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Use of an artificial intelligence (AI)-driven personalised dietary advice or a general dietary advice to improve food intake

Submission date
14/10/2025

Recruitment status
No longer recruiting

Registration date
15/10/2025

Overall study status
Completed

Last Edited
16/10/2025

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Unhealthy diets are associated with a higher risk for non-communicable diseases such as cardiovascular disease, type 2 diabetes or obesity. Therefore, improving dietary habits can help reduce one's risk for these conditions. However, most of the dietary assessments rely on the individuals' ability to remember what they have eaten, which is often prone to bias due to wrong estimation of portion sizes, forgetting or not mentioning the foods that were consumed. Therefore, a more objective and comprehensive tool that assesses people's diet and how it impacts their health is needed. The aims of the study are to determine whether an AI-powered personalised dietary advice is better than a general dietary advice at improving the health (improve body weight, blood pressure, blood glucose, lipid levels) and dietary habits of individuals at higher risk of non-communicable diseases. The AI-powered advice (personalised dietary advice) will contain data from a wearable camera which captures dietary intake, physical activity monitor, as well as data from analysis of blood, urine, and stool samples, which, combined, will provide a personalised dietary advice to the volunteers. The effectiveness of the AI advice will be compared to a general dietary advice arm, which contains dietary recommendations based on WHO guidelines. In addition genetic and epigenetic markers will be determined and linked to the response to the interventions . Gene expresion and microRNA profiles will be analised in a subsample.

Who can participate?
Males or females aged 18 to 65 years with a Body Mass Index (BMI) greater than or equal to 25 kg/m² (Asian ethnicity: BMI greater than or equal to 23 kg/m²) and with a waist circumference greater than or equal to 102 cm in males and greater than or equal to 88 cm in females (Asian ethnicity: (Asian ethnicity greater than or equal 90 cm in males greater than or equal 80 cm in females).

What does the study involve?
The volunteers will be randomly assigned to one of the two intervention groups. The study involves wearing a camera attached to glasses frames or as a pendant attached as a brooch which records food and drink intake for four 1-week periods over a 12-week period. In addition,

the volunteers need to wear an activity monitor, fill in a food diary and attend four in-person study visits at School of Medicine, University of Valencia, Valencia. During two study visits, the volunteers will provide blood and stool samples. During each study visit ,the volunteers will provide a urine sample and undergo body composition and blood pressure measurements in addition to omic biomarkers from blood (genetics, DNA-methylation, microRNA and gene expression).

What are the possible benefits and risks of participating?
The benefits of participating in the study are learning about ways to improve dietary intake to reduce the risk of non-communicable diseases. It will also advance knowledge on the relationship between diet and the metabolic risks that underlie non-communicable diseases such as obesity, type 2 diabetes, heart disease or cancer. There are no risks associated with participating in the study.

Where is the study run from?
The study is run from the School of Medicine at the University of Valencia, Valencia, Spain.

When is the study starting and how long is it expected to run for?
January 2025 to May 2026

Who is funding the study?
The study is funded by the European Union under Horizon Europe grant number 101084642.

Who is the main contact?
Dr Dolores Corella. University of Valencia and CIBEROBN. dolores.corella@uv.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
UV-CDWP5-002-25

Study information

Scientific Title
Proof of principle evaluation of the artificial intelligence (AI)-derived CoDiet tool - a randomised controlled trial

Acronym
CoDiet-Val

Study objectives
1. Assess the impact of Personalised Dietary Advice on improving dietary intake compared to the General Dietary Advice
2. Assess the impact of Personalised Dietary Advice on the markers of cardiovascular disease compared to the General Dietary Advice
3. Assess the impact of Personalised Dietary Advice on blood pressure compared to the General Dietary Advice
4.Analyze the effect of genetic and epigenetic markers on the responses to the interventions
5.Analyze the microRNA and gene expression profiles before and after the interventions for the parameters of interest (subsample).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/09/2025, Institutional review board of Valencia University (human subjects) (Avda. Blasco Ibanez 13, Valencia, 46010, Spain; +34 (0)963864109; vicerec.investigacio@uv.es), ref: 025-MED-4066628

Primary study design
Interventional

Study design
Randomized parallel single-blinded controlled study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Overweight/obesity in general population

Interventions
If the volunteer passes the eligibility criteria, they will be enrolled into the study and randomly allocated (2:1, using a computer based program online) to one of the 2 intervention arms (personalised dietary advice; PDA or general dietary advice; GDA). The study will last 28 weeks (16 weeks wait for analysis to be completed and 12 weeks of intervention and will recruit 105 volunteers (70 on the PDA arm and 35 on the GDA arm). All study visits will take place at the School of Medicine. University of Valencia.

