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Determining efficacy of dynamic multimedia bowel preparation instructions versus standard instructions on adenoma detection and patient reported measures (DIGICLEAN trial): a study protocol for a multicentre, colonoscopist-blinded, randomised controlled trial

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ABSTRACT

Introduction Colonoscopy plays important roles in bowel cancer screening and treatment. Poor bowel preparation occurs in 20–25% of colonoscopies. This negatively impacts adenoma and sessile serrated lesion detection rates, procedural time, requirement for repeat colonoscopies, healthcare costs and likelihood of patient withdrawal from screening programmes. It is unclear whether a combination of multimedia modalities can improve bowel preparation quality, adenoma detection rates and patient-reported measures in those undergoing colonoscopy assessment.

Methods The DIGICLEAN trial is a prospective, parallel, multicentre, colonoscopist-blinded, randomised controlled trial. The trial will enrol 1294 participants aged 45 years and older who are indicated for a colonoscopy as an outpatient with a positive faecal occult blood test, iron deficiency anaemia or rectal bleeding. Participants will be randomised into the interventional arm, where bowel preparation instructions are delivered via a web-based application which uses scheduled short messaging service, regular patient survey assessment, email and videos; or the control arm, where routine standard written, verbal or emailed instructions are administered. The web-based application will assess patient-reported bloating, constipation and dietary adherence leading up to the colonoscopy. Depending on patient responses, additional aperients may be encouraged digitally in the interventional arm with same instructions made available in written format for the control arm. Patient-reported measures will be collected in both arms the day after the procedure using the validated Newcastle ENDOPREM questionnaire. In some sites, participants will undergo digital pre-anaesthetic screening as well. The co-primary endpoints are the adenoma detection rates and patient-reported measures taken after the colonoscopy.

Ethics and dissemination Ethics approval for this study was obtained from the Western Sydney Local Health District Human Research Ethics Committee (2022/ETH00059). Findings will be reported at national and international gastroenterology meetings and published in peer-reviewed journals.

Trial registration number ACTRN12622000747729.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a large multicentre randomised controlled trial examining the utility of incorporating digital multimedia and patient-reported measures on adenoma detection and bowel preparation quality. This has implications in cancer detection, streamlining care pathways, enhancing patient-centred care and patient satisfaction.

⇒ First study to examine patient experience and dynamic instructional materials as a contributing factor to adherence with bowel preparation and digital pre-anaesthetic screening with its associated cost-benefits.

⇒ The study excludes participants who have non-English speaking backgrounds, with severe chronic kidney disease, or severe heart failure. These patients often have the most challenging bowel preparations. The study sample may not be generalisable to all populations.

INTRODUCTION

The Australian National Bowel Cancer Screening Program, a population-based, government-funded programme, aims to reduce bowel cancer through early detection

with immunochemical faecal occult blood tests (iFOBT). In 2019–2020, 2.54 million people returned a completed iFOBT. Of these people, 7% returned a positive result with 62% of these participants proceeding to diagnostic assessment.[1] Quality bowel preparation is vital to effective colonoscopy and in turn, bowel cancer screening. Poor bowel preparation negatively affects polyp and adenoma detection rates, increases procedure time and cost and shortens the interval between recommended repeat colonoscopies. The inconvenience of repeat colonoscopy can also decrease patient willingness to participate in early detection programmes.[2–4] The number of colonoscopies occurring per year in Australia is approaching 1 million.[5] With inadequate bowel preparation suggested to occur in 20–25% of procedures,[4 6] achieving quality bowel preparation is therefore, a clinical imperative.

The adenoma detection rate (ADR) is a clinically important measure of the quality of colonoscopy examinations.[7] ADR is defined as the proportion of screening colonoscopies that detect at least one histologically confirmed colorectal adenoma or adenocarcinoma. Current Australian guidelines suggest individual proceduralists should maintain an ADR greater than 25% across patients aged over 50 years without a diagnosis of inflammatory bowel disease.[8] Addressing poor bowel preparation can have direct benefits for ADR and therefore cancer prevention.

Some tools have been developed for accurate and standardised assessment of bowel preparation. The Boston Bowel Preparation Score (BBPS) is a validated score out of 9, which assigns a subscore of 3 to each part of the colon (ascending, transverse and descending).[9] This scoring can be performed quickly without significant delay to normal care. A BBPS aggregate score of 6 or more is considered 'adequate bowel preparation'.[10] The Australian Commission on Safety and Quality in Health Care recommends 'adequate bowel preparation' on the BBPS score as an appropriate indicator for quality bowel preparation.[7]

Various forms of multimedia have been proposed to achieve better bowel preparation quality, including visual aids, video instructions, short messaging service (SMS) and phone calls from clinicians. Two meta-analyses have demonstrated that multimedia and mobile health technologies contribute to improvements in quality of bowel preparation and, in one meta-analysis, adenoma detection.[11 12] A meta-analysis of 13 trials demonstrated the ADR was higher in participants receiving multimedia-based education compared with controls with a risk ratio of 1.25 (95% CI 1.01 to 1.56, p=0.04).[12] However, it remains unclear whether a combination of multimedia modalities has an enhanced positive affect on adenoma detection and quality bowel preparation.

