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# GP reminders for bowel scope screening non-participants

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| **Submission date**<br>30/01/2017 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>30/01/2017 | **Overall study status**<br>Completed | |
| **Last Edited**<br>04/03/2021 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**

Background and study aims
Flexible sigmoidoscopy (FS) screening is associated with reduced colorectal cancer incidence and mortality when offered as a one-off test to men and women aged 55-64. The test, also referred to as the 'bowel scope screening' (BSS) test, was added to England's national Bowel Cancer Screening Programme in March 2013, where it is offered to men and women aged 55. Since its implementation, uptake of the BSS test has been low, with only 43% of the eligible population attending an appointment. Sending non-participants a reminder at age 56 has been shown to improve uptake by up to nine percentage points at a single centre in London; we hypothesise that adding a general practitioners (GPs) endorsement to the reminder could improve uptake even further.

Who can participate?
Patients aged 56 years at the time of enrollment who meet criteria for bowel scope screening.

What does the study involve?
ll screening-eligible adults who have not responded to a BSS appointment at London North West Healthcare NHS Trust within 12 months of their initial invitation will receive either a GP-endorsed reminder letter or reminder letter without GP endorsement.

What are the possible benefits and risks of participating?
None

Where is the study run from?
St Mark's Hospital, UK.

When is the study starting and how long is it expected to run for?
January 2018 to March 2018

Who is funding the study?
Department of Health

Who is the main contact?
Dr Christian Von Wagner
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# Contact information

### Type(s)
Public

### Contact name
Dr Christian Von Wagner

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
32342

# Study information

### Scientific Title
Impact of GP endorsement on the effectiveness of a 12 months’ reminder to improve uptake of bowel scope screening: a randomised controlled trial in a hard-to-reach population

### Study objectives
Adding a GP endorsement to the 12 months' reminder letter will improve uptake of bowel scope screening (BSS) among previous non-participants.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

Yorkshire & The Humber - Bradford Leeds Research Ethics Committee, 26/07/2016, ref: 16/YH /0298

## Study design
Randomised; Interventional; Design type: Process of Care, Education or Self-Management

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Screening

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Palliative and Supportive Care; UKCRC code/ Disease: Cancer/ Malignant neoplasms of digestive organs, Oral and Gastrointestinal/ Other diseases of the digestive system

## Interventions
All screening-eligible adults who have not attended their BSS appointment at St. Mark's hospital within 12 months' of their initial invitation will be randomised to receive either the intervention of a GP endorsed reminder letter or a reminder letter without GP endorsement. Because usual care is receiving no reminder 12 months' after the initial invitation, both groups will technically be receiving an intervention. However, because a standard reminder at twelve months has been shown to be effective at this centre in this way already, this will act as the control against which the added benefit of a GP-endorsement will be compared.

Details of the intervention:
Reminders will be produced by merging the study database with the reminder letter templates and selecting the relevant cases within each of the two documents (i.e. merging GP-endorsed reminder cases with the GP-endorsed reminder letter template). The study materials, which include: the reminder letter, standard information booklet and freepost return envelope will be mailed to the participant in a single envelope. Participant address labels will be produced by mail merging the study database with the participant label template. This process of sending previous non-participants a reminder 12 months' after their initial will continue until the study sample size (n=1,400) is reached.

Reminders will not offer pre-scheduled appointments, but rather remind participants of the opportunity to book an appointment (self-refer), either by calling the Bowel Cancer Screening Centre Freephone number or by returning an appointment request slip. For recipients who return an appointment request slip, individuals will need to provide a telephone number (either a home or mobile telephone number) so that a member of the St. Mark's Bowel Cancer

Screening centre can contact them to arrange an appointment (both methods of self-referral will require a telephone call between the centre and the recipient to arrange an appointment). Both methods for self-referral will enable participants to choose the day and time of their appointment (factors which have previously been reported as barriers to uptake) (Vernon et al, 1997). After an appointment has been agreed, individuals referring for BSS will be invited to participate in screening as per usual care. Namely, individuals will receive: an appointment confirmation letter shortly after an appointment has been agreed, the bowel preparation kit with instructions for use two weeks before the appointment, a text message reminder one week before the appointment and a telephone call, also one week before the appointment. Appointment attendance will be verified by a member of the direct care team at S.t Mark's hospital four weeks after the delivery of the reminder letter.

### Intervention Type
Other

### Primary outcome measure
Proportion of individuals attending a Bowel Scope Screening within each group is measured using the attendance at bowel scope screening) and will be collected by a member of the clinical care team at St Mark's Hospital as accessed from the Bowel Scope Screening database (linked with patient record database).

### Secondary outcome measures
Differences in attendance among social and demographic groups is measured using the attendance at bowel scope screening) and will be collected by a member of the clinical care team at St Mark's Hospital as accessed from the Bowel Scope Screening database (linked with patient record database).

### Overall study start date
04/08/2016

### Completion date
31/12/2019

## Eligibility

### Key inclusion criteria
1. Aged 56 years at the time they are enrolled in the study
2. Registered with a general practice served by St. Mark's Hospital
3. Registered with a general practice participating in the study
4. Previously been offered, but not attended, a routine BSS appointment more one year ago at the time of the reminder letter
5. Meet the clinical eligibility criteria for BSS

### Participant type(s)
Patient

### Age group
Adult

### Sex

Both

### Target number of participants
Planned Sample Size: 1400; UK Sample Size: 1400

### Total final enrolment
1200

### Key exclusion criteria
1. Individuals who have had their large bowel removed
2. Individuals who have a stoma bag to collect their stool
3. Individuals currently being treated (for example, with steroids) for inflammatory bowel disease in their large bowel (i.e. ulcerative colitis or Crohn's disease)
4. Individuals who are awaiting heart surgery or who have had heart surgery in the last

### Date of first enrolment
01/01/2018

### Date of final enrolment
01/05/2018

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**St Mark's Hospital**
Watford Road
Harrow
United Kingdom
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## Sponsor information

### Organisation
University College London

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### Sponsor type
University/education

### ROR
https://ror.org/02jx3x895

## Funder(s)

### Funder type
Government

### Funder Name
Department of Health

## Results and Publications

### Publication and dissemination plan
Upon completion of the analysis, the results of the trial will be published in a peer-reviewed journal and disseminated at conferences in the field. No patient identifiable data will be published and all data anonymised prior to analysis.

### Intention to publish date
31/12/2020

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Christian von Wagner (c.wagner@ucl.ac.uk)

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 05/05/2018 | 14/05/2019 | Yes | No |
| Results article | results | 01/12/2020 | 04/03/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |