ISRCTN17245519 https://doi.org/10.1186/ISRCTN17245519

Using text message reminders and culturally-tailored telephone calls to promote participation in bowel cancer screening (TOPPS)

Submission date
15/09/2022

Recruitment status
No longer recruiting

Registration date
20/02/2023

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Bowel cancer is a leading cause of cancer-related death in England. Several large studies have shown that screening can improve bowel cancer outcomes by detecting cases early. In light of this, NHS England initiated a national bowel cancer screening programme (BCSP) in 2006. Since then, uptake has been consistently low, falling from 54% in 2010 to 49% in 2015. Further, in London, participation in bowel cancer screening is particularly low in regions where there is high ethnic diversity.
However, previous research suggests that it is possible to improve screening uptake by using text message reminders and patient navigation (one-to-one support and guidance for patients throughout their decision-making regarding screening). This study aims to compare the effectiveness, and cost-effectiveness, of these two strategies to increase bowel cancer screening participation in six areas in London, where screening uptake is known to be low. This will provide policy-decision makers with the information needed to commission these services.

Who can participate?
Men and women aged 60-74 years registered with a participating general practice located within the London Boroughs of Brent, Ealing, Lambeth, Lewisham, Redbridge and Barking and Dagenham, who have not returned a bowel cancer screening kit within 13 weeks of delivery

What does the study involve?
Over a 4-week period, participants will be allocated (at random) to groups receiving either usual care, text message reminders at 13, 15, 17,19 weeks of non-response, or a text message reminder at 13 weeks plus patient navigation at 15, 17, 19 weeks of non-response.

What are the possible benefits and risks of participating?
The risks and burdens to participants are minimal. The NHS Bowel Cancer Screening invitation process will continue, unaffected by this study. Only those who do not participate within 13 weeks of invitation will be included in the study. These individuals will either receive no intervention (usual care), one or more text message reminders (depending on if/how soon they respond), or a call to discuss and rectify any barriers to attendance to support self-referral

(patient navigation).
There is potential that participants may feel that they are receiving too much information about bowel cancer screening, or are being coerced into participating in bowel cancer screening. However, the researchers will endeavour to ensure the interventions focus on enhancing informed choice and are delivered at suitable time points to not overwhelm individuals. This study benefits from a developmental phase, whereby people will help develop intervention content, and lay representatives will provide valuable input to the final designs. An advisory group and a steering group have also been established for this study and potential risks and burdens to participants will be addressed.
The main benefits of this study are that they may encourage participation in bowel cancer screening, which may help detect some bowel cancers at an earlier stage. The early detection of bowel cancer may, in turn, lead to improved cancer experience (e.g. less invasive treatment) and improved chances for survival.

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

When is the study starting and how long is it expected to run for?
August 2021 to October 2024

Who is funding the study?
NHS England (UK)

Who is the main contact?
Dr Robert Kerrison, Robert.Kerrison.13@ucl.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Robert Kerrison

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
299034

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
150666, IRAS 299034

Study information

Scientific Title
Exploring the effectiveness and cost-effectiveness of text-message reminders and telephone patient navigation to improve the uptake of faecal immunochemical test screening among non-responders in London: a randomised controlled trial

Acronym
TOPPS

Study objectives
1. Bowel cancer screening non-responders who receive text message reminders 12 weeks after being sent a screening kit will be more likely to complete and return a test kit, compared with those who do not receive text message reminders (usual care).
2. Bowel cancer screening non-responders who receive text message reminders and telephone patient navigation 12 weeks after being sent a screening kit will be more likely to complete and return a test kit, compared with those who do not receive text message reminders or telephone patient navigation (usual care).
3. Bowel cancer screening non-responders who receive text message reminders and telephone patient navigation 12 weeks after being sent a screening kit will be more likely to complete and return a test kit, compared with those who receive text message reminders only.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/03/2023, Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0212

Study design
Randomized 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 participant information sheet

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

Interventions
Participants will be randomised using computerised, pseudo-random, number allocation (performed using the 'RAND' function within Excel). Individuals will be randomised in equal proportions (1:1:1) to receive either:
1. No intervention (‘usual care only’),
2. A text-message reminder, 13 weeks after invitation, with additional text-message reminders at 15, 17 and 19 weeks, if there is no response (‘usual care + text message reminder(s)), or
3. A text-message reminder, 13 weeks after invitation, followed by PN calls at 15, 17 and 19 weeks, if there is no response (‘usual care + a text message reminder + PN telephone call(s))

Intervention Type
Behavioural

Primary outcome measure
Participation in screening, defined as returning a completed FIT kit, within 24 weeks of dispatch

Secondary outcome measures
The proportion of participants who receive a positive bowel cancer screening test kit result, within 26 weeks of being sent their test kit

Overall study start date
01/08/2021

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Men and women aged 60-74 years
2. Have not returned a bowel cancer screening kit within 13 weeks of delivery
3. Registered with a participating general practice located within the London Boroughs of Brent, Ealing, Lambeth, Lewisham, Redbridge and Barking and Dagenham

Participant type(s)
All

Age group
Mixed

Sex
Both

Target number of participants
2703

Key exclusion criteria
Exclusions will be made according to ‘Type-2 objector’ status, which is defined as: “a request, expressed by a registered patient, logged with a GP Practice, to indicate that personal identifiable information relating to them should not be disseminated or published by NHS Digital.

Date of first enrolment
01/08/2024

Date of final enrolment
01/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS North West London CCG
15 Marylebone Road
London
United Kingdom
NW1 5JD

Study participating centre
NHS South East London CCG
160 Tooley Street
London
United Kingdom
SE1 2TZ

Study participating centre
NHS North East London CCG
UNEX Tower
5 Station Street

London
United Kingdom
E15 1DA

Sponsor information

Organisation
University College London

Sponsor details
UCLH/UCL Joint Research Office, part of the Research Directorate
4th Floor, West
250 Euston Road
London
England
United Kingdom
NW1 2OG
+44 (0)20 7679 2000
pushpsen.joshi1@nhs.net

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Publication and dissemination plan
The results of this study will be reported in peer-reviewed journals and presented at scientific conferences. In addition, the funding body and the stakeholders (in particular the management

of the Bowel Cancer Screening programme) will be informed of the results prior to publication, in case the results merit action in terms of policy or practice.

Intention to publish date
30/12/2025

Individual participant data (IPD) sharing plan
At the end of the study, an anonymised version of the study database will be made available on Open Science Framework. Eligible patients registered at a participating GP practice will be identified by NHS Digital. This list will be transferred securely to an encrypted cloud-based server (iPlato) for randomisation and intervention delivery. Following completion of the study period, this database will be transferred back to NHS digital for data on cancer screening participation (and outcome) to be extracted and anonymised, and relevant participant information to be attached. This will include 'sex', 'age', 'index of multiple deprivation quintile'. The anonymised dataset will then be transferred to UCL's Data Safe Haven for analysis. Consent will not be required at the participant level for research of this nature and will be given by GP participation.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Protocol article		25/06/2024	25/06/2024	Yes	No