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Using annual reminders to facilitate uptake of bowel scope screening in previous non-participants: A Randomised Controlled Trial

Submission date
19/06/2015

Recruitment status
No longer recruiting

Registration date
25/08/2015

Overall study status
Completed

Last Edited
13/11/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background & aims:
Bowel cancer is the fourth most common cancer in England, and the second leading cause of cancer deaths. Detecting the disease early is associated with improved chances for survival; however, most cases are diagnosed late as most patients don't tend to develop symptoms in the early stages. Screening helps to detect cases early, by testing for the disease before any symptoms occur. In England, there is a national bowel cancer screening programme where men and women are invited for a 'one-off' test, called a flexible sigmoidoscopy (or 'bowel scope'), shortly after their 55th birthday. This test is able to save lives from bowel cancer not only by detecting cases early, by preventing them through the timely removal of growths which pre-cancerous (these are commonly referred to as polyps or 'adenomas'). However, less than half of all people (around 40%) attend their screening appointment when invited by the NHS, and this limits the number cancers the programme is able to detect/prevent. There are a number of reasons why people do not screening appointments, such as forgetting to go, being worried that the screening test might be embarrassing or painful and not being unavailable to attend at that time. Anyone who does not attend their appointment can re-book up until the age of 60, but is otherwise not re-invited to participate (people only ever receive one invitation, it is then up to them to contact the screening centre if they want to arrange an appointment). The aim of this study was to examine whether mailed reminders, prompting non-participants to self-refer for screening one & two years after their invitation, could increase screening rates, and whether these 'annual reminders' are more effective when combined with locally tailored information leaflets that have been designed to address patient-related factors for non-attendance (such as worry about the test being painful or embarrassing).

Who can participate?
Adults aged 55-59 registered with a GP Practice in the London Boroughs of Brent and Harrow.

What does the study involve?
In this study, participants are randomly assigned to one of three groups: a 'control group', in which participants do not receive a reminder prompting them to book an appointment; a reminder plus 'standard leaflet' group, in which participants receive a reminder and standard

information leaflet one and (if they still have not booked an appointment) two years after their initial invitation; and a reminder plus locally tailored information leaflet group, in which participants receive a reminder and locally tailored information leaflet designed to address common reasons for non-participation one and (if they still have not booked an appointment) two years after their initial appointment. In addition, participants who attend an appointment are asked to complete a questionnaire about why they did not attend previously and why they decided to make attend an appointment at this time.

What are the possible benefits and risks of participating?
Participants aren't able to enrol in the study, they will be randomly selected from a list of screening eligible 'non-participants'. Participants who made a misinformed (i.e. did not understand the purpose of the screening test) or non-deliberate (i.e. forgot to go to their appointment) decision to not participate in screening previously will benefit from a second opportunity to participate, have their concerns about screening addressed and their risk of getting/dying from bowel cancer being reduced. There are risks associate with flexible sigmoidoscopy screening, including bowel perforation (1 in 3,000), which results in serious bleeding.

Where is the study run from?
St. Marks' Hospital, London (UK)

When is study starting and how long is it expected to run for?
March 2015 to September 2016

How long will the trial be recruiting participants for?
St. Marks' Hospital, London (UK)

Who is the main contact?
Sarah Marshall
sarahmarshall5@nhs.net

Contact information

Type(s)
Scientific

Contact name
Mr Robert Kerrison

Contact details
1-19 Torrington Place
London
United Kingdom
WC1E 7HB
+44 (0)20 7679 8254
robert.kerrison.13@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14/0863

Study information

Scientific Title
Use of a locally tailored information leaflet and mailed reminders to facilitate uptake of flexible sigmoidoscopy (bowel scope) screening in previous non-participants: A three-armed Randomised Controlled Trial.

Acronym
ARfFSS (Annual Reminders for Flexible Sigmoidoscopy Screening)

Study objectives
Receipt of a mailed reminder and locally tailored information leaflet will facilitate uptake in previous flexible sigmoidoscopy (bowel scope) screening non-participants. The reminder will be more effective when sent with a locally tailored information leaflet, rather than the national leaflet. A second reminder delivered one year later will increase uptake further.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board: NRES Committee North East - Tyne & Wear South
Reference: 15/NE/0043
Date study approved: 30th January 2015

Study design
A single centre, three-armed, Randomised Controlled Trial.

