Full/long title of study	Predicting Bowel Preparation Quality Before Colonoscopy: A Prospective Observational Study
Short title	Predicting bowel prep quality
Version and date of protocol	Version 0.1 13/08/2025
Sponsor:	University College London Hospitals NHS Foundation Trust (UCLH)
Sponsor reference number:	[Insert EDGE ID number]
Funder (s):	None
IRAS Number:	361358
ISRCTN no.	[Insert ISRCTN reference no]
UCL Data Protection Number:	Z6364106/2025/08/28

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Sponsor Representative:

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London
NW1 2PG

PROTOCOL VERSION HISTORY

Version Stage	Versions Number	Version Date	Protocol updated & finalised by;	Reasons for Update
Current	0.1	13/08/2025	Laurence Lovat (Chief Investigator) Omer Ahmad (Co-Investigator) Julian Gertner (Principal Researcher) Sharon Cheung (Senior Clinical Trials Coordinator)	N/A

DECLARATIONS

The undersigned confirm that the following protocol has been agreed and accepted and that the investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the U.K. Policy Framework for Health and Social Care Research 2017 (3rd edition) (as amended thereafter), the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018), Sponsor SOPs and applicable Trust policies and legal frameworks.

I (investigator) agree to ensure that the confidential information contained in this document will not be used for any other purposes other than the evaluation or conduct of the research investigation without the prior written consent of the Sponsor.

I (investigator) agree to ensure that no research activity or recruitment will commence at participating research sites until the appropriate regulatory approvals and NHS confirmations of Capacity and Capability have been issued, and Sponsor green light confirmed.

I (investigator) also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any deviations from the study as planned in this protocol will be explained and reported accordingly.

Chief Investigator:

Signature: ……  **…… Date: 13/08/2025**

Print Name (in full): ……. Prof Laurence Lovat**……**

Position: .. Professor of Gastroenterology and Biophotonics.....

On behalf of the Study Sponsor:

Signature: …… Date...../...../.....

Print Name (in full): ……

Position: ……

STUDY SUMMARY

IDENTIFIERS	
IRAS Number	361358
REC Reference No.	TBC
Sponsor Reference No.	TBC
Other research reference number(s) (if applicable)	UCL Data Protection Number: Z6364106/2025/08/28
Full (Scientific) title	Predicting Bowel Preparation Quality Before Colonoscopy: A Prospective Observational Study
Health condition(s) or problem(s) studied	Bowel preparation quality
Study Type i.e. Cohort etc.	A prospective observational cohort study
Target sample size	1,000
STUDY TIMELINES	
Study Duration/length	24 months
Expected Start Date	1st December 2025
End of Study definition and anticipated date	The date the last enrolled participant completes their first colonoscopy following enrolment. Anticipated end date 30th November 2027
Key Study milestones	**Month 0:** Pilot phase recruitment begins **Month 2:** Full recruitment begins **Month 22:** Recruitment completed **Month 24:** Last participant colonoscopy completed (**End of study**) **Month 20+:** Data cleaning and preparation (begins before end of study) **Month 24+:** Data analysis and model development (continues after end of study)
FUNDING & OTHER	
Funding	Investigator led, unfunded.
Other support	n/a
STORAGE of SAMPLES / DATA (if applicable)	
Human tissue samples	n/a

Data collected / Storage	Any personal data collected as part of the qualitative evaluation will be stored in a data safe haven, a technical solution for storing, handling and analysing identifiable data. The UCL Data Safe Haven has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit.
KEY STUDY CONTACTS	
Chief Investigator	Prof Laurence Lovat, Professor of Gastroenterology and Biophotonics, UCL Hawkes Institute, Dept. of Targeted Intervention, Division of Surgery and Interventional Science, University College London, l.lovat@ucl.ac.uk
Study Coordinator	Sharon Cheung, sharon.cheung@ucl.ac.uk
Sponsor	University College London Hospitals NHS Foundation Trust 250 Euston Road London NW1 2PG
Funder(s)	None
Committees	This is an exploratory study. No committees will be involved.
Sub-contractors	None
Other relevant study personnel	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

KEY ROLES AND RESPONSIBILITIES

SPONSOR: The sponsor is responsible for ensuring before a study begins that arrangements are in place for the research team to access resources and support to deliver the research as proposed and allocate responsibilities for the management, monitoring and reporting of the research. The Sponsor also must be satisfied there is agreement on appropriate arrangements to record, report and review significant developments as the research proceeds, and approve any modifications to the design.

FUNDER: The funder is the entity that will provide the funds (financial support) for the conduction of the study. Funders are expected to provide assistance to any enquiry, audit or investigation related to the funded work.

