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GP Endorsement of Bowel Screening

Submission date
29/09/2011

Recruitment status
No longer recruiting

Registration date
29/09/2011

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Colorectal (bowel) cancer is the second leading cause of cancer death in the UK, and costs the National Health Service (NHS) more than £300 million a year in treatment costs. Patient survival could be increased and, costs very much reduced, if patients with bowel cancer received their diagnosis earlier, allowing treatment to begin earlier. The NHS Bowel Cancer Screening Programme (NHSBCSP) was introduced in England in 2006, and aims to screen men and women aged between 60 to 74 years of age for bowel cancer every two years using the faecal occult blood test (FOBt). Initial studies have shown that bowel screening is effective, but the number of patients who participate in screening have been quite low, with only around half of all the people who are invited to participate returning their FOBt kit.
The success of the NHSBCSP relies on a high number of patients participating, and the development of new ways to improve the number participating after they are invited to participate.
The main aim of the study is to assess how effective a GP reminder and additional FOBt kit are on increasing the number who participate in bowel cancer screening, when they have not participated following a previous invitation.

Who can participate?
All adults eligible for bowel screening (aged between 60 to 74 years old). These were patients at a participating general practice in the West Midlands, where the screening rate is less than 50%. These patients had been invited to participate in bowel screening but had not returned their FOBt within 13 weeks of initial invitation by the Midlands and North West Bowel Cancer Screening Hub.

What does the study involve?
We will randomly allocate the participants to one of two groups:
1. GP reminder to participate in bowel screening and additional FOBt kit, OR
2. No additional contact
We compared how may people participated in bowel screening after 13 weeks. This was measured by the number of FOBt kits that were returned to the bowel screening hub by patients in each group. This allowed us to assess if the GP reminder to participate in bowel screening and additional FOBt kit was successful in increasing the participation in bowel screening. A small interview was carried out with some patients who received the GP reminder who returned a FOBt kit.

What are the possible benefits and risks of participating?
There were no direct benefits to the patients who participated, but their participation will allow us to better understand why a person decides to take part in bowel screening, and what may put some people off participating. The findings will be used to help to identify ways to improve the NHS Bowel Cancer Screening Programme, so that future patients can benefit from a more effective screening service. There are no known risks associated with participating in this study.

Where is the study run from?
From the Department of Primary Care Clinical Sciences, at the University of Birmingham, in collaboration with the Department of Primary Healthcare at University of Oxford, and the Midlands and North West Bowel Cancer Screening Hub.

When is the study starting and how long is it expected to run for?
The study began in October 2011 and recruitment continued for approximately six months. The study ended in September 2012.

Who is funding the study?
National Institute for Health Research (NIHR) - School for Primary Care Research

Who is the main contact?
Mrs Sue Clifford
s.clifford@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Sue Clifford

Contact details
Department of Primary Care & General Practice
Primary Care Clinical Sciences Building
Edgbaston
Birmingham
United Kingdom
B15 2TT
-
S.Clifford@bham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10854

Study information

Scientific Title
Evaluating the effectiveness of GP endorsement in increasing participation in the NHS Bowel Cancer Screening Programme: A feasibility trial

Study objectives
This feasibility study will comprise a two-armed randomised controlled trial to evaluate the effectiveness of a GP endorsed reminder in improving patient participation in the NHS Bowel Cancer Screening Programme (NHS BC SP), and a qualitative research study to establish the perceived importance of different components of this complex intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 12 July 2011, ref: 11/WM/0086

Study design
Randomised interventional process of care

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
Bowel Cancer

Interventions
The study population will be adults aged 60 to 74 who have been invited to participate in bowel screening but who have not returned their Faecal Occult Blood Test (FOBt) kit within the 13 week screening episode recorded by the Midlands and North West Bowel Cancer Screening Hub. The Hub will identify general practices with a patient uptake of bowel screening less than 50%. Depending on the number of non-responders at each practice, up to 20 practices will be recruited, and approximately 4,000 people randomised in equal numbers to either the intervention (GP letter and duplicate FOBt kit) or control (no additional contact) arms of the trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The difference in the uptake rate of FOBt screening for bowel cancer (i.e. completion and return of FOBt kit) between the intervention and control groups at 13 weeks after the GP endorsed reminder and duplicate FOBt kit are sent.

Secondary outcome measures
1. Subgroup analyses of uptake by gender, age and deprivation
2. The development and validation of methods for collecting data on intervention costs
3. Qualitative work (30-40 semi-structured interviews) will be undertaken with individuals in the intervention arm who return a FOBt kit. This will investigate the relative importance of the duplicate FOBt kit, reminder to participate, and GP endorsement of that reminder in contributing to individuals decisions to participate in screening. If the feasibility work demonstrates a significant increase in uptake of FOBt screening in individuals receiving the intervention, a future definitive trial can be designed and appropriately powered.

Overall study start date
26/09/2011

Completion date
30/01/2012

Eligibility

Key inclusion criteria
1. Adults aged 60 to 74
2. Non-responders to previous invitation to participate in NHS Bowel Cancer Screening Programme
3. Target Gender: Male & Female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 4380; UK Sample Size: 4380; Description: Patients will be randomised to the intervention or control arms of the study in the ratio of 1:1

Key exclusion criteria

1. Recently undergone an investigation and/or are currently under surveillance.
2. Moved outside age range for screening.
3. Have contacted Hub requesting no further contact.

Date of first enrolment
26/09/2011

Date of final enrolment
30/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care & General Practice
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 3344
no@email.com

Sponsor type
University/education

Website
http://www.birmingham.ac.uk/

ROR

https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR School for Primary Care Research

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	study protocol	20/02/2012		Yes	No