ISRCTN10538845 https://doi.org/10.1186/ISRCTN10538845

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

Submission date 08/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/08/2025	**Overall study status** Ongoing	
Last Edited 25/09/2026	**Condition category** Nutritional, Metabolic, Endocrine	

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.

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 the NIHR Imperial Clinical Research Facility. 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.

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. The volunteers will be reimbursed £400 for participation in the study. There are no risks associated with participating in the study.

Where is the study run from?
The study is run from the NIHR Imperial Clinical Research Facility at Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2025 to February 2027

Who is funding the study?
The study is funded by the European Union under Horizon Europe with UK activities supported by UK Research and Innovation under the UK government's Horizon Europe funding guarantee (grant number 101084642)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
353857

Central Portfolio Management System (CPMS)
69979

Grant code
10060437

Study information

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

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/09/2025, Westminster Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)20 7104 8066; westminster.rec@hra.nhs.net), ref: 25/LO/0626

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diet

Interventions
This study is a randomised parallel, single-blinded controlled study whereby the effectiveness of personalised dietary advice (PDA) in promoting healthy eating habits will be compared to that of 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 NIHR Imperial Clinical Research Facility.

Interested volunteers will be able to contact the study team using the email address on the advert. They will be sent by email the PIS to read and also a pre-screening questionnaire to fill in to assess initial eligibility in the study. The volunteers will be able to discuss further the study with the research team by email or phone. If they are still interested in the study and their answers to the eligibility questionnaire suggest they may be eligible to participate, the volunteers will attend a health screening visit.

Health Screening Visit:
Interested volunteers who responded to the study advert and read the PIS form will be able to attend a screening visit at the NIHR Imperial Clinical Research Facility. They will discuss the study with the research team, and will be shown how the camera and the study equipment works. If the volunteers are satisfied with all the answers they received, they will be able to sign the consent form. Following, they will have their body weight and height, waist circumference and blood pressure measured. All women of childbearing age will have a pregnancy test. The study doctor will take a blood sample to check the general health of the volunteer. The volunteers will also fill in a food preferences questionnaire and a general demographics and medical history questionnaire. The volunteers will receive the urine and stool collection kits, which they will use to provide a stool and urine sample at study visit 1.

If the volunteer passes the eligibility criteria, they will be enrolled into the study and randomly allocated to one of the intervention arms (PDA or GDA).

Pre-intervention period:
The volunteers will need to come to the NIHR Imperial Clinical Research Facility to collect the camera, activity monitors and stool and urine collection kits. They will be able to keep the activity monitor and camera for the study duration. The volunteers will wear a camera attached to their glasses frames or as a chest mount like a badge, which will take pictures of all the food and drinks they consume for 1 week. In addition, the volunteers will wear for 1 week and an activity monitor that tracks their physical activity and sleep. During the week the volunteers are wearing the camera the volunteers will also fill in a 7-day food diary using the Nutritics app or Intake 24. At the end of that week, the volunteers will attend the study visit 1.

Study visit 1:
The volunteers will arrive fasted at the NIHR Imperial Clinical Research Facility. They will provide a fasted urine sample, a stool sample and a fasted blood sample and undergo body composition measurements, have their waist circumference measured, blood pressure measurements. They will also receive a urine and stool collection kit, which they will use to provide a fasted urine and stool sample when they come for study visit 2. After that, they will be able to go home.

All the data collected in study visit 1 will feed into the artificial intelligence model, which will be used to generate the personalised dietary advice (PDA). The volunteers on the GDA arm will receive dietary advice based on the WHO guidelines. Because the analysis of the gut microbiota which is used to feed into the AI model takes some time to be completed, it will be around 16 weeks until the volunteers will be able to start the interventions. This is because only 30 samples can be analysed at a time (in a cost-effective way), so the analysis of the gut microbiota will only begin once we have 30 volunteers recruited. In addition, we will group volunteers in batches of 30 until we reach the recruitment target of 105 volunteers.

Once the PDA and GDA models are ready, the volunteers will receive regular messages and prompts via text messages on their phones to improve their dietary intake throughout the study period. In addition, the study team will be contacting the volunteers using phone calls every two

weeks during the study duration to make sure that they are getting on well with the dietary advice they have received and that they do not have any issues.

Intervention Period begins

Study Visit 2:
One week before study visit 2, the volunteers will need to wear the camera and activity monitor daily for one week. The volunteers will attend a study visit at the NIHR Imperial Clinical Research Facility, where they will have their blood pressure, body composition and waist circumference measured. They will also bring a fasted urine sample and a stool sample. The volunteers will provide a fasted blood sample. They will also be able to discuss anything related to their dietary habits with the study team. They will receive a urine collection kit, which they will use to bring a urine sample at study visit 3. After that, they will be able to go home.

There will be a 5-week gap between study visits 2 and 3. Volunteers will receive regular prompts about how to improve their diet on their phones via text messages.

Study Visit 3:
One week before study visit 3, the volunteers will need to wear the camera and activity monitor daily for one week. The volunteers will attend a study visit at the NIHR Imperial Clinical Research Facility, where they will have their blood pressure, body composition and waist circumference measured. They will bring the fasted urine sample. They will also be able to discuss anything related to their dietary habits with the study team. After that, they will be able to go home. They will receive the urine and stool collection kit during that visit which they will use to bring a urine and stool sample for visit 4.

There will be a 5-week gap between study visits 3 and 4. Volunteers in both intervention arms will receive regular prompts about how to improve their diet on their phones via text messages.

Study Visit 4:
The volunteers will attend a study visit at the NIHR Imperial Clinical Research Facility, where they will provide a fasted urine sample, a fasted blood sample (25 ml), and a stool sample. They will return the camera and activity monitors. They will also have their body weight, waist circumference and blood pressure measured and undergo body composition measurements. After that, the volunteers will be able to go home.

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)

Completion date

28/02/2027

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)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

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
03/11/2025

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
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Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

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.

IPD sharing plan summary
Stored in non-publicly available repository