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General practice endorsement in the Bowel Cancer Screening Programme

Submission date
21/04/2015

Recruitment status
No longer recruiting

Registration date
16/07/2015

Overall study status
Completed

Last Edited
09/08/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel cancer is the second most common cause of cancer death in the UK. Early diagnosis improves survival and in light of this the NHS established the Bowel Cancer Screening Programme (BCSP). This Programme offers screening using a stool testing kit (the faecal occult blood test) to 60-74 year olds. Data from 2012 shows that only 53% of those offered screening take it up and that this varies from more than 60% in the most socially advantaged areas of the country to less than 35% in the most disadvantaged areas. This study aims to increase uptake in the BCSP, and to reduce differences in uptake between the most and least socially advantaged groups, whilst ensuring that uptake does not decline in any socioeconomic (SE) group. The study will test whether or not receiving an endorsement from your GP at the same time that you receive a kit as part of the BCSP is likely to increase uptake and/or reduce SE inequalities.

Who can participate?
Individuals who are routinely invited for screening in the BCSP (age 60-74 with a registered GP).

What does the study involve?
Participants will be randomly allocated either to receive an invitation letter with a GP endorsement or the standard letter currently sent out by the BCSP without an endorsement.

What are the possible benefits and risks of participating?
No benefits or risks are expected as the study is carried out within the participant's standard care pathway as part of the Bowel Cancer Screening Programme – the usual benefits and risks of participating in the Bowel Cancer Screening Programme would still apply.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
March to December 2015

Who is funding the study?
University College London (UK)

Who is the main contact?
Dr Amanda Cross

Study website
http://www.csprg.org.uk/ascend-2/

Contact information

Type(s)
Scientific

Contact name
Dr Amanda Cross

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United Kingdom
W2 1PG

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0 17/03/2015

Study information

Scientific Title
General practice endorsement in the Bowel Cancer Screening Programme: the ASCEND2 project

Acronym
ASCEND2

Study objectives

Receiving an endorsement from the GP at the same time that you receive a screening kit as part of the NHS Bowel Cancer Screening Programme (BCSP) is likely to increase uptake rates and reduce socioeconomic (SE) inequalities in uptake.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands REC, 07/12/2015, ref: 15/EM/0561

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

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
Colorectal cancer/bowel cancer

Interventions
ASCEND2 will compare the effectiveness of using a general practice endorsement banner on kit invitation letters sent as part of the BCSP, against the standard letter currently sent out by the BCSP. Individuals who are routinely invited for screening in the BCSP in England will be allocated to receive an intervention on randomly selected days within a pre-specified time period (cluster randomisation).

Intervention Type
Behavioural

Primary outcome measure
Proportion of people in each Index of Multiple Deprivation (IMD) quintile returning an adequate faecal occult blood test (FOBt) within 18 weeks of being sent their initial invitation letter. An adequate FOBt in this study is defined as reaching a definitive FOBt outcome of either a 'Normal' (no further clinical investigation is required) or 'Abnormal' (referral for prospective colonoscopy).

Secondary outcome measures

1. Time taken to return FOBt by IMD quintile
2. Proportion of spoilt kits and their relationship to IMD quintile
3. Proportion of non-delivered kits by IMD quintile
4. Incremental cost per screening invitation
5. Incremental cost per screening invitation, both by IMD quintile and overall
6. All of the above outcomes analysed using other SE variables

Overall study start date
01/03/2015

Completion date
30/04/2018

Eligibility

Key inclusion criteria
Men and women aged between 60-74 years who have a registered GP

Participant type(s)
Other

Age group
Senior

Sex
Both

Target number of participants
97616

Total final enrolment
394842

Key exclusion criteria
1. We will only be able to randomise eligible people to receive this intervention if they are registered with practices that agreed to endorse the BCSP during the preceding trial, ASCEND.
2. Invited subjects may contact their BCSP hub and opt-out of the current screening episode and others for reasons of informed choice or poor health and they can choose to be ceased from the screening programme. 'Ceased' subjects, if ceased prior to their screening due date will not be invited to be screened.

Date of first enrolment
01/02/2016

Date of final enrolment
11/03/2016

Locations

Countries of recruitment

United Kingdom

Study participating centre
NHS Bowel Cancer Screening Programme
United Kingdom
-

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
South Kensington
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

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
Current publication and dissemination plan as of 11/07/2018:
Analysis and results publication expected in 2018-2019.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. Source data contains patient identifiers and is the property of the NHS BCSP so will therefore not be freely available. Once processed, cleaned and anonymised study data will then be stored in a repository as per sponsor (Imperial College) guidelines.

Previous publication and dissemination plan:
Analysis and results publication expected in 2017.

IPD sharing statement:
The datasets generated during and/or analysed during the current study is not expected to be made available. Source data contains patient identifiers and is the property of the NHS BCSP so will therefore not be freely available. Once processed, cleaned and anonymised study data will then be stored in a repository as per sponsor (Imperial College) guidelines.

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	27/02/2021	11/03/2021	Yes	No
Protocol file	version 1.0	11/11/2015	09/08/2022	No	No
HRA research summary			28/06/2023	No	No