Participant Information Sheet (PIS)
Data-driven integration of emerging technologies to generate a Standardized and Objective Dietary Intake Assessment Tool – SoDiat study

You will be given a copy of this information sheet and a signed copy of your consent form to keep, should you decide to participate in the study.

Before you decide if 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 Participant Information Sheet.

What is the purpose of this study?

Your diet has a huge impact on your health and well-being and unhealthy diets are a major contributor to the development of a range of chronic health conditions, such as diabetes, cardiovascular diseases, and many cancers. Understanding peoples' diets is important to develop public health strategies to tackle nutrition-related health problems, however these strategies are consistently undermined as there is not an accurate method (or 'tool') for people to record their diet (i.e., what they eat and drink) and to calculate their nutritional intakes (e.g., amount of protein or vitamin C people have in their diets).

Tools traditionally used by researchers and nutrition professionals to record peoples' diets include Food Frequency Questionnaires (FFQs), 24hr dietary recalls and food diaries, where people report what they ate and drank for a specified duration (e.g., how much and how often). However, these tools are affected by 'reporting bias', which reduces their accuracy. For example, when people are being observed, they often change their diet to appear 'healthier' or eat foods not usually eaten for ease of reporting (e.g., ready meals are easier to report than homemade recipes), and certain foods/drinks are often forgotten (e.g., sugar in tea or oil for frying). In addition, these traditional tools are burdensome for people recording their diet, and require costly, time-consuming expert support to process what people recorded into nutrient intakes.

To address this problem, the 'Standardised and Objective Dietary Intake Assessment Tool' ('SODIAT') study will explore the ability of three emerging technologies and two online tools to accurately assess what people eat and drink:

1. "Urine biomarker metabolomics": by collecting a small urine sample, we can measure "metabolites" (small molecules) that are produced when the body breaks down substances found in certain foods/drinks, such as fruit and vegetables.

2. "Capillary blood samples": by collecting a few droplets of blood from the tiny blood vessels (capillaries) located under the skin, we can measure substances ("biomarkers") in the blood that tell us what a person has eaten, such as fats and dairy products.

3. "Wearable micro-camera technology": participants will wear tiny cameras to take automated, continuous images of foods and drinks, and we will use specialised image processing software to recognise these foods and estimate their portion sizes.

4. "Online dietary assessment tools" (eNutri and Intake24): participants will use two online tools to report what they have previously eaten/drank and these apps will automatically estimate their dietary intake (for example, how many portions of fruit, how much vitamin C).

To test these technologies/tools, participants will consume two meal plans (healthy and unhealthy) in a highly controlled setting (i.e., we provide all food and drink, so we know exactly what they have eaten and drank).

The findings from this study will identify the strengths and weakness of each technology/tool. We will then identify which combination of these technologies/tools most accurately assesses what people eat/drink. This 'optimal' combination will be tested in future studies in the home-environment (not part of this application).

Who is suitable to participate?

- Male and female healthy participants of all ethnicities (aged 18 to 70 years old)
- Normal to overweight individuals (body mass index (BMI) 20-30 kg/m^2)

You are NOT suitable to participate if you:

- Have been involved in any other study during the previous 12 weeks, are not able to commit to the study (e.g., travel commitments) or are unwilling to collect urine and blood samples and wear the micro-camera.
- Had a weight change of more than 3kg in the preceding 3 months or are currently following a weight-loss diet.
- Have excess alcohol intake (more than 21 units per week) (E.g., a medium glass of wine = 2.3 units).
- Are unwilling to abstain from drinking alcohol and avoiding strenuous exercise during the two 5-day test periods.
- Are unwilling to follow the study menus (e.g., dislike of food items, following a restrictive/specialised diet or receiving specialised dietary advice for a medical condition); you will not be permitted to eat/drink anything else during the two 5-day test periods.