CHIEF INVESTIGATOR (CI): The person who takes overall responsibility for the design, conduct and reporting of a study. If the study involves researchers at more than once site, the CI takes on the primary responsibility whether he/she is an investigator at any particular site.

The CI role is to complete and to ensure that all relevant regulatory approvals and confirmations of NHS Capacity and Capability are in place before the study begins. Ensure arrangements are in place

for good study conduct, robust monitoring and reporting, including prompt reporting of incidents, this includes putting in place adequate training for study staff to conduct the study as per the protocol and relevant standards.

The Chief Investigator is responsible for submission of annual reports as required. The Chief Investigator will notify the REC and JRO of the end of the study (including the reasons for premature termination, where applicable). Within one year after the end of study, the Chief Investigator will submit a final report with the results, including any publications/abstracts to the REC and JRO.

PRINCIPLE INVESTIGATOR (PI): Individually or as leader of the researchers at a site; ensuring that the study is conducted as per the approved study protocol, and report/notify the relevant parties – this includes the CI of any breaches or incidents related to the study.

KEY WORDS

Bowel preparation, colonoscopy, machine learning, artificial intelligence, stool analysis, predictive modelling

LIST OF ABBREVIATIONS

AI	Artificial Intelligence
AUC	Area Under Curve
BBPS	Boston Bowel Preparation Scale
BSS	Bristol Stool Scale
CI	Chief Investigator
CNN	Convolutional Neural Network
CRC	Colorectal Cancer
CRF	Case Report Forms
GDPR	General Data Protection Regulation
HRA	Health Research Authority
IRAS	Integrated Research Application System
NHS	National Health Service
PIS	Participant Information Sheet
PI	Principal Investigator
PPI	Patient and Public Involvement
REDCap	Research Electronic Data Capture
REC	Research Ethics Committee
ROC	Receiver Operator Curve
SOP	Standard Operating Procedure
UCL	University College London
UCLH	University College London Hospitals
GDPR	General Data Protection Regulation

CONTENTS

1 INTRODUCTION

Problem

Colorectal cancer is a leading cause of cancer-related deaths in the UK and worldwide[1]. Colonoscopy is an effective screening tool allowing for early diagnosis and prevention of colon cancer[2]. However, the effectiveness of colonoscopy is limited by inadequate bowel preparation, which reduces its diagnostic sensitivity, increases procedure time and leads to cancellations and repeating of procedures[3]. This leads to patient distress and an increased burden on healthcare resources and costs. In addition, "suboptimal" bowel preparation, where adequacy is only achieved after prolonged intraprocedural cleansing, further contributes to delays and reduced service efficiency.

Main study purpose

The ability to assess participants' stool can help assess and improve bowel preparation for colonoscopy. This study will aim to develop a tool to predict participants' bowel preparation quality in real time following initiation of bowel preparation.

