Participant Information Sheet (PIS)

Combatting Diet Related Non-communicable Diseases through Enhanced Surveillance: CoDiet Study

You are being invited to take part in a research study. Before you decide whether you would like to participate, it is important for you to understand why the research is being performed and what it will involve. Please take time to read the following information carefully and discuss it with your friends, relatives, and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

If you do decide to take part, please let us know beforehand if you have been involved in any other study during the last 12 weeks. You are free to withdraw at any time without giving reason. Thank you for reading this.

What is the purpose of the study?

Diet is a major contributor to the development of non-communicable diseases, such as type 2 diabetes, heart disease, or certain types of cancer. Understanding the relationship between people's dietary habits and the development of non-communicable diseases is essential towards developing public health policies which could reduce the burden of these conditions. However, most of the knowledge that we have regarding people's diets comes from self-reported dietary intake, usually in the form of food diary recalls, food frequency questionnaires and 24-hour dietary recalls. This is often subjected to reporting bias which leads to inaccurate knowledge of people's diets. Specifically, individuals tend to forget what they have eaten especially if they record the foods and drinks which they consumed at the end of the day, or wrongly estimate portion sizes because of difficulties of objectively assessing food quantities. In addition, people may change dietary habits as they are aware that they are being monitored and therefore opt for healthier options. Generally, these traditional dietary reporting tools are time-consuming and require effort from both the person filling in the food diaries and researchers/dieticians/nutritionists to understand the dietary habits of the person completing the dietary information. As a consequence of inaccurate dietary information, it is difficult to understand how people's dietary patterns predispose them to non-communicable diseases and, moreover, how best a dietician can advise their patients to change their diets to improve

their health. For this reason, and due to the high prevalence of non-communicable diseases, it is important to identify more objective and user-friendly dietary tools which can help researchers understand the link between diet and non-communicable diseases development so that these health conditions can be averted.

Therefore, the CoDiet study will explore novel technologies that can be used to record dietary habits more accurately. The study also aims to understand the impact of dietary habits on human health, specifically risk of non-communicable diseases by collecting blood, urine, breath and stool samples and information about the body composition of individuals. Briefly, the following tools will be used to achieve these aims:

1. **Micro-camera:** Participants will wear cameras during waking hours which will take continuous recordings of all the foods and drinks that they consume. The software used in this technology can estimate food type and their portion size. The camera will be the size of an USB stick and will be attached to the frames of the participants' glasses or if they do not wear glasses, the study team will provide lens-free frames.

2. **Urine Measurement**: By collecting samples of the first urine void of the day, we can examine which chemicals the body breaks down when certain foods/drinks are ingested and therefore understand more accurately what people's diets looks like.

3. **Stool Measurement**: By collecting stool samples we can find out what which gut bugs the participants have and how they affect their health.

4. **Blood Measurements**: By collecting small blood samples we can find out information about participants' genetic makeup and how that affects their risk for non-communicable conditions, how their body responds following consumption of a meal, by measuring their glucose and insulin levels, and their general health too.

5. **Breath Measurements**: By collecting breath samples from participants, we can find out information about their risks for certain conditions, such as cancer.

6. **Wristbands**: Participants will wear both during the day and the night wristbands that measure their physical activity levels and sleep patterns.

7. **Online Dietary Recall (Intake24):** The volunteers will record all the foods and drinks that they have consumed in an online app; the information from this app will be linked with the information derived from the camera and the urine and blood samples.

8. **Body composition and the health of your cardiovascular system:** We will use special equipment to measure participants' body composition (body fat, muscle, and water content) and the health of their heart and blood vessels.

To achieve these aims, participants will be asked to wear daily a camera and a physical activity monitor for 3 one-week periods. In addition, participants will be asked to record their dietary habits in their home/work environment and provide blood, stool, breath, and urine samples in a clinical environment at Imperial College London.

The results from this study will help understand objectively people's dietary habits and inform on more suitable and easier to use tools that can be used to record people's diets. In addition, it will help us understand better the relationship between diet and the risk for non-communicable diseases.

