Standardised and Objective Dietary Intake Assessment Tool (SODIAT): protocol of a dual-site dietary intervention study to integrate dietary assessment methods

STUDY PROTOCOL

REVISED Standardised and Objective Dietary Intake Assessment Tool (SODIAT): Protocol of a dual-site dietary intervention study to integrate dietary assessment methods

[version 2; peer review: 2 approved, 1 approved with reservations]

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Abstract

Introduction

Current dietary assessment methods struggle to accurately capture individuals' dietary habits. The 'Standardised and Objective Dietary Intake Assessment Tool' (SODIAT)-1 study aims to assess the effectiveness of three emerging technologies (urine and capillary blood biomarkers, wearable camera technology) and two online self-reporting dietary assessment tools to monitor dietary intake.

Methods

This randomised controlled crossover trial was conducted at two sites (Hammersmith Hospital and the University of Reading) and aimed to recruit 30 UK participants (aged 18-70 years, BMI 20-30 kg/m^2). Exclusion criteria included recent weight change, food

Open Peer Review

Approval Status ✓ ? ✓

	1	2	3
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allergies/intolerances, restrictive diets, certain health conditions and medication use. Volunteers completed an online screening questionnaire via REDCap and eligible participants attended a pre-study visit. Participants consumed, in a random order, two highly-controlled diets (compliant/non-compliant with UK guidelines) for four consecutive days, separated by at least one-week. Dietary intake was monitored daily using wearable cameras and self-recorded using Intake24 (24HR). Two versions of the online eNutri FFQ were completed: at baseline to assess habitual diet and on day 4 of each test period to record food intake. Urine and capillary blood samples were collected for biomarker analysis. Data analysis will assess dietary reporting accuracy across these methods using Lin's concordance correlation coefficient.

Discussion and ethical considerations

The SODIAT project introduced a novel approach to dietary assessment, aiming to address the limitations like misreporting and inclusivity. However, challenges persist, such as variability in biomarker data due to failure to follow sample storage requirements and the practicalities of wearing cameras throughout the day. To protect privacy, participants removed cameras at inappropriate times, and AI removed non-food related images and blurred faces/device screens captured on the images. The accuracy of the tools in a highly-controlled setting will be evaluated in this study. Future studies are planned to validate these tools further in free-living and minority populations.

Keywords
Nutrition, Health, Research, Dietary reporting, Underreporting, Misreporting, Biomarkers

This article is included in the Agriculture, Food and Nutrition gateway.

Any reports and responses or comments on the article can be found at the end of the article.

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Competing interests: JAL is Deputy Chair of the government's Scientific Advisory Committee on Nutrition (SACN) and a Member of the National Diet Nutrition Survey Project Board. GF has received educational funding for research from Nestle, Quorn Foods, Heptares and Unilever. He is also a director of the metabolomic spin out company Melico. AK receives financial support from Kingdom Department of Health and Social Care and contributes National Diet and Nutrition Survey Rolling Programme. IGP holds shares in Melico Sciences and is a director of the company. For all other authors, no competing interests were disclosed.

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REVISED **Amendments from Version 1**

The reviewers provided insightful comments and suggestions that have helped enhance the clarity and depth of this paper. In response, the authors have made meaningful clarifications and revisions to better reflect this feedback.

In the abstract, we have clarified that two versions of the online food frequency questionnaire (eNutri) were used in the study and specified the type of data generated from each. Additionally, we have clarified that participants were recruited from areas local to the two study sites. To address comments on inclusivity, we emphasised that increasing representation of underrepresented populations is the overarching goal of the SODIAT project, rather than a direct outcome of this specific study (SODIAT-1). We have refined verb tense to reflect that the study was completed at the time of peer review. We also provided further details on how dietary reporting accuracy was assessed and elaborated on the integration of data from FFQs with acute dietary information. Moreover, we expanded on the methods for spot urine and blood sample collection, detailing normalisation procedures for urine samples and standardised volume measures for blood samples. Finally, we highlighted the innovative nature of the SODIAT approach in the introduction and clarified the use of artificial intelligence (AI) techniques to ensure participant anonymity during data analysis. These revisions contribute to a clearer, more comprehensive presentation of our study.

Any further responses from the reviewers can be found at the end of the article

Introduction

Optimal nutrition is fundamental for maintaining good health and preventing diseases across the life course.[1] The relationship between dietary habits and noncommunicable diseases (NCDs) is globally recognised,[2,3] and evidence suggests unhealthy diets are strongly associated with increased prevalence of diabetes, various forms of cancer, and cardiovascular diseases.[4–6] The impact of diet on population health has been highlighted by the Global Burden on Disease study that reported over 11 million deaths worldwide per year can be attributed to suboptimal diets.[7]

Nutrition research has a significant role in reducing the detrimental health impact of poor diets globally. Assessing population food intake can provide substantial data on the nation's nutritional status and may be used in planning and implementation of evidence-based public health interventions.[8] However, lack of accurate dietary assessment measures continuously undermines the strength and efficacy of public health strategies.[9,10] Traditional subjective methods of dietary assessment, such as food frequency questionnaires (FFQs), 24-hour dietary recalls, and food diaries, are widely used to capture individuals' dietary information.[11] Despite being non-invasive, easy to use and suitable for large scale studies (depending on method), these self-reporting methods face notable challenges that can compromise the accuracy and reliability of collected dietary data.[12–15] Memory recall bias is a common challenge, as participants may struggle to remember all consumed items, leading to potential underreporting or inaccuracies,[14] whereas social desirability bias occurs when respondents align their reported food choices with perceived societal expectations, impacting the representation of true dietary habits.[16] In addition, estimating portion sizes poses a challenge, as individuals may struggle with accuracy and perceptions of portion sizes differ between individuals (e.g., small, medium and large).[17] Finally, response burden and fatigue, particularly prevalent when individuals weigh and record their dietary consumption over extended periods, can result in incomplete records, whereas day-to-day variability in dietary habits (such as oily fish and alcohol that are not typically eaten daily) may not be adequately captured for shorter recording periods.[9]

Cultural and social influences, lack of standardisation in reporting procedures, and limited detail on food preparation methods further contribute to the complexity of self-reported dietary assessments.[13] The phenomenon of underreporting or overreporting in dietary assessments adds another layer of complexity, for example, individuals with obesity, particularly women, are most likely to underestimate their energy intake by under-reporting high energy foods considered socially undesirable.[18] Mitigating these challenges and improving accuracy is essential for advancing the assessment methodology of population food intake.[14]

In addition to subjective measures, objective methods can also be used to assess dietary intake. These do not rely on participants' self-reported intakes, instead dietary intake is assessed using various physical, biochemical, physiological or environmental measures, such as direct observation, nutritional biomarkers and duplicate diets.[12] The development of advanced technologies, such as sensor-based and image-based tools, has increased the possibilities to address the limitations of self-reporting in nutrition research.[19] Additionally, detecting dietary biomarkers in bodily fluids can reflect food intake and complement traditional dietary assessment methods.[20] Implementing these methods minimise the biases associated with subjective measures, however, each objective method has its own limitations, requires the will of participants to comply (e.g., collect samples, wear cameras) and there is no universally accepted "gold standard".[12]

To address this problem, the 'Standardised and Objective Dietary Intake Assessment Tool' ('SODIAT')-1 study will explore the ability of three emerging objective technologies and two subjective online tools to accurately assess what

people eat and drink. The objective measures include: 1. Urine biomarker metabolomics,[21] 2. Capillary blood biomarkers[22] and 3. Wearable camera technology,[23] and the subjective measures include eNutri (online FFQ tool)[24] and Intake24 (online 24h recall tool).[13,24,25] While each tool has been used in nutrition research individually, it is their integration and collective use to enhance reporting accuracy that make this approach novel. The primary objective of the study is to calibrate the above dietary assessment technologies and tools for effectiveness to monitor exposure to foods/food groups commonly consumed in the UK in a controlled diet intervention. By conducting a comprehensive evaluation of their capabilities in accurately reporting dietary intake, the study aims to identify the most promising features of each technology. Subsequently, the research team will collaboratively integrate these features to create a combined optimal tool that maximises accuracy and usability which will be tested in future studies in the home environment (not described in this protocol).

Methods

Study population

In randomised cross over study SoDiat-1 thirty male and female participants aged between 18-70 years were recruited by the research teams at Imperial College London and University of Reading, with an equal distribution per study location. Participants of all ethnicities with a body mass index (BMI) 20-30 kg/m^2 were eligible. Exclusion criteria were as follows:

- Involvement in any other study during the previous 12 weeks, is unable to commit to the study (e.g., travel commitments) or unwilling to collect urine and blood samples and wear the micro-camera.
- A weight change of more than 3kg in the preceding 3 months or following a weight-loss diet.
- Excess alcohol intake (more than 21 alcohol units per week).
- Unwilling to abstain from drinking alcohol and avoid strenuous exercise during the two 5-day test periods.
- 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).
- Unable to eat fish and/or meat (e.g., are vegan or vegetarian).
- Allergy/intolerance to any of the food items in the menu.
- Use of dietary supplements (e.g., multivitamins, fish oils), unless willing to have a washout of at least 2 weeks prior to taking part in the study.
- Pregnant or lactating.
- Diagnosed with any of the following: eating disorder, 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.
- Taking any of the following medications: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin, or thyroid hormones.
- Illicit substance use.
- Diagnosed with dementia or other conditions affecting memory.
- 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 ability to press buttons).
- Cannot read and understand English.

Recruitment

Various methods of recruitment were employed, including distributing posters around the university campuses, emails sent to the respective clinical unit's volunteer databases and university mailing lists, and social media advertisements for

groups within the universities and surrounding areas. Recruitment started in December 2023 and finished in May 2024, when required sample size was achieved. Recruitment materials included a link and QR code that took interested participants to REDCap, a secure web application for administering online surveys and recording datasets in research studies (https://www.project-redcap.org/), where they could view and download the participant information sheet.

