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Estimating uptake of colorectal cancer screening tests

Submission date
24/04/2013

Recruitment status
No longer recruiting

Registration date
25/04/2013

Overall study status
Completed

Last Edited
14/09/2016

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel cancer is a National Health Service (NHS) priority as 1 in 20 people will develop the disease and half of those will die, equating to 17,000 each year in the UK. Bowel cancer is largely preventable via the timely detection and removal of precancerous growths in the bowel (called adenomas) and chances of survival are improved greatly if bowel cancer is detected early, before the disease causes symptoms. As a result, screening tests for adenomas and bowel cancer in people who do not currently have symptoms are an important method for reducing the number of deaths from bowel cancer. However, the success of any screening test depends on people being willing to be tested so it is essential that tests are as acceptable as possible to invitees in order to maximise uptake. There are several tests that could be used to screen for bowel cancer, each with their own advantages and disadvantages, and there is no clearly superior option. For example, some tests are more accurate than others but screening invitees might consider these to be less convenient than alternatives. It is currently unclear which test people would be most likely to have. It is also uncertain what the specific reasons are that underpin these preferences. This study aims to answer these questions.

Who can participate?
We are recruiting members of the public who are representative of individuals who have not had bowel cancer screening before but are approaching the age at which it is offered. We are sending out questionnaires to men and women aged 45-54 years via their General Practitioner. We are also using several other criteria to ensure that people in our study are similar to those who would be offered screening. For example, individuals will only be invited to take part if they have not previously had a diagnosis of bowel cancer or already have regular bowel tests for reasons unrelated to screening.

What does the study involve?
People who are eligible to take part in the study will be posted a questionnaire and written information about one of the four tests that we are investigating. The test that they will receive information about will be randomly determined. Individuals will be asked to read the information and complete the questionnaire, which asks questions on whether they believe they would be willing to have the test and their impressions of the different aspects of the procedure (for example, how convenient or inconvenient it might be for them). Participants will then send

the questionnaire back to the main study centre, where we will compare peoples responses across the different tests once they have all been collected.

What are the possible benefits and risks of participating?
Participating in the study will allow people to provide their views on future directions for how bowel cancer screening is offered. Otherwise, there are few direct benefits and harms for people taking part in the study. They may find the topic interesting and the information useful if they ultimately experience one of the tests (in a screening setting or if they have bowel symptoms). It is possible that some people may find the subject matter distasteful or distressing. Invitees will be given the contact details of the research team, their GP and other bowel cancer organisations (e.g. Beating Bowel Cancer UK) if they have any questions or concerns.

Where is the study run from?
The study is being co-ordinated from the Department of Epidemiology and Public Health at University College London, located in central London. Three practices are involved in the study (two in Cumbria, one in Middlesex).

When is the study starting and how long is it expected to run for?
May 2013 to August 2013

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Alex Ghanouni
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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
14254

Study information

Scientific Title
Which colorectal cancer screening test would achieve the highest level of uptake? A survey of public attitudes

Study objectives
This study will randomise patients registered at GP practices to receive information on one of several bowel cancer screening tests and a questionnaire. The questionnaire will ask participants whether they think they would have the test and their perceptions on key aspects (e.g. invasiveness and accuracy). Responses will be compared between tests to determine the most acceptable modality that is likely to obtain the highest level of uptake.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West Greater Manchester East, Proportionate Review Sub-Committee, 28/01/2013, ref: 13/NW/0077

Study design
Randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England / Colorectal cancer screening

Interventions
Eligible individuals will be randomised to receive information and a questionnaire regarding one of four bowel cancer screening tests:
1. Flexible-sigmoidoscopy: An internal camera exam that examines the lower third of the large

bowel, can take biopsies, remove pre-cancerous polyps and detect cancer early when it is most treatable; patients would be required to administer an enema before the test
2. Colonoscopy: Another internal camera exam but one that examines the full length of the large bowel; theoretically, it can find and prevent more cancers but also has more risks than flexible sigmoidoscopy; patients would have to undergo a powerful laxative before the test
3. Non-laxative CT colonography: A scan exam that can find and prevent almost as many cancers as colonoscopy with fewer risks and without the laxative preparation beforehand. However, if any abnormalities were detected during the test, patients would require a colonoscopy for further evaluation
4. Laxative CT colonography: Similar to non-laxative CT colonography except that it is even closer to colonoscopy in terms of the ability to find and prevent cancer. However, it requires the same powerful laxative preparation before the test as colonoscopy

The questionnaires will be identical across conditions except for the name of the test. Participants will be asked their opinions about the test about which they have received information but will not be invited to undergo any testing as part of the study.

Follow Up Length: 1 month

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Intention to be screened; Timepoint(s): When questionnaire is returned by post to the main study office

Secondary outcome measures
Current secondary outcome measures as of 08/05/2013:
1. Perceived accuracy; Timepoint(s): When questionnaire is returned by post to the main study office
2. Perceived benefits; Timepoint(s): When questionnaire is returned by post to the main study office
3. Perceived preparation burden; Timepoint(s): When questionnaire is returned by post to the main study office
4. Perceived test burden; Timepoint(s): When questionnaire is returned by post to the main study office
5. Preferred surveillance modality; Timepoint(s): When questionnaire is returned by post to the main study office

Previous secondary outcome measures until 08/05/2013:
1. Perceived accuracy; Timepoint(s): When questionnaire is returned by post to the main study office
2. Perceived benefits; Timepoint(s): When questionnaire is returned by post to the main study office
3. Perceived preparation burden; Timepoint(s): When questionnaire is returned by post to the main study office
4. Perceived test burden; Timepoint(s): When questionnaire is returned by post to the main study office

Overall study start date
13/05/2013

Completion date
08/07/2013

Eligibility

Key inclusion criteria
1. Male and female aged 45-54 years
2. Clinically judged to be suitable to receive a questionnaire and information on a bowel cancer screening test (see exclusion criteria below)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 3040; UK Sample Size: 3040; Description: Patients will be divided equally across all four conditions

Key exclusion criteria
1. Previous diagnosis of bowel cancer or recent diagnosis of other cancer
2. Terminal illness
3. Learning disability
4. Receives regular colonoscopies
5. Experiencing significant cognitive decline

Date of first enrolment
13/05/2013

Date of final enrolment
08/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Epidemiology and Public Health
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
UCL/UCLH/Royal Free Biomedical Research Unit (UK)

Sponsor details
Clinical Research Facility
235 Euston Road
London
United Kingdom
NW1 2BU

Sponsor type
Research organisation

Website
http://www.uclh.nhs.uk/Research/CRF/Pages/Home.aspx

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Central Commissioning Facility (ref: RP-PG-0407-10338)

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?
Results article	results	01/07/2014		Yes	No
Results article	results	13/09/2016		Yes	No
HRA research summary			28/06/2023	No	No