Bowel preparation quality is also affected by participant engagement with the process. In one cross-sectional survey of participants planned for an outpatient colonoscopy on the day prior, patient perception of bowel preparation being annoying and self-perception of success, were significant predictors for successful preparation.[13] A patient-centred care pathway may achieve better bowel preparation quality by understanding and addressing individual concerns, satisfaction, risk factors and instigating appropriate clinical responses during the preparation course.

Various validated patient-reported measures have been developed for bowel cancer and colonoscopy, but fewer for bowel preparation.[14] A systematic review of patient-reported experience measures for colonoscopy and meta-ethnography identified five key patient experience domains that should be encapsulated in a patient-reported measures set: health motivation, discomfort, access to information, a caring clinician-patient relationship and patient understanding. These domains need to be considered temporally, occurring before the procedure, during the procedure and after the procedure.[15] A recently published validated measures set, the Newcastle ENDOPREM questionnaire, consists of 54 questions derived from semi-structured interviews which assess patient experience across five temporal procedural stages. These interviews identified six key themes assessed by the ENDOPREM questionnaire: anxiety, expectations, choice and control, communication and information, embarrassment and dignity and comfort.[16] Using digital platforms to collect patient-reported measures and incorporating them into care pathways may improve the quality of care by responding to patient concerns early in the clinical course.

Dynamic multimedia tools to achieve quality bowel preparation can also play important roles in pre-anaesthetic screening. Digital online pre-anaesthetic questionnaires have been used as routine practice at Sheffield Teaching Hospitals NHS Foundation Trust, with high patient acceptability and good prediction ofAmerican Society of Anaesthesiologists (ASA) scoring.[17 18] The recently published PreAnaesThesia Computerised Health (PATCH) assessment questionnaire, developed through iterative and panel consensus methods, demonstrated high patient acceptability, low burden and moderate to good criterion validity, by measuring the agreement between the patient responses and those obtained during nurse assessment.[19] Incorporating pre-anaesthetic assessments into care pathways can streamline and improve the quality of assessment, and promote patient-centred care.

The use of intestinal ultrasound to determine bowel preparation quality also remains a novel area warranting further study. Incorporating intestinal ultrasound to identify patients who have suboptimal bowel preparation and taking measures to address this prior to colonoscopy may help improve the quality of bowel preparation.

Three areas warrant further research which this study aims to address. First, it remains unclear whether a combination of multimedia communication technologies contributes to improved adenoma detection and quality bowel preparation. Second, there are no studies which explore patient-reported experience and outcome measures as a factor in the bowel preparation course or its use on a digital platform. Third, there are no studied

interventions where multimedia technologies have responded to unsatisfactory patient-reported experience and outcome measures during the bowel preparation course.

This study will determine whether participants who are given bowel preparation instructions through a combination of dynamic multimedia (scheduled SMS, smartphone application, video instructions and email) have better adenoma detection and patient-reported measures compared with participants who are given standard written-based instructions. The study will use ultra-low volume 1 L polyethylene glycol with ascorbic acid (PEG-ASC) as the choice of bowel preparation given its superiority in achieving adequate bowel preparation versus other large volume PEG-based regimens, and possible high patient acceptability given its low volume.[20 21] The study will also identify risk factors that predict poor bowel preparation, compare procedural and clinician time required between the two groups, identify colorectal cancer risk factors and explore the potential financial implications, including in pre-anaesthetic screening. Reporting of this protocol adhered to the Standard Protocol Items: Recommendations for Interventional Trials 2013 Statement.[22] WHO trial registration data set for this trial is presented in table 1.

METHODS AND ANALYSIS

Study design and setting

The DIGICLEAN study is a prospective, parallel, multicentre, colonoscopist-blinded, randomised control trial. The trial will enrol 1294 participants aged 45 years and older indicated for an outpatient colonoscopy with positive faecal occult blood test, iron deficiency anaemia or rectal bleeding. A parallel design will be used with participants randomised into either the interventional arm, where their bowel preparation instructions are delivered via a smartphone web-based application, or the control arm incorporating standard written, verbal or emailed instructions. The smartphone web-based application, *The Clinician*, incorporates the use of surveys, scheduled SMS, smartphone application, email and videos.