Study design

Screening

Interested participants completed an online screening questionnaire on REDCap, after which the respective research teams determined their eligibility and/or requested further information from the interested volunteers.

Consent and pre-study visit

Prior to starting the study, participants attended the NIHR Imperial Clinical Research Facility at Hammersmith Hospital or the Hugh Sinclair Unit of Human Nutrition (HSUHN) at the University of Reading (depending on their preferred location as specified on the screening form). Researchers explained the study in full, reconfirmed eligibility (such as ensuring all food items on the menu can be consumed) and allowed the participant to ask questions before informed written consent was taken. During the pre-study visits, participants were provided with a study handbook and the technologies used during the study were explained and demonstrated to them. Their self-reported BMI was also confirmed by measuring height and weight using a bioelectrical impedance analyser (Tanita MC780 MA P (Imperial) and BC-418 (Reading), TANITA UK Ltd, UK) to ensure the participant was within the correct BMI range. If the volunteer was happy to proceed, they were invited to schedule the two 4-day study visits. They were also provided with urine kits to take home and a reminder checklist/log form for the evening/morning prior to their first visit. A schematic diagram (Figure 1) illustrates the study process from recruitment through to completion.

Randomisation

After the pre-study visit, participants were assigned a study ID code and randomisation was undertaken using REDCap. Participants were randomly allocated to one of two diet orders: Diet 1 followed by Diet 2 or Diet 2 followed by Diet 1. Randomisation was stratified by study centres. The research team and participant was not be blinded to the randomisation, as study menus were provided in advance, making it clear which diet they would follow each week.

Study diets

Participants consumed two controlled diets, one per study period, provided in a random order: Diet 1: non-compliant with UK dietary guidelines (e.g., high in saturated fat, free sugars, and salt and low in fibre); Diet 2: compliant with UK dietary guidelines, e.g., within the dietary reference values for saturated fat (≤10% total energy (TE)), free sugars (≤5 %TE), salt (≤6 g/d) and fibre (≥30 g/d) (Table 1). The diets were matched for energy, protein, total fat and carbohydrate. Foods and drinks selected for each diet were selected to allow investigation of specific biomarkers.[21] Each diet consisted of a 2-day

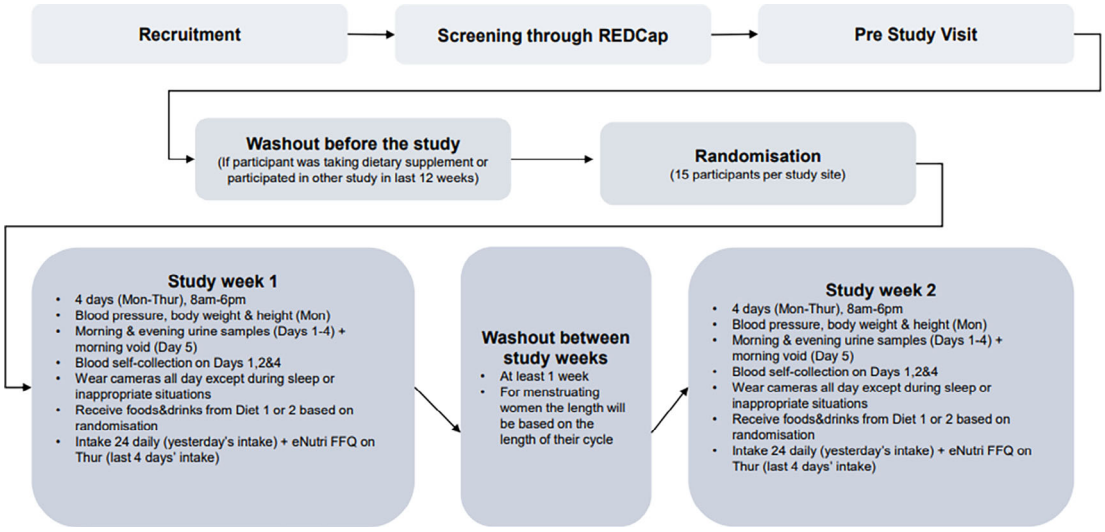

Figure 1. A schematic diagram of SoDiat Study-1.

Table 1. Nutrient composition of the study diets*.

Nutrient	Diet A	Diet B
Energy (kcal/d)	2291	2168
Protein (%TE)	14.8	14.3
Total fat (%TE)	35.6	35.6
Saturated fat (%TE)	16.4	5.7
Carbohydrates (%TE)	46.8	43.5
Free sugars (%TE)	13.6	4.6
Dietary fibre (AOAC) (g/d)	21.8	38.8
Salt (g/d)	7.6	5.6

*Mean of menu 1 and menu 2 per study diet.

repeating menu (e.g., menu A served on days 1 and 3, and menu B served on days 2 and 4) as shown in Tables 2 and 3. Bottled spring water was also be available to drink throughout the day. Meals and snacks were consumed at 2-hour intervals throughout the study days (9 am breakfast, 11 am morning snack, 1 pm lunch, 3 pm afternoon snack, and 5 pm

Table 2. Study menus for diet 1.

Menu	Menu items and quantities
Menu A	
Breakfast	Pain au chocolat (chocolate filled pastry) (45g)
	Honey nut cornflakes (30g) with whole milk (200g)
	Tea (245g) with whole milk (25g) and sugar (5g)
Morning snack	Cheese-flavoured crackers (23g)
	Instant coffee (230g) with whole milk (40g) and sugar (5g)
Lunch	Pepperoni, ham and mushroom pizza baguettes (250g)
Afternoon snack	Chocolate-coated caramel wafer bar (30g)
	Chocolate-flavoured milkshake mix (20g) with whole milk (250g)
Dinner	Beef lasagne ready meal (400g) with frozen mixed vegetables (carrots, peas and green beans) (68g)
	Apple and raspberry juice drink (250g)
Evening snack	Salt and vinegar potato crisps (25g)
Menu B	
Breakfast	White bread toasted (80g) with spreadable butter (20g)
	Baked beans and pork sausages canned in tomato sauce (208g)
	Tea (245g) with whole milk (25g) and sugar (5g)
Morning snack	Coconut macaroon (chewy coconut 'biscuit') (30g)
	Instant coffee (230g) with whole milk (40g) (no sugar)
Lunch	Chicken and bacon pasta in a creamy sauce ready meal (400g)
Afternoon snack	Ready salted potato crisps (18g)
	Fizzy orange drink (330g)
Dinner	Beef stroganoff in a creamy mushroom sauce with rice ready meal (400g) with frozen mixed vegetables (carrots, broccoli and sweetcorn) (68g)
	Apple juice (200g)
Evening snack	Chocolate covered wafer biscuit bar (32g)

Table 3. Study menus for diet 2.

Menu	Menu items and quantities
Menu A	
Breakfast	Muesli with dried fruits (50g) and unsweetened soya drink (200g)
	Wholemeal seeded bread toasted (50g) with peanut butter (25g)
	Tea (240g) with skimmed milk (30g)
Morning snack	Dried apple rings (30g)
	0% fat Greek style flavoured yogurt (115g)
	Instant coffee (220g) with skimmed milk (50g)
Lunch	Chicken and pasta in a spicy tomato sauce ready meal (400g) with frozen mixed vegetables (carrots, broccoli and sweetcorn (68g)
	Mandarins in juice (113g)
Afternoon snack	Reduced salt green pitted olives (30g), cherry tomatoes (75g) and breadsticks (20g)
Dinner	Vegetable Biryani (mildly spiced mixed roasted vegetables with basmati rice) ready meal (400g)
	Onion bhaji (50g)
Evening snack	Reduced salt potato crisps (25g)
Menu B	
Breakfast	Weetabix (38g) with hazelnuts (15g), frozen blueberries (80g) and oat drink (120g)
	Wholemeal bread toasted (44g) with sunflower spread (10g)
	Tea (240g) with skimmed milk (30g)
Morning snack	Peaches in juice (113g) & whole almonds (30g)
	Coffee (220g) with skimmed milk (50g)
Lunch	Moroccan spiced chicken and chickpea soup (300g) with wholemeal bread roll (54g) and sunflower spread (15g) Red grapes (80g)
Afternoon snack	Houmous dip (50g) with lightly salted tortilla chips (30g) Sugar-free lemonade (330g)
Dinner	Salmon pie (salmon in a cream sauce topped with mashed potato and cheese) ready meal (375g) with frozen mixed vegetables (carrots, peas and green beans) (68g)
	Fruit flavoured water drink with sweeteners (250g)
Evening snack	Dried fruit and nut chewy bar (30g)

dinner) and were served using identical tableware at each research unit (white crockery and clear glass on days 1 and 2 and patterned crockery and coloured glass on days 3 and 4); no foods/drinks were consumed directly from their packaging. Participants were also provided with a snack and bottled water to take home to consume before 8 pm and instructed not to eat or drink anything else before returning to the research unit the following day.

Study visits

The study visits took place at the NIHR/Imperial Clinical Research Facility at Hammersmith Hospital or the HSUHN at the University of Reading and included two study periods each consisting of four full-day (8 am to 6 pm) visits from Monday to Thursday with a short visit on the fifth study day (Friday) to return final urine samples and all study equipment. A washout period of at least one week between study periods was required (menstruating women attended study visits at the same phase of their menstrual cycle).

Study visit procedures

The day before starting each study period, participants were asked to restrict their caffeine and alcohol intakes and exercise levels to amounts that were usual for them and fast for 12 hours overnight (not consuming any food or drink, except water). Upon waking, participants also collected a first morning void (FMV) urine sample.

