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Bowel cancer screening information: your response

Submission date 05/07/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2012	**Overall study status** Completed	
Last Edited 15/06/2016	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
In England, the NHS Bowel Cancer Screening Programme (BCSP) offers screening to over 60 year olds. This involves completing a stool sample test at home. Recent data suggests that only 1 in 2 people who are offered the test, go on to complete it. However, this figure varies from more than 60% in the most socially advantaged groups to less than 35% in the most disadvantaged groups. The aim of this study is to reduce this difference in uptake rates between social groups. This study aims to test the effect of a leaflet by assessing its impact on participants intentions to use the test in a group of adults approaching the age of screening.

Who can participate?
Men and women aged between 45 to 59 and half years, who can read and write English.

What does the study involve?
The study involves sending all potential participants a study pack. The pack contains a covering letter from the participants GP practice, an 8-page questionnaire, a freepost return envelope, and an NHS envelope containing an example of the NHS BCSP invitation letter and a facts booklet about bowel cancer screening. For half of the participants, a narrative leaflet will also be included in the NHS envelope. Participants will be asked to read the contents of the NHS envelope before completing and returning the questionnaire in the freepost envelope to the research team.

What are the possible benefits and risks of participating?
Participants will benefit by learning about an important public health initiative and by contributing to the development of enhanced information materials about the NHS BCSP. There are no known risks of participating in this study.

Where is the study run from?
University College London, UK

When is the study starting and how long is it expected to run for?
June to October 2012

Who is funding the study?
National Institute of Health Research and Cancer Research UK

Who is the main contact?
Dr Lesley McGregor
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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
11935

Study information

Scientific Title
Assessing the impact of additional patient narrative information on attitudes, beliefs and future intentions to complete the Faecal Occult Blood (FOB) test in adults approaching the age for bowel cancer screening

Study objectives
Bowel cancer is the second most common cause of cancer death in the UK. Finding cancer early can save lives; therefore, in 2006, the NHS launched a Bowel Cancer Screening Programme (BCSP). In England, the BCSP offers screening to 60-69 year olds (up to 74 years in some areas). Screening involves completing a stool sample test kit (the faecal occult blood test, FOB test) at home. Recent data suggests that only 54% of those offered the FOB test complete it. However, this figure varies from more than 60% in the most socially advantaged groups to less than 35% in the most disadvantaged groups. The current study is part of a larger research programme (the

ASCEND Project) funded by the National Institute of Health Research (NIHR) that aims to reduce this difference in uptake rates between social groups. This study specifically aims to assess the influence of a narrative leaflet on future intentions to use the FOB test. The narrative leaflet includes quotes from people who have completed the FOB test. Research has shown that people respond positively to stories of personal experiences when making health related decisions. Participants, aged 45-59 (and who, therefore, have not yet taken part in the BCSP), will be recruited through GP practices. All participants will be sent an example of the usual BCSP invitation pack containing an invitation letter and a facts booklet, with 50% also receiving the narrative leaflet. A questionnaire accompanying the invitation pack will ask about the participant's views on bowel cancer and bowel cancer screening. Participants will be asked to read all the information in the invitation pack before completing the questionnaire. The impact of the narrative leaflet will be assessed by comparing questionnaire responses between the group receiving the usual materials and those receiving the usual materials plus the narrative leaflet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Northern and Yorkshire , 15/02/2012, ref: 12/NE/0058

Study design
Randomised interventional trial

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 a patient information sheet

Health condition(s) or problem(s) studied
Bowel cancer

Interventions
All participants will receive the usual invitation pack sent by the NHS BCSP. Half of the participants will recieve an additional narrative leaflet.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Intention to be screened

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2012

Completion date
21/11/2012

Eligibility

Key inclusion criteria
1. Men and women registered with one of the GP practices supporting this study
2. Aged between 45-59.5 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 1500

Key exclusion criteria
1. Patients who have had bowel cancer, a recent diagnosis of cancer or other significant illness, are terminally ill, have a learning disability, already receives regular colonoscopies, or are experiencing cognitive decline
2. GPs will be asked to exclude any patients they believe may become distressed by receiving the questionnaire
3. Patients who are not able to read English. The study involves completing a questionnaire which elicits responses to written materials, and so competancy in English is essential

Date of first enrolment
25/07/2012

Date of final enrolment
21/11/2012

Locations

Countries of recruitment

United Kingdom

Study participating centre
West Hampstead Medical Centre
London
United Kingdom
-

Study participating centre
Morris House Group Practice
London
United Kingdom
-

Study participating centre
Brunswick House Medical Group
Carlisle
United Kingdom
-

Sponsor information

Organisation
University College London (UK)

Sponsor details
Department of Epidemiology and Public Health
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK ref: 148000

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
National Institute for Health Research Grant Programme (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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 expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/03/2015		Yes	No