All participants will use ultra-low volume 1 L PEG-ASC (macrogol 3350, sodium ascorbate, sodium sulfate anhydrous, ASC, sodium chloride, potassium chloride; PLENVU Norgine) solution for bowel preparation over a 2-day split dose regimen. However, depending on a history of constipation, diverticular disease or bloating, participants will be stratified into groups according to their indicated bowel preparation regimen: Standard Bowel Preparation, where participants use PEG-ASC alone, or an Enhanced Bowel Preparation group, where participants will use an additional one sachet of Movicol (sodium chloride, potassium chloride, bicarbonate, macrogol 3350) and two tablets of Senokot (sennoside) every morning in the 7 days leading up to the procedure (figure 1).

In the interventional arm, participants will be assessed daily for constipation and bloating via the smartphone web-based application. If indicated by participant responses, participants will be automatically recommended additional bowel preparation comprising of two sachets of Movicol every morning in the Standard Bowel Preparation arm, or an additional one sachet in the Enhanced Bowel Preparation arm, until the colonoscopy occurs. These same additional aperients will be instructed in the control arm, but constipation and bloating will not be assessed, and aperients will not be actively encouraged if indicated. These additional aperients were selected as they are currently routinely used as additional aperients for more challenging bowel preparations. All participants will be asked to commence a low fibre diet 5 days prior to the procedure. After completion of PEG-ASC but before the colonoscopy, participants will be asked to self-report their stool colour and consistency and may be recommended a Fleet enema on arrival for their procedure if indicated.

Participants will be recruited for the study from Blacktown and Mount Druitt Hospitals, Concord Repatriation General Hospital, Campbelltown Hospital, Westmead Hospital, St George Hospital, Wollongong Hospital and Gosford Hospital. The study is anticipated to take 12–18 months to complete recruitment.

Inclusion and exclusion criteria

Inclusion criteria are participants indicated for an outpatient colonoscopy with a positive iFOBT, rectal bleeding or iron deficiency anaemia; aged 45 years or older; access to a working email address and a smartphone device that supports web browsing and *The Clinician* web-based application; and able to independently give informed consent.

Exclusion criteria are participants from non-English speaking backgrounds; current inpatients; participants whose colonoscopy date has been changed or delayed affecting the normal care sequence; participants having already received a colonoscopy within the last 5 years; participants with a previous bowel resection or stoma precluding complete assessment; glucose-6-phosphate dehydrogenase deficiency (due to the presence of ASC in PEG-ASC); New York Heart Association heart failure classes III or IV; clinical contraindications for standard bowel preparation regimens; hypersensitivity to any ingredient in PEG-ASC (PLENVU); cognitive disorder which would normally preclude from independent standard bowel preparation; diagnosis of inflammatory bowel disease; known polyps, or a diagnosis of colorectal cancer.

Recruitment strategy, allocation and randomisation

Eligible participants will be approached by the faecal occult blood tests nurse or gastroenterologist involved in triaging patients for colonoscopy. Participants will be consented for the procedure and participation in the study (online supplemental file 1). Medical history and clinical history will be obtained and stratified according to the indicated bowel preparation regimen.

Table 1 WHO trial registration data set

Data category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trials Registry ACTRN12622000747729
Date of registration in primary registry	25 May 2022
Secondary identifying numbers	No secondary identifying numbers
Source(s) of monetary or material support	Western Sydney Local Health District Research Education Network; Norgine Limited
Primary sponsor	Dr Viraj Kariyawasam
Secondary sponsor(s)	Dr Michael Au
Contact for public queries	Dr Michael Au
Contact for scientific queries	Dr Michael Au
Public title	Digitising colonoscopy care pathways and enhancing bowel preparation quality with patient-reported measures (DIGICLEAN)
Scientific title	A multicentre, colonoscopist-blinded, randomised controlled trial to determine the efficacy of dynamic multimedia bowel preparation instructions versus standard instructions as control on adenoma detection and patient-reported measures in adults aged 45 years and older indicated for a colonoscopy
Countries of recruitment	Australia
Health condition(s) or problem(s) studied	Colorectal cancer
Intervention(s)	Web-based smartphone dynamic multimedia app to facilitate bowel preparation.
Key inclusion and exclusion criteria	Inclusion 1. Indicated for colonoscopy as an outpatient with a positive faecal occult blood test, rectal bleeding or iron deficiency anaemia. 2. Aged 45 years and above. 3. Have a smartphone device which can support web browsing and use the web-based application. Exclusion 1. Non-English speaking backgrounds. 2. Inpatient at any hospital. 3. Scheduled colonoscopy date changed or delayed due to provider factors affecting the normal care sequence. 4. Colonoscopy within the last 5 years. 5. Previous bowel resection or stoma. 6. Glucose-6-phosphate dehydrogenase deficiency (due to the presence of ascorbic acid in PEG-ASC). 7. New York Heart Association heart failure classes III or IV. 8. Chronic kidney disease stages 4 and 5 (eGFR <30 mL/min/1.73 m^2). 9. Cognitive disorder which would normally preclude from independent standard bowel preparation. 10. Inflammatory bowel disease. 11. Known polyp or diagnosis of colorectal cancer.
Study type	Prospective randomised controlled trial
Date of first enrolment	Enrolment has not yet begun
Target sample size	1294
Recruitment status	Recruitment has not yet begun
Primary outcome(s)	1. Comparison of the adenoma detection rate based on histopathology assessment of biopsy samples collected at the time of colonoscopy in patients randomised to receive dynamic multimedia bowel preparation instructions versus those that receive verbal and/or written bowel preparation instructions. 2. Compare the patient-reported measures using the validated colonoscopy-specific Newcastle ENDOPREM questionnaire on the day after colonoscopy between patients randomised to receive dynamic multimedia bowel preparation instructions versus those that receive standard verbal and/or written bowel preparation instructions.
Key secondary outcomes	Comparison of the Boston Bowel Preparation Scores, caecal intubation rate, mean procedural time, cancellation and non-presentation rates in the interventional and control groups.

eGFR, estimated glomerular filtration rate; PEG-ASC, polyethylene glycol with ascorbic acid.

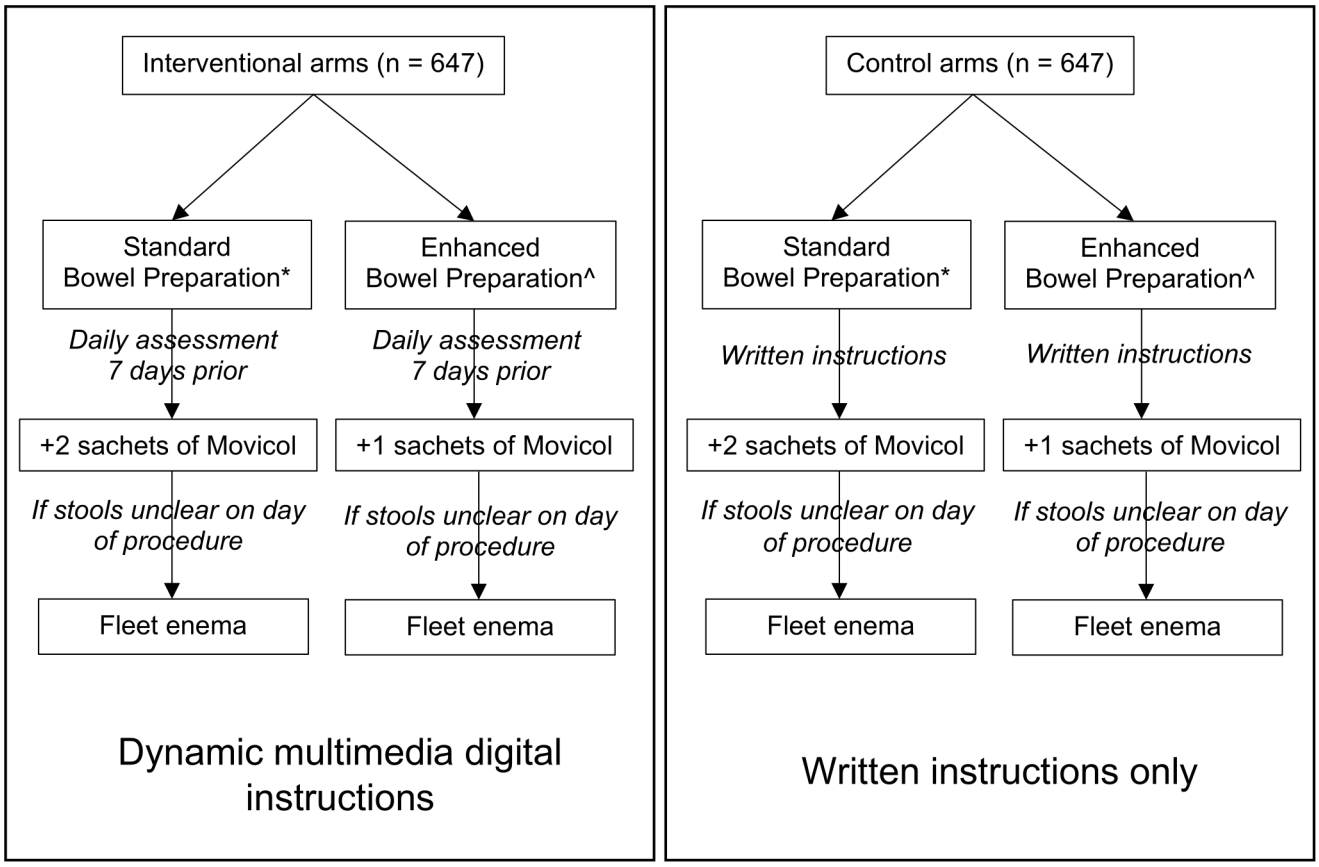

Figure 1 Study arms and stratification. *Standard Bowel Preparation consists of 1 L PEG-ASC and commencement of low fibre diet from 5 days prior ^Enhanced Bowel Preparation consists of 1 L PEG-ASC and one sachet of Movicol and two Senokot tablets in the 7 days leading up to colonoscopy and commencement of low fibre diet from 5 days prior for those with a history of constipation, diverticular disease or bloating. PEG-ASC, polyethylene glycol with ascorbic acid.

Allocation concealment will be in place to ensure individuals enrolling the subject into the study have no a priori knowledge of group assignment. Permuted block randomisation within strata will occur with randomly mixed block sizes of two and four. Randomisation sequences will be generated using a random number generator. Once allocated, participants will likely know which arm they have been assigned to, and therefore this is an open-label trial. However, the proceduralist performing the colonoscopy will be unaware of the patient's allocation. Around 100 participants will also participate in intestinal ultrasound substudy assessment of bowel preparation prior to their colonoscopy.

Endpoints

The co-primary endpoints of the trial are comparisons of the ADR and the patient-reported experience and outcome measures, measured using the Newcastle ENDOPREM questionnaire, taken after the colonoscopy between the intervention and control arms. Secondary endpoints are hierarchically considered if the former endpoints are found not to be significant. The secondary endpoints are comparison of the BBPS, mean caecal intubation rate, mean procedural time and cancellation or non-presentation rates between the interventional and control groups.

Exploratory endpoints include comparisons of the mean clinician-patient contact time leading up to colonoscopy (measured in minutes), mean time (measured in minutes) and cost of procedures (in $A), the quality of right-sided bowel preparation (measured using the BBPS), the inter-rater reliability of the BBPS by comparing the scoring of the colonoscopist versus an expert reviewing panel and intestinal ultrasound findings, and colorectal cancer risk factors. The trial will inform calculation of the number needed to treat with dynamic multimedia bowel preparation to prevent one patient from having poor bowel preparation.

Assessment will also be made between intervention and control arm responses on self-reported engagement with healthcare, questionnaire completeness, and turnaround time in pre-anaesthetic screening for participants randomised to complete a digitised pre-anaesthetic screening questionnaire versus participants completing standard paper-based pre-anaesthetic screening.

Intervention details

This study will use a web-based clinical application interface, *The Clinician* (https://theclinician.com/), as a core component of the research intervention. There are two primary components within *The Clinician* platform: the Patient App and the Provider Portal. The Patient App