Participants attended the research unit at 8 am on day 1 (Monday) of each study period. Upon arrival, blood pressure, height and body weight were measured. A fasted capillary blood sample (OneDraw) was also self-collected and participants were set up with the wearable camera (which was worn continuously except if participants used bathroom) before being provided with breakfast. Habitual diet was recorded using the eNutri tool (4-week version). With the exception of mealtimes, participants had the rest of the day as free time but remained in the research unit. At the end of the study day (6 pm), participants were provided with bottled water and a snack for the evening, urine kits (for last evening void (LEV) and FMV samples) and a reminder checklist/log. Days 2-4 repeated day 1 except: 1) Intake24 was used on days 2-4 to record dietary intake during the previous 24 hours, 2) 4-day version eNutri was repeated at the end of day 4 (Thursday) to record dietary intake during the previous 4 days, and 3) capillary blood samples were not collected on day 3 (Wednesday). On day 5 (Friday), participants collected a final FMV, completed Intake24 and returned samples/equipment to the research unit.

Participants' compliance to the study protocol was recorded by study investigators during the times when they were in the controlled environment. For the times spent outside the research unit, compliance was measured using sample/data collection records and self-reported deviations to study menus.

Objective dietary assessment tools

Spot urine samples

Participants collected spot urine samples using previously described methods.[21] For each collection, participants were provided with four additive-free vacuum collection tubes (4 ml) (plus two spares), urine transfer straws and a disposable collection cup (Figure 2). Participants collected their FMV urine and LEV urine for all four study days in each study period as well as a FMV sample on day 5 and LEV on evening before day 1 using the collection cup. Participants would then transfer samples to four tubes via the transfer straw and store at 4 °C. During each study day, samples were processed in the research unit using previously described methods to render them acellular then they were stored at -80 °C until the end of the study.[26]

Urinary biomarkers of dietary intake will be measured at Aberystwyth University using a combination of Ultra-High Performance Liquid Chromatography (UHPLC) Triple Quadrupole Mass Spectrometry (QqQ-MS) and high-resolution mass spectrometry (HRMS). Previous studies have determined a list of dietary intake biomarkers that reflect intake of common UK diet components and are sufficiently robust and reproducible in spot urine samples from dietary intervention studies.[27] Spot urine samples are normalised based on specific gravity prior to extraction. Specific gravity correction

Figure 2. Urine transfer and straw kit.

factors are calculated for urine samples as a fold change of each urine specific gravity to a value of 1.006. Global dietary patterns will be assessed by measuring the urine samples using Proton Nuclear Magnetic Resonance (^{1}H-NMR) at Imperial College London. A global dietary score will be generated from the 1H-NMR urinary metabolic profiles following a previously validated methodology[28] that will indicate the quality of the diet in combination with a complementary set of urinary dietary biomarkers.

Capillary blood samples

Capillary blood samples were self-collected by participants prior to breakfast on days 1, 2 and 4 using a OneDraw kit (Drawbridge, Thorne Research, Summerville SC, US) as shown in Figure 3. The single-use device attaches to the upper arm or thigh via a hydrogel adhesive and vacuum and collects 150 µl of capillary blood with little discomfort for the participant. The capillary blood is directly collected onto two paper strips.[22] When the collection is finished, the cartridge containing the blood samples is placed in the transport sleeve then left at room temperature for at least 48 hours to allow the blood to dry prior to storage at -80 °C.

The dried blood samples will be extracted at the University of Cambridge using a standard protocol for dried blood spots[29] and the lipid profile will be analysed using a combination of UHPLC and HRMS, and lipids will be quantified against internal standards as published previously.[22]

Wearable camera technology

To effectively capture the dietary habits and food-related activities of individuals in UK households, a comprehensive passive dietary assessment system has been meticulously designed for this study. This system is a fusion of both hardware and software components, each with distinct functionalities to enhance the accuracy and efficiency of dietary data collection.

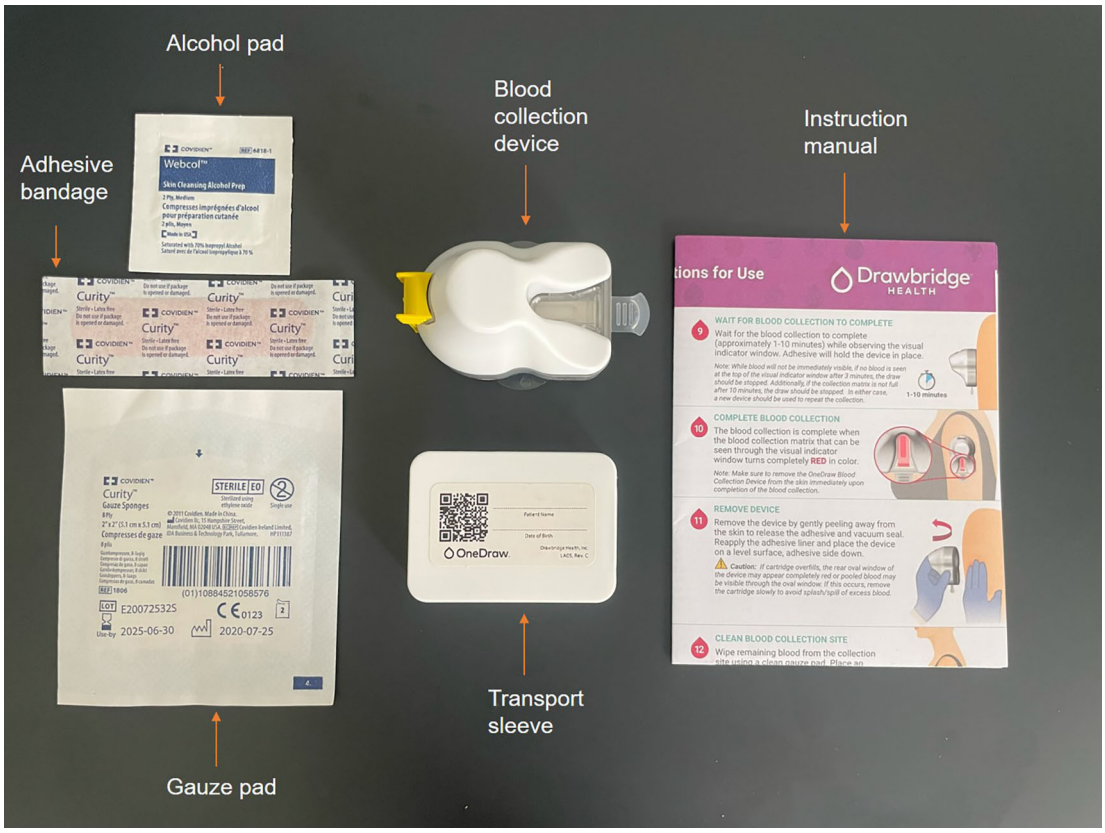

Figure 3. OneDraw blood collection kit.

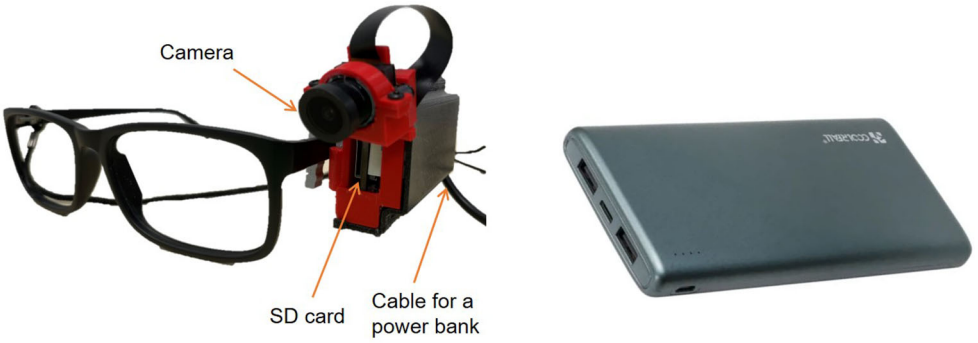

Figure 4. Wearable camera equipment.

Hardware

For this pilot study, prototype of the camera was developed - wearable camera capable of recording up to 20hrs called M2.1. The wearable camera device is a high-definition camera with a maximum resolution of 2592x1944 pixels, mounted on the side arm of lens-less eye glasses frames to align with the user's viewpoint and is connected to a rechargeable powerpack whilst in use (Figure 4). It is designed to be used during daytime, capturing images of the eating process at frequency of one image every 1.5 seconds. The camera is powered by a built-in STM32 microcontroller with a 32-bit arm processor. The device begins recording upon the insertion of an empty 128 GB SD card and the camera is turned on. The camera is turned on automatically once is connected to the external battery.

Prior to breakfast on day 1, participants received a camera device mounted on a glasses frame (or they can mount this on their own glasses frame) and were instructed to wear this until they went to bed, with the exception of when it is not suitable for the camera to be worn (such as when getting dressed and using the bathroom) in which case the glasses were be temporarily removed and details noted on the camera log. Upon arrival to the research unit on days 2-5, the SD cards were removed from the camera device by the research team and uploaded in duplicate to two encrypted external hard drives. Whilst the cameras were not in use overnight, participants were instructed to fully charge the power packs and start wearing the cameras the following morning before returning to the research unit (days 2-4).

Software

To ensure the anonymity of individuals, all footage captured by wearable cameras will undergo pre-processing prior to analysis. Initially, a large foundation model known as the Recognize Anything Model (RAM)[30] will be employed. RAM specializes in image tagging and has been developed through extensive training on a large number of general images. This model will play a crucial role in identifying images captured by our customised wearable camera. Its function will be to detect the presence of food items within these images. Upon detection of food items, RAM will assign a 'food tag' to the relevant images. This tagging mechanism is both efficient and precise, ensuring that only images with clear food content are marked for inclusion. The images that receive a 'food tag' from RAM will then be segregated from the rest and earmarked for further analysis, forming the core dataset for the study. Meanwhile, we have also designed 'excluding tags' for our model, which include around 20 categories of items such as bathrooms, mobile phone screens, and PC screens, with the flexibility to add or remove items as needed. This design is intended to prevent sensitive items from appearing alongside food in the collected data. Furthermore, for the retained images, an additional layer of protection will be implemented by blurring the faces of the participants and other individuals residing with them, as well as any other visible phone and computer screens that were unintentionally missed in the previous step. This step will use YOLOv8,[31] a deep learning technique renowned in the field of image recognition, to prevent the inadvertent disclosure of identities and personal information. Only after this pre-processing will the images be subjected to further analysis.

Following pre-processing is the food recognition phase, where we will leverage large language models (LLMs)[32] capable of processing both text and images. These models have been extensively trained on vast datasets, allowing them to recognize a wide range of food types without the need for additional training or fine-tuning. Portion size estimation also plays a pivotal role in dietary assessment, and our approach is tailored to address the unique challenges associated with using a wearable camera that captures only red-greed-blue (RGB) images, without the depth information provided by stereo imaging. This brings us to the issue of scale ambiguity, which is a significant problem given that our system cannot rely on stereoscopic methods to estimate the volume of food items. To circumvent the need for users to place a reference

object next to their food - which would be an inconvenience and could disrupt a natural eating environment - we are exploring the potential of leveraging large-scale artificial intelligence (AI) foundation models to learn the general context of objects and their environmental surroundings in relation to food. By understanding these contextual relationships, the model can make more accurate inferences about the portion sizes of the food being consumed.

Subjective dietary assessment tools

24-hour dietary recall

Participants completed a self-administered 24-hour dietary recall following each study day to measure both the accuracy of self-reporting and usability of repeated 24-hour dietary recalls. Participants used Intake24 (intake24.com), which is a validated, web-based, open-source computerised dietary recall system based on the multiple pass method.[33] The tool, currently maintained by the University of Cambridge, Monash University and Newcastle University, is used by the UK's National Diet and Nutrition Survey Rolling Programme.[25,33] Participants used Intake24 to record everything they ate and drank the day before from midnight to midnight by using free text to list each food/drink item consumed per meal as part of the initial 'quick list'. Next, the detailed pass stage involved searching Intake24's food database for the closest match for each item then estimating their portion size using the images presented on the screen. Intake24 also prompted the participant about foods usually consumed together, e.g., if they recorded coffee then it will ask if they added milk and/or sugar, as well as frequently forgotten foods, such as condiments. Additional questions were presented if Intake24 identified long time gaps without food or very low energy intakes, and the recall ended with the participant reviewing their entries. Prior to completing Intake24 for the first time, participants were encouraged to watch the tutorial video (accessible via the Intake24 menu). At the end of the study, data was exported from Intake24 including the quantities and nutritional intakes for each food item recorded per recall, after which mean daily intakes per day per participant will be calculated.

FFQ

The eNutri web app, developed by researchers from the University of Reading, includes an FFQ based on UK diets.[34] The current version includes 157 food, drink and supplement items. For each food and drink item, users first select how often they consumed it during the previous 4 weeks from 10 frequency buttons (such as 'not in the last 4 weeks' and 'once a day'). If consumed, they then select their typical portion size from 7 portion size photos/buttons. Certain items (n=37) also request additional details, for example, the type of milk (if any) added to their coffee and whether the item consumed was a low-fat or low-sugar variety (e.g., soft drinks, yogurts); each of these items also has an 'I'm not sure' option. Users also report frequency of use of salt (added at the table and/or during cooking) and 8 dietary supplements. Using this information, eNutri automatically calculates mean daily intakes (g/d) of each food item, from which it estimates a large range of food group intakes (e.g., vegetables, dairy) and nutrient intakes (e.g., protein, vitamin C). In addition to dietary intake, eNutri also records certain demographic and lifestyle information about the users (such as age, sex, ethnicity, education level, physical activity levels and smoking status).

For this study, participants used the eNutri FFQ tool on day 1 of study period 1 to measure their habitual diet by recording what they ate and drank during the previous 4 weeks. Prior to using eNutri for the first time, participants watched the short tutorial video on the web app. To measure dietary intake during the two 4-day study periods, a separate version of eNutri was created that adapted the frequency options to reflect 4 days of dietary intake (such as 'not in the last 4 days' and '1x in the past 4 days'). This was completed on day 4 of each study week.

Participant feedback and usability of technologies

Participants completed the system usability scale (SUS) questionnaire following their first use of eNutri (day 1, week 1) and Intake24 (day 2, week1) via REDCap. The SUS questionnaire is widely-used to "measure people's subjective perceptions of the usability of a system" and comprises of 10 alternating positive and negative statements regarding the user experience (Table 4).[35] For each statement, respondents rate their agreement on a 5-response-scale from "Strongly Disagree" to "Strongly Agree" and, using the method described by Brooke (1995), a SUS score ranging from 0 to 100 is calculated, with higher scores indicating better usability.[36] Overall usability is also evaluated with a general question: "Overall, I would rate the user-friendliness of this system as:" with 7 options from "Worst Imaginable" to "Best Imaginable".

At the end of the study (day 4, week 2), participants also provided feedback about all of the tools used during the study. This included free text and Likert questions and were completed via REDCap.

Table 4. SUS* questionnaire.

1	I think that I would like to use this system frequently.
2	I found the system unnecessarily complex.
3	I thought the system was easy to use.
4	I think that I would need the support of a technical person to be able to use this system.
5	I found the various functions in this system were well integrated.
6	I thought there was too much inconsistency in this system.
7	I would imagine that most people would learn to use this system very quickly.
8	I found the system very awkward to use.
9	I felt very confident using the system.
10	I needed to learn a lot of things before I could get going with this system.

*System usability scale.

Statistical analysis

Previous studies have shown that the misreporting rate of total energy expenditure between self-reported dietary assessment tools and double labelled water was 35 % with a standard deviation of 33 %.[37] To reduce the misreporting rate to <10%, an *a priori* sample size calculation determined that to achieve a power of 80 % with a type 1 error of 5%, a total of 27 participants are required. This was increased to 30 participants to account for potential dropouts. Two separate clinical research centres were used, with both centres recruiting participants to ensure consistent demographics between sites (sex, age, and BMI).

The FFQ data collected at baseline will be used to describe cohort demographics and serve as a covariate in analysis to account for differences in habitual dietary patterns among participants. Additionally, the data from 4-day FFQ will provide average dietary intake data for the two study weeks, which can be combined with daily aggregated data, such as Intake24. This data will be compared with metabolomic data and images to assess consistency and identify any biases. Such comparisons are crucial for evaluating the alignment of self-reported dietary data with objective biomarkers.

Bootstrapped Lin's concordance correlation coefficient (CCC) with 95% confidence intervals will be used to test the extent of agreement between each dietary assessment tool/technology and the nutrient composition of known diets and recorded compliance.

Primary and secondary outcomes to be measured

The primary outcome will be the accuracy of dietary reporting, measured at the end of each intervention week using the known quantities of consumed foods given to participants during the intervention days and dietary data collected from wearable cameras, spot urine samples, capillary blood samples, and self-reported dietary assessments.

Secondary outcome measures include: 1) the creation of a multiplatform model of dietary intake using g/day measured from wearable cameras and self-report dietary assessments, and µg/ml of dietary exposure biomarkers from spot urine samples and capillary blood samples at the end of the study, and 2) the design of a dietary intake study in a free-living population that will be informed by the results of the current dietary intake study protocol.

Dissemination

The results of this study will be presented at medical meetings, research conferences and published open access in peer-reviewed scientific journals and lay publications, approximately 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 (BSc, MSc, PhD) or other qualification, and shared with the press and media. The datasets will be made available and deposited in public databases at the point of publication. All data will be released within 2 years of the project's completion and will be made accessible.

Discussion

The SODIAT project provides a novel approach to dietary assessment by addressing the significant limitations present in traditional methods, such as those used in the National Diet and Nutrition Survey[10] and other population surveys.[33] The novel methods tested in SODIAT-1 and two following studies will reduce participant burden, requiring less detailed

recording of foods and drinks consumed. For individuals with conditions affecting memory, this approach also eliminates reliance on recall, thus reducing the risk of inaccurate data collection.[13] Furthermore, in future the methodology will particularly be helpful to capture dietary intake of underrepresented populations, including individuals with illiteracy, language and cultural differences as well as marginalised groups such as homeless people, whose dietary intake is difficult to capture accurately through traditional self-reporting methods and are often left out from the nationwide studies.[38] The ability to access these populations broadens the scope and applicability of dietary assessments, providing a more comprehensive understanding of dietary patterns across different demographics.

Despite these strengths, there are also limitations to this this approach when used in less controlled conditions. For instance, participants were asked to keep their urine samples refrigerated before returning them to the study centre, but failure to comply could affect biomarker detection during analysis, potentially compromising the accuracy of the data.[20] The use of cameras to record dietary intake also presents challenges. For example, accurately measuring foods and drinks consumed directly from their packaging (e.g., cans of fizzy drinks and packets of crisps) remains difficult and amount of the leftovers cannot be detected. Additionally, distinguishing between types of foods and drinks (e.g., low-fat versus whole yoghurts or sugar-free versus sugar-sweetened drinks) through visual means can be challenging as well as composite meals (e.g., pies, curries) and stacked foods (e.g., sandwiches, burgers) where some ingredients are covered or obscured. Moreover, this method relies on participants consistently wearing and correctly using the cameras, which may not always be practical or adhered to.[19]

Ethical approval

The study received a favourable opinion for conduct by the Camden & Kings Cross Research Ethics Committee (23/LO/0437) on 4th July, 2023 and the University of Reading Research Ethics Committee (23/19) on 19th May, 2023. The study will be conducted according to the principles expressed in the Declaration of Helsinki.

Ethical considerations

Prior to screening, potential participants received an ethically approved participant information sheet containing full details of the study. They had adequate time to consider taking part in the study and had an opportunity to ask questions before attending the pre-study visit where they were given written informed consent.

When participants wore the cameras, they collected images of the participant, people around them and their devices (e.g. smartphones). To ensure everyone's anonymity and privacy, any people and device screens recorded on the images will be automatically blurred prior to analysis, as described above. In addition, any non-food related images will be removed from the dataset. Both processing steps will be achieved via an artificial intelligence methodology and only the pre-processed dataset will be analysed by the research team. Regular audits of AI pre-processing will be conducted, with results evaluated through sampling to ensure compliance and address any privacy concerns that may arise during the experiment. Participants were also advised to remove their camera when it is not appropriate to wear them (such as when in the bathroom and dressing) and to log these instances.

Data management

The data collected through the SODIAT-1 study was pseudonymised and anonymised. Pseudonymised data was shared among research partners for data analysis purposes. The confidentiality of study participants was preserved under the Data Protection Act. Acellular urine samples were transferred to Aberystwyth university and dried blood samples were sent to the University of Cambridge in compliance with the Human Tissue Authority (HTA) regulation. The data generated from the wearable cameras was stored on encrypted hard drives and transferred to Imperial College London after the data collection was completed. For subjective dietary assessment tools eNutri and Intake24, participants used pre-generated weblinks and/or login details to avoid using personal information such as email addresses and names. Other data was input on REDCap by study researchers, which was double checked by the study coordinator at each site before the records were locked.

Study status

Recruitment for this study concluded in May 2024, with data collection completed in mid-June 2024. At the time of paper submission, blood and urine samples, as well as camera images, have been transferred to the respective research teams, and data analysis is currently in progress.

Trial registration

The study was registered at ISRCTN (ISRCTN13562899).

Data availability

Underlying data

No data is associated with this article.

Extended data

Zenodo: A-dual-site-dietary-intervention-study-to-integrate-dietary-assessment-methods. https://zenodo.org/records/13360114.[39]

This project contains the following extended data:

- Dual_site_dietary_intervention_Menus.pdf (Study Meal Plans)
- Dual_site_dietary_intervention_PIS.pdf (Participant Information Sheet)
- Protocol_Version1.0_15032023.pdf (Study Protocol)
- Consent form
- SPIRIT 2013 Checklist

Software availability statement

- Source code for The Recognize Anything Model (RAM) is available from: https://github.com/xinyu1205/recognize-anything (the GitHub repository)
- Source code for YOLOv8 is available from: https://github.com/ultralytics/ultralytics (the GitHub repository)
- The large language model (LLM) mentioned in this study is being developed in-house by the research team at Imperial College London and will be shared in a separate paper once completed.

Acknowledgements

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Open Peer Review

Current Peer Review Status: ✔ ? ✔

Version 2

Reviewer Report 13 May 2025

https://doi.org/10.5256/f1000research.179575.r374529

✔ **Cătălina Cuparencu**
University of Copenhagen, Copenhagen, Denmark

I would like to thank the authors for thoroughly considering my feedback. I find that the argumentation and changes included in the text are satisfactory. The paper is a lot clearer now. Only a minor comment, related to the secondary outcomes. It would help the reader to get an impression of the quantitative biomarkers the authors plan to measure without needing to read the reference by Beckmann et al. (if possible to include a few examples). Best of luck to the authors with this important research!

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: biomarkers of food intake, dietary assessment, nutrition research, metabolomics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 02 May 2025

https://doi.org/10.5256/f1000research.179575.r377257

✔ **Hidemi Takimoto**
National Institutes of Biomedical Innovation, Osaka, Japan

The study protocols presented are informative, and useful for researchers conducting similar

research. One thing I am interested is the feasibility of wearing cameras during the study period. I wonder if it wasn't annoying for the participants to start wearing the cameras the following morning before returning to the research unit. There are no descriptions regarding physical activity status of these subjects, however, they should be addressed in future studies.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Nutritional epidemiology and dietary assessment methodologies.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 03 February 2025

https://doi.org/10.5256/f1000research.170884.r359796

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OVERVIEW AND GENERAL COMMENTS

This protocol describes a controlled feeding study designed to assess the effectiveness of three technologies (urine biomarkers, capillary blood biomarkers, wearable camera technology) alongside two self-report dietary assessment tools. While this is a well-defined population and

study design, it is unclear if the proposed correlational analyses will be sufficient to determine "effectiveness" of these tools. Generally, this is a well-written protocol to address a need in dietary assessment that is highly relevant. It is acceptable for indexing given the general concern above and below comments are addressed.

SPECIFIC COMMENTS

Abstract: Which of the assessment methods are considered novel? Diet records and food frequency questionnaires are commonplace in nutrition research, and details regarding biomarkers and wearable technology are quite limited in the description provided. Further, is "actual" food intake (i.e., weighed/portioned food delivered in a controlled setting) the comparator for each of the five proposed assessment methods?

Abstract: It seems a food frequency questionnaire would be an odd choice for assessment of a four-day diet, as the purpose of this instrument is to assess usual intake over a defined period of time (typically 30 days or more). Has the eNutri tool been validated for this recall period? How will data be integrated between diet assessment instruments?

Abstract: Which urine and capillary biomarkers will be measured? How will they be measured (e.g., targeted vs untargeted approaches)?

Abstract: Authors do not describe how this study will reduce misreporting or enhance inclusivity.

Introduction: While a good point, stating that shorter recording periods for dietary assessment are problematic for capturing day-to-day variability seems to be counterproductive to the main rationale for conducting a study with four-day controlled feeding periods that may not be reflective of usual intake.

Introduction: Consider person-first language; "obese individuals" could be re-written as "individuals with obesity."

Methods, Study population: What is the rationale for the BMI I/E criterion of 20-30 kg/m^2? This does not fully capture the "normal" range (18.5-24.9 kg/m^2) and does include those with obesity (BMI^{3}30 kg/m^2). Thus, this range seems a bit arbitrary.

Methods, Study diets: Were diets designed only to be matched in terms of nutrient composition, or were similar foods/food groups balanced as well? Authors state "foods and drinks for each diet were selected to allow investigation of specific biomarkers," but this does not shed much light on the details for these selections.

Methods, Study diets: It remains unclear which specific biomarkers will be employed/tested, though references are provided under the "spot urine samples" and "capillary blood samples" sections. It may be helpful to include examples of these compounds in table format. Is a one-week washout period adequate based on the expected half-life of these biomarkers, and are they expected to be sufficiently different between diets?

Methods, Study visit procedures/24-hour dietary recall/FFQ: It appears habitual diet as assessed on Day 1 of the protocol using the eNutri tool reflects usual intake prior to the study

period? How is it used in this study? Why is Intake24 not used on Day 1?

Methods, Objective dietary assessment tools: Information on the type of analysis (metabolomics at minimum) would be helpful to include earlier in the protocol.

Methods, Objective dietary assessment tools/Capillary blood samples: Is a capillary blood draw completed only in the morning of each study visit on Days 1, 2, and 4? What is the rationale for excluding day 3?

Methods, Wearable camera technology: It is not clear why the participants will be asked to continuously wear the mounted camera outside of eating windows.

Methods, FFQ: As mentioned in the abstract, it is not clear that the eNutri tool has been validated for four-day recall periods – is part of the objective of this study to validate the "separate version" that was created? If so, how will this be done?

Methods, Statistical analysis: Are simple measures of correlation between instruments adequate to measure accuracy? Are the biomarkers selected indicative of specific nutrients (e.g., fat, sodium), foods, or food groups? If the latter are not controlled for or not substantially different between diets, what is the expectation for how accuracy will be determined if the biomarkers do not distinguish at this level? Where will participants report/record compliance? Or is the study team measuring this? Details are lacking for evaluation of these methods.

Methods, Primary outcomes: How will "accuracy" be determined amongst the data collected? Which measure is "true?"

Methods, Secondary outcomes: It is not clear how this multiplatform model will be designed or how all of the assessment measures will be integrated together. Further, with no detail on the biomarkers of interest, it is impossible to evaluate if the goal of assessing ug/mL of dietary exposure biomarkers is realistic. Many untargeted metabolomics assays do not provide data at this level (e.g., relative abundance vs quantitative measures/concentrations). While the use of triple quad indicates some targeted panels may be run and thus this may be possible, the stated goal to create a simple "global dietary score" from NMR data does not align with this stated objective.

Discussion: While the end goal is to reduce participant burden, this reviewer would argue the study increases it given the number of data collection procedures. Consider specifying that if the methods tested are reliable, reproducible, etc. and can be incorporated into clinical practice and/or future research, this could reduce burden.

Discussion: Similar to comments in the abstract, it is not immediately clear how these methods will improve assessment in underrepresented populations, particularly those who are experiencing homelessness, as stated in text. It would be near impossible to give someone the wearable technology or ask them to appropriately collect and store biospecimens such as urine under those conditions.

Discussion: Consider adding to strengths/limitations the length of collection for blood (small capillary sample vs venous draw) and urine (spot vs 24 hour). While these methods may reduce

participant burden, they also weaken the ability to capture precise measures reflective of longer periods of intake.

Ethical considerations: While perhaps outside the scope of this protocol manuscript, it is not clear how AI technology being employed is protective of personally identifiable information – what program "sees" this? The reviewer notes the software availability statement but feels this may be inadequate.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Partly

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: dietary assessment, metabolomics, nutrition intervention, behavior change

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 20 Mar 2025

Eka Bobokhidze

Dear Emily

Thank you for your feedback and comments on our manuscript. We have refined the relevant sections to reflect your thoughtful review, and we appreciate the opportunity to strengthen our work.

