian to receive a personalised diet plan through MetaDieta mobile application
3. Personalised plan group, in which, in addition to advice from the dietitian and a personalised diet through the use MetaDieta app and PREVENTOMICS' app, will also receive prompts to help change food and lifestyle choices

Each intervention will last for 4 months. At the start and at the end of the intervention, subjects will visit GP for health status screening, anthropometric measurements, and blood, urine, saliva, and faeces sample collection. In the collected material, analyses of genome, metabolome, and microbiome will be performed.

## **Intervention Type**

Device

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Not provided at time of registration

### **Primary outcome(s)**

1. Waist circumference will be measured at baseline and 4 months

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

1. Classic clinical biomarkers measured using Enzyme-Linked Immunosorbent Assay (ELISA) at baseline and 4 months
2. Metabolomics biomarkers measured using Nuclear Magnetic Resonance (NMR) and Liquid Chromatography-Mass Spectrometry (LC/MS) at baseline and 4 months
3. Food intake biomarkers measured using Liquid Chromatography-Ion Mobility Spectrometry-Quadrupole Time of Flight Mass Spectrometry (LC-IMS-QToF MS) at baseline and 4 months
4. Microbiome analysis in faeces using Next Generation Sequencing (NCS) at baseline and 4 months

### **Completion date**

30/04/2022

## **Eligibility**

### **Key inclusion criteria**

1. Aged between 18-65 years
2. Waist circumference >94 cm for men or >80 cm for women
3. BMI between 25-40 in kg/m<sup>2</sup>
4. Provided written informed consent

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

### **Sex**

All

### **Total final enrolment**

265

### **Key exclusion criteria**

1. Diabetes
2. Severe hyperlipidemia

3. Other endocrine and metabolic diseases
4. Chronic inflammatory states
5. Diseases of the digestive or respiratory systems
6. Chronic kidney disease
7. Cardiovascular disease
8. Alcohol addiction
9. Pregnancy or lactation

**Date of first enrolment**

01/11/2020

**Date of final enrolment**

31/08/2021

## Locations

**Countries of recruitment**

Poland

**Study participating centre**

**Jagiellonian University Medical College**

Department of Clinical Biochemistry

Kopernika 15A

Kraków

Poland

31-501

## Sponsor information

**Organisation**

Jagiellonian University

**ROR**

<https://ror.org/03bqmcz70>

## Funder(s)

**Funder type**

Government

**Funder Name**

Horizon 2020 Framework Programme

## Alternative Name(s)

EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

# Results and Publications

## Individual participant data (IPD) sharing plan

All the data is stored in GDPR-compliant servers at EURECAT (leading Project partner in Barcelona) and it is only available to consortium members in a restrictive mode. It is planned to create a common database with the data from the different partners.

## IPD sharing plan summary

Stored in non-publicly available repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			19/06/2023	No	No
<a href="#">Other publications</a>	Cost-effectiveness	01/06/2025	04/06/2025	Yes	No
<a href="#">Participant information sheet</a>	version v1.0	13/01/2020	03/12/2020	No	Yes
<a href="#">Protocol file</a>			28/09/2022	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes