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A feasibility study of patient navigation in bowel scope screening

Submission date 01/07/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2015	**Overall study status** Completed	
Last Edited 28/05/2020	**Condition category** Digestive System	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-way-to-support-people-as-they-make-a-decision-to-have-bowel-scope-screening

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18256

Study information

Scientific Title
Using specialist screening practitioners (SSPs) to increase uptake of the bowel scope screening programme: a feasibility study of patient navigation within South Tyneside NHS Foundation Trust

Study objectives
Bowel cancer prevention and early diagnosis is an NHS priority. Bowel Scope Screening (BSS) has recently been introduced to the NHS Bowel Cancer Screening Programme in an attempt to reduce future bowel cancer incidence. BSS involves a Flexible Sigmoidoscopy (FS), a procedure that can prevent bowel cancer by finding and removing growths in the bowel before they turn into cancer. BSS is currently offered as a one-off test to men and women aged 55 years. However, the success of any screening programme is dependent on uptake. A recent pathfinder programme of BSS in England found uptake to be as low as 28%. Patient navigation (PN) is an intervention that offers individual support to patients to help them overcome their barriers to screening. In this study, PN will involve Specialist Screening Practitioners (SSPs) from the South of Tyne ScreeningCentre calling people who either fail to confirm or attend their BSS appointment. SSPs will encourage discussion of the individual's barriers to screening attendance and will offer suitable solutions and support. SSPs will be trained to communicate the aims, benefits and risks of BSS, to ensure that people make an informed choice about whether participation is right for them. To assess whether PN is feasible in increasing the uptake of BSS, non-attenders will be randomly assigned to one of two groups: usual care or usual care with PN. We will monitor the number of people who participate in BSS after PN and the patient experience of this service. We will also conduct qualitative interviews with SSPs to evaluate the impact that PN has on their workload. A feasibility study is very important in this context because non-attenders are difficult to involve in research studies. If PN is effective and acceptable, we will apply for funding for a larger, multi-centre trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London – Bloomsbury, 30/01/2015, ref: 14 LO 2308)

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Gastroenterology; Subtopic: Gastroenterology; Disease: All Gastroenterology

Interventions
Patient Navigation (PN), an intervention that offers individual support to patients to help them overcome their barriers to screening. In this study, PN will involve specialist screening practitioners (SSPs) from the South of Tyne Screening Centre calling people who either fail to confirm or attend their BSS appointment. SSPs will encourage discussion of the individual's barriers to screening attendance and will offer suitable solutions and support. SSPs will be trained to communicate the aims, benefits and risks of BSS.

Intervention Type
Other

Primary outcome measure
Uptake of Bowel Scope Screening; Timepoint(s): when the outcome data is extracted for the UCL team to analyse

Secondary outcome measures
N/A

Overall study start date
19/05/2015

Completion date
19/11/2015

Eligibility

Key inclusion criteria
1. As part of the NHS Bowel Scope Screening Programme (BCSP), participants need to be 55 years (and up to 2 months) during the recruitment period, and live in the South of Tyne area served by the South Tyneside NHS Trust
2. Target Gender: Male & Female
3. Aged at least 55

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 384; UK Sample Size: 384

Total final enrolment
152

Key exclusion criteria
Patients invited will be identified as eligible for bowel scope screening by the Bowel Cancer Screening Programme (BCSP)

Date of first enrolment
19/05/2015

Date of final enrolment
19/11/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
Gower Street
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Sponsor information

Organisation
University College London

Sponsor details
UCL Biomedicine Research & Development Unit, Maple House, 149 Tottenham Court Road
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England
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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

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 provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/09/2016		Yes	No
Results article	results	15/02/2019	04/03/2020	Yes	No
Plain English results			28/05/2020	No	Yes