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

Submission date	Recruitment status	[_] Prospectively registered
25/08/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/01/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/04/2024	Surgery	

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

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Additional identifiers

EudraCT/CTIS number
2018-003248-21

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/06/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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
England

United Kingdom

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

Sponsor details
Derby Road
Nottingham
England
United Kingdom
NG7 2UH

Sponsor type

Hospital/treatment centre

Website
www.nuh.nhs.uk

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Other

Funder Name
Midland Gastroenterological Society

Results and Publications

Publication and dissemination plan
Results of the study will be published in a medical journal in 2019

Intention to publish date
01/09/2019

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?
Abstract results		01/01/2021	29/03/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		18/03/2024	02/04/2024	Yes	No