Yours Sincerely,
Julie A. Lovegrove
On behalf of the manuscript authors

Response to the reviewer's comments:

1. Abstract: Which of the assessment methods are considered novel? Diet records and food frequency questionnaires are commonplace in nutrition research, and details regarding biomarkers and wearable technology are quite limited in the description provided. Further, is "actual" food intake (i.e., weighed/portioned food delivered in a controlled setting) the comparator for each of the five proposed assessment methods?

The tools used are combination of both well-established methods and emerging technologies. While each individual tool may not be considered novel on its own, as the tools used are combination of both well-established methods and emerging technologies, the unique combination of these tools together and their integration of tools to improve reporting accuracy is, can be considered a novel approach. Due to the abstract word limit (300 words) this information has been included at the end of the Introduction (line 52-54).

The comparator for each tool will be the known food intake and corresponding nutrient intake of the two recorded diets that were consumed by all participants in the controlled environment.

2. Abstract: It seems a food frequency questionnaire would be an odd choice for assessment of a four-day diet, as the purpose of this instrument is to assess usual intake over a defined period of time (typically 30 days or more). Has the eNutri tool been validated for this recall period? How will data be integrated between diet assessment instruments?

In SODIAT-1, we utilised two versions of eNutri: a 4-week version to assess habitual intake and a 4-day version to specifically capture participants' food consumption during both study periods. Although FFQs typically report intakes over a longer period, they can also be used for shorter timeframes. As identified by the DIET@NET consortium "FFQs ranged from the previous day to usual intake over the previous year with 11 (32%) measuring long-term intake (>6 months) and six (16%) measuring short-term intake (one day)" (Hooson et al, 2019).

The data from the 4-day FFQ will provide an average intake across the two study periods, allowing integration with other daily aggregated data, such as Intake24. This information will be analysed alongside metabolomic data and images to evaluate consistency and identify potential biases. Its inclusion is essential for assessing the alignment between self-reported dietary data and objective biomarkers, directly contributing to the trial's overarching goal of improving accuracy in dietary assessment methods. We added more details about eNutri data integration in the statistical analysis section (line 355-361).

The validation of eNutri (4-day FFQ) against the known 4-day dietary intake data from each controlled diet will be evaluated after the formal study analysis.

3. Abstract: Which urine and capillary biomarkers will be measured? How will they be measured (e.g., targeted vs untargeted approaches)?

Authors will publish the detailed list of biomarkers alongside the results as such information is outside of the scope of protocol paper. The analysis of known intake biomarkers in urine and blood is with targeted quadrupole mass spectrometry methods for reporting of primary and secondary outcomes. Due to the word count limitation this information was not included in the abstract and can be found in the sub-section of "Spot urine samples" (line 199-205).

4. Abstract: Authors do not describe how this study will reduce misreporting or enhance inclusivity.

In response to the both reviewers' comments, we have revised this section to clarify that the overarching goal of reducing misreporting and increasing inclusivity applies to the broader SODIAT project, rather than specifically to the SODIAT-1 study. Further details on how the SODIAT project aims to achieve this objective are provided in the Discussion section of the main text.

5. Introduction: While a good point, stating that shorter recording periods for dietary assessment are problematic for capturing day-to-day variability seems to be counterproductive to the main rationale for conducting a study with four-day controlled feeding periods that may not be reflective of usual intake.

This highly controlled clinical trial was not designed to reflect participants' usual intake during the 4-day study periods. Instead, its primary objective was to calibrate each tool and technology against a known intake (controlled menus) and evaluate whether they, individually and in combination, can accurately represent food consumption. Findings from the SODIAT-1 study will inform data-driven modelling approaches for subsequent studies. In SODIAT-2, the research team plans to test these tools in a free-living population over a longer period (5 weeks).

6. Introduction: Consider person-first language; "obese individuals" could be re-written as "individuals with obesity."

The authors appreciate this suggestion and the appropriate amendments were maid in the text (line 32).

7. Methods, Study population: What is the rationale for the BMI I/E criterion of 20-30 kg/m^2? This does not fully capture the "normal" range (18.5-24.9 kg/m^2) and does include those with obesity (BMI^{3}30 kg/m^2). Thus, this range seems a bit arbitrary.

The sample size calculation to ensure that this study was adequately powered was based on data from the Pettitt et al 2016, on the mis-reporting rate of total energy expenditure. While the BMI range we used for our inclusion criteria is not considered the "normal" range, it reflects the BMI range of participants from the Pettitt et al 2016 study. Additionally, as the

mean BMI of UK adults is 27.6 Kg/m 2, a BMI range of 20-30 Kg/m2 is more representative of the UK population.

8. Methods, Study diets: Were diets designed only to be matched in terms of nutrient composition, or were similar foods/food groups balanced as well? Authors state "foods and drinks for each diet were selected to allow investigation of specific biomarkers," but this does not shed much light on the details for these selections.

Two (4 day) isoenergetic diets were designed one of which had a nutritional portfolio that complied to current UK healthy eating guidelines and another that related to an unhealthy dietary profile. We have demonstrated that this methodology produces distinct metabolomic profiles (DOI: 10.1016/S2213-8587(16)30419-3). Each of the diets were made up from a variety of commonly consumed foods taken from the NDNS dietary profiles of people who consume a healthy and unhealthy dietary profile. All foods and drinks offered to the volunteers were weighed as was as all unconsumed foods and drinks. This tested the research tools' ability to pick up dietary differences.

9. Methods, Study diets: It remains unclear which specific biomarkers will be employed/tested, though references are provided under the "spot urine samples" and "capillary blood samples" sections. It may be helpful to include examples of these compounds in table format. Is a one-week washout period adequate based on the expected half-life of these biomarkers, and are they expected to be sufficiently different between diets?

While we welcome the Reviewers suggestion, the authors feel that detailed reporting of biomarker lists and detailed discussions on wash-out periods, half-life and their utility, etc... would be better placed within a publication of the trial results; not in a trial protocol paper. The biomarkers selected have been validated in controlled intervention and free-living experiments to ensure that they are representative of foods commonly consumed in UK.

10. Methods, Study visit procedures/24-hour dietary recall/FFQ: It appears habitual diet as assessed on Day 1 of the protocol using the eNutri tool reflects usual intake prior to the study period? How is it used in this study? Why is Intake24 not used on Day 1?

The FFQ data collected at baseline will be used to assess habitual diet for the purpose of reporting cohort demographics and may be used as a covariate in data analysis to control for differences in habitual diet between participants. We added this information in Statistical analysis section (Line 356-357).

Participants completed Intake24 (a self-administered 24-hour dietary recall) to records their dietary intake during the study periods. To measure both the accuracy of self-reporting and usability of repeated 24-hour dietary recalls, participants were asked to complete Intake24

after each study day and recall their intake during the previous day. As there was nothing to recall on day 1, participants started using Intake24 on day 2 of each study week.

11. Methods, Objective dietary assessment tools: Information on the type of analysis (metabolomics at minimum) would be helpful to include earlier in the protocol.

These methods have been published in detail elsewhere and therefore authors think it is outside of the scope of the manuscript (DOI:10.1002/mnfr.202000517).

12. Methods, Objective dietary assessment tools/Capillary blood samples: Is a capillary blood draw completed only in the morning of each study visit on Days 1, 2, and 4? What is the rationale for excluding day 3?

The first sample (day 1) was a test sample for the participant to become familiar with the Onedraw device. The key samples are on day 2 and day 4. Taking a sample on day 3 would not service a specific purpose and therefore not be ethical to take unnecessary blood sample and create a significant increase in the costs of the work.

13. Methods, Wearable camera technology: It is not clear why the participants will be asked to continuously wear the mounted camera outside of eating windows.

The SODIAT project aims to develop a tool that is practical and works in real-life settings. While SODIAT-1 was a highly controlled study and not fully representative of a real-world environment, our goal was to evaluate the feasibility of using camera technology throughout most of the day, both inside and outside the clinical unit. We were concerned that if participants were only required to wear the cameras during eating windows, they might forget to put them on before consuming food or beverages in a real-life setting, particularly for spontaneous eating events such as snacks and drinks.

14. Methods, FFQ: As mentioned in the abstract, it is not clear that the eNutri tool has been validated for four-day recall periods – is part of the objective of this study to validate the "separate version" that was created? If so, how will this be done?

While the validation of the 4-day eNutri FFQ is not a primary focus of the SODIAT project, the authors have considered this possibility. Specifically, we have explored the potential for validating eNutri against the known 4-day intake from the controlled menus and, possibly, against dietary data collected through Intake24.

15. Methods, Statistical analysis: Are simple measures of correlation between instruments adequate to measure accuracy? Are the biomarkers selected indicative of specific nutrients (e.g., fat, sodium), foods, or food groups? If the latter are not controlled for or not substantially different between diets, what is the expectation for

how accuracy will be determined if the biomarkers do not distinguish at this level? Where will participants report/record compliance? Or is the study team measuring this? Details are lacking for evaluation of these methods.

To clarify, accuracy will not be measured between instruments. The primary reporting accuracy will be measured between each tool and the known intake (as clarified in statement 1).

Most dietary components will be metabolised and will not be identical to their originating food components. For instance, palmitate will be in food mainly as an ester part of the triglycerides (oils), but in the circulation it can be part of phospholipids, different triglycerides or other lipids and therefore the measurement of those lipids in the circulation is not directly related to the intake. However, measuring the absolute concentrations will allow for direct comparison with other studies, while relative concentrations are very dependent on all the other compounds measured at the same time. So, the quantitation is aimed to make the results as transferable as possible. The imprecision of the sampling is an issue and will always be a limitation, but quantitation of the biomarkers in that particular sample will always be more transferable than relative amounts, which can always be calculated from the absolute amounts.

