

Improving bowel preparation for colonoscopy with the use of an educational video

Submission date 25/08/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/01/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/04/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Endoscopy (colonoscopy) is the gold standard investigation for abnormalities of the gastrointestinal tract, allowing for direct visualisation, taking tissue samples and, where required, therapeutic intervention. It is well recognised that the quality of bowel preparation affects the outcome of colonoscopy. Inadequate bowel preparation can lead to diseases being missed or for the procedure needing to be repeated. Up to 20% of colonoscopies have inadequate bowel preparation. Repeat procedures can be stressful for patients and delay diagnosis. It is therefore vital to optimise bowel preparation for colonoscopy. To improve the safety and quality of bowel preparation, some units employ a team specialised in pre-colonoscopy assessment but this is a costly option. According to the office of national statistics, 86% of households in Great Britain had internet access in 2015. A reliable internet-based educational video may be an effective method to educate patients about bowel preparation leading improved adequacy. This study will assess whether an educational video explaining how to take bowel preparation leads to a more effectively cleared bowel.

Who can participate?

Adults who speak English and require a colonoscopy to assess for bowel disease, and have access to the internet or a DVD player

What does the study involve?

The study will assess whether an educational video regarding bowel preparation for colonoscopy improves its effectiveness. Half the participants will receive access to the video, whilst the other half will not. Who receives access will be determined by chance. The effectiveness of the bowel preparation for the colonoscopy will then be recorded and compared between the two groups.

What are the possible benefits and risks of participating?

A more effectively cleared bowel allows a more thorough examination of the colon. Therefore, if the video is successful in improving bowel preparation then participants who have access to it are less likely to have abnormalities missed. They are also less likely to require a repeat procedure due to poor preparation. The possible risks involved are the standard risks of a colonoscopy examination; however, watching the video will not increase these risks.

Where is the study run from?

Nottingham University Hospital and 5 other hospitals in the UK

When is the study starting and how long is it expected to run for?

June 2018 to June 2019

Who is funding the study?

The Midland Gastroenterological Society (UK)

Who is the main contact?

Dr Thomas Archer

videobowelprep@outlook.com

Contact information

Type(s)

Public

Contact name

Dr Thomas Archer

ORCID ID

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Contact details

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S5 7AU

Additional identifiers

Clinical Trials Information System (CTIS)

2018-003248-21

Protocol serial number

18GA045

Study information

Scientific Title

Can an educational video improve the adequacy of bowel preparation for patients under going their first colonoscopy compared to standard written instructions alone?

Study objectives

An educational video will improve bowel preparation for colonoscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham Research Ethics Committee 1, 11/12/2018, ref: 18/NW/0768

Study design

Interventional randomised controlled trial

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Colonoscopy bowel preparation

Interventions

Patients will be randomised to viewing an educational video which explains what a colonoscopy is and how to take bowel preparation, alongside standard written instructions or to standard written instructions alone.

Participants will be randomised using simple randomisation to two groups, the control group and the intervention group. The control group will receive the standard written instructions provided prior to colonoscopy explaining how to take the bowel preparation solution. The intervention group will receive the standard written information and will also receive access to an educational video with the same content but presented in a different media format.

Participants will be asked to review this information prior to taking the bowel preparation solution. They will complete questionnaires prior to and subsequent to the endoscopy to collect data on patient demographics, anxiety, satisfaction and comfort. Once they have completed the questionnaires after the endoscopy their involvement in the study will be completed.

Intervention Type

Behavioural

Primary outcome(s)

Adequacy of bowel preparation, assessed using the Boston Bowel Prep Score (BBPS) at the time of endoscopy

Key secondary outcome(s)

1. Mean BBPS between the groups, assessed using the Boston Bowel Prep Score as in the primary outcome measure
2. Number of patients with excellent (BBPS >7) and adequate (BBPS 5-7), as per primary outcome measure
3. Adenoma detection rate, recorded in the endoscopy report at the time of endoscopy
4. Number of adenomas, recorded in the endoscopy report at the time of endoscopy
5. Number of polyps, recorded in the endoscopy report at the time of endoscopy
6. Caecal intubation rate (whether the endoscopy is completed), assessed at the time of endoscopy

7. Insertion time (time taken to reach the caecum), assessed in minutes and seconds at the time of endoscopy
8. Patient comfort scores, assessed at the end of the endoscopy using the following:
 - 8.1. Nurse-patient comfort score
 - 8.2. Visual analogue scale, completed by patient
9. Patient acceptability of the video, assessed using a visual analogue scale prior to the colonoscopy whilst the patient awaits the examination
10. Effect of the video on patients anxiety regarding the procedure, assessed using a visual analogue scale prior to the colonoscopy whilst the patient awaits the examination
11. Overall effect on patients satisfaction of the experience, assessed using a visual analogue scale prior to the colonoscopy whilst the patient awaits the examination

Completion date

01/06/2019

Eligibility

Key inclusion criteria

1. Aged 18 years or older
2. Requiring colonoscopy for investigation of their gastrointestinal tract
3. General fitness deemed sufficient to undertake colonoscopy
4. Able and willing to provide informed consent
5. Access to either a DVD player or the internet
6. Not previously had a colonoscopy
7. Able to attend clinic on a weekday with either a morning or afternoon appointment

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

513

Key exclusion criteria

1. Intolerant to endoscopy
2. Not clinically fit for standard endoscopy as judged by their clinical team
3. Known Crohn's disease or colonic strictures
4. Lacking the visual acuity to clearly read text and watch and clearly interpret a TV screen or computer monitor

5. Unable to understand English to a low intermediate level
6. Unable to take the first line bowel preparation Moviprep

Date of first enrolment

01/10/2018

Date of final enrolment

01/04/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Northern General Hospital

Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre

Queens Medical Centre

Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre

Royal Derby Hospital

UTTOXETER ROAD
Derby
United Kingdom
DE22 3NE

Study participating centre

Chesterfield Royal Hospital

Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
LINCOLN COUNTY HOSPITAL
Greetwell Road
Lincoln
United Kingdom
LN2 4AX

Study participating centre
Sherwood Forest Hospital
Mansfield Road
Mansfield
United Kingdom
NG17 4JL

Sponsor information

Organisation
Nottingham University Hospital

ROR
<https://ror.org/05y3qh794>

Funder(s)

Funder type
Other

Funder Name
Midland Gastroenterological Society

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Thomas Archer (email videobowelprep@outlook.com). The data will be available when the analyses has been published. The data will be available for 5 years and will be anonymised.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/03/2024	02/04/2024	Yes	No
Abstract results		01/01/2021	29/03/2021	No	No
HRA research summary			28/06/2023	No	No