PROTOCOL ADAPT study

FULL TITLE: A randomised controlled trial to evaluate the feasibility of web-based dietary assessment for improved personalised dietary advice in routine clinical dietetic practice of irritable bowel syndrome (IBS) patients

SHORT TITLE: The Acceptability of online Dietary Assessment in clinical Practice Trial

Sponsors

Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (Sponsor reference number: **A096133)**

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Key words

Feasibility

Web-based dietary assessment

Personalised dietary advice

Clinical dietetic care

Irritable Bowel Syndrome

Intervention study

Abbreviations

CETU – Cambridge Epidemiology and Trials Unit

DMP – Data Management Policy

DRR – Dietary Recall Report (Clinical Team)

GDPR – General Data Protection Regulations

IBS – Irritable Bowel Syndrome

IBS-AR – IBS Adequate Relief question

IBS-QoL – IBS Quality of Life questionnaire

IBS-SSS – IBS Severity Scoring System questionnaire

PID - Participant Identifier

PROMS – Patient Reported Outcome Measures

RPAQ – Recent Physical Activity Questionnaire

SRD – Secure Research Domain

Abstract / summary

Background and aim

Detailed dietary assessment during routine clinical dietetic care to provide personalised advice irritable bowel syndrome (IBS) symptom improvement is challenging. Clinical practice barriers include competing demands, lack of time, dietary and disease complexities, and the rising incidence and thus clinical pressure. This research project aims to establish the feasibility, acceptability and effectiveness of using a web-based 24-hr dietary recall system (Intake24) for improved personalised dietary advice versus usual dietetic clinical care of IBS patients.

Study Design

In a parallel, randomised controlled intervention study, a sample between 80 and 100 patients diagnosed with IBS will be randomly allocated (1:1) to web-based 24-hr dietary recalls or routine dietetic practice (dietary history interview method) and followed for 6 months. Patients allocated to the intervention will be invited to complete at least two 24-hr dietary recalls prior to the dietetic appointment (one-to-one consultations or group sessions). This will provide 1) quantified online dietary feedback upon completion of each recall for the patient's review, and 2) upload of a detailed dietary results report to the patient's electronic medical notes for the dietitians' review to tailor dietary advice to patients during one-to-one consultations. Current routine dietetic practice uses dietician-led diet history interviews during one-to-one consultations or no dietary assessment for group sessions. All IBS patients enrolled to the study will be invited to complete web-based 24-hr dietary recalls prior to initial dietetic consultation and at end of study (6 months).

Population and duration

We will recruit and enrol for a maximum of 3 months a sample of 100 newly admitted patients diagnosed with IBS (whichever comes first) at the Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust. All patients will be followed for 6 months.

Outcome measures

Primary outcome: IBS adequate relief and symptom severity score

Secondary outcomes:

- Quality of dietetic practice
- Adherence to dietetic advice
- Response rates and acceptability of dietary assessment method and feedback
- Quality of life (IBS specific)
- Dietetic consultation time (for one-to-one dietetic consultation arms)
- Frequency of follow-up dietetic consultations (for one-to-one dietetic consultation arms)

1 Background and rationale of the study

Irritable bowel syndrome (IBS) is a relapsing disorders of gut-brain interactions characterized by chronic or recurrent symptoms of abdominal pain associated with disordered defecation (constipation or diarrhoea or both) and abdominal distension (bloating). IBS is not a detectable organic disease and is defined by the symptom-based (Rome) diagnostic criteria.[1, 2] Globally, the prevalence of IBS is 11.2%[3, 4] whilst it has been estimated to occur in 10 to 20% of the UK population[3], especially in those aged <50 years.[4] IBS is a life-long disorder with significant negative impact on the patient's quality of life (QoL)[5], social and occupational functioning and a considerable burden on health-care delivery due to increased use of health-care and related costs of consultations.[5]

The management of IBS involves a range of dietary and lifestyle approaches with limited successful evidence for pharmacological treatment.[1] The risk of developing IBS has been linked to Western dietary patterns[6] with 50 to 84% of IBS patients reporting a wide range of specific dietary triggers.[7] To improve their symptoms, IBS patients are highly interested in exploring dietary triggers including irregularity of meals, missed meals or long gaps between meals, low fluid intake, excessive intake of caffeinated beverages, lactose from dairy products or sorbitol, low or excessive fibre intake, high alcohol or fizzy drink consumption, high fruit intake.[1] If IBS symptoms persist, specialist dietetic services offer support with strict exclusion diets of fermentable oligosaccharides, disaccharides, monosaccharides and polyols diet (FODMAP) in one-to-one dietetic consultations or group sessions. The complexity and the range of potential dietary triggers to assess and the emerging rise in evidence for the efficacy of dietary therapy and strict exclusion diets has increased demand for specialist dietetic services and improved efficacy.