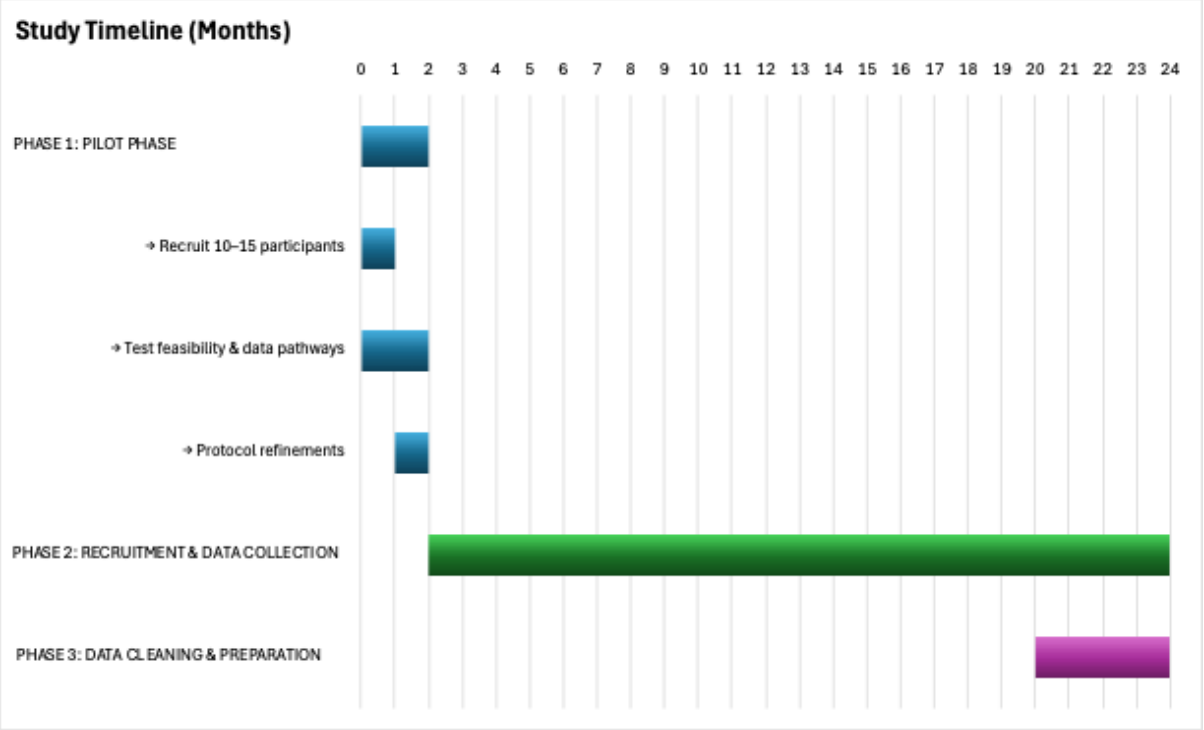
How the study will be conducted

Participants will be initially recruited from University College London Hospital (UCLH). Consent to the study will be obtained. Metadata will be collected including medical history, previous colonoscopy and bowel preparation outcomes. Participant data will be collected which may include medical histories, questionnaire responses, images of participant stool, colonoscopy video recordings and smart device data.

Potential benefits

Predicting the quality of bowel preparation in real time could allow for rescheduling of colonoscopies. After predicting a poor-quality bowel preparation, there is potential for intervention to improve the bowel preparation prior to colonoscopy. This could improve clinical outcomes following colonoscopy as well patient satisfaction and endoscopy unit efficiency.

Study Timeline



2 BACKGROUND AND RATIONALE

Colorectal cancer (CRC) is the second most common cause of cancer deaths both in the UK and globally[1]. CRC can be prevented by removing precancerous lesions at colonoscopy; screening with colonoscopy is effective at reducing CRC mortality[2]. However, inadequate bowel preparation negatively impacts on colonoscopy by reducing the diagnostic sensitivity[3], increasing the duration of the procedure and need for repeat procedures[4], and increasing costs[5]. Current strategies recommended to improve bowel preparation include: a preceding low fibre diet, providing enhanced instructions and split-dose bowel preparation[6]. Targets for the proportion of colonoscopies having adequate bowel preparation are more than 85%[7]. Despite this, up to 35% of colonoscopies have inadequate bowel preparation highlighting the need for improvement[8–10].

In addition to the well-recognised issue of "inadequate" bowel preparation, there is an unmeasured but important problem of "suboptimal" bowel preparation. In these cases, bowel preparation may be scored as "adequate" but only after significant time and effort spent cleansing the bowel during the colonoscopy. This intraprocedural washing and suctioning prolongs procedures and reduces the

efficiency of endoscopy lists. One study found that "fair" preparations required an average of 8.72 minutes of intraprocedural cleansing, over three times longer than "excellent" preparations, highlighting the added burden[11]. Although rated as "adequate", these "suboptimal" cases also contribute to delays, increased strain on resources and reduced operational efficiency.

The quality of bowel preparation can be assessed at colonoscopy by the endoscopist using the Boston Bowel Preparation Scale (BBPS). This rating scale demonstrates good interrater reliability and has been thoroughly validated [12]. Multiple AI (artificial intelligence) systems have already been developed and tested to assess adequacy of bowel preparation by analysing images[13,14] or videos[15–18] at, or after, colonoscopy. However, there is a paucity of research into assessment and improvement of bowel preparation pre-colonoscopy.

Importantly, the BBPS does not capture the burden of “suboptimal” bowel preparation, where adequacy is only achieved after prolonged intraprocedural cleansing. Moreover, the effectiveness of cleansing during colonoscopy is limited where MacPhail et al[11] found that only 6% of initially “fair” or “poor” preparations were successfully converted to “adequate” during the procedure. This underscores the need for improved pre-procedural assessment and timely intervention to achieve high quality bowel preparation and reduce the burden of suboptimal preparation.

Prior research:

Patient-reported assessments of rectal effluent have been shown to correlate poorly with endoscopist-rated bowel preparation quality. Fatima et al[19] found that patients reporting brown liquid or solid effluent had a 54% likelihood of fair or poor bowel preparation, suggesting that visual features of stool may have predictive value if evaluated using standardised methods.

