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A dual-site dietary intervention study to integrate dietary assessment methods

Submission date
03/08/2023

Recruitment status
No longer recruiting

Registration date
01/09/2023

Overall study status
Completed

Last Edited
04/10/2023

Condition category
Nutritional, Metabolic, Endocrine

[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
Diet has a huge impact on the health and well-being of individuals and is a major contributor to the development of a range of chronic health conditions, such as diabetes, cardiovascular diseases, and many cancers. Many countries are facing rising levels of obesity and diet-related disease due to changes in dietary choices and eating behaviour, as well as more sedentary lifestyles. The robustness and impact of strategies aimed at addressing nutrition-related problems are consistently undermined by misreporting of dietary intake caused by our lack of an accurate tool to assess and monitor dietary intakes. Self-reporting tools used traditionally to capture information about diet include Food Frequency Questionnaires (FFQs), 24-hour dietary recalls and food diaries. These tools struggle to categorise and represent accurately dietary intake and often involve costly expert researcher support, a substantial burden to study/survey participants and are subject to poor compliance, dietary change, and significant reporting bias. To improve dietary reporting, the researchers will bring together three additional technologies which have shown promise in improving accurate reporting of dietary intake. These are urine biomarkers, capillary blood biomarkers and wearable micro cameras. The overall aim of this study is to improve the accuracy of dietary reporting by combining all these tools.

Who can participate?
Healthy volunteers aged 18 to 70 and have a Body Mass Index (BMI) between 20-30 kg/m2

What does the study involve?
Participants will attend to undergo two 4-day dietary interventions and return the samples on the 5th day with a minimum of 1 week between both visits, with the administration of a healthy diet intervention compliant with current dietary healthy guidelines and an unhealthy diet intervention. Diets will consist of a 2-day repeating menu delivered twice over the 4 days. Participants will be given a micro camera to wear for the duration of the two, four-day study periods. The camera will automatically capture images of everything that a participant eats and drinks at regular intervals (e.g., one image per second) and must be worn continuously during the study period, including when at home. Participants will also collect first morning urine and evening urine samples on all study days plus a first morning urine on day 5. These samples will be returned to the research facility each day the participant attends. In addition to the urine samples, participants will also collect a capillary blood sample. These blood samples will be

collected by the participant on days 1, 2 and 4 of each study period. The blood collection uses a device called 'OneDraw' and involves attaching the devices to your upper arm where it then collects 3 small drops of blood. Participants will collect these samples while at the research centre, and a researcher will be present if the participant requires any assistance with the sample collection.
Participants will also use two online self-reporting dietary assessment tools called eNutri and Intake24. These online tools are simple to use and can be used on any type of device (laptop, tablet, smartphone) which has a web browser. Intake24 records a person's diet from the previous 24 hours, so participants will complete this a total of eight times during the study (four times for each study period). eNutri features a graphical FFQ that asks participants about their dietary intake over a longer period. Participants will record their dietary intake using eNutri at the start of the study to capture their habitual diet and again at the end of each study period to capture foods/drinks consumed in the test diets.
Participants will be asked to complete a short questionnaire on how easy/difficult they found completing the five different dietary assessment methods

What are the possible benefits and risks of participating?
Participants will receive £400 upon completion of the study to reimburse them for the time they have taken to attend study visits.

Where is the study run from?
1. Imperial College London (UK)
2. Hugh Sinclair Unit for Human Nutrition at the University of Reading (UK)

When is the study starting and how long is it expected to run for?
September 2022 to October 2024

Who is funding the study?
1. Medical Research Council (MRC) (UK)
2. Biotechnology and Biological Sciences Research Council (BBSRC) (UK)

Who is the main contact?
1. Dr Katerina Petropoulou, katerina.petropoulou12@imperial.ac.uk
2. Dr Michelle Weech, m.weech@reading.ac.uk

Study website
https://sodiat.org

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
321986

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
22HH8106, IRAS 321986, CPMS 58355

Study information

Scientific Title
Data-driven integration of emerging technologies to generate a Standardized and Objective Dietary Intake Assessment Tool – Study 1

Acronym
SODIAT

Study objectives
Integration of multiple dietary assessment technologies (wearable micro cameras, spot urine samples and capillary blood samples) can increase the accuracy of the measurement of nutritional intake during a controlled dietary intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2023, Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8089; CamdenandKingsCross.REC@hra.nhs.uk), ref: 23/LO/0437

Study design
Randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home, University/medical school/dental school

Study type(s)
Screening

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Nutritional intake

Interventions
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 and will include two 4-day study periods as follows: Study period 1 will involve 4 full day visits and another visit on the 5th day to return samples and study equipment. Between the two-study period, there will be a minimum of a 1-week gap. Study period 2 will involve the same number of visits as study period 1.

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

Simple randomisation will be used to assign the order in which participants receive the intervention menus. In randomised order, participants will receive a test diet during each study period that has a different level of compliance with UK healthy eating guidelines. Diet 1 is designed to be far from meeting healthy eating dietary guidelines (e.g., high in saturated fat, free sugars, and salt and low in fruit, vegetables, and fibre), whereas Diet 2 is compliant with healthy eating dietary guidelines (e.g., high in fibre, fruits and vegetables, and low in saturated fat, free sugars and salt).

Participants will be served meals and snacks throughout the eight study days (8 am – 6 pm) according to the diet they have been randomly assigned 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 6 pm of the four study days, they will return home with a snack and bottled water to be consumed in the evening. They will be instructed not to eat or drink anything, except for the evening snack and drinks provided between each 4-day study period.

Intervention Type
Other

Primary outcome measure
The accuracy of dietary reporting will be measured at the end of each intervention week using dietary data collected from wearable micro cameras, spot urine samples, capillary blood samples, and self-report dietary recalls. Total daily consumption (grams per day) will be reported by wearable micro cameras and self-report dietary recalls. Liquid chromatography-mass

spectrometry (LC-MS) will measure biomarkers of dietary components in spot urine samples and capillary blood samples and daily dietary intake will be reported using µg/ml concentrations of dietary exposure biomarkers.

Secondary outcome measures
1. Creation of a multiplatform model of dietary intake using g/day measured from wearable micro-cameras and self-report dietary recalls, and µg/ml of dietary exposure biomarkers from spot urine samples and capillary blood samples at the end of the study
2. Design a dietary intake study informed by the results of the dietary intake study protocol in a free-living population at the end of the study

Overall study start date
01/09/2022

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Aged 18 – 70 years
2. Body Mass Index (BMI) 20-30 kg/m²

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. 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
2. Had a weight change of more than 3kg in the preceding 3 months or are currently following a weight-loss diet
3. Have excess alcohol intake (more than 21 units per week) (e.g., a medium glass of wine = 2.3 units)
4. Are unwilling to abstain from drinking alcohol and avoiding strenuous exercise during the two

5-day test periods
5. 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); participants will not be permitted to eat/drink anything else during the two 5-day test periods
6. Are not able to eat fish and/or meat (e.g., are vegan or vegetarian)
7. Have an allergy/intolerance to any of the food items in the menu
8. Have taken any dietary supplements in the last 3 months (e.g., multivitamins, fish oils)
9. Are pregnant or lactating
10. 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
11. Are taking any of the following medications: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin, or thyroid hormones
12. Use illicit substances
13. Have been diagnosed with dementia or other conditions affecting memory
14. 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)
15. Cannot read and understand English

Date of first enrolment
01/09/2023

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor type
University/education

Website
https://www.ic.ac.uk/clinicalresearchgovernanceoffice

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this study will also be presented at medical meetings and research conferences and published in scientific journals 6 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. The researchers also hope to publish the results in the press and media.

Intention to publish date
01/02/2025

Individual participant data (IPD) sharing plan
Anonymised data will be made publicly available through deposition in online public repositories upon dissemination and publication of study results. Raw data from mass spectrometry analysis of collected biofluids (urine and blood) will be deposited in the MetaboLights repository (https://www.ebi.ac.uk/metabolights/) and all experimentally derived data will be deposited in the Zenodo repository (https://zenodo.org/) at the time of publication.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 2.0	07/06/2023	17/08/2023	No	Yes