Currently, routine clinical dietetic care does not use dietary assessment in group sessions and uses structured retrospective dietitian-led dietary history interview method to assess dietary habits in 30 minute one-to-one dietetic consultations. The dietary history interview requires significant consultation time and provides only a global overview of dietary habits instead of detailed, quantified dietary results to identify potential dietary triggers. Recent development of a web-based 24-hr dietary recall system (Intake24) allows patients to complete repeated 24-hr dietary recalls remotely at their own time, pace and with more privacy for the patient. A multiple pass method is used which allows the patient to structurally recall foods and beverages consumed in the past 24 hours using images for more accurate portion size estimation.[8, 9] Automated processing of reported dietary information allows immediate dietary feedback to the patient upon completion and upload of detailed, quantified dietary result report to the electronic medical notes. The dietary results report is for review by the dietitian before the dietetic consultation allowing personalised dietetic advice to increase efficacy and quality of specialist dietetic services.

There is currently limited knowledge available on the utility of online 24-hr dietary recalls in clinical settings as well as in IBS patients. Hence, this project aims to examine feasibility, acceptability and effectiveness of using web-based 24-hr dietary recalls in the usual dietetic care to support tailored dietary advice in IBS patients.

2 Objectives and outcome measures

The overall objective of this research project is to examine the feasibility and effectiveness of using web-based 24-hr dietary recall system (Intake24) compared to dietitian-led dietary history interviews (usual care) for improved personalised dietary advice in IBS patients. The following primary and secondary outcomes will be evaluated:

Primary outcome: Changes in IBS adequate relief and symptom severity score

Secondary outcomes: Changes in:

- Adherence to dietetic advice
- Quality of dietetic practice
- Response rates and acceptability of dietary assessment methods
- Quality of life (IBS specific)
- Dietetic consultation time (for one-to-one consultations only)
- Frequency of follow-up dietetic consultations (for one-to-one consultations only)

3 Study design

In a parallel, randomised controlled intervention study, a sample between 80 to 100 newly admitted patients diagnosed with IBS at the Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust will be recruited and enrolled for a period of 3 months (whichever comes first). Patients will be randomly allocated (1:1) to dietetic practice using web-based 24-hr dietary recalls (Intake24) for personalised dietary advice or routine dietetic care and will be followed for 6 months. Patients allocated to the Intake24 arms will be invited to complete dietary recalls at least 2x within 2 weeks prior to each upcoming dietetic appointment. Patients allocated to routine dietetic care (control) will receive a dietitian-led diet history interview during one-to-one consultations or no dietary assessment for group sessions. We follow patients for 6 months as most patients are generally discharged within 6 months unless very complex cases. All patients will be invited to complete Intake24 at least 2x within 2 weeks at baseline and at 6 months of follow-up, a discharge questionnaire and monthly online questionnaires to assess study outcomes (**Figure 1**).

3.1 Dietary assessment

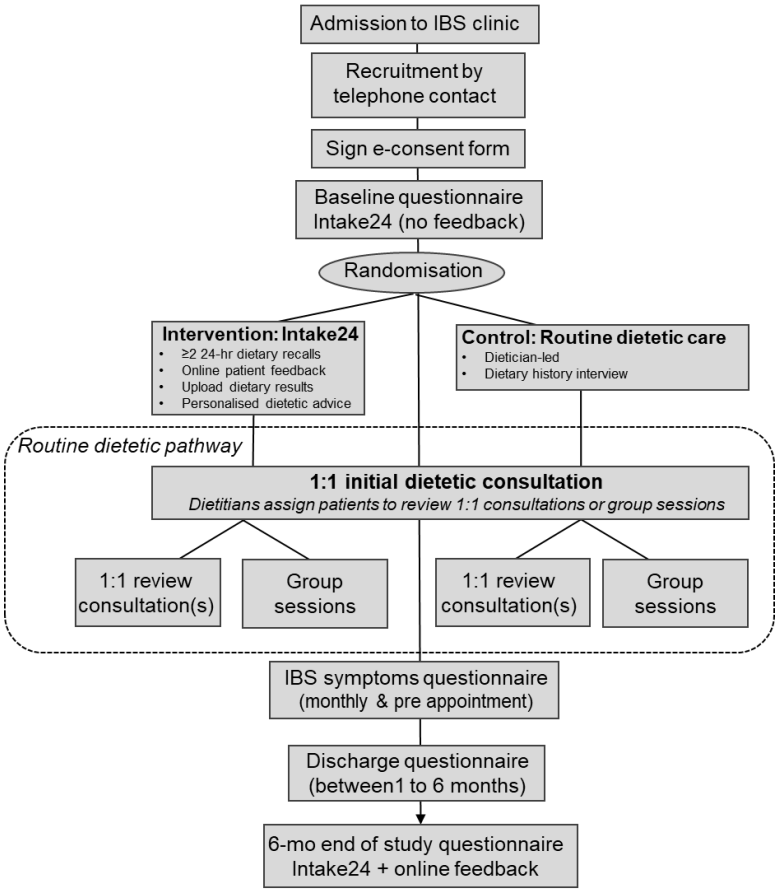
The intervention includes random assignment (1:1) to 1) Web-based, self-administered 24-hr dietary recalls for personalized dietary advice or 2) routine dietetic care (dietitian-led dietary history interview during one-to-one consultations or no dietary assessment for group sessions) – which is discussed in more detail below and presented in **Figure 1**.

3.1.1 Web-based, self-administered 24-hr dietary recalls (Intake24)

Patients allocated to Intake24 will be invited by email to complete at least 2 online 24-hr dietary recalls including 1 weekday and 1 weekend day within 2 weeks pre-consultation. A user-specific URL allows the patient to directly access the dietary recall system via computer or tablet. A 5-minute video on how to complete Intake24 is available on the welcoming screen. Patients will be sent up to 4 reminder emails to optimise completion of at least 2 dietary recalls as average dietary results of

multiple recalls are more reliable and have been found to represent habitual dietary habits.[9] We give the option to complete more recalls as well as random whenever the patient feels it would be helpful as we noticed in a cohort study that some liver transplant patients were keen to improve their diet and completed Intake24 more often and at random time points than required (internal communication). Patients assigned to Intake24 will receive online standardized dietary results according to recommendations and with reference to the Eatwell Guide upon completion of each dietary recall.[10] To independently investigate baseline dietary intakes and changes in diet over the study period, all enrolled patients will be invited as described above at baseline and end of study to complete at least 2 online 24-hr dietary recalls. Dietary recall reports at baseline will be uploaded to the patient notes for the dietitian's review prior to each 1:1 dietetic consultation to tailor dietary advice.

Figure 1. Schematic study design including time points of self-reported online measurements throughout the 6-months study period



Dietary Recall Report (Clinical Team)

For patients allocated to the one-to-one dietetic consultation arm, dietary data will be automatically processed with average and daily dietary results reported in an anonymous Dietary Recall Report (DRR; Clinical Team); an example is presented in **Appendix 1**. The DRR will be uploaded as a PDF-file to the patient notes. This allows the dietitian to review and identify dietetic issues pre-consultation to discuss with the patient. The dietitian has the expertise to interpret the dietary results and to define tailored dietary advice. The dietitian will discuss the dietary results and personalised dietary advice

with the patient during the dietetic consultation. Dietary results presented in the DRR have been carefully discussed in collaboration with the gastroenterology specialist dietitians and the NIHR Cambridge BRC Dietary Assessment Platform to ensure presented dietary information is applicable and reliable to tailor dietary advice for IBS patients. This feasibility study will enable us to identify which additional dietary information or system features may be helpful for future implementation as part of routine dietetic practice and larger nutritional research studies in IBS patients.