Pre-colonoscopy bowel preparation assessment using AI was tested by Lu et al[20]. This prospective multicentre colonoscopist-blinded randomised study was carried out on 1434 patients. A convolutional neural network (CNN) was trained with colonoscopy images from a single centre. Patients were randomised into the control group or the AI-CNN experimental group. After taking bowel preparation, patients uploaded photographs of rectal effluent. The photographs were self-assessed in the control group or assessed by the AI-CNN in the experimental group with a ‘pass’ or ‘not pass’ result. Colonoscopies were performed and given a ‘pass’ assessment for bowel prep if the total BBPS score was ≥ 6. The AI-CNN model performed as well as the control group showing pre-

colonoscopy bowel preparation assessment using AI can be achieved. Limitations included excluding patients over the age of 60 and those with known polyps. In addition, the AI-CNN model was trained using images labelled with 'pass' or 'not pass' by a single experienced nurse rather than a validated scoring scale.

Zhu et al[21] used an AI-supported smartphone application demonstrating proof of concept for both assessment and improvement of bowel preparation pre-colonoscopy. This prospective colonoscopist-blinded randomised study on 578 patients used a CNN to identify images of inadequate bowel preparation with an accuracy of 95.15% and an area under the curve (AUC) of 0.98. An AI-assisted smartphone app was used in the experimental group pre-colonoscopy to deliver personalised improvement suggestions when the bowel preparation was assessed as inadequate by the CNN based on photographs of rectal effluent. Colonoscopies were carried out and bowel preparation was defined as adequate if the total BBPS score was ≥ 6 and all individual segment scores were ≥ 2. The AI-assisted app group demonstrated significantly higher rates of adequate bowel preparation compared to the control group (88.5 vs 65.6%, $p < 0.001$).

A limitation of this study is the unusually poor rate of adequate bowel preparation in the control group. Most importantly, as well as the AI-driven smartphone app giving personalised improvement suggestions when assessing patients' bowel preparation as inadequate, it had two further functions. It gave bowel preparation schedules based on booked colonoscopy times and it gave re-enforced education irrespective of its assessment of the patients' bowel prep. The study does not demonstrate if the better rate of adequate bowel preparation was due to general use of the app or specifically due to the personalised improvement suggestions triggered by an inadequate bowel preparation assessment by the CNN.

Ramprasad et al[22] developed an AI-based image classification model to assess bowel preparation adequacy from images of stool output submitted via text. Among the 576 patients who responded to phone call or text message reminders, 84.7% indicated they would text a photo of their stool output and 72.1% of those actually submitted a photo. This suggests patients are generally willing to engage with this type of technology and approach, highlighting its potential applicability in clinical practice.

This will be the first study to collect multimodal longitudinal data, including information about patient perception of stool form and frequency, stool images and patient metadata, from participants undergoing colonoscopy. This research could help patients by improving assessment of

bowel preparation prior to colonoscopy allowing for interventions or rescheduling. This could reduce inconvenience and clinical risks to patients by reducing the need for repeated colonoscopies. It could also reduce costs and improve efficiency of endoscopy units and therefore the wider NHS.

3 AIM(S) AND OBJECTIVES

Aim: To collect longitudinal multimodal data from participants prior to colonoscopy, including medical history, stool images, patient questionnaires 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.

3.1 Primary Objective

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

3.2 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

4 STUDY DESIGN & METHODS OF DATA COLLECTION

Type of Study

This is a prospective exploratory observational cohort study aimed at collecting multimodal data from participants 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 participant 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 and 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).

5 STUDY SCHEDULE

Enrolment Process

Participants will be screened via scheduling lists or endoscopy referral pathways and approached during pre-assessment phone calls or clinic visits. Eligible individuals will be given a participant information sheet and complete electronic informed consent. Participants may also be identified and approached through outpatient clinics, inpatient wards or other relevant clinical services.

Pilot Phase

A pilot study phase will be conducted prior to full recruitment to test study procedures with a small group of participants. This phase will assess the clarity and usability of the stool image instructions and submission process, the feasibility of image submission using participants' smartphones, and the efficiency of the recruitment and consent processes. Data quality, logistics, and feedback from participants and study staff will be continuously evaluated. The pilot phase will last approximately 8 weeks, with iterative adjustments made to procedures and processes as necessary before full recruitment.

Follow-Up

Follow-up will consist of data collection up to the day of the procedure, along with final data extraction from procedural records and electronic health records post-colonoscopy. Additional follow-up may occur if repeat procedures take place within the study timeframe.

Withdrawal Criteria and Data Management

Participants may withdraw at any point during the study. On withdrawal, no further data will be collected. Participants can opt to have all previously collected data deleted unless it has already been de-identified and used in model training, in which case it will be excluded from new analyses only. Withdrawal will be documented in the study database.

End of Study Definition

The end of the study is defined as the date on which the last enrolled participant completes their first colonoscopy following enrolment. Data analysis and reporting will continue after this date.

6 ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

Participants need to meet all the following 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

6.2 Exclusion Criteria

Participants will be excluded if they meet any of the following 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

7 RECRUITMENT

Recruitment will occur over a 22-month period or until the target sample size is reached.

Method for Identifying and Recruiting Participants

Participants will be identified by endoscopy staff performing pre-assessment clinics, reviewing colonoscopy scheduling lists, or healthcare staff working in outpatient clinics or inpatient wards. A PIS will be provided to participants in-person, via post, or electronically. Participants will then be approached by a member of the research team to complete informed consent either in person or via telephone call. No Patient Identification Centres (PICs) will be used.

Resources

Study posters and flyers may be displayed in the endoscopy unit and other appropriate clinical settings. All study data will be stored securely as per the electronic data capture plan described in Section 4.

Screening Documentation

A screening log will be maintained to document reasons for ineligibility, eligible participants who decline participation, and reasons for withdrawal when provided.

Intended payments

No payments will be made to any study participant.

8 CONSENT

Written Material and Participant Discussion

Informed consent will be obtained prior to participants undertaking any study-specific instructions. Participants will be given sufficient time to consider their involvement. Participants will be provided

with a PIS either in person or electronically ideally at least 24 hours in advance of consent. However, in some cases, participants may be offered consent on the same day as referral, for example due to unpredictable colonoscopy scheduling or other time-sensitive clinical circumstances. This is particularly relevant in inpatients where a decision to perform a colonoscopy may be made at short notice. This is a particularly important group to study as these patients tend to have poor bowel preparation. Where possible, inpatients will be approached by a member of the study team on the ward and given the PIS. A second visit by the study team member will be scheduled and the participant will confirm whether they have had adequate time to consider whether they wish to take part. The PIS will detail the study's purpose, procedures, potential benefits and risks, and data use. A member of the research team will discuss the PIS with the participant and encourage them to ask questions. Participants will be informed that they have no obligation to enrol in the study and that they can withdraw at any time, without needing to provide a reason and without affecting their clinical care.

Capacity and Vulnerable Participants

Consent will be obtained from willing participants who have capacity as demonstrated by understanding the purpose, nature, risks and benefits of the research. They need to be able to retain and weigh the information before making an informed choice, and communicate their decision. When consenting vulnerable participants, additional care will be taken to emphasise the voluntary nature of participation in the study in order to protect their interests.

Provisions For Specific Populations

Translated versions of study documents and interpretation services will be available to support participants who may require language support.

Electronic Consent

Following input from PPI (Patient and Public Involvement), we may use electronic informed consent (eConsent) to support flexible participation. REDCAP, UCL's Research Data Collection Service may be used for eConsent and data collection, either for collection of all source data, or as an alternative to paper methods. Refer here for further information: https://www.ucl.ac.uk/isd/it-for-slms/redcap-research-data-collection-service. Patient identifiable data will be stored in the UCL Safe Haven.

Document Storage and Updates

A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained in the Investigator Site File and a copy placed in the medical notes. The PIS and consent form may be reviewed and updated if necessary, throughout the study and participants will be re-consented as appropriate.

9 DATA ANALYSIS

Reason for Choice of Study Design and Statistical Analysis Plan

This prospective observational cohort design allows for collection and analysis of stool images, metadata, and colonoscopy outcomes. This approach enables prediction of bowel preparation quality and/or other outcomes.

The statistical analysis will be structured in two stages:

1. Descriptive statistics – to summarise the study population and explore correlations between metadata, stool image submission and colonoscopy outcomes including quality of bowel preparation
2. Predictive modelling – to develop and evaluate a machine learning tool that can predict bowel preparation adequacy and/or other outcomes using stool image data and metadata

Summary of Baseline Data

Baseline data may include demographics (age, sex, ethnicity), medical and surgical history, medication history, previous colonoscopy reports and BBPS scores, smart device metrics, bowel preparation regimen and self-reported adherence, number of uploaded images of stool during bowel preparation, colonoscopy details including BBPS scores, total procedure time, intraprocedural cleansing time and need for repeat procedures.

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

Descriptive statistics will be used to summarise the information (means, standard deviations, medians, interquartile ranges, counts, proportions). Group comparisons (e.g. adequate vs inadequate bowel preparation) will be performed using appropriate statistical tests based on data type and distribution (e.g. t-tests, chi-square tests, Mann-Whitney U tests).

