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Pilot clinical trial on using health and dietary monitoring technologies to prevent diet-related diseases

Submission date 18/10/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/10/2023	**Overall study status** Completed	
Last Edited 23/01/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Unhealthy diets are associated with metabolic changes and increased risk of non-communicable diseases (NCDs). However, current understanding of the relationship between diet and the development of NCD is limited by a number of factors. These include a lack of understanding of dietary mechanisms that drive NCD, inaccurate tools to collect dietary information, a nascent understanding of the role of personalised nutrition, and the lack of data in vulnerable groups where NCDs are often over-represented.

The relationship between dietary intake and the development of NCD is complex. The understanding of how diet relates to the development of metabolic risk factors on a background of non-modifiable risk factors is improving with the greater understanding of the metabolic pathways that are responsive to dietary profile and lead to change in NCD risk. Tools that profile the genome, metabolome, epigenome, microbiome, and inflammation are key to understanding the impact of diet on NCDs. However, these systems are mostly studied in isolation and their relative importance of how they interact with each other is not understood.

Who can participate?
Healthy volunteers (male and female), aged 18-65 years old, with BMI over 25 kg/m² and two other risk factors.

What does the study involve?
Participants will need to wear a micro-camera that tracks their dietary intake and a wristband that measures their physical activity and sleeping patterns for seven days each on three separate occasions. In addition, while the volunteers are wearing the camera and the wristband, they will need to complete a five-day food diary online. At the end of the first and third period of wearing the devices and completing the food diaries, the volunteers will be asked to attend two studies, where they will have their body composition and general health assessed, provide blood, stool, breath, and urine samples. In addition, during these two study visits and only at the Imperial College London site, the volunteers will be asked to undergo a mixed meal tolerance test where the participants will consume a standard meal and then have blood samples taken

over a six hours period.
At the end of the second period of wearing the devices and completing the food diaries, the volunteers will be asked to attend a 30-minutes study visit where they will only have their body composition and general health assessed (no biofluids will be taken). After the volunteers have completed all study visits, they will be asked to complete short questionnaires through which they will be able to express their views on participating in the study.

What are the possible benefits and risks of participating?
Participants will receive £200 upon completion of the study to reimburse them for the time they have taken to attend study visits.
No risks

Where is the study run from?
1. Imperial College London (UK)
2. Aristotle University Thessaloniki (Greece)
3. CIC bioGUNE (Center for Cooperative Research in Biosciences) (Spain)
4. University of Valencia (Spain)
5. Atlanta Clinical Trials (Ireland)

When is the study starting and how long is it expected to run for?
January 2023 to September 2024

Who is funding the study?
1. European Union under Horizon Europe project
2. UK Research and Innovation

Who is the main contact?
1. Dr Aygul Dagbasi, a.dagbasi16@imperial.ac.uk
2. Monica Hill, m.mischie18@imperial.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
330755

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 330755, CPMS 59206

Study information

Scientific Title
Combatting Diet Related Non-Communicable Diseases through Enhanced Surveillance

Acronym
CoDiet

Study objectives
Integrating multiple methods of assessing dietary intake (micro-camera technology and online food diaries) with collection and analysis of a wide range of bio fluids (blood, urine, faeces and breath) and with non-invasive body composition measurements can help understand better the relationship between dietary intake and risk of non-communicable diseases.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 03/11/2023, London - Surrey Research Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8088; surrey.rec@hra.nhs.uk), ref: 23/PR/1109

2. approved 24/10/2023, Cork Research Ethics Committee (Lancaster Hall, 6 Little Hanover Street, Cork, T12 WV09, Ireland; +353(0)21204901901; crec@ucc.ie), ref: ECM 3 (III) 24/10/2023

3. approved 18/10/2023, Ethics Committee on Human Research at the University of Valencia (Avda. Blasco Ibañez, 13, Valencia, 46010, Spain; +34 (0) 963864109; vicerec.investigacio@uv.es), ref: 2023-MED-2857718

4. approved 19/01/2023, Committee for Ethics in Research, Aristotle University Thessaloniki (Aristotle University, Thessaloniki, 54124, Greece; +3023109988427; ethics@rc.auth.gr), ref: 20023/2023

5. approved 29/09/2023, Ethics Committee for Research with Medicinal Products in the Basque Country (Department of Health of the Basque Government C/ Donostia-San Sebastián, nº 1, Vitoria-Gasteiz, 01010, Spain; +34 945 01 92 96; ceic.eeaa@euskadi.eus), ref: PI2023134

Study design
Multicenter observational study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Healthy individuals at risk of developing non-communicable diseases (heart disease, type 2 diabetes, cancer).

