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Information Sheet for Research Participants

Full title: A randomised controlled trial to evaluate the feasibility of web-based dietary assessment for improved personalised dietary advice in the routine clinical dietetic practice of irritable bowel syndrome (IBS) and inflammatory bowel disease (IBD) patients.

Short title: Acceptability of online Dietary Assessment in clinical Practice Trial (ADAPT)

You are being invited to take part in a research study which will look at the feasibility of using a web-based 24-hr dietary recall system (Intake24) compared to dietitian-led dietary history interviews (usual care) for improved personalised dietary advice in IBS and IBD patients. Before you decide if you would like to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read carefully through this information sheet and discuss it with your family, friends, GP, or others if you wish.

Part 1 informs you about the purpose of the study and what happens if you take part. Part 2 gives you more detailed information about the conduct of the study. Please take your time to decide whether or not you wish to take part.

You can contact us if you have questions or if you would like more information. Please email us at adapt.study@mrc-epid.cam.ac.uk. We will then contact you to answer your questions.

Part 1

What is this study about?
This study will investigate the feasibility of using a web-based 24-hr dietary recall system (Intake24) compared to dietitian-led dietary history interviews (usual care) for improved personalised dietary advice to IBS/IBD patients. This will be tested by assigning newly admitted IBS/IBD patients to dietary assessment by web-based 24-hr dietary recalls or dietitian-led dietary interviews. All patients enrolled in the study will be followed up for 6 months to evaluate if the dietary assessment method influences relief of IBS/IBD symptoms and quality of life.

Why do we think this is important?
Globally, the prevalence of IBS is 11.2% whilst it has been estimated to occur in 10 to 20% of the UK population, especially in those aged over 50 years old. IBS is a life-long disorder which can have a significant impact on the person's quality of life. It can also put pressure on healthcare delivery due to increased use of health care and related costs of consultations. If we find that the use of Intake24 is a feasible way to improve dietetic clinical care, this will ease the pressure on healthcare delivery and could help the health and wellbeing of people across the UK and worldwide.

Who is eligible to be part of the study?
We are looking for men and women over the age of 18 years who have been newly referred to the IBS/IBD clinic at Addenbrookes Hospital. The dietitians at the clinic may have contacted you to tell you about the study and informed you that you would be eligible to take part.

You will be able to volunteer if you meet the below criteria:

- Men and women over the age of 18
- Have been diagnosed with Irritable Bowel Syndrome (IBS) or inflammatory Bowel Disease (IBD).
- Have been newly referred to the IBS/IBD clinic at Addenbrookes hospital.

You will <u>NOT</u> be able to volunteer if you:

- have an eating disorder,
- do not have availability or access to a computer, tablet, or internet,
- have insufficient English language proficiency
- are participating in another intervention study at the same time
- are unwilling to sign informed consent

If you are in doubt about whether or not you are suitable to volunteer, please do not hesitate to contact the researchers at adapt.study@mrc-epid.cam.ac.uk

Do I have to take part?
An expression of interest does not commit you to participate. It is up to you to decide whether or not to volunteer. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you choose not to take part in the study, or withdraw from the study at any time, this will not affect your usual healthcare.

What do I have to do if I decide to take part in the ADAPT study?
If you choose to take part you will be asked to sign a web-based informed consent form and provide your contact details. You will then be randomly allocated to one of two groups (1) web-based 24-hr dietary recalls (Intake24) or (2) dietitian-led interviews (routine dietetic care). Patients in both groups will be followed up for 6 months.

Patients allocated to the Intake24 method will be invited by email to complete at least 2 online 24-hr dietary recalls (writing down everything you have eaten in the past 24 hours) within 2 weeks before their next dietetic appointment. Patients will be provided with a link which allows them to directly access the dietary recall system via a computer or tablet. A 5-minute video on how to complete Intake24 is available on the welcoming screen. Upon completion of each pre-consultation dietary recall, patients will receive online dietary results. These results will also be sent to your dietitian for review if your next appointment is a one-to-one dietetic consultation.

Patients allocated to routine dietetic care (control group) will receive a dietitian-led diet history interview during the one-to-one dietetic consultations, which is the usual dietetic care pathway for IBS/IBD clinic patients.

As part of the usual dietetic care, all patients referred to the IBS/IBD clinic will receive an initial one-to-one consultation with a dietician to decide on the treatment plan. Depending on your treatment plan, the dieticians may see you in further one-to-one consultations or in group sessions run by the IBS/IBD clinic.

