

Evaluation of a 'gist-based' information leaflet to be used in the NHS Bowel Cancer Screening Programme

Submission date 22/06/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 05/05/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Participation in the NHS Bowel Cancer Screening Programme is low, particularly in people from a lower socioeconomic status. The information materials provided to people can be difficult to understand for people with lower levels of literacy, and may therefore inadvertently discourage participation. This study aims to test a low literacy information booklet to be incorporated within the NHS Bowel Cancer Screening Programme.

Who can participate?

Patients registered at four GP practices, aged 45-59

What does the study involve?

Participants are randomly allocated to be sent either the standard information materials, or the standard materials along with a low literacy information booklet.

What are the possible benefits and risks of participating?

Participants learn about the topic of bowel cancer and bowel cancer screening. There are no risks to taking part in the study.

Where is the study run from?

CRUK & UCL Cancer Trials Centre (UK)

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

July to September 2012

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Samuel Smith
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Contact information

Type(s)

Scientific

Contact name

Mr Samuel Smith

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

12483

Study information

Scientific Title

Evaluation of a 'gist-based' information leaflet to be used in the NHS Bowel Cancer Screening Programme: a randomised study

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) at home. Recent data suggests that only 54% of those offered the FOB test choose to do 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 gist-based leaflet developed by the research team, on future intentions to use the FOB test. Participants aged 45-59 (who have not yet taken part in the BCSP), will be recruited through GP practices. All participants will be sent the usual BCSP information leaflet 'Bowel Cancer Screening: The Facts', while the intervention group will also receive a gist-based leaflet. A questionnaire will ask about the participants views (e.g. intention to be screened, comprehension, attitudes, beliefs) on bowel cancer and bowel cancer screening.

Answers will be compared between the two groups in order to assess the impact of the gist-based leaflet.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee Yorkshire & The Humber - Leeds West, 12/YH/0106; First MREC approval date 07/02/2012

Study design

Randomised; Interventional; Design type: Not specified

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

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

All participants will be sent the usual BCSP information leaflet 'Bowel Cancer Screening: The Facts', while the intervention group will also receive a gist-based leaflet.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Intention to be screened

Secondary outcome measures

Not provided at time of registration

Overall study start date

02/07/2012

Completion date

24/09/2012

Eligibility

Key inclusion criteria

1. Registered with a GP Practice
2. Aged between 45-59, Male & Female

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 840; UK Sample Size: 840

Key exclusion criteria

1. Patients whom are unable or do not wish to provide informed consent
2. Patients whom the GP advises should not be approached (e.g. recent diagnosis of cancer or other significant illness, terminally ill, learning disability, already receives regular colonoscopies)
3. Patients who are not able to read English

Date of first enrolment

02/07/2012

Date of final enrolment

24/09/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

CRUK & UCL Cancer Trials Centre

London

United Kingdom

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Sponsor information

Organisation

University College London (UK)

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Sponsor type

University/education

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research - Programme Grant for Applied Research (PGfAR)

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	01/04/2015		Yes	No