

# General practice endorsement in the Bowel Cancer Screening Programme

<b>Submission date</b> 21/04/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/08/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

## Contact information

### Type(s)

Scientific

### Contact name

Dr Amanda Cross

### ORCID ID

<https://orcid.org/0000-0002-0893-2377>

### Contact details

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Screening

## **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(s)**

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).

## **Key secondary outcome(s)**

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

## **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

## **Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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

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**Sponsor information****Organisation**

Imperial College London (UK)

**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

**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?
<a href="#">Results article</a>	results	27/02/2021	11/03/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1.0	11/11/2015	09/08/2022	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes

