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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
25/08/2018		<pre>Protocol</pre>		
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 precolonoscopy 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**

http://orcid.org/0000-0002-0330-5585

#### Contact details

Endoscopy department Northern General Hospital Herries Road Sheffield United Kingdom S5 7AU

## 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