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Bowel scope screening: interventions to increase uptake in Yorkshire

Submission date	**Recruitment status**	[X] Prospectively registered
30/04/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/05/2018	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/11/2020	Cancer	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bowel cancer is the second most common cause of cancer-related deaths in England. Bowel scope screening (BSS) can prevent bowel cancer by removing pre-cancerous growths within the bowel before they become cancerous. Previous research has shown that BSS can lower a person' s risk of getting bowel cancer by a third and their risk of dying from bowel cancer by half. The NHS in England now offers BSS to 55 year olds registered with a general practice (GP), but uptake is low, particularly in more deprived areas. The aim of this study is to find out whether GP practice based interventions can increase uptake of BSS in Hull and other parts of Yorkshire.

Who can participate?
People aged 55 due to receive their NHS BSS invitation (identified through GPs)

What does the study involve?
Participants are randomly allocated to one of three groups:
1. Usual care: no contact from GPs
2. Primer and self-referral letter: A letter advising of the future delivery of a BSS invitation is sent by the participant's GP, along with a locally tailored leaflet explaining the test. If the practice receives notice that an individual did not attend their appointment, a letter highlighting the self-referral process is sent.
3. Primer and patient navigation: As above, a letter and leaflet are sent ahead of the NHS BSS invitation. If the practice receives notice that an individual did not attend their appointment, a call to the participant is made to identify and address personal barriers to uptake and, if appropriate, help arrange a new appointment. If no telephone contact is possible, a self-referral letter is sent.
Screening attendance is monitored and compared between the groups.

What are the possible benefits and risks of participating?
Patients may become more informed about what BSS is and attend their BSS appointment, helping to reduce their risk of bowel cancer. These interventions may increase BSS uptake and reduce the number of bowel cancers diagnosed in Yorkshire, and involve no risk to the patients.

Where is the study run from?
1. The Bridge Group Practice
2. James Alexander Family Practice
3. Market Weighton Group Practice
4. Leven and & Beeford Medical Practice
5. Riverside Medical Centre
6. South Holderness Medical Practice
7. Dr AK Choudhary & Dr SR Danda Practice
8. Kingston Medical Group
9. Wilberforce Surgery
10. The Quays
11. Good Heart Surgery
12. Cottingham Medical Centre
13. The Medical Centre, Driffield
14. Dr AC Milner
15. Greengates Medical Group
16. Beverley & Molescroft Surgery
17. Hancocks ME (Hallgate Surgery)
18. The Chestnuts Surgery
19. Peeler House Surgery

When is the study starting and how long is it expected to run for?
April 2017 to September 2019

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Dr Lesley McGregor
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35266

Study information

Scientific Title
Using primary care to increase uptake of the Bowel Scope Screening Programme in Yorkshire: evaluating paper and telephone based interventions

Study objectives
Bowel cancer is the second most common cause of cancer-related deaths in England. Bowel scope screening (BSS) can prevent bowel cancer by removing pre-cancerous growths within the bowel before they become cancerous. Previous research has shown that BSS can lower a person' s risk of getting bowel cancer by a third and their risk of dying from bowel cancer by half. The NHS in England now offers BSS to 55 year olds registered with a general practice (GP); however, uptake is low, particularly within more deprived areas. For this study, the aim is to answer the question: Can GP practice based interventions help increase uptake of BSS in Hull and other parts of Yorkshire?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Harrow Research Ethics Committee, 24/04/2018, ref: 17/LO/1723

Study design
Randomised; Interventional; Design type: Screening, Process of Care, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Bowel cancer

Interventions
Randomisation
The UCL research team will supply each GP practice with a template of the 'study database', which will contain a pre-set randomisation list. Participants added to the database will therefore be assigned to one of three study groups below. The pre-set randomisation list will be generated using block randomisation to ensure each practice has a similar number of patients within each study group. Each person added to the study database will have their address checked against other individuals within the study database. If someone resides at an address that has already been entered into the study database, they will automatically be given the same study group as the first person at that address. This will make sure people living at the same address receive the same intervention, thereby reducing the opportunity for contamination.

Phase 1: Randomised Controlled Trial
Over a 6 month period, individuals due to receive their NHS BSS invitation (identified through GPs) will be randomly be assigned to one of three groups with attendance monitored and compared between groups:
1. Usual care: no contact from GPs.
2. Primer and self-referral letter (up to 10 minutes to read and respond to): A letter advising of the future delivery of a BSS invitation will be sent by the individual's GP, along with a locally tailored leaflet explaining the test. If the practice receives notice that an individual did not attend their appointment, a letter highlighting the self-referral process will be sent.
3. Primer and patient navigation call (lasting up to 45 minutes): As above, a letter and leaflet will be sent ahead of the NHS BSS invitation. If the practice receives notice that an individual did not attend their appointment, a call to the individual will be made. This call will aim to identify and address personal barriers to uptake and, if appropriate, help arrange a new appointment. If no telephone contact is possible, a self-referral letter will be sent.

Phase 2: Process Evaluation
The GP practice will send a letter to a selection of patients who received the interventions in the RCT, inviting them to contact the UCL researchers if they would like to take part in a telephone interview (conducted by UCL researchers). An email with a link to the online survey, with an attached information sheet, from the UCL researchers will be sent to all relevant GP practice staff. A reminder will be sent after two weeks.

