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Steps towards increasing bowel cancer screening uptake: a randomised controlled trial

Submission date
23/02/2018

Recruitment status
No longer recruiting

Registration date
02/03/2018

Overall study status
Completed

Last Edited
22/04/2021

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel cancer screening uptake has traditionally been lower than the government would like it to be. As screening can spot early signs of cancer and even stop bowel cancer from occurring, the public health service would like to improve screening rates.
This study aims to test a set of new, evidence-based materials, informed by psychological theory, to increase the return of the stool-based bowel cancer screening kit the NHS uses, in the North East region of England.

Who can participate?
Adults age 60 – 74 years eligible for bowel cancer screening

What does the study involve?
Participants are randomly allocated to one of four groups. All participants are sent an initial invitation letter for bowel cancer screening and the standard NHS information booklet.
Those in the first group receive an intervention pack four days after the letter, with an information sheet and short paper based task encouraging them to connect barriers likely to be encountered with effective responses. They receive the bowel cancer screening test four days later.
Participants in the second group receive an intervention pack containing the information sheet and a motivational leaflet. They receive the screening kit in the post four days later.
Participants in the third group receive both of the above intervention packs in the post four days after the initial letter, before the screening kit four days later.
Participants in the last group receive no additional information, and get a screening kit in the post eight days after the initial letter.

What are the possible benefits and risks of participating?
Participants help to improve bowel cancer screening services for their own and others future health needs. There are no risks associated with the study as all participants receive the usual care.

Where is the study run from?
North East Bowel Cancer Screening Hub (UK)

When is the study starting and how long is it expected to run for?
June 2016 to July 2018

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
Prof Daryl O'Connor (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
n/a

IRAS number
224425

ClinicalTrials.gov number
n/a

Secondary identifying numbers
IRAS224425_V6_22.05.17

Study information

Scientific Title
Effectiveness of a health behaviour change intervention to promote bowel cancer screening uptake: a randomised controlled trial

Acronym
STICS trial

Study objectives
The delivery of a new, low-cost, health behaviour change intervention will be effective in increasing uptake of bowel cancer screening in the North East of England. A randomised controlled trial will test a) an implementation intentions-based intervention, b) a motivational-based intervention and c) their combination, against d) a control group receiving usual care. We hypothesise that participants in any of the three intervention groups will have higher screening uptake in comparison to the Control group and that people in the Combination group will have higher screening uptake in comparison to the other three study groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Health Research Authority Research Ethics Committee, 10/10/2017, ref: 17/ES/0085
2. Confidentiality Advisory Group (CAG), 10/10/2017, ref: 17/CAG/0119
3. NHS Bowel Cancer Screening Programme Research Ethics Committee, 23/11/17, ref: BCSPRAC_184 (ODR 1617_264)
4. Office of Data Release, 29/01/2018, ref: ODR1617_264 (BCSPRAC_184)

Study design
2 x 2 cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
PIS is not available in web format, please contact A.I.Tsipa11@leeds.ac.uk. to request a PIS

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

Interventions
Participants are randomised to one of four groups to evaluate the separate and combined effects of two psychological, evidence-based interventions. All participants are sent an initial letter of invitation for bowel cancer screening and the standard NHS information booklet and the different groups receive one of the following before being sent a guaiac faecal occult blood test (gFOBT):

1) Implementations Intentions (IMPS) intervention: Four days after the initial letter participants receive an intervention pack containing an information sheet and a short, implementation intentions, paper-based task designed to help them construct effective 'if-then' plans. This involves connecting barriers likely to be encountered (IFs) with effective responses (THENs) to aid participants' decision-making process with regards to completion of the guaiac faecal occult blood test (gFOBT) screening kit, which is sent in the post four days later.
2) Motivational intervention: Four days after the initial letter, participants receive an intervention pack containing an information sheet and a motivational-intervention leaflet. The leaflet contains information regarding some of the social norms surrounding bowel cancer screening (e.g. how many people do engage in screening) and is designed to motivate participants to take part in gFOBT screening. Participants receive the gFOBT screening kit four days later.
3) Combination intervention: Four days after the initial letter, participants receive an intervention pack containing an information sheet, an implementation intentions paper-based task and a motivational-intervention leaflet. Participants read the information sheet, motivational leaflet and complete the short implementation intentions tasks to help them plan to use their screening kit when it arrives approximately four days later.
4) Control group: Participants receive the gFOBT screening kit eight days after the initial letter (usual care).

Intervention Type
Other

Primary outcome measure
Screening uptake measured by the proportion of people in each intervention condition returning an adequate gFOBT kit within 8 weeks of being sent an invitation

Secondary outcome measures
1. Time taken by participant to return kit
2. Variation in screening uptake (defined as the return of an adequate gFOBT kit within 8 weeks of being sent an invitation) by
2.1. Gender
2.2. Age
2.3. Past screening history
2.4. Level of socioeconomic deprivation

Overall study start date
01/06/2016

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Men and women eligible to be screened for bowel cancer in the North East region of England
2. Aged between 60-74 years

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
20,000

Total final enrolment
34633

Key exclusion criteria
Participants that are classed as Type II objectors

Date of first enrolment
05/03/2018

Date of final enrolment
12/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East Bowel Cancer Screening Hub
Queen Elizabeth Gateshead Hospital
Sheriff Hill
Gateshead
United Kingdom
NE9 6SX

Study participating centre
NHS Digital
1 Trevelyan Square
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)
YCR

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is planned that the study will be written up and published in a high-impact peer reviewed journal. This will be approximately a year following data analysis following the end of the study.

Intention to publish date
31/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request using the contact details above.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2020	22/04/2021	Yes	No
HRA research summary			28/06/2023	No	No