ISRCTN82867861 https://doi.org/10.1186/ISRCTN82867861

GP reminders for bowel scope screening non-participants

Submission date 30/01/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2017	**Overall study status** Completed	
Last Edited 04/03/2021	**Condition category** 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
c.wagner@ucl.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Christian Von Wagner

ORCID ID
https://orcid.org/0000-0002-7971-0691

Contact details
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 6BT
+44 20 7679 1614
c.wagner@ucl.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Screening

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(s)

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).

Key secondary outcome(s)
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).

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
St Mark's Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Department of Health

Results and Publications

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?
Results article	results	01/12/2020	04/03/2021	Yes	No
Protocol article	protocol	05/05/2018	14/05/2019	Yes	No
HRA research summary			28/06/2023	No	No