Interventions:
1. Personalized Dietary Advice (PDA)

PDA is based on an AI-derived system that consists of two interconnected components:
• Recommender System:
This system will generate individualized dietary recommendations by analysing associations between dietary intake and biological and social parameters. The parameters that are part of the Recommender system are selected from previous analyses conducted in the CoDiet WP2 analysis which showed significant associations with non-communicable disease risk. The primary goal of the Recommender system is to suggest a personalized healthy eating profile.
• Education System:
Designed to enhance compliance with the AI-generated recommendations, the education system will guide participants toward achieving optimal biological risk factor levels. It will provide real-time feedback using vision technology and metabolite profiling. Its dietary advice will adapt to the dietary needs of each participant and also to how the participant complies to the dietary advice received during the study.

The AI system is structured to prevent adverse dietary modifications. It will adhere to current healthy eating guidelines as a baseline and will not reduce recommended nutrient intake. For example, if a participant already consumes more than the recommended five portions of fruit and vegetables per day, they will be encouraged to maintain, rather than decrease, this intake.

2. General Dietary Advice (GDA)
Participants in the GDA group will receive dietary guidance based on the World Health Organization's (WHO) current dietary guidelines (Who healthy diet). These guidelines have been chosen for their alignment with diverse health policies across Europe. The advice will be provided to the volunteers through text messages, phone calls or emails.

Intervention Type
Behavioural

Primary outcome(s)
Dietary intake assessed using the Healthy Eating Index Score at baseline and at the end of the study (12 weeks)

Key secondary outcome(s)
1. Plasma risk factors for non-communicable diseases, assessed by calculating plasma glucose, HbA1c, total cholesterol, LDL cholesterol, HDL cholesterol, and triglyceride levels at baseline and the end of the study (12 weeks)
2. Blood pressure levels measured using a blood pressure monitor at baseline and the end of the study (12 weeks)
3. Asociation between genetic factors (SNPs at the genome-wide-level and genetic risk scores) and epigenetic factors (DNA-methylation) and the primary and the other secondary outcomes
5. Changes in microRNA and RNA expresion associated with the relevant parameters after the intervention

Completion date
30/05/2026

Eligibility

Key inclusion criteria
1. Aged 18-65 years old
2. Body Mass Index (BMI) greater than or equal to 25 kg/m² (Asian descent individuals BMI

greater than or equal to 23 kg/m²)
3. Waist circumference greater than or equal to 102 cm in males and greater than or equal to 88 cm in females (Asian descent individuals: greater than or equal to 90 cm in males greater than or equal to 80 cm in females)
4. Ability to consent on their own and understand what the study involves

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Individuals with type 2 diabetes, chronic gastrointestinal conditions such as Crohn's disease, irritable bowel syndrome, celiac disease or ulcerative colitis, acute infectious diseases, cancer, cardiovascular diseases, and autoimmune conditions
2. Individuals who have been on antibiotics in the past three months and/or during the study duration
3. Pregnant or breastfeeding women
4. Currently participating in other clinical trials or who have participated in clinical trials in the past 3 months
5. Individuals who are undergoing medical interventions during the study

Date of first enrolment
22/10/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
Spain

Study participating centre
University of Valencia
Blasco Ibañez, 15

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Sponsor information

Organisation
Universitat de València

ROR
https://ror.org/043nxc105

Organisation
CIBEROBN

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon, Horizonte Europa

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The dataset will be stored on CESNET infrastructure to support the anonymity of the study volunteers. Genetic data will not be available for sharing. For the other

data, permision to collaboration will be requested to the Steering Committee and approval must be needed.

IPD sharing plan summary

Stored in non-publicly available repository