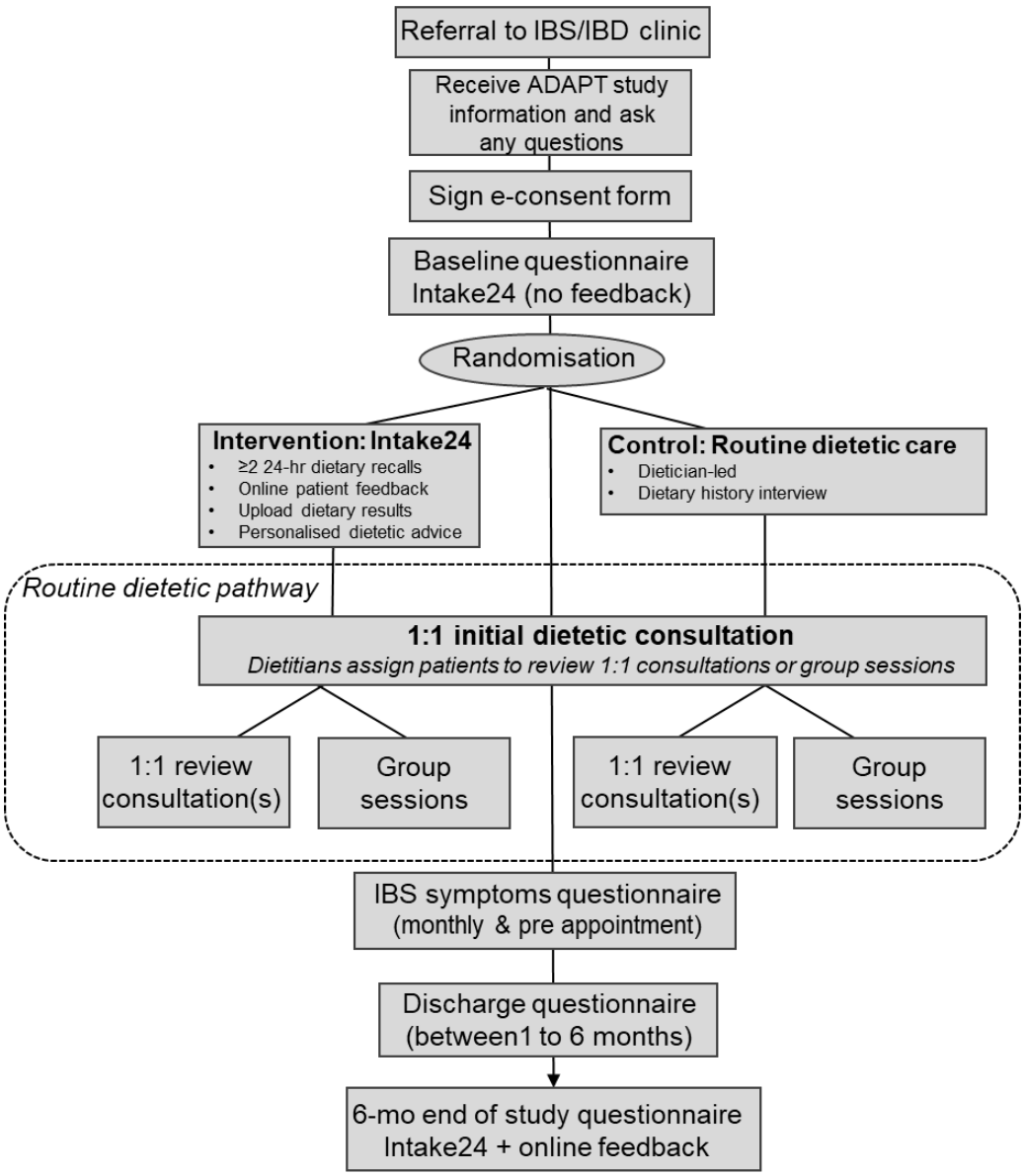
All patients enrolled in the study will be invited to complete Intake24 at least twice, once at the start (baseline) and then at end of the study (6 month follow up). All enrolled patients will also be invited to complete monthly online questionnaires.
See the study pathway below (diagram 1 below, page 4) for further explanation of the two groups.