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
We are investigating whether a mailed reminder, with instructions on how to book an appointment, can facilitate uptake of flexible sigmoidoscopy (bowel scope) screening in previous non-participants

Interventions
Trial Arm 1: Control (i.e. usual care, which is invitation to participate in BSS at 55 only - participants randomly allocated to this arm of the study will not receive anything additional to usual care as a result of this study).
Trial Arm 2: Intervention Arm A (Participants randomly allocated to this group will receive a mailed reminder stating they previously did not attend BSS, but can self-refer up until the age of 59. The mailed reminder will include instructions on how to book an appointment, as well as an 'appointment request slip' which the patient can return to St. Marks' screening centre using the free-post envelope provided. A copy of the national information leaflet will also be provided. The intervention will be delivered a second time one year later, for those participants who have still not attended an appointment).
Trial Arm 3: Intervention Arm B (Participants randomly allocated to this group will receive a mailed reminder stating that they previously did not attend BSS, but can self-refer up until the age of 59. The mailed reminder will include instructions on how to book an appointment, as well as an 'appointment request slip' which the patient can return to St. Marks' screening centre using the free-post envelope provided. Participants in this arm will receive a locally tailored information leaflet, designed specifically to address barriers to BSS, rather than a copy of the national information leaflet. The intervention will be delivered a second time one year later, for those participants who have still not attended an appointment).
In both intervention groups, participants who attend an appointment will be asked to complete a questionnaire about why they previously did not attend BSS, and why they decided to attend on this occasion.

Intervention Type
Behavioural

Primary outcome measure
1. Uptake in each of the trial arms
2. Uptake in each trial arm between genders
3. Uptake after one round of 'annual reminders'
4. Uptake after two rounds of 'annual reminders'

Secondary outcome measures
1. Patient preferences for a same sex practitioner by gender
2. Reasons for previously not participating in BSS
3. Reasons for participating in BSS on this occasion

Overall study start date
16/03/2015

Completion date
25/09/2016

Eligibility

Key inclusion criteria

Adults who meet the study-specific eligibility criteria (listed below) will be identified on the NHS Bowel Cancer Screening Programme’s in-house IT system, BCSS (Bowel Cancer Screening System) by a member of the direct patient care team at St. Marks' Hospital:
1. Must be 56-58 years of age at the time they are enrolled in the study
2. Must be registered with a GP practice served by the St Marks BCSC (i.e. a GP practicce in the London Boroughs of Brent and Harrow)
3. Must have previously been offered, but not attended, a routine BSS appointment at least one year ago.
4. Must meet the clinical eligibility criteria for BSS (see exclusion criteria, below)

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
1,386

Total final enrolment
1218

Key exclusion criteria
Exclusion Criteria:
The St Marks BCSC will exclude any individuals who do not meet the clinical-specific criteria for BSS (as listed below) from the study. These include:
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 (i.e. ulcerative colitis or Crohn’s disease)
4. Individuals who are awaiting heart surgery or who have had heart surgery in the last three months

Date of first enrolment
16/03/2015

Date of final enrolment
25/07/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. Marks' Hospital
Watford Road
Harrow
London
United Kingdom
HA1 3UJ

Sponsor information

Organisation
University College London Joint Research Office

Sponsor details
Joint Research Office, Floor 1, Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN

Sponsor type
University/education

Website
N/A

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
University/education

Funder Name
St. Marks' Hospital, London (UK)

Funder Name
University College London

Alternative Name(s)

University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We plan to disseminate the findings of this study by way of academic conferences and publication in peer-reviewed journal articles.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of feasibility study	29/03/2016		Yes	No
Results article	results of first 14 months	01/06/2016		Yes	No
Results article	overall results	01/01/2017		Yes	No
Results article	results	22/10/2018	13/11/2019	Yes	No
HRA research summary			28/06/2023	No	No