Compliance was recorded by study investigators when the participants were in the controlled environment, and for the time outside the controlled environment compliance was measured using sample/data collection records and self-reported deviations to study menus (added in the main text line 182-185).

16. Methods, Primary outcomes: How will "accuracy" be determined amongst the data collected? Which measure is "true?"

The true measure will be the known quantities of consumed foods given to participants during the intervention days within the clinical trial centres. We clarified this in the manuscript (line 368-369). Accuracy will be measured at the level relative to the dietary assessment tool. For example, Intake24 reports nutrient level data, where biomarkers report at the food group level.

17. Methods, Secondary outcomes: It is not clear how this multiplatform model will be designed or how all of the assessment measures will be integrated together. Further, with no detail on the biomarkers of interest, it is impossible to evaluate if the goal of assessing ug/mL of dietary exposure biomarkers is realistic. Many untargeted metabolomics assays do not provide data at this level (e.g., relative abundance vs quantitative measures/concentrations). While the use of triple quad indicates some targeted panels may be run and thus this may be possible, the stated goal to create a simple "global dietary score" from NMR data does not align with this stated objective.

The analysis of known intake biomarkers in urine and blood is with targeted quadrupole mass spectrometry methods. For the majority of the biomarkers, the inclusion of

authenticated standards allows for the quantitative measurements. For some biomarkers where standards are unavailable, quantification is performed using a surrogate, with similar physiochemical properties and ionisation behaviour; within the specific sample matrix. This will mean that some of the concentrations from targeted analyses, will be semi-quantitative.

The secondary analysis using NMR to create a global dietary score, is based on a previously validated methods (DOI: 10.1016/S2213-8587(16)30419-3), and provides complementation to mass spectrometry analysis.

18. Discussion: While the end goal is to reduce participant burden, this reviewer would argue the study increases it given the number of data collection procedures. Consider specifying that if the methods tested are reliable, reproducible, etc. and can be incorporated into clinical practice and/or future research, this could reduce burden.

While we acknowledge the reviewer's comment, we would like to emphasise that reducing participant burden is the overarching goal of the SODIAT project. We recognise that the SODIAT-1 study, due to its extensive data collection procedures, is not the best example of this aim. However, we hope the clarifications made in the Discussion section help to better convey this point. Additionally, the findings from SODIAT-1 will inform researchers in identifying the most effective combinations of study tools, allowing future studies to be less burdensome for participants while not undermining the date quality. Ultimately, insights from the SODIAT-2 study will contribute to developing a more streamlined and inclusive research tool that minimises participant burden by reducing the need for recall or requiring minimal input (for example, shorter FFQ that adds on the biomarker and camera data).

19. Discussion: Similar to comments in the abstract, it is not immediately clear how these methods will improve assessment in underrepresented populations, particularly those who are experiencing homelessness, as stated in text. It would be near impossible to give someone the wearable technology or ask them to appropriately collect and store biospecimens such as urine under those conditions.

We appreciate the reviewer's comment and acknowledge the challenges of conducting dietary research among individuals experiencing homelessness. In the remote SODIAT-2 study, participants will collect their urine and blood samples at home and mail them to research centres using pre-paid envelopes. We believe this approach can be adapted to accommodate the circumstances of individuals experiencing homelessness, although we recognise it presents additional challenges. Ultimately, the final SODIAT tool aims to address these difficulties and improve dietary assessment methodologies for underrepresented populations, including those without stable housing.

20. Discussion: Consider adding to strengths/limitations the length of collection for blood (small capillary sample vs venous draw) and urine (spot vs 24 hour). While these methods may reduce participant burden, they also weaken the ability to capture

precise measures reflective of longer periods of intake.

We think that it is too early to give a detailed strengths/limitations discussion on the length of sample collection. We have no evidence at the moment that for the measurement of the biomarkers in 24h urine or venous blood samples are more informative than the measurement in spot urine or capillary blood samples. Neither methods are functional as quantitative biomarkers (like the sodium measured in 24h urine samples can be used to calculate salt consumption). The biomarkers are likely to be used as qualitative biomarkers, revealing consumption and change of consumption of specific food or food groups. Very few projects have integrated blood based and urine based biomarkers and our work will enable the further development of these biomarkers in the integrated projects.

21. Ethical considerations: While perhaps outside the scope of this protocol manuscript, it is not clear how AI technology being employed is protective of personally identifiable information – what program "sees" this? The reviewer notes the software availability statement but feels this may be inadequate.

The "recognise anything" model automatically tags each captured image, ensuring that only food-related images are retained for further analysis. Our experiments demonstrate that more than 99.5% of redundant images are removed, significantly reducing the risk of handling non-relevant data.
To further protect personally identifiable and sensitive information such as faces, laptop and phone screens, documents, we apply blurring using YOLOv8, a state-of-the-art (SOTA) deep learning model for image recognition. This process achieves an accuracy rate of 99.8%, effectively safeguarding participants' identities and those around them, also blurring screens and paper documents if captured by the camera technology.
Regarding software availability, we are currently working on a research article that will provide detailed information about the models used, as the anonymisation technique itself represents a novel aspect of this project. The specifics of our approach will be disclosed in that publication.

Competing Interests: No competing interests were disclosed.

Reviewer Report 17 December 2024

https://doi.org/10.5256/f1000research.170884.r341524

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Comments:
The manuscript describes the protocol for a study designed to integrate dietary assessment tools covering traditional technologies (FFQs and recalls) with last-generation technologies (biomarkers of food intake measured in biological samples and wearables). The study is great in many ways and has the potential to shed light into the applicability and cost-effectives of the new dietary assessment tools, as well as providing a first attempt to cross-validate these tools against each other. The concept is novel and highly needed to move dietary assessment forward in nutrition research and provide a more accurate estimate of the human diet.

Some considerations:
Abstract:
The cross-over design is 2x4 days with wash out. How will the FFQs information be integrated with the acute dietary information?
Dietary intake will be monitored continuously through wearable cameras (abstract). I would imagine the cameras (glasses) have to be taken off at times (also stated by the authors later in the abstract)? Maybe "continuously" is not the best term here.
In the discussion point (abstract) it is unclear how the study will enhance the inclusivity of underrepresented populations with literacy or language barriers, since the study will primarily recruit from Imperial College London and Reading University. If this is a perspective (future application of this methodology / impact), it should be seeded in the introduction, for coherence.
I suggest the authors be somewhat more cautious when stating "reducing misreporting and enhancing inclusivity". The methodologies they will test are far from being validated and fully accurate, and the cross-validation still relies on participants turning the wearables on. It is therefore yet to be investigated if this integrative approach will indeed reduce misreporting.

Introduction - I suggest cautiousness in classifying wearables as part of "objective" measures, since they essentially also rely on the will of the study population to actually record everything.

Recruitment – it is stated that recruitment will start in December 2023 -> change to started? although later in the manuscript it is stated that it is also already completed. This can be already stated from the start.

Study design:
- In what cases will the washout before study not be needed? (Figure 1)
- Habitual diet will be recorded with the eNutri tool. How is this data relevant to the study?
- It is slightly unclear if day 2-4 are conducted also at the research center? I would assume not, but some clarification with help the reader

Objective dietary assessment tools
- How will the spot urines be normalized?
- Is the blood collection device standardized for volume of blood, or how would this be quantified?
- Wearables: very interesting technology developed, that takes into account some limitations of such technologies (eg privacy). Few points: is the recorded dietary data connected to the same food composition database as the subjective tools used (eNutri, intake24)? How does the dietary recording work with stacked foods (i.e., burgers or sandwiches) to disentangle

the identity and quantities of the ingredients? What about composite meals?
- Wearables: here it is stated that participants come to the research center days 2-4; yet, later the authors refer to “natural eating environment”. This should be clarified, as an experimental diet, even if designed according to national dietary guidelines, it is by no means a natural eating environment, even more so if it is consumed at a research center

Primary outcome: what will be the “golden standard” among the 4 methodologies? In other words, how do the authors define “the accuracy of dietary reporting”? Logically, it would be the reflection of the diet in comparison with the dietary intervention – if this is correct, it should be clearly stated. Moreover, will this be measure at the nutrient, food group or dietary pattern level?

Secondary outcome: ug/ml of dietary exposure biomarker indicates quantitative biomarkers. This may be true for nutrients, but most foods are not covered by quantitative biomarkers reflecting their intake. Considering the spot sampling with potential imprecise information of volume (leading to inaccurate urines concentration, potentially also for blood spots, depending on the device used), quantifying amounts consumed with biomarkers can be challenging. What are the authors’ thoughts on this?

Ethics: how is the data privacy through AI being monitored?

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: biomarkers of food intake, dietary assessment, nutrition research, metabolomics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 29 Jan 2025

Eka Bobokhidze

Dear Reviewer,

We appreciate your feedback and insights on our submission to F1000Research. Below we

have outlined our responses to each of the points raised during the review process.

Yours Sincerely,
Julie A. Lovegrove
On behalf of the manuscript authors

Response to the reviewer's considerations.

1. **The cross-over design is 2x4 days with wash out. How will the FFQs information be integrated with the acute dietary information?**

Thank you for this query. The FFQ data collected at baseline will be used to assess habitual diet for the purpose of reporting cohort demographics and may be used as a covariate in data analysis to control for differences in habitual diet between participants.
The 4-day FFQs were then administered at the end of each study week, specifically recording what participants consumed during the previous 4 study days in which they ate the test diets. This FFQ data will provide average intakes across the two study weeks, which can be integrated with daily aggregated data, like Intake24. This data will be compared with metabolomic data and images, enabling evaluation of consistency and identifying potential biases. Its inclusion is essential to test how well self-reported dietary data aligns with objective biomarkers, directly addressing the trial's core aim of improving accuracy in dietary assessment methodologies.
We clarified this in abstract and added further details in the data analysis section.