Why have I been chosen to participate?

You have been chosen to participate because you are a **healthy adult who is eligible to participate in this study as per our eligibility criteria below. Your participation** can help us understand the relationship between dietary habits and the risk for developing non-communicable diseases.

Who is eligible to participate in the study?

You are eligible to participate if you meet all of the following criteria:

- Male and Female aged 18-65 years old
- BMI greater than 25 kg/m^2 **plus any two of the four factors**:
  - Raised blood triglycerides: ≥ 100 mg/dL (1.7 mmol/L)
  - Reduced HDL cholesterol: < 40 mg/dL (1.03 mmol/L) in males or < 50 mg/dL (1.29mmol/L) in females.
  - Raised blood pressure: systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg.
  - Raised fasting plasma glucose (FPG): ≥ 90 mg/dL (5.0 mmol/L).
  - Current smokers

You are <u>not eligible</u> to participate if you:

- 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,
- Were on antibiotic treatment in the 12 weeks preceding enrolment of the clinical trial,
- Pregnant or currently breastfeeding,
- Are currently participating in other clinical trials or participated in another trial within the last 12 weeks,
- Require any medical interventions during the study period,
- Cannot give consent by yourself.

Do I have to participate in this research study?

It is entirely up to you to decide whether you want to participate in this research study. If you do decide to participate, you will be given an informed consent form to sign and keep for your records. You will also be given a copy of this patient information sheet to keep. With your consent, we will inform your GP of your participation in this study. You can withdraw from this study whenever you wish so, and you do not need to give any reason for your decision. Your participant status and standard of care will not be affected by your withdrawal from this study.

What will happen to me if I take part?

- **Screening and Pre-Study Visit (Up to 1 hour):**

If you are eligible and you decide to participate in this study, you will be invited to come to the NIHR/Wellcome Trust Imperial Clinical Research Facility at Hammersmith Hospital W12 0HS for a screening and pre-study visit. You will be able to ask us any further questions you might have about the study. You will also receive a hard copy of this information sheet. After all your

questions have been answered and you are still willing to participate in the study, you will be able to sign a consent form.

Once this happens you will go through a health screening for the study where you will be interviewed and examined by one member of the research team. You will have a blood test (to check your liver, kidneys, cholesterol and ensure that you are not anaemic or diabetic) and height, weight, ECG (Electrocardiogram), and blood pressure measurements will be taken. All women of childbearing age will have a pregnancy test. During this visit, you will complete a brief study questionnaire in which you will need to complete information about any medication you are taking, past medical and family history of any conditions, GP details, ethnicity, dietary habits and physical activity habits. The results of these measurements (weight, height, blood pressure and pregnancy test) will be recorded in this questionnaire.

During this visit, we will explain to you how to use the micro-camera and the wristband that you will need to wear for three one-week periods. We will also show you how to use the online dietary recall (Intake24) and the stool and urine collection kits. The screening and pre-study visit should be 1 hour long.

You will be informed (by phone or e-mail) by a member of the research team whether the blood test, blood pressure and body weight measurements results make you eligible or not to participate in the study. Your GP will receive a copy of your blood test results.

Micro-camera

The micro-camera will be attached to your glasses, it is lightweight, and it is the size of an USB stick. It will automatically take images (for example, 1 image per second). If you do not wear glasses, you can use the lens free glasses provided by the research team. The cameras will not capture any sounds, nor will they record video footage. Full instructions on how to wear and activate the camera will be given as well as instructions on how to plug the cameras into the chargers at night. The camera technology will capture everything in its vision, which includes food, drink, and potentially other people. Additionally, when you wear the micro-camera at home/work, you may capture images of people who live/work with you. To ensure everyone's anonymity, any footage of people recorded by the micro-cameras will be automatically blurred prior to analysis of your food intake. When the image data is being downloaded, this is achieved via an artificial intelligence methodology which only considers

the food and drink images and not face recognition. All the images that do not capture food or drinks intake will be automatically deleted and will not be used in any analysis.