Other Statistical Considerations

To assess the performance of the predictive models, data will be split into training, validation, and test sets. Performance will be evaluated using standard classification metrics (e.g. accuracy, sensitivity, specificity, F1 score, AUC-ROC). Model interpretability will be supported using appropriate techniques (e.g. feature importance analyses or SHAP) to assess the relative contribution of different metadata inputs to the final prediction.

Software

Statistical analysis and modelling will be performed using widely accepted scientific software tools such as Python or R.

10 PATIENT AND PUBLIC INVOLVEMENT (PPI)

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. Potential PPI contributors were identified by clinical staff during admission to the UCLH endoscopy unit. Those who expressed interest provided their email address and were contacted with a link to an online survey. The group included individuals with different backgrounds, including variation in age, sex, ethnicity, and confidence with digital technology. 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.

Acceptability and design

PPI input has helped develop the participant information sheet and consent forms. This ensured the language is clear and accessible, the purpose of the study is easily understandable, and that the process of submitting stool images is acceptable and not overly burdensome.

Management and Undertaking

A small advisory group which may include a combination of patients, carers and family members, will be formed to meet periodically throughout the study. This group will provide continual input for participant communications and suggestions to promote engagement and adherence.

Analysis and Dissemination

Although the data analysis will be performed by the research team, PPI contributors will help suggest ways for the data to be presented to ensure they are understandable and interpretable by the public. They will also contribute to the development of lay summaries and the design of dissemination materials intended for non-specialist audiences.

11 FUNDING AND SUPPLY OF EQUIPMENT

The study funding has been reviewed by the UCLH/UCL Joint Research Office, and deemed sufficient to cover the requirements of the study. NHS costs will be supported via UCLH and/or the Local Clinical Research Network.

No dedicated research grant has been awarded for this study. The research costs for the study have will be supported using existing institutional resources within UCL/UCLH.

The study will initially be conducted at UCLH with potential for future expansion to other NHS sites subject to appropriate approvals. Any additional sites will be incorporated following acceptance of relevant amendments and in accordance with local research governance procedures.

No specialised equipment is required for the study and there are no excess treatment costs. Participants will use their own smartphones to upload stool images via REDCap. No equipment or software is being supplied by external parties.

The Chief Investigator and all study members confirm that they have no financial or personal interests in any organisation associated with the conduct or support of the study that may represent a conflict of interest.

12 DATA HANDLING AND MANAGEMENT

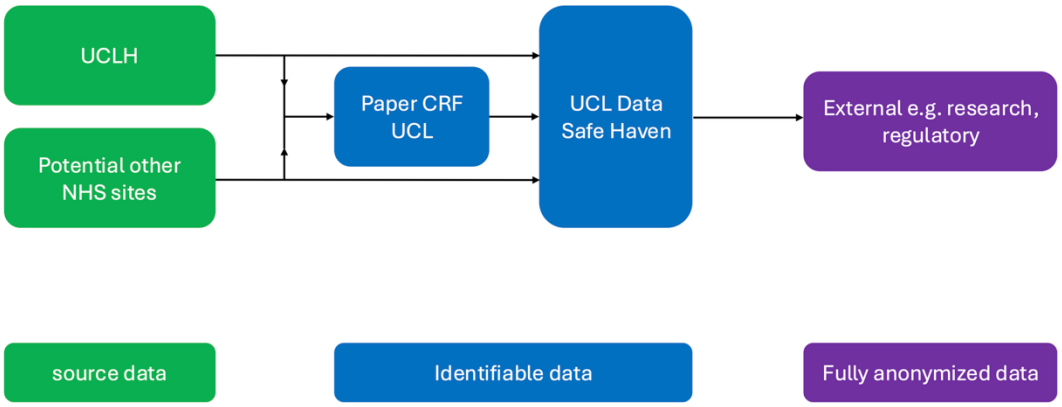
The study is compliant with the requirements of General Data Protection Regulation (2016/679) and the UK Data Protection Act (2018). All investigators and study site staff will comply with the requirements of the General Data Protection Regulation (2016/679) with regards to the collection, storage, processing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

In the study, data will be collected from participants in accordance with the participant consent form, participant information sheet and section 4 of this protocol.

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.



13 PEER AND REGULATORY REVIEW

The study has been peer reviewed in accordance with the requirements outlined by UCLH. This study has been peer reviewed within UCLH, by an independent and relevant peer reviewer on 13th August 2025. The Sponsor has accepted these reviews as adequate evidence of peer review.

The study was deemed to require regulatory approval from the following bodies: NHS REC Favourable Opinion. **Before any site can enrol participants into the study,** the Chief Investigator/Principal Investigator or designee will ensure that the appropriate regulatory approvals have been issued, and NHS Confirmations of Capacity and Capability and Sponsor green lights are in place.