- Are not able to eat fish and/or meat (e.g., are vegan or vegetarian).
- Have an allergy/intolerance to any of the food items in the menu.
- Have taken any dietary supplements in the last 3 months (e.g., multivitamins, fish oils).
- Are pregnant or lactating.
- Currently, suffer from any of the following: eating disorders, diabetes, cancer, gastrointestinal disorders (e.g., inflammatory bowel disease or irritable bowel syndrome), kidney disease, liver disease, pancreatitis, HIV or AIDS or any other chronic illness.
- Are taking any of the following medications: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin, or thyroid hormones.
- Use illicit substances.
- Have been diagnosed with dementia or other conditions affecting memory.
- Have difficulty using laptops/tablets (e.g., cannot use these devices without assistance, are blind or have other conditions affecting sight, or have physical disabilities/conditions that affect your ability to press buttons).
- Cannot read and understand English.

Do I have to take part?

It is up to you to decide whether to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are free to withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will I have to do?

Screening:

If you are interested in taking part, you will either be contacted by one of our researchers over the phone or via email (Imperial College) or be directed to a website (University of Reading). In both instances, you will receive/download a copy of the participant information sheet to read, have an opportunity to discuss the study and have any questions answered by a study researcher. You will also be asked some questions regarding your suitability and availability for the study (either over the phone or an online form).

Additionally, a list of foods will be provided to you to ensure that you will be able to consume the food items provided. A full list of food products can also be found at the end of this document.

Consent and Pre-Study visit:

If you are eligible and you decide to participate, you will initially be invited to attend the NIHR/ Imperial Clinical Research Facility at Hammersmith Hospital or the Hugh Sinclair Unit of Human Nutrition at the University of Reading (depending on your location) prior to taking part in the study. You will receive a hard copy of this information sheet to keep and have an

opportunity to ask any additional questions. After these have been answered to your satisfaction and you are happy to take part, you will be asked to sign the study consent form.

You will then spend around 2 hours in the research facility to familiarise yourself with the different technologies that will be used during the study. This includes the micro-cameras, and the equipment used to self-collect capillary blood samples ('OneDraw') and spot urine samples (transfer straw and vacuum tube).

Study Visits:

The study visits will take place at the NIHR/ Imperial Clinical Research Facility at Hammersmith Hospital or the Hugh Sinclair Unit of Human Nutrition at the University of Reading (depending on where you live) and will include two 4-day study periods as follows:

- Study period 1: 4 full day visits (8am to 6pm) then return to the unit on the 5th day to return samples/equipment.
- Wash out: there will be a gap of at least 1 week between study periods (this will be longer for menstruating women who will attend study visits at the same phase of their menstrual cycle).
- Study period 2: another 4 full day visits then return to the unit on the 5th day to return samples/equipment.

You will be asked to attend the research unit at 8am every morning of the 8 study days, following a 12 hour overnight fast (not consuming any food or drink, except water) and remain in the unit until 6pm. Blood pressure, height and body weight will be measured when you arrive on the first day of each study period.

In a randomised order, you will receive a test diet during each study period that has a different level of compliance with UK healthy eating guidelines:

- Diet 1: far from meeting healthy eating dietary guidelines (e.g., high in fat, sugar, and salt and low in wholegrains, fruit, vegetables, and fibre)

- Diet 2: fully compliant with healthy eating dietary guidelines (e.g., high in fruits and vegetables as well as good quality protein and fat, and wholegrains).

You will be served meals and snacks throughout the 8 study days (8am – 6pm) according to the diet you have been randomly assigned to during each study period. Diets will consist of a 2-day repeating menu (e.g., menu 1 on days 1 and 3, and menu 2 on days 2 and 4). At 6pm of the 4 study days, you will return home with a snack and bottled water to be consumed in the evening. You will be instructed not to eat or drink anything, except for the evening snack and water provided between each 4-day study period.

We will collect urine samples and blood samples from you at various time points during the study days, which are explained in detail below. The samples will be labelled with your participant identification code (not your name) and will be stored securely in freezers at the

laboratory facilities of Imperial College London or University of Reading in compliance with the Human Tissue Act. At the end of the study, a material transfer agreement will be created, and all study samples will be sent to our project partners via a courier service who are approved for securely transporting biological samples (e.g., UPS, FedEx). Urine samples will be sent to Aberystwyth University and blood to the University of Cambridge, where they will be analysed for substances ("biomarkers"/"metabolites") that indicate what people have been eating and drinking (samples are not being analysed to assess your health).