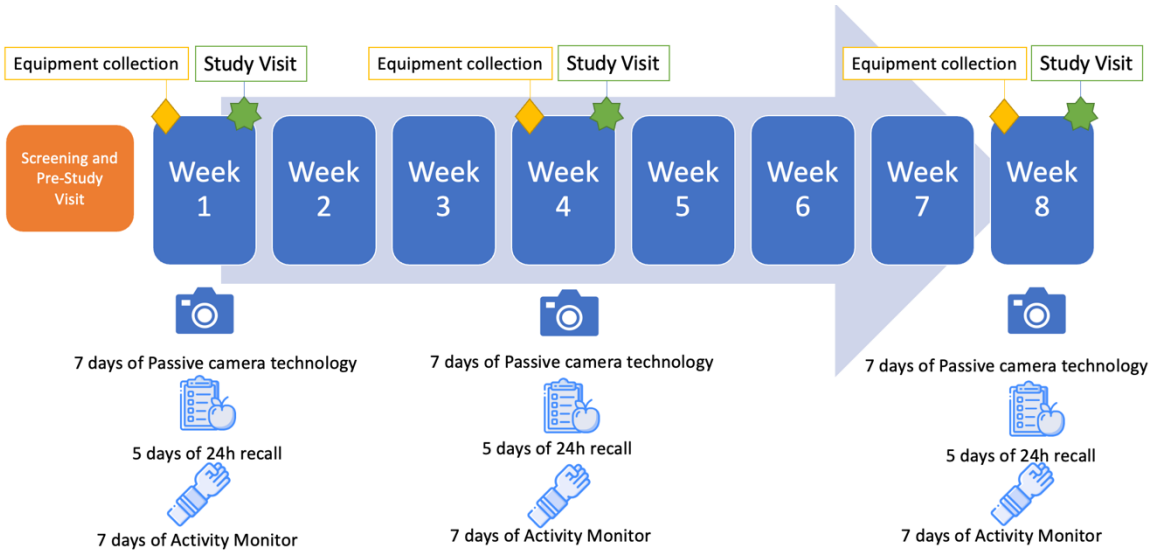
Online dietary recall tool

Intake24 is an easy-to-use, self-reporting online tool that records what a person eats and drink. It can be used on any device (tablet, laptop, smartphone) via a web browser (e.g., Chrome, Safari) and you will be provided with login details (you will not be required to input your email address or name). Each tool also has a tutorial video for participants to watch before starting.

Intake24 is a 24-hour multi-pass dietary recall. You will record what you have been eating and drinking during the 3 one-week periods before each study visit). Intake24 guides you through the process which starts by listing what you ate/drank the previous day, then asking how much you had using portion size photos as well as recording extra details (e.g., if you had a cup of tea, did you add milk and, if so, what type?). This takes around 15 minutes to complete.

There is a 2-week gap between Study Visit 1 and 2 and a 3-week gap between Study Visits 2 and 3. The whole study visit will take 8 weeks to complete as shown in the diagram on the next page.

Diagram of Study Outline:



- **Study Visits 1 and 3 (Up to 7 hours):**

Seven days before you are scheduled to come for Study Visit 1 and 3, you will need to come to the NIHR/Wellcome Trust Imperial Clinical Research Facility at Hammersmith Hospital W12 0HS to receive the camera, the wristband and the urine and stool collection kits. We will explain again how to use them. You will need to wear the camera continuously for 7 days (except when going to toilet, having a shower, and sleeping) and the wristband both during the day and night continuously for 7 days.

Five days before you are scheduled to come for Study Visit 1 and 3, you will need to start recording the foods and drinks that you consume in the online app, Intake 24. We will send you reminders to do this.

The evening before you are due to come for Study Visit 1 and 3, we ask you to avoid alcohol and be fasted from 9 pm (drinking water is fine).