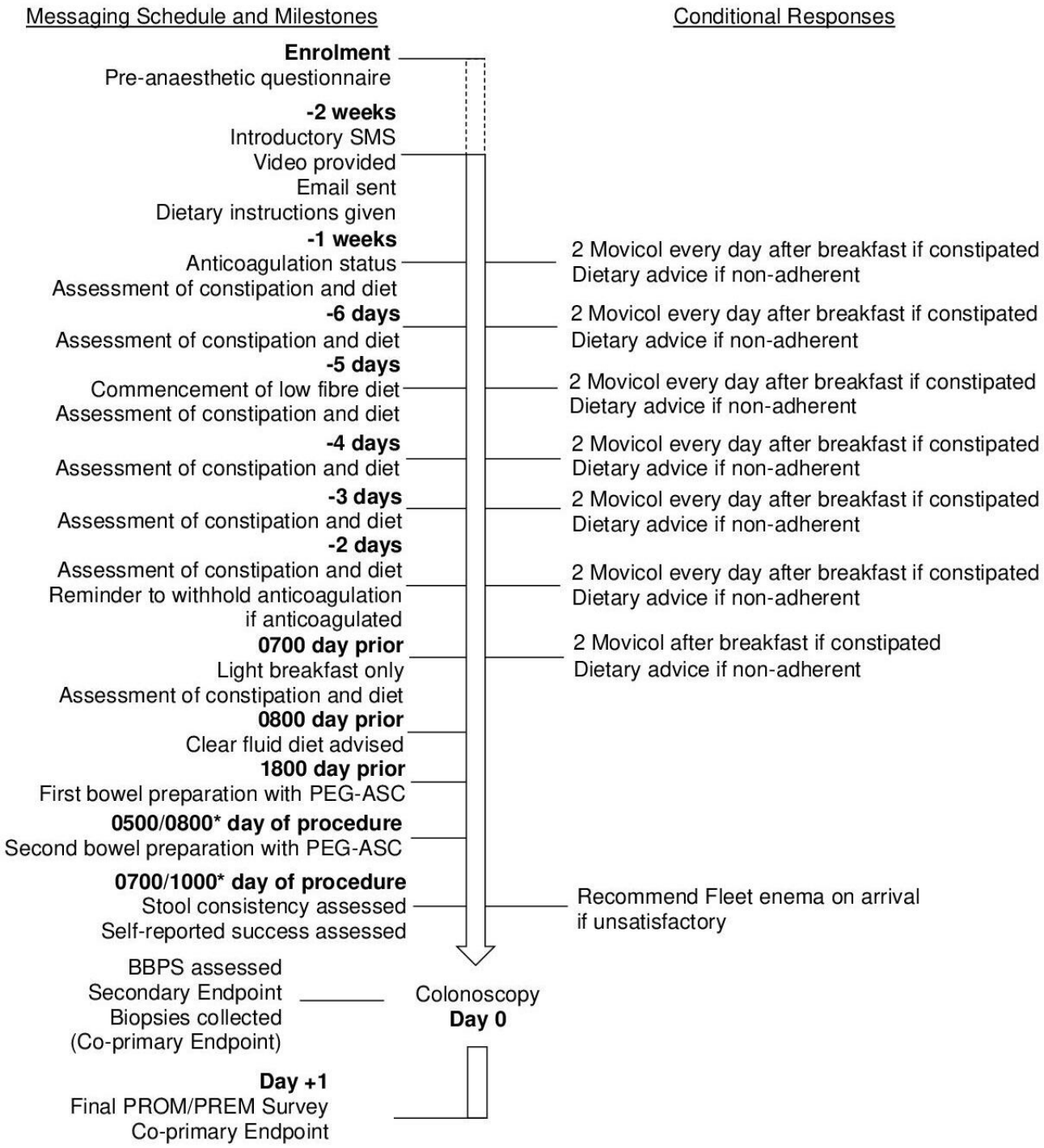

Figure 2 Care sequence in interventional Standard Bowel Preparation arm. *Timing will depend on morning list or afternoon list for colonoscopy. BBPS, Boston Bowel Preparation Score; PGC-ASC, polyethylene glycol with ascorbic acid; PREM, patient-reported experience measure; PROM, patient-reported outcome measure; SMS, short messaging service.

collects data from patients. The Provider Portal is the interface for all provider-facing interactions including scheduling of data collection and notifications, consolidation of results, analytics and patient administration. A 'care journey' will be sequenced on *The Clinician* through the Provider Portal, including scheduled SMS sent during the week leading up to the colonoscopy (figures 2 and 3). On the day prior to procedure, SMS will be sent at times when bowel preparation is indicated advising to consume the bowel preparation. Patients will also receive one to two SMS per day in the 7 days leading up to the colonoscopy reminding about appropriate bowel habits and dietary adherence. Most SMS will have a hyperlink directing participants to the Patient App, which will collect patient-reported outcome and experience measures daily. Depending on patient responses, this may trigger alert messages to alter bowel preparation. Reminder SMS will be automatically sent if questionnaires have not been