For any amendments to the study, the Chief Investigator or designee, in agreement with the Sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments as well as the study delivery team) to confirm ongoing Capacity and Capability for the study.

All correspondence with the Sponsor, REC and HRA will be retained. The Chief Investigator will notify the Sponsor and REC of the end of the study.

It is the Chief Investigator's responsibility to produce the annual progress reports when required; an annual progress report (APR) will be submitted to the Sponsor and REC within 30 days of the anniversary date on which the favourable opinion was issued, and annually until the study is declared ended.

If the study is ended prematurely, the Chief Investigator will notify the Sponsor and REC, including the reasons for the premature termination.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the Sponsor and to the REC and HRA.

14 ASSESSMENT AND MANAGEMENT OF RISK

This is a low-risk observational study with no clinical interventions or biological samples involved. The minimal risks are justified by the potential benefit of developing a tool to predict bowel preparation adequacy and other outcomes, which may improve care for future patients.

<u>Potential risks</u>

Potential risks include psychological discomfort related to capturing and submitting stool images. There are general data privacy risks associated with handling sensitive health information, and minor practical risks such as the possibility of dropping a phone while capturing images.

Mitigations

These risks will be mitigated through voluntary participation with the ability to withdraw at any time, clear participant instructions, and robust data protection measures. Images and metadata will be pseudonymised and stored securely in accordance with GDPR. Participants will be advised to take care when capturing images with smartphones.

Safeguarding

Any participant disclosures suggesting risk of harm to themselves or others will be reviewed by the CI. Concerns will be escalated following UCLH safeguarding protocols and shared with appropriate clinical or safeguarding teams if necessary.

15 RECORDING AND REPORTING OF EVENTS AND INCIDENTS

The types of research-related incidents that may occur include data breaches or losses, protocol deviations, mismanagement of participant data and safeguarding disclosures by participants.

All events and incidents (and near misses) that occur to participants and/ or staff that are **unexpected** and directly **related** to the research study will be reported to the Sponsor via Trust Datix; and host sites via their Trust reporting systems, and documented in the Trial Master File/Investigator Site File via study-specific incident logs (and related correspondence). This will be completed by the CI or PI. The Sponsor will be responsible for investigating, reviewing, or escalating to a serious breach if required.

15.1 Personal Data Breaches

Personal data breaches will be immediately reported to the UCLH Information Governance team and the UCLH Data Protection Officer UCLH.IGQueries@nhs.net and to the Sponsor via

https://redcap.slms.ucl.ac.uk/surveys/?s=NE5dypTdFo or Research-incidents@ucl.ac.uk. Sites will additionally follow their Trust incident reporting mechanisms and will document this within their ISFs.

15.2 Adverse Events and Serious Adverse Events Sponsor Reporting Requirements (if applicable)

Adverse events are any untoward medical occurrence in a patient or study participant, which does not necessarily have a causal relationship with the procedure involved. These do not require reporting to the Sponsor, but the severity, causality and expectedness will be recorded in the participant's medical records, CRF and AE log with a description of clinical symptoms and the event, including dates as appropriate.

SAEs (any event that results in death, is life-threatening, requires hospitalisation or prolongation of existing inpatient hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect) that have been determined to be **unrelated** to the research intervention by the CI/PI do not require reporting to the Sponsor, but will be recorded in the participant's medical records, CRF and site file. Additionally, **expected** SAEs that are likely to occur on a regular basis and offer no further new information to the safety profile, or are related to the disease area of the participants, do not require reporting to the Sponsor, but must be recorded as previously stipulated. Sponsors will however be notified where the frequency and severity of unrelated SAEs are unusual; research sites will report as per Sponsor reporting requirements.

In some instances, **unexpected and related SAEs** may occur in observational research. In rare instances, participants may disclose information such as suicidal ideation to the research team. All reportable SAEs will be recorded in the medical records and CRF, and reported to the Sponsor via the JRO REDCAP research incident reporting form or research-incidents@ucl.ac.uk, within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the Sponsor as soon as possible.

15.3 Incidental Findings in Research

Incidental findings are highly unlikely to occur in this study. All research staff must follow participating sites' incidental findings policies, and training will be provided as part of initiation to the research study (where applicable).

15.4 Protocol deviations and notification of protocol violations

Protocol deviations are usually an unintended departure from the expected conduct of the study protocol/SOPs, which does not need to be reported to the Sponsor. The CI will monitor protocol deviations, and if found to frequently recur, will discuss in the first instance with the Sponsor to determine re-classification and reporting requirements.