Accuracy of dietary data

Intake24 is designed as a self-complete instrument using a multiple pass method in which the respondent recalls foods and beverages consumed – and their quantities – in the past 24 hours. To limit the potential of errors, quantities are assessed by selecting images of various portion sizes and the system probes questions for commonly forgotten foods e.g. addition of sugar to tea or coffee.[11] For timely clinical use of the DRR the actual recorded dietary information will be presented. The dietitian has the expertise to notice misreported dietary data (e.g. exceptionally large or small energy or nutrient intakes or portion sizes). Additionally, training will be provided by the study team to identify common misreports experienced with use of Intake24 in other research studies.

3.1.2 Dietitian-led dietary history interview method (routine dietetic practice)

Patients allocated to the control group will receive routine dietetic practice which includes a dietitian-led interview using the dietary history method to assess dietary habits during the one-to-one dietetic consultation. The dietitian will discuss dietary habits with the patient and will provide feedback during the consultation. Dietitians are not able to quantify dietary results due to lack of time. Dietary habits of patients assigned to the group sessions are routinely not assessed.

3.2 Study outcome measurements

For this research project, study outcome measures will be collected via online questionnaires and will be retrieved from the CUH electronic medical notes at various time points during the 6-month study period (**Figure 1, Table 1**). There is no interference of the routine dietetic pathway; patients will attend the usual dietetic appointments, the dietitian discusses and decides with the patient assignment to review one-to-one consultations or group sessions during the initial assessment consultation, and if deemed appropriate by the dietician patients can switch between review one-to-one consultations to group sessions. Patients are not required to attend additional clinic visits specifically for this research project.

3.2.1 Patient Reported Outcome Measures (PROMs)

The research team will invite patients to complete the online questionnaires by email. The patient will have direct access to the questionnaire by clicking one URL; the individual study outcome measure questionnaires are combined into one online questionnaire to be accessed by using a single URL. Our recent experiences with remote data collection showed higher response rates using one URL compared to use of separate URLs for each individual questionnaire (internal, unpublished data). An overview of PROMs with time points of collection is presented in **Table 1**.

Table 1. Overview of PROMs with time points of collection

	Patient Reported Outcome Measures	Time points				
		1	2	3	4	5
Informed consent		X				
Contact details	First and last name, email address, phone number	X				
Demographics	Including age at enrolment, gender, ethnicity, educational level, socio-economic status, smoking habits	X				
Dietary recalls (Intake24)[9, 12]	24-hr dietary recalls, no online feedback (all patients)	X				X
	24-hr dietary recalls, online feedback (Intake24 intervention)			X		
IBS symptoms	IBS adequate relief (IBS-AR)[13], IBS severity scoring system (IBS-SSS)[14], self-reported adherence to dietary advice	X	X	X	X	X
Quality of Life	IBS Quality of Life (IBS-QoL)[15]	X			X	X
Physical Activity	e-RPAQ[16]	X			X	X
Satisfaction, acceptability and Quality of Care	Satisfaction and acceptability of dietary assessment method and feedback, quality of care				X	

Time points are as follows: 1: baseline, 2: monthly, 3: within 2 weeks pre-dietetic appointment, 4: discharge, 5: end of study (6 months).

3.2.2 Outcome measures from CUH electronic medical notes

Clinical information essential for research purposes will be collected for all patients enrolled to this research project from the CUH electronic medical notes (**Table 2**)

Table 2. Overview of time points of clinical data collection

	Clinical data collected	Time points				
		1	2	3	4	5
Dietetic consultation/group session information	Assignment to one-to one dietetic consultations/group sessions, date next consultation/group session, check-in and check-out time of last consultation, total number of consultations/group sessions, diet plan/advice	X	X	X	X	X
Clinical data	Rome IV criteria, IBS classification, height, weight, medical history e.g. co-morbidities, diagnostic lab results, use and dosage of probiotics and/or medication				X	

Time points are as follows: 1: baseline, 2: at 2 weeks then monthly, 3: within 2 weeks pre-consultation/group session, 4: discharge, 5: end of study (6 months).

