

Patient Information Sheet (PIS)

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

Chief Investigator: Prof Laurence Lovat

Sponsor: University College London Hospitals (UCLH)

Version: 1.0, 13AUG2025

1. Introduction

You are being invited to take part in a research study. Before you decide whether to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and talk to others if you wish. Ask us if there is anything that is not clear or if you would like more information.

2. 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 looking at whether we can use photos of stool (poo) and other details, like answers to health questions, to help work out whether someone's bowel is ready for the colonoscopy.

3. Why have I been invited?

You are being invited because you are booked for a colonoscopy at University College London Hospital, or you have a condition where photos of your stool (poo) may help us understand your health. We are inviting up to 1000 people to take part in the study.

4. Do I have to take part?

No. Participation is entirely voluntary. If you decide not to take part, it will not affect your care in any way. If you decide to take part, you can withdraw at any time without giving a reason. Any data collected before withdrawal may still be used unless you request otherwise.

5. What will happen if I take part?

If you agree to participate:

- 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 may 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 (if relevant), or medical condition.

The colonoscopy camera used for your procedure will also record a video of the inside of your bowel. This will allow researchers to assess the quality of bowel preparation. These recordings will be securely stored and only accessed by authorised members of the research team.

There will be no change to your medical care. No extra hospital visits or procedures are required. If you are booked for a colonoscopy, it 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.

6. Stool Photo Guidelines

We will ask you to take photographs of your stool (poo).

- If you are taking bowel preparation for a colonoscopy, after starting the bowel preparation, take a photo every time you open your bowels

When taking a photo:

- 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.

7. What are the possible risks and benefits 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.

There is no direct benefit to you. However, the information you give us may help improve bowel-related assessments for future patients.

8. How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your MRN (medical record number) and name. 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 your information. We will share your information related to this research project with the following types of organisations:

- regulatory authorities if required for monitoring and inspection
- approved research team members involved in the analysing the study data

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

- storing your data in secure systems such as UCL's Data Safe Haven and REDCap
- replacing your name and personal details with a unique code
- restricting access to your identifiable information to authorised study staff only

Your data will not be shared outside the UK.

9. How will we use information about you after the study ends?

We will keep your study data for a maximum of 5 years. The study data will then be fully anonymised and securely archived or destroyed.

10. 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 access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. 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.

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.

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

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

- our leaflet www.hra.nhs.uk/patientdataandresearch
- asking one of the research team, or
- by sending an email to bowelprepstudy@ucl.ac.uk.

12. Who is organising and funding the research?

This study is being led by Prof Laurence Lovat. It is sponsored by UCLH and supported by internal UCL resources.

13. Who has reviewed the study?

This study has been reviewed and approved by an NHS Research Ethics Committee and the Health Research Authority.

14. What if something goes wrong?

If you have a concern about any aspect of this study, please speak to the research team first. Contact details are at the end of this sheet. If you remain unhappy, you can raise your concern with UCLH Patient Advice and Liaison Service (PALS). via phone (0203 447 3042) or email (uclh.pals@nhs.net).

Study contact details: bowelprepstudy@ucl.ac.uk