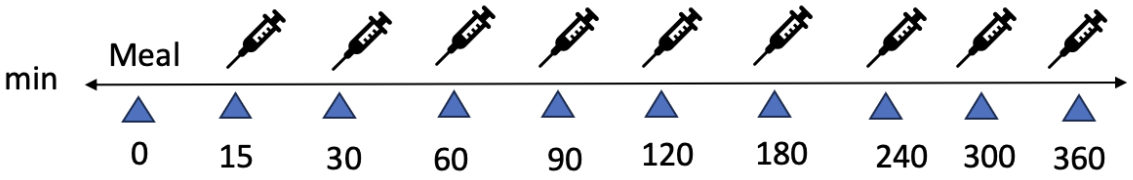
On the day of Study Visits 1 and 3, we ask participants to arrive fasted at around 9 am. You will be able to return the camera and the activity wristband. You will need to bring with you a

small sample of your first urine void of the day (20ml) and a stool sample as well. The stool sample can be provided during the visit as well.

Members of the study team will take body measurements (body composition and weight), and a couple of other measurements that assess the health of your cardiovascular system. Women of child-bearing age will also have a pregnancy test. Participants will be asked to provide two breath samples.

Following this, a member of the research team will place a cannula in your arm that will stay in place during the study visit which will allow us to take blood without causing you any further discomfort. We will take 25 ml at the first blood sample. After this, we will give you a meal drink and you will be allowed 10-15 minutes to consume it.. After you had the meal drink, we will take 9 blood samples (5ml each) over the course of 6 hours. So, in total we will take 65ml of blood (4 tablespoons or 13 teaspoons of blood) at each Study Visit 1 and 3. You will not be able to consume any other food or drink, except for water during this study visit .At the end of the visit we will remove your canula and offer you a food of your choice from our hospital menu. Following this, you will be able to go home. This visit will not be longer than 7 hours.

Diagram of when we will take blood samples from you:



- **Study Visit 2 (Up to 1 hour):**

Seven days before you are scheduled to come for Study Visit 2, you will need to come to the NIHR/Wellcome Trust Imperial Clinical Research Facility at Hammersmith Hospital W12 0HS to receive the camera, the wristband and the urine and stool collection kits. Alternatively, we can send them by post if easier for you. You will need to wear the micro-camera and the wristband as above. **Five days before you are scheduled to come for Study Visit 2**, you will need to start recording the foods and drinks that you consume in the online app, Intake 24. We will send you reminders to do this.

On the day of Study Visit 2, you will need to return the camera and the wristband. In addition, we will do a pregnancy on women of child-bearing age and measure your body composition and a couple of other measurements that assess the health of your cardiovascular system. No blood, urine, breath or stool samples will be collected. This visit should not take more than 30 minutes.

At the end of the study, you will be asked to complete an online feedback form in which you will need to report how you felt taking part in the study, how easy and convenient using the camera, the online food diary and the physical activity monitoring were. In addition, 10 participants from the whole study cohort (200 volunteers) will be selected at random (using a random number generator system matched to participant study number) for a one-hour in-depth interview with a member of the research team in which they will provide more detailed feedback on how they felt about the study and how the techniques that were developed could be used in the wider population.

What are the potential advantages if I decide to participate?

The study will not directly benefit you, however we hope that the information which we will gather through your participation will help us identify better tools at recording and understanding more accurately people's dietary intake. In addition, through this study we hope to gain more understanding into the relationship between dietary intake, markers of food intake and the risk of non-communicable diseases.

What are the potential risks and/or disadvantages if I decide to participate?

In the event we discover something about your health that you were not aware of, such as abnormal kidney test result or possible type 2 diabetes, we will inform you of this immediately. If you require more urgent assessments, we will arrange these for you immediately within the hospital. In addition, your GP will be informed of the blood test results that were taken at the consent and screening visit.

The micro-camera that will be used to record food intake is small and lightweight (size of an USB stick) and should not pose any discomfort. In addition, the camera will not record any sounds and the faces of people in the images will be blurred to ensure anonymity. Only images related to food and drinks will be used in the data analysis.

Procedures such as recording your weight, height, physical activity, and sleep do not pose any risks to your health. Self-collection of stool and urine samples may lead to contamination while collecting them, however, these risks have been reduced by providing you with easy-to-use collection kits that are hygienic, and which involve minimal handling.