4 Participant study entry

4.1 Recruitment procedures

Following the usual practice, eligible, newly admitted patients diagnosed with IBS will be contacted via the hospital patient portal (MyChart), the NHS email service or post by gastroenterology administrators with an invitation to call the IBS clinic to book their first consultation and will be provided the participant information sheet. During this call the gastroenterology administrators will check if the patient has read the participant information sheet, will give further study details and will be able to answer any questions the patients may have. If the gastroenterology administrators receive verbal consent from the patients, they will pass on an expression of interest to the study team. Interested patients will be sent an invitation email via the hospital patient portal (MyChart) or the NHS email service with the Participant Information Sheet and a link to a secure web form to obtain informed e-consent. Participants have until two weeks prior to the first dietetic appointment to decide if they would like to take part. A few days before the recruitment cut off, patients' could be sent an invitation reminder via text, email or letter. This correspondence will include a study poster. Once informed consent is given, the patient is invited to complete personal and demographic details and a baseline questionnaire including at least 2 24-hr dietary recalls. Advertisement posters may be displayed around the gastroenterology clinic, Addenbrooke's Hospital and local GP practices.

4.2 Inclusion- and exclusion criteria

A sample between 80 and 100 newly admitted patients older than 18 years of age, who meet the ROMEIV criteria for IBS diagnosis according to the National Institute of Health and Care Excellence (NICE) guidelines[1] will be invited to participate. Patients will be ineligible if they are younger than 18 years, have a co-existing gastrointestinal disease (e.g. inflammatory bowel disease, celiac disease) or eating disorder, no availability or access to a computer, tablet or internet, insufficient English language proficiency, or were unable to give informed consent.

4.3 Randomisation

Once the patient has signed the e-consent form, patients will be randomly allocated (1:1 allocation ratio) to the intervention (Intake24) or control group (routine dietary history review). A random allocation table will be created by a senior statistician from the MRC Epidemiology Unit and will be integrated into the study database for automated allocation.

4.4 Withdrawal criteria

Patients are free to withdraw their consent to continued participation at any time, without giving a reason. If a patient withdraws from the study, data collected until that time will be securely stored and will only be accessible by the study team.

5 Adverse events and compliance

The dietary assessment intervention and self-reported measurements are regarded as the study procedures and require monitoring. Adverse events related to the intervention or outcome measures will be documented according to the unit policy and CETU SOP015 (Recording and reporting adverse events). Accidental protocol deviations can happen at any time. Any deviations will be adequately

documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable and will require immediate action and could potentially be classified as a serious breach. Any issues with the running of the project will be discussed within the research team and at the MRC Epidemiology CETU Steering Meetings.

6 Data governance and analysis

6.1. Data governance

The Cambridge Epidemiology & Trials Unit (CETU) within the MRC Epidemiology Unit has an over-arching data management policy (DMP) that encompasses the standards and processes applied to all research and operational activities in the Unit. The Information Security Policy of the CETU is aligned with the Clinical Schools Information Governance Policy and details how research data is stored electronically and transmitted across networks, covering research including sensitive or personal information. The Principal Investigator and the CETU will ensure that all data generated, stored and shared from this study will be handled in compliance with the DMP, the General Data Protection Regulations (GDPR) and the Data Protection Act 2018. The University of Cambridge will be data controller.

Data collected in this research project is electronic using online questionnaires and from the electronic CUH patient notes. Electronic data will be held on the Unit's secure network, collated in version controlled uniquely identified databases. Patients will be assigned a unique participant identifier (PID) which will be unique to them on completion of the e-consent form. All data will be collected and stored using PID and not the participant name. Linkage of PID and patients personal details will be stored in a separate database on the Secure Research Domain (SRD) within the MRC Epidemiology Unit with restricted access to the database manager and the CETU study coordinator. The SRD is an approved safe haven within the University of Cambridge Clinical School which is compliant with the NHS Digital Data Security and Protection Toolkit requirements. The PID will be used for linkage of all study measurements. The study database will hold the patients email address to send automated email to invite patients to complete the online questionnaires.

Access to the server and databases are controlled by two-factor authentication including unique usernames and strong passwords which are not used to access other Unit systems. All databases are encrypted. Physical access to the IT infrastructure and study offices are controlled by building card access. All systems are run by professional IT staff and data handling and back-up processes are managed to standards equivalent to those defined in the MRC Information Security Policy and meet the University of Cambridge Data Security Policy.

Patient enrolment with PID and random allocation will be added to the CUH electronic medical notes. Demographic and clinical information (**Table 2**) will be extracted from the CUH electronic medical notes directly onto and anonymised database on the SRD. To minimize administrational time of the clinical dietetic team, data administration using the CUH electronic medical notes will be done by a verified member of the research team with approved research passport.