Interventions
Participants will be asked to wear a micro-camera attached to glasses for 3 one week periods that will record what they eat. In addition, they will need to wear a physical activity monitor

Intervention Type
Other

Primary outcome(s)
1. The effectiveness of the micro-camera technology to measure and determine the volunteers' food and drinks intake continuously for a week during weeks 1, 4 and 8 in comparison to the dietary information that the volunteers input in the online food diaries during weeks 1, 4 and 8.
2. Determination of the volunteers' non-communicable disease risk during their participation in the study at the end of weeks 1 and 8 by measuring: 1) the metabolites found in the volunteers' stool, fasted urine, fasted blood, and breath samples using nuclear magnetic resonance, liquid chromatography, and gas chromatography, 2) the volunteers' dietary habits using the camera technology and online food diaries and 3) the volunteers' physical activity using wristband activity monitors. Information from 1), 2) and 3) will be combined using machine learning to obtain a comprehensive non-communicable disease risk for each volunteer at the end of weeks 1 and 8

Key secondary outcome(s))
1.Body composition measurements, cardiovascular system health and autonomic nervous system measurements conducted at the end of weeks 1, 4 and 8:
1.1. Body composition will be measured using a Body Composition Analyser, called InBody
1.2. Cardiovascular system and autonomic nervous system health will be measured using a heart rate variability and accelerated photoplethysmograph analyzer, called SA3000P
1.3. Cardiovascular system health will also be measured using an Advanced Glycation End (AGE) products analyser
2. Physical activity levels and sleeping patterns of the volunteers measured continuously for a week during weeks 1, 4 and 8 using wristband activity monitors.
3. Assess the volunteers' acceptance of the developed technologies (micro-camera, online food diaries, physical activity and sleep monitor, samples donation and non-invasive body measurements) at the end of the clinical trial using questionnaires and interviews.

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Male and Female aged 18-65 years old
2. Individuals at high risk of developing a non-communicable disease assessed through the metabolic risk score:
2.1. Overweight or obesity (BMI greater than 25 kg/m^2) plus any two of the four factors:
2.2. Raised triglycerides: ≥ 100 mg/dL (1.7 mmol/L)
2.3. Reduced HDL cholesterol: < 40 mg/dL (1.03 mmol/L) in males or < 50 mg/dL (1.29mmol/L) in

females.
2.4. Raised blood pressure: systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg.
2.5. Raised fasting plasma glucose (FPG): ≥ 90 mg/dL (5.0 mmol/L).
3. Current smokers

Participant type(s)
Healthy volunteer

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. Suffer from the following conditions: type 2 diabetes, chronic gastrointestinal conditions (Crohn’s disease, irritable bowel syndrome, ulcerative colitis etc.), acute infectious diseases, cardiovascular diseases, hypertension, autoimmune conditions,
2. Were on antibiotic treatment in the 12 weeks preceding enrolment of the clinical trial,
3. Pregnant or currently breastfeeding,
4. Are currently participating in other clinical trials or participated in another trial within the last 12 weeks,
5. Require any medical interventions during the study period,
6. Cannot give consent by yourself.

Date of first enrolment
01/12/2023

Date of final enrolment
01/03/2024

Locations

Countries of recruitment
United Kingdom

England

Greece

Ireland

Spain

Study participating centre
NIHR Imperial Clinical Research Facility
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Study participating centre
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Study participating centre
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Avda. Blasco Ibañez, nº 15
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Study participating centre
Laboratory of Forensic Medicine and Toxicology
School of Medicine Aristotle University Thessaloniki
Thessaloniki
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Study participating centre
CIC bioGUNE, Precision Medicine and Metabolism Lab
Bizkaia Science and Technology Park bld 801 A

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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

Funder Name
European Union Horizon Programme

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	version 1.2	31/03/2025	23/01/2026	Yes	No
Participant information sheet		10/10/2023	20/10/2023	No	Yes
Study website		11/11/2025	11/11/2025	No	Yes