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A study testing a motivation-based messaging, planning tool, and a suggested deadline to help people aged 50–74 in North East England take part in NHS bowel screening

Submission date
01/08/2025

Recruitment status
Not yet recruiting

Registration date
12/06/2026

Overall study status
Ongoing

Last Edited
27/05/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Bowel cancer is one of the most common cancers in the UK, and early detection can save lives. The NHS offers a free bowel cancer screening programme, where adults aged 50 to 74 are sent a simple test kit to use at home. Despite this, many people do not return their test kits. Screening rates are especially low in areas of higher deprivation and among some minority ethnic groups. This study, called the BENE-FIT Trial, is designed to test whether sending additional support materials can help more people complete and return their bowel screening kits. It will test two simple tools: one aims to increase motivation by sharing positive messages about how many people take part in screening, and also helps people make a plan for when and how they'll do the test. A second tool suggests a clear deadline for returning the kit. These tools are based on research in psychology and behavioural science.
The BENE-FIT trial aims to find out whether these tools, used on their own or together, are more effective than the usual NHS information in helping people take part in bowel screening.

Who can participate?
Adults aged 50 to 74 years who are invited to take part in bowel cancer screening through the NHS North East Bowel Cancer Screening Programme Hub. People taking part are those already eligible for screening and due to receive a test kit. No additional sign-up or consent is needed, and people will not be contacted directly by the research team.

What does the study involve?
People taking part in this study will receive either the usual NHS screening invitation or one of the two types of additional support materials, sent through the post a few days before their kit arrives. The materials vary depending on which group people are randomly assigned to:
Group 1: Motivation and planning tool (helps people think about why screening matters and plan when to do it)
Group 2: Suggested deadline (adds a date to aim for when returning the kit)
Group 3: Both motivation/planning and deadline tools

Group 4 (Control): Usual NHS screening information, with no additional materials
All materials are delivered by post, and there is no extra effort required from the participant other than reading the information that comes with their invitation. Six months after invitations are sent, the research team will check anonymised NHS data to see how many people in each group returned their kits.

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 known risks to taking part in this study.

Where is the study run from?
The study is run by researchers at the University of Leeds and the University of Glasgow, in collaboration with the NHS North East Bowel Cancer Screening Programme Hub, and NHS England (UK)

When is the study starting, and how long is it expected to run for?
The study is expected to start in July 2026 and will run until August 2026. The main trial will take place over several weeks during the NHS screening invitation process, and data will be analysed after a 6-month follow-up period.

Who is funding the study?
Cancer Research UK

Who is the main contact?
Prof. Daryl O'Connor, d.b.oconnor@leeds.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Daryl O'Connor

Contact details
University of Leeds
School of Psychology
University Road, Woodhouse
Leeds
United Kingdom
LS2 9JT
+44 (0)1133431813
d.b.oconnor@leeds.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
347604

Protocol number

2025-NCT53

Study information

Scientific Title
BENE-FIT Trial: A randomised controlled trial evaluating the effectiveness of a motivation and planning intervention, a suggested deadline, and their combination versus usual care on bowel screening kit return at six months in adults aged 50–74 in North East England

Acronym
BENE-FIT

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) a motivation-based and implementation intentions-based intervention, b) a suggested deadline for test kit return and c) their combination, against d) a control group receiving usual care. It is hypothesised 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
Ethics approval required

Ethics approval(s)
approved 15/01/2026, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8241; leedswest.rec@hra.nhs.uk), ref: 26/YH/0008

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Screening

Study type(s)
Screening

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

Interventions
Participants are allocated to one of four groups to assess the impact of two psychological interventions, either alone or in combination, on bowel cancer screening uptake. Allocation is conducted using a pre-generated randomisation schedule, developed by Dr Darren Greenwood using Stata version 19.5, which is applied to daily batches of screening invitations, resulting in clustering by day of invitation mail-out. The allocation sequence is applied en masse by the BCSS team for each mail-out.

All interventions are delivered by post approximately six days after the standard NHS invitation, and two days before the FIT kit arrives.
1. Motivation-Planning Intervention includes: (a) a motivational leaflet using a Social Norms Approach, which highlights how many people participate in screening to increase perceived social approval and encourage engagement; and (b) a Volitional Help Sheet, which supports decision-making by guiding participants to form 'if-then' plans, linking common barriers (e.g., embarrassment or forgetfulness) with practical solutions (e.g., reminders of health benefits or setting a specific time to complete the test).
2. Suggested Deadline intervention consists of a brief letter asking participants to return their FIT kit within 14 days of receipt, providing a specific date to encourage timely action.
3. Combined Intervention includes both the motivational materials and the suggested deadline letter.
4. Control group receives usual care, with the FIT kit arriving eight days after the initial NHS invitation and no additional materials

The following measures will be assessed using study data at 6 months post-intervention:
Participant characteristics (to evaluate kit return rate by participant characteristic and permit covariate adjustments):
1. Age at invite: to assess kit return rate by age x condition interaction, and permit covariate adjustments
2. Gender: to assess kit return rate by gender x condition interaction, and permit covariate adjustments
3. Number of previous screening invitations an individual has received, to evaluate kit return rate by participant characteristic, and permit covariate adjustments
4. Number of previous screening episodes / positive responses to invitations from the individual, to evaluate kit return rate by participant characteristic, and permit covariate adjustments
5. Whether there was "adequate participation" by the individual in the most recent screening episode / other marker of previous positive response by the individual to the invitation – to assess kit return rate by screening history x condition interaction, and permit covariate adjustments
6. Ethnicity Mix at most recent episode (NOMIS - using Lower Layer Super Output Areas [LSOAs] derived from participant postcodes before anonymisation of the data. Delivered by BCSS): to assess kit return rate for each ethnic group
7. Index of Multiple Deprivation (IMD) decile at most recent episode (derived from LSOA of participant postcode before anonymisation of the data. Delivered by BCSS): to assess kit return rate by level of socioeconomic status x condition interaction

Method of contact and randomised allocation:
1. Allocated intervention condition (four conditions)
2. Attempt to contact the individual by app (yes/no)

3. Whether the individual had the app installed (yes/no)
4. Response to app message (yes/no)
5. Date and day of the week the intervention was mailed out
6. Date and day of the week the screening test kit was mailed out

Intervention Type
Behavioural

Primary outcome(s)
1. Kit return as a binary outcome (yes/no) measured using study records of kit receipt at within 6 months of kit distribution

Key secondary outcome(s))
1. Time to kit return measured using the recorded date of kit return from study records within 6 months of kit distribution
2. Screening test result measured as a binary outcome using clinical records indicating whether further investigation (i.e., colonoscopy) was required within 6 months of kit distribution
3. Colonoscopy uptake (if offered) measured as a binary outcome using clinical records indicating whether a colonoscopy appointment was attended within 6 months of kit distribution
4. Colonoscopy results (if offered) measured using clinical records of diagnostic outcomes within 6 months of kit distribution

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Aged 50-74 years
2. Living in an area under the care of the North East Bowel Screening Hub
3. Eligible for bowel cancer screening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
74 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Participants who have opted out of research using the National Opt Out scheme

Date of first enrolment
01/07/2026

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Gateshead - Queen Elizabeth Hospital
Queen Elizabeth Hospital
Sherriff Hill
Gateshead
England
NE9 6SX

Study participating centre
NHS England
Wellington House
133-135 Waterloo Road
London
England
SE18UG

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Daryl O'Connor (d.b.oconnor@leeds.ac.uk)

IPD sharing plan summary
Available on request