2. Dietary intake will be monitored continuously through wearable cameras (abstract). I would imagine the cameras (glasses) have to be taken off at times (also stated by the authors later in the abstract)? Maybe "continuously" is not the best term here.

This is correct. Participants wore the cameras all the time while being in the research unit (until 6pm) and they were asked to continue to wear them continuously after leaving too. The glasses with the cameras were only taken off during the inappropriate times, such as using the bathroom, bathing children, while driving for safety reasons, etc. We have removed both instances of the word "continuously" from the abstract after considering the reviewer's comment. In addition, we have removed the same word from the main text (line 237) and revised the phrasing in line 168 for clarity.

3. **In the discussion point (abstract) it is unclear how the study will enhance the inclusivity of underrepresented populations with literacy or language barriers, since the study will primarily recruit from Imperial College London and Reading University. If this is a perspective (future application of this methodology / impact), it should be seeded in the introduction, for coherence.**
I suggest the authors be somewhat more cautious when stating "reducing misreporting and enhancing inclusivity". The methodologies they will test are far from being validated and fully accurate, and the cross-validation still relies on participants

turning the wearables on. It is therefore yet to be investigated if this integrative approach will indeed reduce misreporting.

The authors note that the original text was misleading as it suggested participants were all *from* Imperial College London and the University of Reading. This has now been edited to make it clear that these were the two study locations, not the location for recruitment. Participants were recruited from the areas local to the two study sites and included people with differing demographics.

The long-term goal of the SODIAT project is to develop a dietary intake assessment tool that will enable us to enhance inclusivity of underrepresented populations (e.g., by reducing reliance on memory recall and negating the need for high literacy skills) as well as minimise the current biases of traditional tools that contribute to misreporting. We have edited the text to clarify that these are the overall aims of the SODIAT project (rather than suggesting this will be achieved from this first study) and noted that this is the first of three studies to evaluate the novel tool.

4. **Introduction - I suggest cautiousness in classifying wearables as part of "objective" measures, since they essentially also rely on the will of the study population to actually record everything.**

Wearable cameras are considered objective measures in dietary assessment because they capture visual evidence of what participants consume without relying on self-reported data, which is prone to memory errors or biases. This is in line with how other authors outside of our research group also categorize wearable cameras – some examples include: Chan et al 2021 (https://doi.org/10.3390/nu13061806), Scott et al 2022 (https://doi.org/10.1017/jns.2022.81), Gemming et al 2015 (https://doi.org/10.1016/j.appet.2015.05.019).

However, we agree that this objectivity depends on whether participants consistently wear the devices as instructed. This is noted as a potential limitation of the camera technology (line 388-389) and mentioned it in the introduction when discussing objective measures as the will of participants could also apply to the collection of biosamples (line 45).

5. **Recruitment – it is stated that recruitment will start in December 2023 -> change to started? although later in the manuscript it is stated that it is also already completed. This can be already stated from the start. (statement in rec section)**

The paper was written while the study was in planning and early running stages, thus the wording. To avoid the confusion among the readers, we have updated the Study Status Statement and re-worded the appropriate sections to reflect that the study is now finished. We will update the sections about data analysis once its finished.

6. **In what cases will the washout before study not be needed? (Figure 1)**

The washout before study was applied if the eligible participant was taking any dietary supplement or participated in another study during last 12 weeks. In other cases, no

washout period was needed. This detail was added to the Figure 1.

7. **Habitual diet will be recorded with the eNutri tool. How is this data relevant to the study?**

The FFQ data collected at baseline will be used to assess habitual diet for the purpose of reporting cohort demographics and may be used as a covariate in data analysis to control for differences in habitual diet between participants. As mentioned in the reply to the comment 1, details about how the data from habitual data will be used has been added in the statistical analysis section (line 348-354).

8. **It is slightly unclear if day 2-4 are conducted also at the research center? I would assume not, but some clarification with help the reader**

Participants visited and stayed in study centres from 8am to 6pm during 4 days (Monday-Thursday) and came back for a short visit on Friday morning to drop off the Friday morning urine samples and study equipment. This is described in “Study visits” and “Study visit procedures” sections.

9. **How will the spot urines be normalized?**

Spot urine samples are normalised based on specific gravity prior to extraction. Specific gravity correction factors are calculated for urine samples as a fold change of each urine specific gravity to a value of 1.006. This information has been added to the “Spot urine samples” section (line 196-199).

10. **Is the blood collection device standardized for volume of blood, or how would this be quantified?**

OneDraw blood collection kit is a standardised FDA approved device that collects approximately 150 µl of blood at each administration. This detail was added in the text (line 208).

11. **Wearables: very interesting technology developed, that takes into account some limitations of such technologies (eg privacy). Few points: is the recorded dietary data connected to the same food composition database as the subjective tools used (eNutri, intake24)? How does the dietary recording work with stacked foods (i.e., burgers or sandwiches) to disentangle the identity and quantities of the ingredients? What about composite meals?**

Our system is not currently integrated with the databases used by eNutri or intake24 and instead uses our own set of food categories. However, aligning our categories with intake24 is something we are actively considering, as it would improve consistency and comparability for future analyses, particularly in large-scale dietary studies.

For stacked foods, such as burgers or sandwiches, our passive monitoring approach captures images of the internal components when the food is bitten into. This allows for

more accurate identification of individual ingredients and estimation of portion sizes, even in complex food arrangements.

When it comes to composite meals, such as curry rice, our method is designed to identify and list visible ingredients along with their estimated portions. Admittedly, this is challenging when some ingredients are covered or obscured and has been included in the limitations section. To address these complexities, we are exploring advanced solutions like leveraging large language models (LLMs), which have shown significant promise in separating ingredients and estimating portions with greater accuracy.

To consider reviewer's comment we have added a sentence about composite meals and stacked foods in the discussion section of the main text as follows: "Additionally, distinguishing between types of foods and drinks (e.g., low-fat versus whole yoghurts or sugar-free versus sugar-sweetened drinks) through visual means can be challenging as well as composite meals (e.g., pies, curries) and stacked foods (e.g., sandwiches, burgers) where some ingredients are covered or obscured."

12. **Wearables: here it is stated that participants come to the research center days 2-4; yet, later the authors refer to "natural eating environment". This should be clarified, as an experimental diet, even if designed according to national dietary guidelines, it is by no means a natural eating environment, even more so if it is consumed at a research center.**

We acknowledge that the participants consumed these meals in an experimental setting at the research centre, which is not representative of a natural eating environment. To clarify, the phrase in the text refers to the design method used in the study, rather than environment itself; we have amended the word 'the' to 'a' to avoid confusion.

13. **Primary outcome: what will be the "golden standard" among the 4 methodologies? In other words, how do the authors define "the accuracy of dietary reporting"? Logically, it would be the reflection of the diet in comparison with the dietary intervention – if this is correct, it should be clearly stated. Moreover, will this be measure at the nutrient, food group or dietary pattern level?**

The gold standard will be the known quantities of consumed foods given to participants during the intervention days within the clinical trial centres. Accuracy will be measured at the level relative to the dietary assessment tool. For example, Intake24 reports nutrient level data, where biomarkers report at the food group level.

14. **Secondary outcome: ug/ml of dietary exposure biomarker indicates quantitative biomarkers. This may be true for nutrients, but most foods are not covered by quantitative biomarkers reflecting their intake. Considering the spot sampling with potential imprecise information of volume (leading to inaccurate urines concentration, potentially also for blood spots, depending on the device used), quantifying amounts consumed with biomarkers can be challenging. What are the authors' thoughts on this?**

The reviewer raises an interesting point, indeed essential nutrients exogenous compounds, can be directly correlated to intake. However most dietary components will be metabolised and will not be identical to their originating food components. For instance, palmitate will be in food mainly as an ester part of the triglycerides (oils), but in the circulation it can be part of phospholipids, different triglycerides or other lipids and therefore the measurement of those lipids in the circulation is not directly related to the intake. However, measuring the absolute concentrations will allow for direct comparison with other studies, while relative concentrations are very dependent on all the other compounds measured at the same time. So, the quantitation is aimed to make the results as transferable as possible. The imprecision of the sampling is an issue and will always be a limitation, but quantitation of the biomarkers in that particular sample will always be more transferable than relative amounts, which can always be calculated from the absolute amounts.

In the particular case of spot urine samples, while there are limitations due to the temporal heterogeneity of urine excretion; there are well documented examples (https://doi.org/10.1093/jn/nxz138) on the utility of spot samples in comparison to 24-hour urine samples, and the correspondence in biomarker concentrations between sample types for reporting dietary exposure.

15. Ethics: how is the data privacy through AI being monitored?

All footage will undergo 2-step pre-processing procedure. Initially, RAM (described in “Software”) will be applied to remove the images that do not contain foods or drinks. Additionally, this method will be used to remove the photos with sensitive information – for example, “excluding tags” function will allow to remove pictures that contain bathroom. Additionally, an extra layer of security will be applied to the retained images by blurring participants' faces, the faces of others present, and any visible phone or computer screens that may have been overlooked in the initial step. This process will utilize YOLOv8, a highly regarded deep learning method in image recognition, to ensure that identities and personal information remain protected. Images will only proceed to further analysis after this pre-processing step. Additionally, regular audits of AI pre-processes and results will be conducted through sampling to ensure compliance and address any emerging privacy concerns throughout the experiment. We reflected this in the ethics section (line 417)

Competing Interests: No competing interests were disclosed.