Micro camera

You will be given a micro camera which can be attached to the frame of eyeglasses or a broach or a pendant for the two 4-day study periods to take images of everything that you eat and drink. The camera will have to be worn continuously for the 4-day study period (it can be removed when having a shower, sleeping, etc.) and will automatically take images (for example, 1 image per second). 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, although you will eat separately to other participants in the research unit, there is a chance of being captured in the images of other study participant. Likewise, when you wear the micro-camera at home, you may capture images of people who live with you. To ensure everyone's anonymity, any footage of people recorded by the 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.

Spot urine samples

For each study period, you will be asked to collect small samples of your first morning urine and evening urine on all study days plus first morning urine on day 5. These samples will be returned to the research facility daily. You will be provided with detailed instructions and a kit to collect, store, and transport your urine samples. It is important that the urine samples are chilled so you might be asked to store these overnight in secure containers in your fridges at home.

Self-collection blood samples

Additionally, you will be asked to provide us with a self-collected capillary blood sample on days 1, 2 and 4 to be taken by you in the unit (a researcher will be present if assistance is required but they will not take the blood samples). 'OneDraw' is a single-use system that simplifies the collection, stabilisation, and transport of blood samples. A researcher will provide guidance on how to use the equipment and clear instructions will be given. In summary, the OneDraw device attaches to your upper arm via a vacuum mechanism and two

small lancets (retractable needles) pierce the skin. The device then collects approximately 3 drops of blood on a strip of filter paper, which the researchers will collect from you and store in the freezer. The whole process, including reading the instructions, takes about 20 minutes.

Online dietary assessments: Intake24 and eNutri

Intake24 and eNutri are easy-to-use, self-reporting online tools that records what a person eats and drink. They can be used on any device (tablet, laptop, smartphone) via a web browser (e.g., Chrome, Safari, Edge) 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 8 study visits by using Intake24 the following day (for example, on day 2 you will recall what you ate and drank during day 1, etc.). Intake24 guides you through the process that 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.

You will also complete the eNutri food frequency questionnaire. You will be presented with a detailed list of food and drink items and asked to report how often you had each during the previous 4 weeks and how much you typically ate/drank by selecting from one of the portion size photos/buttons. This takes around 25 minutes to complete. It will be used at the start of day 1 of the first diet period only to record your habitual (usual) diet. It will then be used again towards the end of day 4 for both diet periods to record what you ate and drank during study visits only.

Usability of the study tools/techniques

For each of the tools/techniques listed above, you will be asked how easy/difficult you found each to use by answering a short questionnaire on one occasion. Your responses and direct quotes might be used as ''feedback examples'' in scientific journals or dissemination materials in a fully anonymised form (i.e., you will not be identifiable).

Will I get paid for participating?

You will be reimbursed £400 for successful completion of the study. This includes completing 8 full days in the unit, returning on day 5 for each study period to return samples and completing the final Intake24 diet recall as well as spending 2 hours in the unit for the pre-study visit. This will be paid via a bank transfer, which may take up to 2 months to be processed and deposited in your bank account. If you withdraw from the study prior to completion, you will receive £25 for every day completed.

What are the possible disadvantages and risks of taking part?

In the event that we discover something about your health that you were unaware of we would immediately inform you of this. However, the data we are collecting is not designed for discovery of health issues, so this is very unlikely.

Some of the procedures in this study, such as the recording of your weight, height and blood pressure present no risk to you. Other procedures, such as taking blood samples, can cause mild discomfort. For the purposes of this study, we will ask you to collect your own samples by using a self-test kit. This might result in slight discomfort when taking the sample and possible bruising after collection and a localised infection. However, these procedures will be taken with researcher's guidance under aseptic conditions to minimise any risks.

There are no major side effects associated with eating the foods and drinks included in this study design. These are commonly consumed foods within the UK and will be eaten in regular portion sizes.