Blood sampling may produce mild discomfort when the needle is inserted, possible bruising and localised infection. To reduce any of these risks, blood sampling will only be performed by adequately trained doctors, nurses, or members of research team under aseptic conditions.

Will I be reimbursed for my travel expenses and time?

You will receive £200 for completing all three study visits (£80 for each of Study Visits 1 and 3 and £40 for Study Visit 2). In addition, you will receive compensation for travel expenses provided you show us proof of travel (e.g., bus/train ticket).

What happens when the research study stops?

Once the study has finished, the data that was gathered will be analysed by members of the research team. Then, the results can be made available to you if you wish so. If you have any problems immediately following the study, then you should contact one of the research team members on the numbers provided.

What if new information becomes available?

Sometimes during a research study, new information becomes available about the intervention that is being studied. If this happens, the research team member will tell you about it and discuss with you whether you want to continue in the study. If you decide to continue with the study, you will be asked to sign an updated informed consent form. Also, on receiving new information the research team member might consider whether it would be in your best interests to withdraw you from the study.

What will happen if I no longer wish to continue participating in this research study?

You can withdraw from the study any time you wish so, without giving any reason. Your participant status will not be affected. No further samples (blood, breath, urine, and faeces) and data will be collected if you decide to withdraw. Any samples (blood, breath, urine, and faeces) and personal data that are identified as belonging to you that have already been collected will be retained and used in the data analysis and, if you gave consent, for future

ethically approved studies. In the unlikely event that you lose capacity to consent during the study you will be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected, or any other research procedures carried out.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Prof Gary Frost, e-mail: g.frost@imperial.ac.uk). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

What could I do if I have complaints or concerns?

If you wish to complain or have any concerns regarding the ways you have been treated during this research study, you should contact the Principal Investigator of this study, Professor Gary Frost by phone 0207594739 or by e-mail g.frost@imperial.ac.uk.

How will we use information about you?

Imperial College London (Sponsor ID: 23IC8501) is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in April 2024.
For more information / confirmation regarding the end date please contact the study team, see **'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information from you for this research project.
This information will include your:

- NHS number
- Name
- Contact details

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Some of your information will be sent to Spain, Greece, and Ireland. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"); Health and care research should serve the public interest, which means that we have to demonstrate

that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes.

International Transfers:

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

Sharing your information with others

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
- the following Research Collaborators:

- Teagasc Ashtown Food Research Centre in Ireland which will analyse the stool samples and data.
- Aristotle University in Thessaloniki, Greece which will analyse urine and blood samples and data.
- CIC bioGUNE in Spain which will analyse the blood and urine samples and data.
- AZTI centre in Spain which will analyse the genetic information of the blood samples and data
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Potential use of study data for future research

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of the data collected.

if data will be used for future research: If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team members
- by sending an email to imperial.dpo@nhs.net
- by ringing us on 020 3311 7344

Complaint

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to g.frost@imperial.ac.uk or by ringing us on 020 7594 0959.Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?

The results of this study will be published in relevant nutrition peer-reviewed journal articles or presented at scientific conferences, internal conferences/group meetings. Your confidentiality will always be ensured, and you will not be identified in any publication or scientific conference. The published results of this study may be sent to you if you are interested in finding out the outcomes of the study.

Who is organising and funding the research?

The study is being organised and sponsored by Imperial College London and is part of a grant funded by the UK Research and Innovation under the UK government's Horizon Europe guarantee (grant number: 101084642). The sponsors of this study will pay the Imperial College Clinical Research Facility for including you in this study.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by the Research Ethics Committee, REC reference.

Contact for further information.

The Principal Investigator coordinating this study, Prof Gary Frost, can be reached during working hours by phone 0207 594 7239 or by e-mail: g.frost@imperial.ac.uk. At all other times, you can get in touch with the Hammersmith Hospital Switchboard at 020 8383 1000.

Thank you for reading this!

If you are interested in taking part in the study, please contact the study team to arrange a screening appointment.

A copy of this written information and signed Informed Consent form will be given to you.