ISRCTN14826060 https://doi.org/10.1186/ISRCTN14826060

Predicting bowel preparation quality before colonoscopy

Submission date 01/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/10/2025	**Overall study status** Ongoing	
Last Edited 04/12/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Bowel preparation before a colonoscopy is very important to make sure the procedure is successful. If the bowel is not cleaned out properly, the colonoscopy may not be accurate and sometimes it has to be done again. The study is looking at whether photos of stool (poo) and other details, like answers to health questions, can help work out whether someone's bowel is ready for the colonoscopy.

Who can participate?
Adults aged 18 or over who are scheduled for a routine (elective) colonoscopy at University College London Hospitals (UCLH) will be invited to take part.

What does the study involve?
If a person agrees to participate:

They will be asked to provide consent (this may be done electronically).
They will be asked to take photographs of their stool (poo) using their smartphone.
They may be asked to answer questions about their medical history and bowel habits at the start of the study.
Information will be collected from their medical records, for example details related to their colonoscopy (if relevant), or medical condition.
If the participant is having a colonoscopy, the procedure may be video recorded to 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 the participant's medical care. No extra hospital visits or procedures are required. If a colonoscopy is booked, it will proceed as planned. The participant's GP will also be informed that they are taking part in this research study, unless they request otherwise.

What are the possible benefits and risks of participating?
There are no physical risks. Some people may find taking photos of stool (poo) unpleasant. All

participation is optional and participants may stop at any time. There is no direct benefit to the individual. However, the information provided may help improve bowel-related assessments for future patients.

Where is the study run from?
The study is based at University College London Hospitals NHS Foundation Trust (UCLH) (UK)

When is the study starting and how long is it expected to run for?
The study is expected to begin in December 2025 and run for up to 24 months.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Julian Gertner
Principal Researcher
bowelprepstudy@ucl.ac.uk

Contact information

Type(s)
Public, Scientific

Contact name
Dr Julian Gertner

ORCID ID
https://orcid.org/0009-0001-2880-7928

Contact details
Charles Bell House
43-45 Foley Street
London
United Kingdom
WC1E 6BT
+44 2076799060
j.gertner@ucl.ac.uk

Type(s)
Principal investigator

Contact name
Prof Laurence Lovat

Contact details
Charles Bell House
43-45 Foley Street
London
United Kingdom

WC1E 6BT
+44 2076799060
l.lovat@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
361358

ClinicalTrials.gov (NCT)
Nil known

Study information

Scientific Title
Predicting bowel preparation quality before colonoscopy: a prospective observational study

Study objectives
Aim: To collect longitudinal multimodal data from participants prior to colonoscopy, including medical history, stool images, and smart device data, and to use this dataset to develop machine learning models for predicting the adequacy of bowel preparation and other key outcomes.

Primary Objective
1. To develop a machine learning model for predicting the quality of bowel preparation prior to colonoscopy using multimodal participant data

Secondary Objectives
1. To develop a machine learning model for predicting human-derived BBPS scores prior to colonoscopy using multimodal participant data
2. To develop a machine learning model for predicting procedure duration prior to colonoscopy using multimodal participant data
3. To develop a machine learning model for predicting procedure rescheduling prior to colonoscopy using multimodal participant data
4. To assess the feasibility of collecting multimodal data, including stool images, from participants prior to colonoscopy, and in other clinical contexts where stool image analysis may support disease state assessment

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Study design
Prospective observational cohort study

Primary study design

Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Bowel preparation quality

Interventions
Type of Study
This is a prospective exploratory observational cohort study aimed at collecting multimodal data from patients scheduled for colonoscopy, in order to develop machine learning models for predicting bowel preparation quality and other procedure-related outcomes.

Study Population and Groups
Participants will be adults (aged ≥18 years) scheduled for elective colonoscopy at participating clinical sites. Participants will be identified through referral and scheduling pathways. Eligible participants will receive a patient information sheet and offered the chance to enrol in the study.

Planned Number of Participants and Sample Size Justification
This exploratory study aims to develop a predictive model, and therefore no formal sample size calculation has been performed. At UCLH, approximately 6,000 colonoscopies are performed annually, and we anticipate the potential to enrol up to 1,000 participants over a 22-month recruitment period. Given the study's exploratory nature, the precise sample size required for model development is not yet known. Larger studies will be needed to evaluate the performance of the model once developed.

Sampling Technique and Rationale
Convenience sampling will be used, recruiting consecutive eligible participants from scheduled colonoscopy lists at UCLH. This approach allows practical feasibility and accessibility of data collection. It ensures efficient data capture without disrupting clinical workflows, while providing sufficient variability in bowel preparation quality and participant characteristics.

