Participant Information Sheet

IRAS ID: 361358

Study Title: Predicting Bowel Preparation Quality Before Colonoscopy: A Prospective Observational Study

Invitation:
University College London Hospitals NHS Foundation Trust (the Sponsor of the study) would like to invite you to take part in a research study as you have been booked for a colonoscopy. Before you decide we would like you to understand why the study is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish.

Part 1 - *What is involved in the Research Study?*
Tells you the purpose of this study and what will happen to you if you take part.

Part 2 – *Supporting Information*
Gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part. We appreciate it may not answer all of your questions, so please do not hesitate to contact a member of the study team via bowelprepstudy@ucl.ac.uk if you would like to discuss any aspect of the study further.

Important things you need to know
This is a study in patients who are booked for a colonoscopy. The aim is to improve how we check if someone's bowel is clean enough before a colonoscopy. We are investigating whether stool (poo) photos and other information can help us check if your bowel is ready for a colonoscopy.

There are no direct benefits to you by taking part, but the information we get from this study may help improve our understanding of how we assess the effectiveness of bowel preparation. There are no physical risks, but some people may find taking photos of stool (poo) unpleasant.

The study will mostly be conducted at University College London Hospital. You will be asked to take photos of your stool (poo) and answer questions about your medical history. We may also collect information from your medical records and from your colonoscopy video recording. The study will not require any extra hospital visits or procedures.

You do not have to take part in this study and you are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive.

Part 1 - What is involved in the Research Study?

1. What is the purpose of the Study?

The aim of this study is to improve how we check whether someone's bowel is clean enough before a colonoscopy. If the bowel is not cleaned out properly, the colonoscopy may not be accurate and sometimes it has to be done again. We are investigating if stool (poo) photos and other information can help us check if your bowel is ready for a colonoscopy.

2. Why have I been invited?

You are being invited because you are booked for a colonoscopy. We are inviting up to 1000 people to take part in the study.

3. Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form, you will be given a copy of the consent form and participant information materials to take away with you. You are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive.

4. What will happen to me if I decide to take part?

If you agree to participate in this study, the following will happen:

- You will be asked to provide consent (this may be done electronically).
- You will be asked to take photographs of your stool (poo) using your smartphone.
- You will be asked to answer questions about your medical history and bowel habits at the start of the study.
- We will collect information from your medical records, for example, details related to your colonoscopy or medical condition.
- The colonoscopy camera used for your procedure may also record a video of the inside of your bowel to allow researchers to assess the quality of bowel preparation.
- There will be no change to your medical care, and no extra hospital visits or procedures are required.
- Your colonoscopy will proceed as planned.
- We will also inform your GP that you are taking part in this research study, unless you tell us not to.

Study Duration

Your participation starts when you consent to the study and continues until the results of your colonoscopy are recorded. The study activities, like taking photos and answering questions, typically happen over 1 to 2 days, on the day before and the day of your colonoscopy.

5. What will I have to do?

As a participant, you will be asked to do the following:

- **Take photographs of your stool (poo):** We will ask you to take photographs of your stool (poo) using your smartphone. This includes:
    - A few photos of your 'normal' stool before you start your bowel preparation.
    - A photo every time you open your bowels after you start the bowel preparation .
- **Guidelines for taking photos:**
    - Take the photo after you open your bowels, but before wiping.
    - Make sure the stool is clearly visible and in the centre of the photo.
    - Use good lighting so the stool is well lit and not in shadow.
    - Keep the toilet rim just in view - do not zoom in or out too much.
    - Do not include toilet paper or any other materials in the photo.
- You will be given simple instructions and support to help you take the photos safely and hygienically.

- **Answer questions:** You will be asked to answer a short two-part questionnaire. Part 1 asks about your medical history and lifestyle and is completed after joining the study. Part 2 asks about your experience with the bowel preparation and is completed at the hospital just before your colonoscopy.
- **Maintain your routine:** You should follow the standard instructions given by your clinical team for your colonoscopy preparation.

6. What are the possible disadvantages and risks of taking part?

There are no physical risks. Some people may find taking photos of stool (poo) unpleasant. All participation is optional and you may stop at any time.

7. What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from this study will help improve our understanding of how we assess the effectiveness of bowel preparation. This could lead to better outcomes for future patients undergoing colonoscopy.

8. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet – Supporting Information. If you have any concerns or complaints you should contact the research team in the first instance.

9. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2 – Supporting Information.

10. Contact Details

Chief Investigator: Prof Laurence Lovat
Research Team Contact: bowelprepstudy@ucl.ac.uk
This completes Part 1 of the Information Sheet. 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 - Supporting Information

1. What will happen if I don't want to carry on with the study?

As mentioned, your participation in the study is entirely voluntary and you can withdraw from the study at any time without giving a reason. You can do this by emailing bowelprepstudy@ucl.ac.uk or telling the research team but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data that we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. This data will be stored securely in UCL's REDCap system within the UCL Data Safe Haven.

2. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (email: bowelprepstudy@ucl.ac.uk). If you remain unhappy and wish to complain formally, you can do raise your concern with UCLH Patient Advice and Liaison Service (PALS) via phone (0203 447 3042) or email (uclh.pals@nhs.net).

However, if you remain unhappy or have a complaint about any aspect of this study and wish to speak to someone independent of the research team/hospital, please email the UCL OR UCLH Joint Research Office on: research-incidents@UCL.ac.uk

Every care will be taken in the course of this research study to ensure your safety. However in the unlikely event that you are injured in the course of the study, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (University College London Hospitals NHS Foundation Trust) negligence then you may be able to claim compensation. After discussing with research team, please make the claim in writing to Prof Laurence Lovat who is the Chief Investigator for the study and is based at care of UCLH, Joint Research Office, 4th Floor, 250 Euston

Road, London NW1 2PG. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. If you have a claim then it might be helpful to consult a lawyer.

3. How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your:

- Initials
- NHS / Hospital number
- Name
- Contact details
- Month and Year of Birth

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

UCLH is responsible for looking after you information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:

- The implementation of policies and procedures that tell our staff and students how to collect and use your information safely;
- Training our staff and students to ensure they understand the importance of data protection and how to protect your data;
- The implementation of security standards and technical measures that ensure your information is stored safely and securely;
- All research projects involving personal data are scrutinised and approved by a research ethics committee

4. International transfers

Your data will not be shared outside the UK. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 20 years. The study data will then be fully anonymized and securely archived or destroyed.

5. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have

- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

6. Where can you find out more about how your information is used?

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

- at www.hra.nhs.uk/information-about-patients/
- on our website UCL OR UCLH General Privacy Notice for Participants and Researchers in Health and Care Research Studies

  UCL Privacy Statement:

  https://www.ucl.ac.uk/joint-research-office/about-us/data-protection-statement

  UCLH Privacy Statement:

  https://www.uclh.nhs.uk/research/research-and-data/protecting-patient-data-research-security-storage-and-consent
- by asking one of the research team
- by sending an email to bowelprepstudy@ucl.ac.uk
- by sending an email to the sponsor's data protection officer at UCLH.IGQueries@nhs.net

Further information can also be found at; http://www.hra.nhs.uk/patientdataandresearch (if you are unable to access the internet and/or would prefer a paper copy, please ask us and we can provide a print out).

7. Will my GP be informed of my involvement?

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study.

8. What will happen to any samples I give?

This study does not involve the collection of any new tissue, blood, or other biological samples. Instead, we are collecting digital samples in the form of stool photographs and colonoscopy videos, which will be securely stored.

9. What will happen to the results of the study?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. In addition, summary results will be available at ISRCTN. The data will be anonymous and none of the patients involved in the study will be

identified in any report or publication. Should you wish to see the results, or the publication, please ask your research team.

10. Who is organising and funding the research?

The study is funded by internal UCL resources and sponsored by University College London Hospitals NHS Foundation Trust (UCLH).

11. How have patients and the public been involved in this study?

Patients and members of the public have been involved in the preliminary stages of this research to ensure that the study is acceptable, relevant, and designed with their perspectives in mind. Input was gained through informal discussions and an online survey completed by 10 individuals, most of whom were undergoing or had previously undergone colonoscopy, while some had never had one. Feedback focused on the clarity of the information provided to participants, the acceptability of capturing and submitting stool images using a mobile device and views on electronic consent.

12. Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee and the Health Research Authority, to protect your interests. This study has been reviewed and given favourable opinion by _____Research Ethics Committee *and Health Research Authority approval.*

13. Further information and contact details

You are encouraged to ask any questions you wish, before, during or after the study. If you have any questions about the study, please speak to the research team, who will be able to provide you with up to date information about the procedures involved. If you wish to read the research on which this study is based, please ask your research team. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Chief Investigator: Prof Laurence Lovat
Research Team Contact: bowelprepstudy@ucl.ac.uk

If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep. A copy of the signed consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

CONSENT FORM

Study Title: Predicting Bowel Preparation Quality Before Colonoscopy: A Prospective Observational Study

IRAS Number: 361358

Participant Identification Number:

Name of Researcher:

Please initial each box to indicate your agreement:

1. I confirm that I have read and understand the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the sponsor of the study (University College London Hospital) and responsible persons authorised by the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to my GP being informed of my participation in the study	
5. I agree to provide photographs of my stool during bowel preparation and to submit these electronically via the study platform.	
6. I understand that my colonoscopy may be video recorded to assess bowel preparation and that the recording will be secured stored and used for research.	
7. I understand that my data will be stored securely and handled in accordance with data protection laws.	
8. I understand that if I choose to withdraw, any data already de-identified may still be used for analysis and publication.	

9. I understand that my coded data may be used in publications and shared with other research organisations/institutions, or commercial entities, for the purposes of future research.	
10. I agree to take part in the above study.	

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature
Name of Witness (if applicable)	Date	Signature

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept in medical notes.