What will be measured?
We will measure your dietary (food) intake using Intake24. We will invite you to complete online questionnaires to assess your symptoms (monthly), quality of life (3x), physical activity (3x), and your opinion of the healthcare provided upon discharge. Clinical information essential for research purposes (e.g. IBS/IBD diagnosis, dietetic advice, medication use) will be collected from your Cambridge University Hospital electronic medical notes.

The quality of life questionnaire includes some sensitive questions relating to your mental well-being. It is well-known that feelings of low mood and depression may influence symptoms and your dietitian may therefore discuss this with you as part of their routine dietetic care. If you have a higher score on questions that may indicate

potential low mood and depression, we will inform your dietitian to discuss this with you during the consultation.

Diagram 1: Patient study pathway



What are the possible disadvantages and risks of taking part?
There are no risks to taking part, but you will be asked to give your time to complete online dietary assessments and questionnaires.

Will I get paid for participating?
No, unfortunately we are not able to reimburse you for your time.

What happens when the research study stops?
Once the study has finished, the results of the study will be made available to you. We will send you a summary sheet with the results explained.

What if there is a problem?
Please contact the research team immediately if you experience any problems at any time. We will address all your complaints including if you feel unsatisfied with how you have been dealt with during the study or if you experience any possible harm. The detailed information on this is given in Part 2.

Will my details be confidential?
Yes, any personal information will be handled strictly confidential. We follow a strict ethical and legal practice that is detailed in Part 2.

Who is conducting the study?
This study is organised by scientists at the University of Cambridge. The study will be conducted with study Coordination staff at the Cambridge Epidemiology & Clinical Trials Unit of the MRC Epidemiology Unit. The Principal Investigator is Dr. Linda Oude Griep. This project is funded by the NIHR Cambridge Biomedical Research Centre. The study is jointly sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge.

Has the study been ethically approved?
The ADAPT study has been approved by the East of England - Cambridgeshire and Hertfordshire Research Ethics Committee, and NHS body.

This completes part 1.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time and you do not need to give a reason. We will anonymise identifiable data so that it will be retained for analyses unless you state otherwise.

What will happen if I lose the capacity to carry on with the study?
If you lose capacity that makes it very difficult for you to carry on with the study, we will withdraw you from the study. We will anonymise identifiable data and so that it will be retained for analyses unless you state otherwise.

What can I do if I have any complaints or concerns?
If you wish to complain or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the Chief Investigator (Dr. Linda Oude Griep via adapt.study@mrc-epid.cam.ac.uk.

Alternatively you can contact your local Patient and Advice Liaison Service (PALS):

Telephone: 01223 216756
Email: pals@addenbrookes.nhs.uk

Will my taking part in this study be kept confidential?
Yes, all information that is collected about you during the research will be treated as strictly confidential. Information we collect during the study will be kept strictly confidential**.** With your permission, information we collect will be stored anonymously at the MRC Epidemiology Unit, University of Cambridge. You will be assigned a unique code when you first take part in ADAPT. This code will be used to label all data collected during the study and is used in place of personal information. People will use this information to do the research or to check your records to make sure that the research is being done properly.

Personal identifiable information, such as the contact details we use to keep in touch with you, will be kept separate from any other data we collect. The database containing personal information is on a secured network drive on computers in the MRC Epidemiology Unit, University of Cambridge.

We will need to use information from your medical records for this research project. Information collected from your medical notes will only be accessed by an approved member of the research team, and they will only look at specific information relevant to this study. Information will be de-personalised before it is transferred from your medical notes to a secure research data system at the MRC Epidemiology Unit.

Cambridge University Hospitals NHS Foundation Trust (CUHNFT) and University of Cambridge are joint sponsors for this study based in the United Kingdom.

CUHNFT and the University of Cambridge will be using information from you in order to undertake this study and will act as joint data controllers. This means that both organisations are responsible for looking after your information and using it properly. CUHNFT and the University of Cambridge will keep identifiable information about you for 5 years after the study has finished and it will then be destroyed.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at:

- https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data/
- https://www.hra.nhs.uk/information-about-patients/
- Or by asking one of the research team by email: adapt.study@mrc-epid.cam.ac.uk

For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information,
or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

What will happen to the results of this study?
The results are likely to be published six months following the study. Your confidentiality will be ensured at all times and you will not be identified in any publication. At the end of the study, the results of the study can be made available to you and/or your GP should you wish.

Contacts for further information
Please contact the study team if you have any questions or would like to know more about the study via adapt.study@mrc-epid.cam.ac.uk

Thank you very much for taking the time to read this information