Participants in other relevant clinical contexts may also be recruited using convenience sampling, where suitable opportunities arise. These may include outpatient gastroenterology clinics or inpatient hospital wards.

Data to be Collected and How
Data will include: Demographics (age, sex, ethnicity), medical and surgical history, medication history, previous colonoscopy reports and BBPS scores, smart device metrics, self-reported bowel preparation regimen adherence, self-captured images of stool during bowel preparation using the participant's smartphone, colonoscopy details including BBPS scores, total procedure time, need for repeat procedures.

All observational data will be collected via electronic case report forms (eCRFs). Participants will receive guidance on capturing stool images using their smartphones and uploading the photos to a secure research server.

Electronic Data Capture
The study will use either REDcap hosted within the UCL Data Safe Haven, or a combination of

UCLH's secure electronic health records for identifiable data and standard UCL REDCap for pseudoanonymised data capture and storage. Stool images will be timestamped and stored with participant IDs.

Study Site
The is a single site study and will be conducted at UCLH.

Setting Appropriateness
UCLH is an appropriate setting for recruiting participants and collecting data related to their colonoscopy, given its high volume of colonoscopy procedures and integrated gastroenterology services. Clinical sites within UCLH, such as outpatient clinics and inpatient wards, also offer suitable settings for data collection in other relevant clinical contexts.

Site-Specific Requirements
None.

Enrolment and Follow-up Duration
Participant involvement will begin at the point of informed consent. Data collection will typically occur over 1-2 days, on the day before and/or the day of their colonoscopy. The total study duration is estimated to be 24 months.

Remote Consent
The study will incorporate electronic informed consent using REDCap and/or UCLH's secure electronic healthcare records system, to allow remote enrolment if in-person contact is restricted (e.g. due to pandemic lockdowns).

Intervention Type
Other

Primary outcome(s)
The adequacy of bowel preparation observed at colonoscopy, as assessed by the Boston Bowel Preparation Scale (BBPS)

Key secondary outcome(s))
1. BBPS scores predicted using machine learning models and compared to clinician-assigned BBPS scores obtained from colonoscopy
2. Colonoscopy procedure duration predicted using machine learning models and compared to observed colonoscopy procedure time
3. Colonoscopy rescheduling due to inadequate bowel preparation predicted using machine learning models and compared to rescheduling data captured in electronic health records following the colonoscopy
4. Feasibility of data collection assessed by the proportion of participants who successfully submit stool images and metadata using smartphones during the 1–2 days prior to colonoscopy

Completion date
30/11/2027

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Able to give informed consent
3. Access to a smartphone and willing to capture and upload stool images
4. Scheduled for an outpatient or inpatient colonoscopy at UCLH

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Failure to provide informed consent
2. Unwilling or unable to use a smartphone for stool image capture and upload
3. Aged under 18 years

Date of first enrolment
01/02/2026

Date of final enrolment
01/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London

England
NW1 2PG

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon requested from Dr Julian Gertner, j.gertner@ucl.ac.uk.

The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing and disclosure of personal information, and will uphold the Act's core principles.

Data to be Collected and How
Data will include: Demographics (age, sex, ethnicity), medical and surgical history, medication history, previous colonoscopy reports and BBPS scores, smart device metrics, self-reported bowel preparation regimen adherence, self-captured images of stool during bowel preparation using the participant's smartphone, colonoscopy details including BBPS scores, total procedure time, need for repeat procedures.

Colonoscopy procedures will be video recorded to allow for blinded review and assignment of BBPS scores by trained reviewers.

All observational data will be collected via electronic case report forms (eCRFs). Participants will receive guidance on capturing stool images using their smartphones and uploading the photos to a secure research server.

Electronic Data Capture
The study will use either REDcap hosted within the UCL Data Safe Haven, or a combination of UCLH's secure electronic health records for identifiable data and standard UCL REDCap for pseudoanonymised data capture and storage. Stool images will be timestamped and stored with participant IDs.

In the study, data will be collected from patients in accordance with the patient consent form and participant information sheet.

The data controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. All study data will be analysed by internal study personnel.

UCL will process, store and dispose of all study data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 2018 and any amendments thereto. Any paper CRFs will be stored centrally at UCL at in a locked filing cabinet controlled by the Chief Investigator.

Direct access to the data will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit study-related monitoring, audits and inspections, in line with participant consent.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	13/08/2025	18/08/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 0.1	13/08/2025	18/08/2025	No	No