6.2 Sample size and data analysis

We aim to randomise 100 patients in a 1:1 ratio to either the Intake24 intervention (N=50) or routine dietetic care (control group) (N=50). Given the little published information on which to base our assumptions for a sample size calculation, we base our statistical power calculation on average reductions of IBS symptom severity scores of a 4-week clinical FODMAP educational programme using different delivery methods (one-to-one consultation vs leaflets vs mobile application) in 51 IBS patients.[17] Dimidi *et al* (2020) reported standard deviations for changes in IBS symptom scores (maximum score of 500) from baseline of 90, 56 and 62 for the 3 intervention groups.[17] Using the mean of these values (69.3), with 100 participants we would have 80% power to detect a difference between groups of 39 in IBS symptom score, and 90% power to detect a difference of 45, assuming no withdrawals from the study and using a 5% significance level. These differences in symptom severity are similar in magnitude to those observed by Dimidi *et al*., when comparing the dietitian and leaflet groups in their study. If 20% of patients were to withdraw (or if a smaller sample of 80 patients was recruited), the detectable differences would be 44 (80% power) and 51 (90% power).

Baseline characteristics and study outcomes at baseline and 6 months follow-up will be summarised within each randomised group. Change in study outcome between baseline and 6 months follow-up will also be summarised, and compared between the intervention and control groups using linear regression, adjusted for baseline value of the outcome (i.e. analysis of covariance). Estimates of the intervention effect and 95% confidence intervals will be obtained from this model.

7 Project management

This project will be jointly sponsored by the CUH and the University of Cambridge and will carry out the role of Co-Sponsor in accordance with the Research Governance Framework. They will take on responsibility for securing the arrangements to initiate, manage and finance the study, and to ensure any risks are identified and managed and that the research is of high quality.

The project will be managed by the MRC Epidemiology Unit through its CETU which is accredited by UKCRC. The CETU study coordinator (AS) will be responsible for the day-to-day running of the study management with supervision from the CI (LOG) and Dr Jennifer Furman, CETU trial manager. The CI will oversee the project. The research team will work in close collaboration with the CUH co-investigators/Intestinal Failure and Gastroenterology Specialist Dietitians.

The NIHR Cambridge Biomedical Research Centre Dietary Assessment Platform and the CETU will provide advice and support with project management and procedures. Any issues with the running of the project will be discussed at the MRC Epidemiology CETU Steering Meetings.

8 Regulatory review and protocol compliance

Before patients will be enrolled into the study, the Chief Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

For any amendment to the study, the Chief Investigator and study coordinator, will follow the existing guidance on amendment submission. Protocol amendments will be submitted to the sponsor for

approval prior to submission to the REC. The Chief Investigator and study coordinator will work with sites (R&D departments at NHS sites as well as the research team) to put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended. The amendment history will be tracked in **Appendix 2**.

9 Peer review

This protocol has been externally reviewed for methodological quality by two independent researchers who are highly qualified experts in the field of dietary assessment, e-health and nutritional epidemiology. The protocol was adjusted to clarify and address their questions and suggestions.

10 Patient and Public Involvement

This project has been designed alongside the Intestinal Failure and Gastroenterology Specialist Dietitians', who highly acknowledge the need for improved dietary assessment in the clinical dietetic care. The Dietary Results Report has been adjusted to the Dietitians requirements for dietary advice to IBS patients within the current possibilities. The research team will keep close contact with the dieticians during the study to inform future improvement of the Dietary Results Report.

During this feasibly study, we will conduct PPI via the use of the acceptability questionnaire. This questionnaire will ask questions relating to the patients' experience and the acceptability of Intake24 in a clinical setting. Results of this feasibility study will inform improvement of the dietary reporting to the clinic and development of a larger research study.

The dietary assessment tool used in the study (Intake24) has been extensively evaluated among different populations in the field for its use, generally and for the National Diet and Nutrition Survey (NDNS) specifically.[12, 18] The tool was found user-friendly allowing dietary assessment without interviewer presence and participant feedback has led to helpful improvements.

11 Indemnity

The University of Cambridge will provide indemnity in the case of negligent and non-negligent harm for research conducted through its Units when it is Sponsor and for employees or others acting on behalf of the University. This study is also covered by the NHS indemnity scheme as it is sponsored by an NHS organisation.