What are the possible benefits of taking part?

The study will not directly benefit you, however we hope that the information we gather with your assistance might help to improve the collection of dietary data in the future.

What happens when the research study stops?

Once the study has finished, a summary of the study results can be made available to you. If you have any problems immediately following the study, then you should contact one of the researchers on the numbers provided below.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, and you do not need to give a reason. Any identifiable data, stored blood or urine samples that were already collected with your consent and up to the point of your withdrawal would be retained and used in the study. However, if you have specifically asked us to withdraw your previous consent to use your data and samples up to the point of withdrawal, your data and samples will be destroyed before the analysis starts.

What if something goes wrong?

Imperial College London (the study sponsor) holds insurance policies which apply to this study and covers both research facilities. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College 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 Principle Investigator (Professor Gary Frost; g.frost@imperial.ac.uk; 020 8383 3242). The normal NHS complaint services 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 (contact information below).

Will my taking part in this study be kept confidential?

Yes, your participation will be kept confidential.

What will happen to the results of the research study?

The results of this study will likely be presented at medical meetings, research conferences and published in scientific journals, six months following the end of the study. They will also be used by research students who are associated with this project in work that will contribute to their degree or other qualification. We also hope to publish the results in the press and media. Your confidentiality will be ensured at all times, and you will not be identified in any publication. Only group information will be presented. At the end of the study, the results of the study can be made available to you on request.

Who is organising and funding the research?

This study is being sponsored by Imperial College London and organised by scientists at Imperial College London and the University of Reading. Delegated responsibilities will be assigned to the NHS trusts conducting in this study and the University of Reading. This research project is part of a grant funded by the MRC/BBSRC Programme led by Aberystwyth University and also includes the MRC Epidemiology Unit at the University of Cambridge.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called a Research Ethics Committee (REC). This study has been reviewed and given favourable opinions for conduct by London - Camden & Kings Cross Research Ethics Committee as well as the University of Reading Research Ethics Committee.

Who can I contact for independent research information?

If you have any questions about being in a research study, you can contact the Trust's Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice. You can find your nearest PALS office on the NHS website, and you can also ask your GP surgery, hospital, or phone NHS 111 for details of your nearest PALS.

Further information

Thank you in advance for considering participation in this study. If you have any questions about this research, the study staff will be more than happy to answer them.