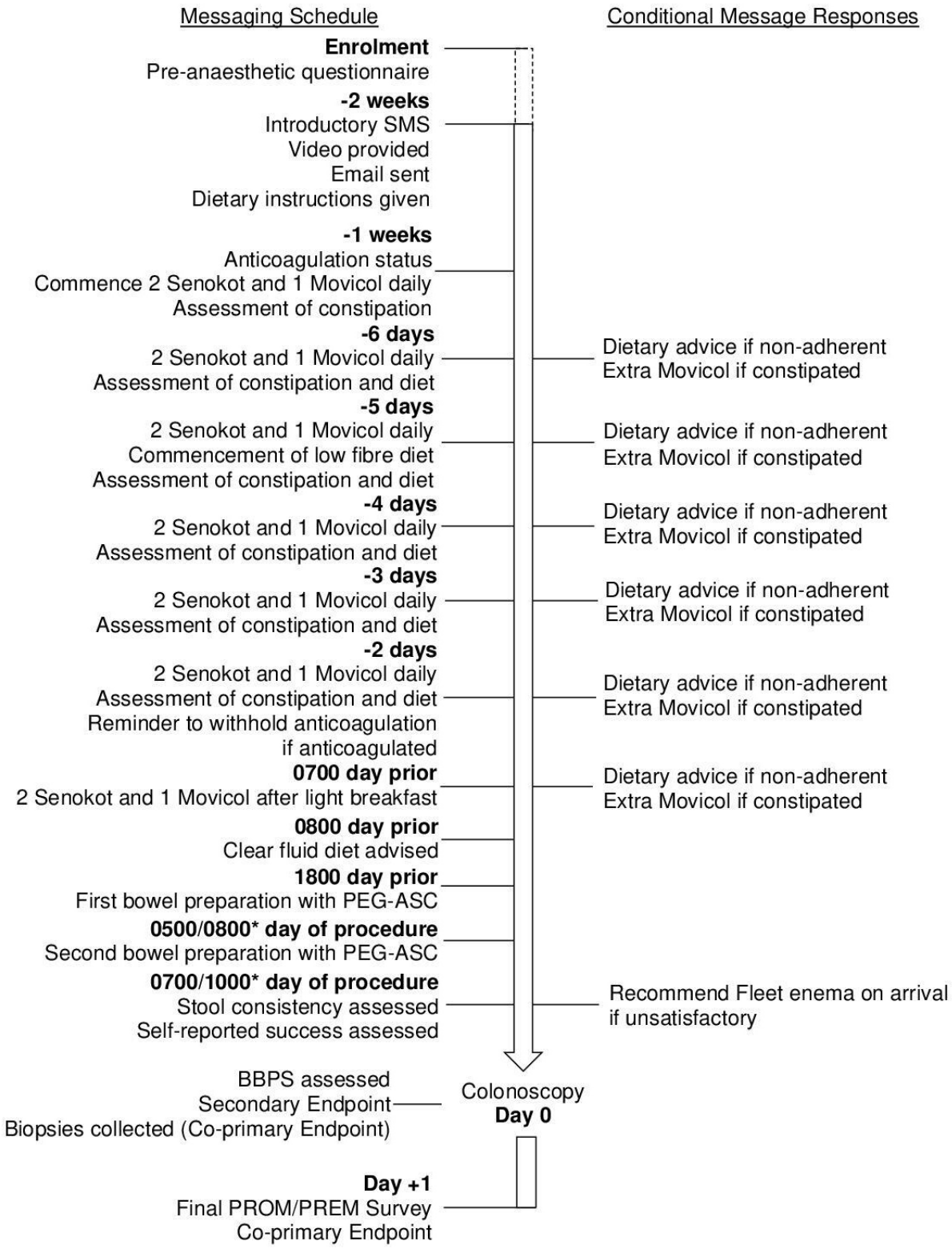

Figure 3 Care sequence in interventional Enhance Bowel Preparation arm. *Timing will depend on morning list or afternoon list for colonoscopy. BBPS, Boston Bowel Preparation Score; PGC-ASC, polyethylene glycol with ascorbic acid; PREM, patient-reported experience measure; PROM, patient-reported outcome measure; SMS, short messaging service.

Table 2 Summary of key data items

Domain	Data items
Pre-anaesthetic assessment	PATCH questionnaire ASA
Bowel preparation and colonoscopy quality	Boston Bowel Preparation Score (from proceduralist and expert panel) Caecal intubation rate Procedural time (from time of colonoscopy insertion to time of removal from anal canal) Procedural complications Procedural abandonment, cancellation, no-show Total amount of bowel preparation/aperients used Recommended interval for repeat colonoscopy Intestinal ultrasound findings
Patient-reported outcome measures	Constipation Bloating Stool consistency Stool colour Self-reported bowel preparation adherence Self-reported dietary adherence Self-reported success
Histopathology	Polyp count Histopathology findings (co-primary endpoint)
Colorectal cancer risk	Age Weight Height Medications Smoking status First degree family history of bowel cancer
Patient-reported experience measure	Newcastle ENDOPREM questionnaire (co-primary endpoint) Annoyance Involvement in care
Financial implications	Clinician-patient contact time (minutes)

ASA, American Society of Anaesthesiologists; PATCH, PreAnaesThesia Computerised Health.

completed. An instructional video on bowel preparation will also be made available via the Patient App 2 weeks prior to procedure for participants in the interventional arm. These instructional videos are also delivered via SMS and the web-based App. The videos and SMS were reviewed by eight patients undergoing routine colonoscopy in June 2022 with their recommendations incorporated into the final SMS and videos.

Data collection

Table 2 summarises the key data items collected. All data collected will be de-identified and entered in the Research Electronic Data Capture (REDCap) online database.

In the interventional arm at time of allocation, participants will complete the PATCH questionnaire, a validated digital pre-anaesthetic questionnaire in *The Clinician*.[19] Depending on responses, *The Clinician* will alert the Clinical Nurse Screener via email whether a full anaesthetic assessment is required. Conditions that would trigger a full anaesthetic review were determined by consensus from a team of anaesthetists and the Clinical Nurse Screener at Blacktown and Mt Druitt Hospital. Participants in the control group will complete the standard paper-based pre-anaesthetic questionnaire which accompanies the *Referral for Admission*.