A protocol violation is a breach which is likely to effect to a significant degree: –
(a) the safety or physical or mental integrity of the participants of the study; or
(b) the scientific value of the study

The CI and Sponsor will be notified immediately of any case where the above definition applies via Trust Datix and uclh.randd@nhs.net.

15.5 NHS Serious Incidents and near misses

A serious incident or near miss is any unintended or unexpected event that could have or did lead to harm, loss or damage that contains one or more of the following components:

a. It is an accident or other incident which results in injury or ill health.
b. It is contrary to specified or expected standard of patient care or service.
c. It places patients, staff members, visitors, contractors or members of the public at unnecessary risk.
d. It puts the Trust in an adverse position with potential loss of reputation.
e. It puts Trust property or assets in an adverse position or at risk.

Serious Incidents and near misses will be reported to the Sponsor and Trust Quality & Safety department as soon as the study team becomes aware of them.

15.6 Complaints from research participants

In the first instance, research participant complaints (patients or healthy volunteers) will be reported to the CI/PI to investigate, as documented in the participant information sheet(s), and to the Sponsor via research-incidents@ucl.ac.uk and the UCLH Complaints process; for participants who are NHS patients, complaints will be reported to the NHS Complaints Manager at the Trust where the recruitment and study procedures was undertaken. Complaints from NHS patients are handled under NHS complaints policies and procedures, with involvement from PALS and the Sponsor where necessary.

16 MONITORING AND AUDITING

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the Sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

17 TRAINING

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

18 INTELLECTUAL PROPERTY

All background intellectual property rights (including licences) and know-how used in connection with the study shall remain the property of the party introducing the same and the exercise of such rights for purposes of the study shall not infringe any third party's rights.

All intellectual property rights and know-how in the protocol, the study data and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used independently of the study by each participating site, shall belong to UCL. All intellectual property

rights deriving or arising from the material or any derivations of the material provided to UCL/UCLH (delete as applicable) by the participating site shall belong to UCL/UCLH (delete as applicable). Each participating site agrees that by giving approval to conduct the study at its respective site, effectively assigns all such intellectual property rights ("IPR") to UCL and discloses all such know-how to UCL.

Nothing in this section shall be construed so as to prevent or hinder the participating sites from using its own know how or clinical data gained during the performance of the study, as its own risk, in the furtherance of its normal activities or providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information of the infringement of an intellectual property rights of UCL/UCLH (delete as applicable), or their funder. This section does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the study.

19 INDEMNITY ARRANGEMENTS

UCLH will provide NHS indemnity cover for negligent harm, as appropriate and is not in the position to indemnify for non-negligent harm. NHS indemnity arrangements do not extend to non-negligent harm and NHS bodies cannot purchase commercial insurance for this purpose; it cannot give advance undertaking to pay compensation when there is no negligence attributable to their vicarious liability. The Trust will only extend NHS indemnity cover for negligent harm to its employees, both substantive and honorary, conducting research studies that have been approved by the R&D Department. The Trust cannot accept liability for any activity that has not been properly registered and Trust approved. Additionally, UCLH does not accept liability for sites such as GP surgeries in primary care; investigators/collaborators based in these types of sites must ensure that their activity on the study is covered under their own professional indemnity. Potential claims should be reported immediately to the Joint Research Office.

20 ARCHIVING

UCLH and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he/she will archive the study master file at UCL for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents in line with all relevant

legal and statutory requirements. Study documents will be archived for a minimum of 5 years from the study end, and no longer than 20 years from the study end.

The Trial Master File will be archived at UCL in accordance with the *JRO Standard Operating Procedure 10 Archiving of the UCLH Investigator Site File/Trial Master File*. It will be archived for a minimum of 5 years from the study end, and no longer than 20 years from study end.

21 PUBLICATION AND DISSEMINATION

All proposed publications will be discussed with and reviewed by the Sponsor prior to publishing other than those presented at scientific forums/meetings. Please refer to UCL Publication Policy.

22 REFERENCES

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15. Lee, J. Y. *et al.* Artificial intelligence for assessment of bowel preparation. *Gastrointest. Endosc.* (2021) doi:10.1016/j.gie.2021.11.041.
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23 APPENDICES

Please find all Participant Information Sheets, Informed Consent Forms and delegation log in separate documents.

23.1 Associated Documents

Document Name	Document Version	Document Date
Consent_Form	1	13AUG2025
Participant_Information_Sheet	1	13AUG2025
Delegation_log	1	13AUG2025
PPI_survey_results	1	22JUL2025
GP_letter	1	13AUG2025
Cover_letter	1	13AUG2025
Organisation_Information_Document	1	13AUG2025
SoE	1	13AUG2025