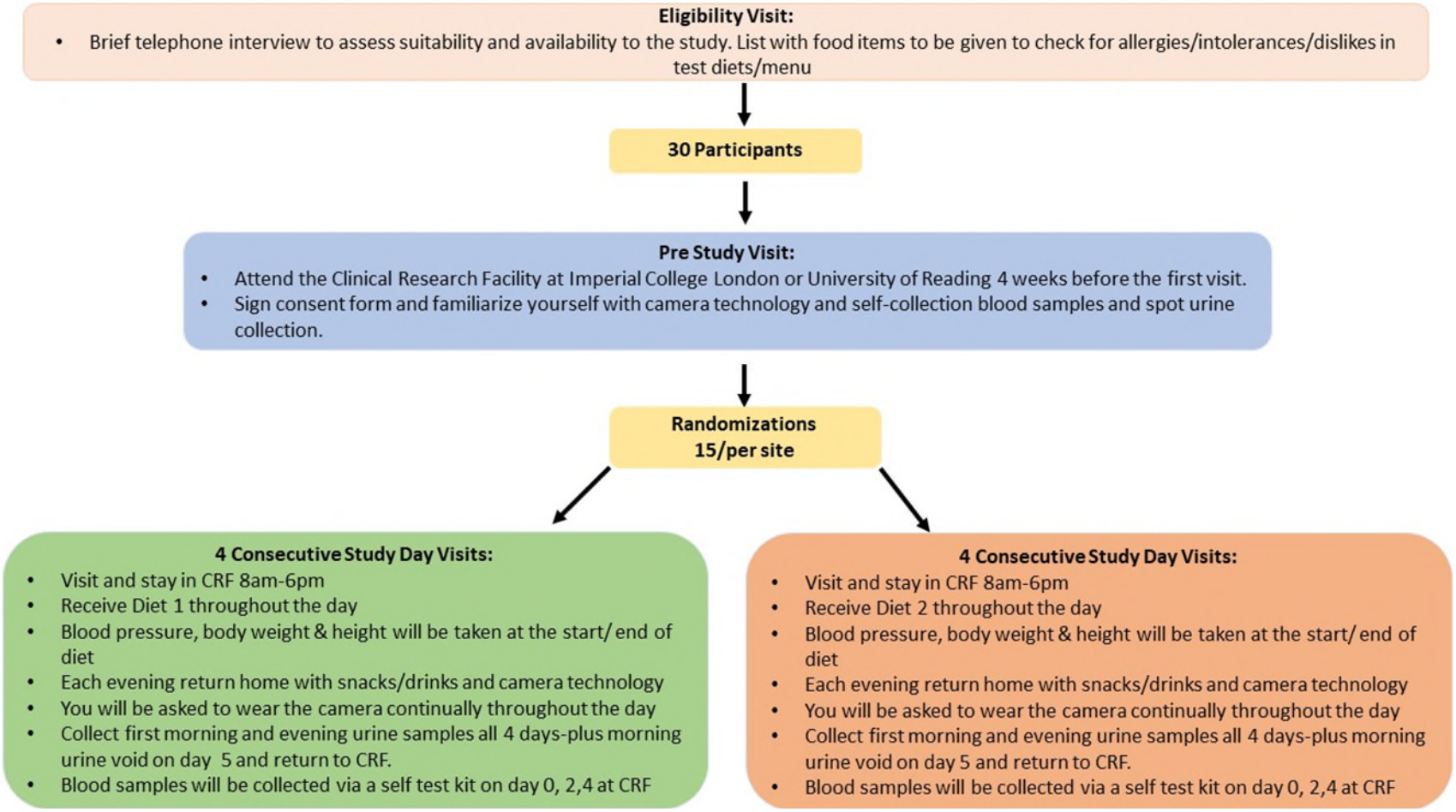
Study Investigator contact details

Professor Gary Frost

Email : g.frost@imperial.ac.uk

Phone Number: 020 8383 3242

Study schedule flowchart



PARTICIPANT PRIVACY INFORMATION

Research Study Title: Data-driven integration of emerging technologies to generate a Standardised and Objective Dietary Intake Assessment Tool - SoDiat

IRAS ID: 321986

This study is part of a large project which is led by Aberystwyth University with Imperial College London, University of Reading, and University of Cambridge as co-investigators (also referred to here as ''project partners''). The unique partnership has also been mentioned below ''sharing information with others'' section.

Imperial College London (UK) is the sponsor for this study based in the United Kingdom and will act as the Joint-Controller with the University of Reading for this study.

This means that we (Imperial College London and University of Reading) will be using information from you in order to undertake this study and will act as the data controller for this study. Additionally, we are responsible for looking after your information and using it appropriately. Imperial College London and the University of Reading will keep identifiable information about you 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.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf

A link to Imperial College London's data protection webpage may be found at https://www.imperial.ac.uk/admin-services/legal-services-office/data-protection/ but this is the notice most applicable to the information provided by participants and therefore takes precedence for all purposes described hereunder.

Your rights

Your usual statutory rights to access, change or move your information are limited, because of exceptions applicable to some types of research, and because we need to manage your information in specific, lawful ways for the research to be reliable and accurate. If you withdraw from the research study which has processed your personal data, dependent on the stage of withdrawal, we may rely on this lawful basis to continue using the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

Legal basis

As universities we use personally identifiable information to conduct research to improve health, care, and services. As publicly funded organisations, we must ensure that it is in the public interest when we collect, analyse, use, share and retain 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:

Under data protection law, we are required to inform you that this use of personal data we may hold about you in on the lawful basis of being a public task in 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 https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnicity data etc.), Imperial College London and University of Reading use this where it is necessary for "scientific or historical research purposes or statistical purposes''.

