ADAPT: Acceptability of online dietary assessment of irritable bowel syndrome (IBS) patients in clinical practice

Submission date	Recruitment status	[X] Prospectively registered		
07/12/2021	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/01/2022	Completed	Results		
Last Edited	Condition category	[] Individual participant data		
04/08/2025	Digestive System	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

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 clinical time, dietary and disease complexities, and the rising incidence and thus clinical pressure. This research project aims to evaluate the feasibility, acceptability and effectiveness of using a web-based 24-hr dietary recall system (Intake24) for personalised dietary advice versus usual dietetic clinical care of IBS patients.

Who can participate?

Newly admitted patients (male and female) 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 will be invited to participate.

What does the study involve?

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. Participants will be followed up for 6 months and will be invited to complete online questionnaires on outcome measures including IBS symptom severity and relief, quality of life, satisfaction and acceptability of dietary assessment method, and quality of dietetic care.

What are the possible benefits and risks of taking part?

For participants in the Intake24 arm, they will receive tailored dietary feedback from their Intake24 dietary assessment. We do not foresee any adverse events over and above those associated with everyday life and routine health care that could be attributable to the intervention. During the study, participants will be asked to complete the 24hr Dietary recall and study questionnaires multiple times, this could be seen as an inconvenience/burden to the participants.

Where is the study run from? Cambridge Epidemiology Trials Unit based at the MRC Epidemiology Unit, University of Cambridge (UK)

When is the study starting and how long is it expected to run for? December 2021 to July 2024

Who is funding the study?
NIHR Cambridge Biomedical Research Centre (UK)

Who is the main contact?

Dr Linda Oude Griep - Chief Investigator linda.oudegriep@mrc-epid.cam.ac.uk

Study website

https://www.mrc-epid.cam.ac.uk/research/studies/ibs-study/

Contact information

Type(s)

Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

305797

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 305797, CPMS 51905

Study information

Scientific 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

Acronym

ADAPT

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/03/2022, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)2071048096; cambsandherts. rec@hra.nhs.uk), ref: 22/EE/0038

Study design

Parallel randomized controlled intervention study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Irritable bowel syndrome (IBS)

Interventions

A sample between 80 and 100 patients diagnosed with IBS will be randomly allocated (1:1) to web-based 24-hour 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-hour 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 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 in the study will be invited to complete web-based 24-hour dietary recalls prior to initial dietetic consultation and at the end of the study (6 months).

Intervention Type

Behavioural

Primary outcome measure

IBS adequate relief and symptom severity score measured by IBS symptoms questionnaire at baseline, monthly, within 2 weeks pre-dietetic appointment, discharge and end of study time points.

Secondary outcome measures

- 1. Adherence to dietetic advice measured by IBS symptoms questionnaire at baseline, monthly, within 2 weeks pre-dietetic appointment, discharge and end of study time points.
- 2. Quality of dietetic practice measured by Satisfaction, acceptability and Quality of Care questionnaire at the discharge timepoint. Also measured using information from CUH electronic medical notes at at baseline, monthly, within 2 weeks pre-dietetic appointment, discharge and end of study time points.
- 3. Response rates and acceptability of dietary assessment methods measured by Satisfaction, acceptability and Quality of Care questionnaire at the discharge timepoint.
- 4. Quality of life (IBS specific) measured by IBS Quality of Life questionnaire at baseline, discharge and end of study timepoints.
- 5. Dietetic consultation time (for one-to-one consultations only) measured using information from CUH electronic medical notes at at baseline, monthly, within 2 weeks pre-dietetic appointment, discharge and end of study time points.
- 6. Frequency of follow-up dietetic consultations (for one-to-one consultations only) measured using information from CUH electronic medical notes at at baseline, monthly, within 2 weeks predietetic appointment, discharge and end of study time points.

Overall study start date

07/12/2021

Completion date

31/07/2024

Eligibility

Key inclusion criteria

- 1. Newly admitted patients older than 18 years
- 2. Meet the ROME IV criteria for IBS diagnosis according to the National Institute for Health and Care Excellence (NICE) guidelines

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80 - 100

Total final enrolment

20

Key exclusion criteria

- 1. Younger than 18 years
- 2. Co-existing gastrointestinal disease (e.g. inflammatory bowel disease, celiac disease) or eating disorder
- 3. No availability or access to a computer, tablet, or internet
- 4. Insufficient English language proficiency
- 5. Unable to give informed consent

Date of first enrolment

01/06/2022

Date of final enrolment

31/12/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Intestinal Failure and Gastroenterology Clinic, Addenbrookes Hospital

Department of Nutrition & Dietetics

Box 119

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus

Hills Road

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

Sponsor details

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Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital Box 277 (level 4 S block)
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CB2 0QQ
+44 (0)1223 349810
research@addenbrookes.nhs.uk

Sponsor type

Hospital/treatment centre

Website

https://www.cuh.nhs.uk/our-services/addenbrookes-clinical-research-centre/

ROR

https://ror.org/04v54gj93

Organisation

University of Cambridge

Sponsor details

School of Clinical Medicine, Box 111
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+44 (0)1223 769291
research_governance@medschl.cam.ac.uk

Sponsor type

University/education

Website

https://researchgovernance.medschl.cam.ac.uk/

ROR

https://ror.org/013meh722

Funder(s)

Funder type

Government

Funder Name

NIHR Cambridge Biomedical Research Centre

Alternative Name(s)

Cambridge Biomedical Research Centre, NIHR Cambridge BRC, National Institute for Health Research Cambridge Biomedical Research Centre

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed high-impact scientific journals.

Intention to publish date

30/12/2024

Individual participant data (IPD) sharing plan

Data requests should be made to Dr Linda Oude Griep at linda.oudegriep@mrc-epid.cam.ac.uk. Data would be fully anonymised and only shared with bona fide researchers attached to an academic/research institution. Participants will have given consent for their data to be shared anonymously with other researchers.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol file	version 4	19/07/2023	29/07/2025	No	No