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Primary care based text-reminders in colorectal cancer screening

Submission date 17/09/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/09/2015	**Overall study status** Completed	
Last Edited 15/01/2018	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Colorectal cancer (CRC, also known as bowel cancer) is the fourth most common cancer and the second leading cause of cancer related deaths in England. Screening the at risk population for CRC by way of biennial faecal occult blood testing (FOBt) reduces CRC deaths by detecting CRC early, at a time when it is easier to treat. In England, the National Health Service (NHS) runs an organised population-based CRC screening programme (Bowel Cancer Screening Programme, BCSP), which offers biennial screening via guaiac-based faecal occult blood testing (gFOBt) to any men and women aged 60-74. With 54% overall uptake, CRC screening has the lowest uptake rate amongst all of the organised National Cancer Screening Programmes (Breast and Cervical Cancer Screening) in England. As such, there is an important need for interventions to promote uptake of FOBt in the capital to reduce inequalities in uptake. Increasing evidence demonstrates that General Practitioner (GP) endorsement promotes CRC screening uptake and there is a growing interest in the use text-message reminders to increase participation in cancer screening. The present study aims to investigate the effectiveness of a primary care based text-message reminder to promote CRC screening uptake in London.

Who can participate?
Adults aged between 60 to 75 who are eligible for bowel cancer screening.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants are sent an invitation letter with screening information booklet by their local Hub. They then receive the gFOBt kit and instructions 8-10 days letter. They are asked to collect samples of three separate bowel motions and send the completed kit back to the hub. A letter is sent after four weeks of non-response. Those allocated to the first group receive a text message reminder to send their kit back. Those in the second group receive the standard screening materials. Uptake in both groups will be measured at 18 weeks and compared for statistically significant differences.

What are the possible benefits and risks of participating?
Not provided at the time of registration.

Where is the study run from?
NHS Bowel Cancer Screening Programme London Hub (UK). This study will be conducted in 180 primary care practices in London.

When is the study starting and how long is it expected to run for?
July 2015 to January 2017

Who is funding the study?
North West London Hospitals Trust (UK)

Who is the main contact?
Dr Christian von Wagner

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial to test the effectiveness of primary care-based text-message reminders in facilitating uptake of colorectal cancer screening in London

Acronym
TRICCS

Study objectives

The aim of this study is to test the effectiveness (intention-to-treat analysis) and efficacy (per-protocol analysis) of primary care based text-message reminders to promote uptake of bowel cancer screening in London.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. East Midlands Derby Ethics Committee, 01/04/2015, ref: 15/EM/0159
2. Confidentiality Advisory Group,12/08/2015 ref: 15/CAG/0156

Study design
Non-clinical randomised controlled trial

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 to request a patient information sheet

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

Interventions
At age 60, and then every two years up to and including age 74, all patients registered with a GP and living in England (who have not explicitly opted out of screening) are sent an invitation letter with the screening information booklet by their local Hub. The gFOBt kit and instructions follow 8-10 days later. The individual is asked to collect samples from three separate bowel motions, and return the completed kit to the Hub in a pre-paid envelope for processing (see Figure 1). Repeat gFOBt kits are sent out following a ‘spoilt kit’, ‘technical failure’, or an ‘unclear result’. A reminder letter is sent after four weeks of non-response. The screening episode is closed if there has been no response within 13 weeks without another notification to the individual. The GP practices will receive a letter for their patients’ non-attendance. Following an abnormal result a referral is made to the local screening centre for further diagnostic investigations.

Intervention group:
People who are randomised to the intervention group will receive a text-message reminder in addition to the standard materials if they have not returned the test kit at eight weeks of their screening episode (i.e. three weeks after the ‘reminder letter’). The reminder text will include

the name of the GP practice, GP endorsement, the purpose of the text-message, and guidance on where to get more information. The content of the text-message has been selected by a steering group involving patient representatives, GP Cancer Leads, Public Health England-Behavioural Insights Team and the BCSP London Hub.

Usual Care group:
Individuals in the control group will only receive the standard NHS CRC screening materials.

Intervention Type
Behavioural

Primary outcome measure
The proportion of people classified as adequately screened within 18 weeks of the invitation letter in the control and intervention group.

Secondary outcome measures
1. Participant update in the control and intervention groups, is evaluated in the 18th week of the screening episode
2. The effect of the intervention on screening uptake by demographic variables (socioeconomic status i.e. Index of Multiple Deprivation (IMD) rank, gender, age, CCG and screening round) measured at the end of the intervention

Overall study start date
06/07/2015

Completion date
02/01/2017

Eligibility

Key inclusion criteria
1. Aged between 60 and 75
2. Registered with a participating London GP practice enrolled in the study.
3. Eligible for bowel cancer screening

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3118

Key exclusion criteria

1. Stoma patients who have had their entire large bowel removed
2. Stoma patients who have had an Ileostomy
3. Opted out from text-messaging services which is provided by their registered GP practice

Date of first enrolment
01/12/2015

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Bowel Cancer Screening Programme London Hub
St Marks Bowel Cancer Screening Centre
St Marks Hospital,Watford Road
Harrow
Middlesex
London
United Kingdom
HA1 3UJ

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
University College London
Gower Street
London
United Kingdom
WC1E 6BT.

Sponsor type
University/education

Website

www.ucl.ac.uk/jro

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North West London Hospitals Trust

Results and Publications

Publication and dissemination plan
We are currently aiming to publish the study protocol before we commence with the trial in a peer reviewed journal. Furthermore, the results of the trial will be written up for publication in a peer reviewed journal and presented at conferences which will target health professionals, academics and policy makers.

Intention to publish date
01/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/01/2016		Yes	No
Results article	results	23/05/2017		Yes	No
HRA research summary			26/07/2023	No	No