Intervention Type
Other

Primary outcome measure
The proportion of individuals attending a bowel scope screening appointment within each study group. Data on the attendance status of each person will be obtained at the end of the study, 12 weeks after the distribution of the final self-referral reminder letter/patient navigation call. The data will be obtained by NHS Digital, who will extract the 'Date of attended appointment' of each person from the NHS Bowel Cancer Screening System using each patient's NHS Number. The NHS numbers will be removed from the dataset prior to transfer and analysis by the UCL research team.

Secondary outcome measures
1. The proportion of individuals attending screening within each group before and after the delivery of non-participant interventions (i.e. uptake within each group before and after the delivery of the self-referral reminder letter/patient navigation telephone call). Data on the attendance status of each person will be obtained immediately before the delivery of non-participant interventions and again 12 weeks after the distribution of the final self-referral reminder/patient navigation telephone call. This information will be obtained by the GP Practice and NHS Digital, who will record the 'Hub letter outcome' (which reports attendance at the appointment offered by the NHS Bowel Cancer Screening Programme and is used to determine which individuals in the intervention groups should receive non-participant interventions) and 'Date of attended appointment' respectively. Comparisons between the interventions groups (Groups 2 and 3) and the control (Group 1), immediately before the delivery of the non-participant interventions, will then be used to determine the impact of the primer letter on uptake. Comparisons within groups, immediately before the delivery of non-participant interventions and 12 weeks after the delivery of the final self-referral reminder letter/patient navigation call, will conversely be used to assess the impact of the self-referral reminder letter and patient navigation call on uptake. Again, all data will be anonymised prior to analysis by the UCL research team.
2. The demographic composition of individuals who respond to self-referral reminder letters and patient navigation telephone calls. Data on the sex and ethnicity of each person will be added to the dataset using data within the GP Clinical System. Data on the area-level deprivation of each person's home address will also be added to the dataset. This will also be done by the GP practice, who will convert the postcode of the individual's home address (also available on the GP clinical system) into a score on the 2015 Index of Multiple Deprivation (IMD). These data will then be used to assess the demographic composition of individuals who respond to the self-referral reminder letter and patient navigation telephone call.
3. The proportion of individuals attending follow-up colonoscopy within each group. Data on the offer and uptake of follow-up colonoscopy will be added to the dataset using data available on the NHS bowel cancer screening system. The proportion of individuals attending follow-up colonoscopy within each group will then be assessed to determine whether the interventions had any impact on attendance at follow-up colonoscopy.
4. The cost-effectiveness of the interventions to improve bowel scope screening uptake. Pre-existing data on lifetime costs and benefits will be used in the analysis.
5. The acceptability of interventions to bowel scope screening invitees and GP practices. At the end of the study, the trialists will interview a selection of individuals who received the interventions to ask about their views on the materials received and their possible influence on their decision making. They will also seek to obtain the views of staff members from the GP practices involved in the RCT using an online survey.

Overall study start date
01/04/2017

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Individuals (aged 55 years and 1 month) registered with a participating GP practice served by the Bowel Cancer Screening Centre in Hull

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 2000; UK Sample Size: 2000

Key exclusion criteria
Individuals will be excluded if:
1. They do not meet the clinical eligibility criteria for BSS (i.e. they have had their large bowel removed; they have a stoma bag to collect their stool; they are currently being treated for inflammatory bowel disease; they are awaiting heart surgery or have had heart surgery in the last three months)
2. They are registered on the clinical system as being a type 2 objector/opt out (i.e. have indicated that their confidential information cannot be shared by NHS Digital for any purposes beyond their own immediate care)
3. They are known to be receiving palliative care
4. They have been diagnosed with cancer (of any type) in the past 12 months
Further exclusions will apply at the GP practice's discretion

Date of first enrolment
04/06/2018

Date of final enrolment
29/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Bridge Group Practice
Hull
United Kingdom
HU6 9BX

Study participating centre
James Alexander Family Practice
Hull

United Kingdom
HU7 4DW

Study participating centre
Riverside Medical Centre
Hull
United Kingdom
HU3 2RA

Study participating centre
Dr AK Choudhary and Dr SR Danda practice
Hull
United Kingdom
HU7 4DW

Study participating centre
Kingston Medical Group
Hull
United Kingdom
HU3 1TY

Study participating centre
The Quays Medical Centre
Hull
United Kingdom
HU1 3SA

Study participating centre
Goodheart Surgery
Hull
United Kingdom
HU7 4DW

Study participating centre
Cottingham Medical Centre
Cottingham
United Kingdom
HU16 4AJ

Study participating centre
Greengates Medical Group
Beverley
United Kingdom
HU17 0HB

Study participating centre
Beverley and Molescroft Surgery
Beverley
United Kingdom
HU17 9GQ

Study participating centre
Market Weighton Group Practice
United Kingdom
YO43 3FF

Study participating centre
Leven and Beeford Medical Practice
United Kingdom
HU17 5NL

Study participating centre
South Holderness Medical Practice
United Kingdom
HU19 2PZ

Study participating centre
Wilberforce Surgery
United Kingdom
HU1 3SA

Study participating centre
The Medical Centre, Driffield
United Kingdom
YO25 6UH

Study participating centre
Dr AC Milner
United Kingdom
HU10 6QH

Study participating centre
Hancocks ME (Hallgate Surgery)
United Kingdom
HU17 9GQ

Study participating centre
The Chestnuts Surgery
United Kingdom
HU16 4QX

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research; Grant Codes: UCL407

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be published in a peer-reviewed journal. Planned publication of the results in a high-impact peer reviewed journal and presentation at academic conferences within one year of the overall trial end date.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/07/2018	23/11/2020	Yes	No
HRA research summary			28/06/2023	No	No