12 Publication policy and dissemination

This project will be registered with the ISRCTN. Findings of this research project will be published in peer-reviewed scientific journals and will be presented at targeted national and international academic and dietetic meetings to ensure wide reach of the results. A summary of findings and links to the published scientific articles will be published on the website as well as the brief announcements on the social media of the MRC Epidemiology Unit. Once study results have been published, these will be disseminated to the participants via email. Authorship will be granted according to the guidelines of the International Committee of Medical Journal Editors.

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Appendix 1: Example Dietary Recall Report (Clinical Team)

Page 1 presents average daily consumption of total energy, macro- and micro-nutrients and several food groups across the completed 24-hr dietary recalls

Average daily consumption - Visit 0 (Assessment visit)

Username	Test8Tky9		
Number of recalls	1	06/11/2019	Wednesday

Average daily consumption of energy, macro- and micronutrients

Nutrients	Average intake		Contribution to total energy intake (%)	Dietary recommendation		Difference
Energy	1945	kcal		2250	kcal	-305 kcal
Protein	90	g	18	15%	of total energy intake	3 %
Carbohydrates	241	g	46	≥50%	of total energy intake	-4 %
Free sugar	111	g	21	≤5%	of total energy intake	16 %
Dietary fibre	21	g		≥30	g	-9 g
Fat	75	g	35	≤35%	of total energy intake	0 %
Alcohol		units				
Lactose		g				
Calcium	1155	mg		700	700 mg	455 mg
Iron	12.4	mg		14.8	14.8 mg	-2.5 mg

Average daily consumption of individual food groups

Food groups	Average intake	
Fruits and vegetables		g
Fruit, excl fruit juice		g
Vegetables, excl potatoes		g
Meat		
Milk and milk products		g
Non-alcoholic beverages (excl milk)		g
Tea, coffee, water		g
Fruit juice (100%)		g
Soft drinks		g

3

Consecutive pages present consumption of energy, macronutrients and Intake24 entry results for each completed dietary recall

Username Test8Tky9 **Completion date:** Wednesday 06/11/2019

Reported consumption of energy, macro- and micronutrients per recall day

Nutrients	Average intake	Contribution to total energy intake (%)	Dietary recommendation	Difference
Energy (kcal)	1945 kcal		2250 kcal	-305 kcal
Protein (g)	90 g	18	15% of total energy intake	3 %
Carbohydrate (g)	241 g	46	≥50% of total energy intake	-4 %
Fat (g)	75 g	35	≤35% of total energy intake	30 %

Reported consumption of foods and beverages

Meal #	Time of Meal/snack		Food description	Amount
1	07:15	Breakfast	Muesli with fruit & nuts (eg. Dorset cereals	75
1	07:15	Breakfast	Semi skimmed milk	154
1	07:15	Breakfast	Coffee, instant	325
1	07:15	Breakfast	Water (from tap, including filtered)	500
2	12:30	Lunch	Multiseed wholemeal bread	74
2	12:30	Lunch	Peanut butter, smooth	45
2	12:30	Lunch	Banana	126
2	12:30	Lunch	Fruit yoghurt, virtually fat free, with artificial	200
2	12:30	Lunch	Diet Coca-Cola, e.g. Coke Zero, Pepsi Max	260
3	15:20	Afternoon snack or drink	Rice pudding, low fat, ready to eat, not canned	180
3	15:20	Afternoon snack or drink	Treacle	8
3	15:20	Afternoon snack or drink	Orange squash, no added sugar, diluted	489
4	18.15	Evening meal	Pasta shapes, white/tricolore	180
4	18.15	Evening meal	Tomato-based pasta sauce, with mushrooms	75
4	18.15	Evening meal	Parmesan cheese	8
4	18.15	Evening meal	Minced beef, fried	116
4	18.15	Evening meal	Onions	26
4	18.15	Evening meal	Garlic	3
4	18.15	Evening meal	Mushrooms	50
4	18.15	Evening meal	Orange squash, no added sugar, diluted	531
4	18.15	Evening meal	Decaf coffee, instant	329
5	8.45	Late snack	Decaf tea	310
5	8.45	Late snack	Semi skimmed milk	34

Appendix 2: Amendment history

Amendment #	Protocol version	Date issued	Author(s) of change	Details of changes made

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date: ...../...../.....

.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date: 24/11/2021

Name: (please print): Dr Linda Oude Griep