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Personalised nutritional advice to aid weight loss

Submission date
19/10/2020

Recruitment status
No longer recruiting

Registration date
03/12/2020

Overall study status
Completed

Last Edited
04/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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/m2 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
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Study website
https://preventomics.eu/study-personalised-nutritional-advice-weight-loss/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
See study outputs table

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

Secondary outcome measures
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 feaces using Next Generation Sequencing (NCS) at baseline and 4 months

Overall study start date
13/09/2018

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/m2
4. Provided written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
264

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
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Sponsor information

Organisation
Jagiellonian University

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Jagiellonian University Medical College
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Sponsor type
University/education

Website
https://cm-uj.krakow.pl/index.php/en/index

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, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals.

Intention to publish date
31/12/2022

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?
Participant information sheet	version v1.0	13/01/2020	03/12/2020	No	Yes
Protocol file			28/09/2022	No	No
Basic results			19/06/2023	No	No
Other publications	Cost-effectiveness	01/06/2025	04/06/2025	Yes	No