Data on the quality of bowel preparation will be recorded by the proceduralist at the time of colonoscopy using the BBPS. Other indicators of bowel preparation quality include caecal intubation, adenoma and polyp count, procedure time, procedural abandonment and non-presentation. Histopathology report findings will be obtained from the medical record.

Each section of the colon will be photographed at the time of colonoscopy. An expert panel consisting of two to three experienced gastroenterologists will independently review these photos and assign a BBPS. The panel will be blinded to participant allocation to intervention or control arm. Disagreements among the panel will be resolved by consensus. The inter-rater reliability between the colonoscopist and the expert panel will then be assessed.

In both arms, any clinician involvement in providing care will be documented, measured in minutes. The time spent by the Clinical Nurse Screener in reviewing pre-anaesthetic questionnaires will also be assessed.

In both the interventional and control arms, patient reported experience measures will be collected via *The Clinician* using the colonoscopy-specific Newcastle ENDOPREM questionnaire. Questions on colorectal cancer risk will also be collected with the PATCH questionnaire in the interventional arm and with the ENDOPREM questionnaire in the control arm.

There is no planned data monitoring committee for this study. There are no significant critical safety concerns expected to arise from this study. Adverse events identified in this study will be collected and reported as appropriate to the ethics committee.

Statistical plan

Power calculations are based on a previous randomised controlled trial by Walter *et al*, which compared the quality of bowel preparation and ADRs with 2 L PEG-ASC, in participants undergoing colorectal cancer screening or surveillance who received a smartphone application with push notifications versus participants who received written materials that had the same contents.[23] That study indicated that the ADR among controls is 0.27. If the true ADR for experimental subjects is 0.35, the DIGICLEAN trial will need to study 524 experimental subjects and 524 control subjects to be able to reject the null hypothesis that the ADRs for experimental and control subjects are equal with power of 0.80. The Type I error probability associated with this test of this null hypothesis is 0.05. The DIGICLEAN trial will use an uncorrected χ^2 statistic to evaluate this null hypothesis. The trial anticipates a dropout rate of 10%. This requires enrolment of 1294 participants with 647 participants in each of the interventional and control arms.

All statistical calculations will be performed using R statistical programming (www.r-project.org) and RStudio to facilitate data processing. This study will take an intention-to-treat approach with all participants analysed in their respective allocated groups. No interim analyses are planned for this study.

Descriptive statistics will be used for patient characteristics. Data will be presented as mean with SD for normally distributed data, and median with IQR for data that is not normally distributed. Data will be assessed for normality and independent samples t-tests will be used if normally distributed, otherwise Mann-Whitney U test or Wilcoxon signed-rank test will be used. To compare the proportions of the ADRs between the two groups, χ^2 tests will be used. To assess the BBPS, the trial will use independent sample t-tests if normally distributed. Additionally, participants will be categorically grouped as having 'adequate' or 'inadequate' bowel preparation (defined as BBPS ≥6 as adequate) and analyse this using χ^2 test for association. The trial will calculate the number needed to treat to prevent one patient with poor bowel preparation. Procedural time durations between the two groups will be compared using independent sample t-tests if normally distributed. Comparison of the inter-rater reliability of the BBPS will be performed with independent samples t-test or Mann-Whitney U test depending on the distribution. To identify risk factors associated with poor quality of bowel preparation and colorectal cancer risk, the trial will use multivariate analysis of the study variables. Patient-reported measures will be compared, with participant responses initially presented as proportions and compared between groups.

Patient and public involvement

Eight patients were involved in reviewing the SMS and video script in June 2022. Only minor changes were made to the wording of SMS and video scripts. No changes were made to the design, methods or conduct of the study.

ETHICS AND DISSEMINATION

Ethical and scientific approval for this multicentre study to proceed has been obtained from Western Sydney Local Health District Human Research Ethics Committee (2022/ETH00059). No further ethics approval is required for study commencement. The trial is registered with the Australian and New Zealand Clinical Trials Registry. All important changes to the protocol will be communicated to Western Sydney Local Health District Human Research Ethics Committee and the Australian and New Zealand Clinical Trials Registry. A full copy of the protocol can be accessed by contacting the authors.

At the completion of the study, all data collected on *The Clinician* will be deleted. De-identified data will be stored for 10 years in the REDCap database, which is Health Insurance Portability and Accountability Act (HIPPA) compliant, encrypted and password protected. After 10 years this data will be deleted, and the REDCap project page removed.

Findings from this study will be published in a peer-reviewed scientific journal and presented at domestic and international gastroenterology conferences. A dissemination strategy will be developed with hospital sites and patient-led cancer advocacy groups. There are no plans at this stage for sharing of the participant-level data set.

ADDITIONAL INFORMATION

Trial status

Recruitment has not yet begun.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods and analysis section for further details.

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