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). 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 European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard 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.

This includes: other Imperial College London/University of Reading 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 study has the following research partners: University of Reading, University of Cambridge, and Aberystwyth University. Data sharing will occur across all university partners, with overall data management and data analysis for the project being performed by Aberystwyth University.

Only researchers conducting the study will collect personally identifiable data from participants and undertake the processing of this data. A pseudo-anonymised dataset processed by Imperial College London and University of Reading (i.e., with participant ID codes but no other personally identifiable information) will be created for analysis purposes. Other pseudo-anonymised datasets (e.g., micro-camera footage, biological sample analysis, eNutri and Intake 24 dietary intakes) will be generated by project partners and shared between partners for the purposes of analysis.

Potential use of study data for further 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 or University of Reading. Data and blood/urine samples collected from you in this study will be preserved and made available in fully anonymised form so that they can be consulted and used by other academic institutions/organisations (UK and non-UK based) to support research and/or develop new tests/devices. 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.

Where can you find 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 or by sending an email to Professor Gary Frost g.frost@imperial.ac.uk.

Complaints

If you wish to raise a complaint on how we have handled your personal data, please contact the lead research team first by sending an email to Professor Gary Frost (g.frost@imperial.ac.uk), or by ringing us on 020 8383 3242.

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 via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ. If you are a participant at the University of Reading, please direct your queries to the University Data Protection Officer (imps@reading.ac.uk; Information Management & Policy Services, Whiteknights House, Pepper Lane, Whiteknights, Reading, RG6 6UR).

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). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator. You can find out more about your rights on the ICO website.

Meals

Diet 1 - Meal Plan A		
Meal	**Time**	**Menu**
Breakfast	8:00 - 9:00	Porridge with soya milk & banana Wholemeal toast with peanut butter Fruit smoothie Tea with skimmed milk
Snack	10:00 - 11:00	Orange, mixed nuts Coffee with skimmed milk
Lunch	12:00-14:00	Moroccan vegetable & chickpea tagine with couscous Red grapes
Snack	15:00-16:00	Green olives & cherry tomatoes Tea with skimmed milk
Dinner	18:00-20:00	Salmon Florentine (spinach cheese sauce) Potatoes, carrots & broccoli Peaches in juice
Snack	21:00-22:00	Ready salted potato crisps

Diet 1 - Meal Plan B		
Breakfast	8:00 - 9:00	Weetabix with soya milk Almond, Strawberries Tea with skimmed milk Wholemeal seeded toast Sunflower spread
Snack	10:00 - 11:00	Apple Coffee with skimmed milk
Lunch	12:00-14:00	Egg mayonnaise sandwich

		Tomato & red pepper soup
Snack	15:00-16:00	Houmous dip Carrot sticks Tea with skimmed milk
Dinner	18:00-20:00	Chicken korma, masoor dahl, rice Onion bhaji Grapes
Snack	21:00-22:00	Fruit & nut snack bar

Diet 2 - Meal Plan A		
Breakfast	8:00 - 9:00	Scotch pancakes with maple syrup Salted caramel flavoured Greek yoghurt Tea infused with whole milk & sugar
Snack	10:00 - 11:00	Shortbread biscuits Hot chocolate
Lunch	12:00-14:00	Cheese & ham sandwich Cream of chicken soup
Snack	15:00-16:00	Breadsticks with cream cheese dip Coffee with whole milk
Dinner	18:00-20:00	Steak & mushroom stroganoff, rice, peas
Snack	21:00-22:00	Salt & vinegar crisps

Diet 2 - Meal Plan B		
Breakfast	8:00 - 9:00	White toast with butter Baked beans with pork sausages Orange juice
Snack	10:00 - 11:00	Coconut macaroon Coffee with whole milk
Lunch	12:00-14:00	Chicken & bacon pasta in a creamy sauce green beans Water
Snack	15:00-16:00	Fizzy drink Potato crisps
Dinner	18:00-20:00	Beef lasagne with broccoli
Snack	21:00-22:00	Kit Kat Chunky