ISRCTN28168392 https://doi.org/10.1186/ISRCTN28168392

# Evaluation of an intervention co-designed with key stakeholders to improve colorectal cancer screening participation

**Submission date**
02/11/2022

**Recruitment status**
No longer recruiting

**Registration date**
04/11/2022

**Overall study status**
Completed

**Last Edited**
11/12/2023

**Condition category**
Cancer

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

## Plain English summary of protocol

Background and study aims
Colorectal cancer is one of the most commonly occurring types of cancer worldwide. It negatively impacts people's quality of life and is costly for both health services and patients. If colorectal cancer is found early, it's easier to treat and there's a better chance of recovery. Screening is a very effective way of detecting the disease in its early stages. However, of those who are invited to take part in screening in Ireland, only 41.9% take part.
Research from around the world has shown that there may be many reasons for people not taking up screening (e.g. fear or negative attitudes to screening, lack of time or ability to access screening, poor knowledge about the benefits of screening or healthcare professionals not advising patients to take part in screening).
This study aims to improve colorectal cancer screening uptake and improve patient outcomes. This will be done by developing a new screening invitation letter and a new information leaflet to encourage people to participate in colorectal cancer screening.

Who can participate?
People aged 60 years old who are invited to participate in colorectal cancer screening for the first time and randomly allocated by the National Screening Service to be invited to participate in the study

What does the study involve?
Participants are invited to complete an online consent and a questionnaire accessible online. They can complete this questionnaire whenever suits them, within 3 months from the receipt of the letter. This takes about 15 minutes. The data collected in the questionnaire will be treated anonymously. At the end of the questionnaire, participants will be offered the possibility to provide their contact details on another form if they wish to participate in an interview (about 30-60 minutes depending on their availability) to give more feedback about the BowelScreen programme and the materials they received. Their contact details will not be related to their questionnaire responses. Completing the questionnaire does not require them to participate in an interview.

What are the possible benefits and risks of participating?
Completing the questionnaire: There are no direct benefits for participants in taking part. They may enjoy the experience of participating in a research study and having the opportunity to give their opinion on how people are invited to take part in the BowelScreen programme.
Taking part in an interview (optional after having completed the questionnaire): A 15 euros voucher will be offered to participants as a thank you for their time. This voucher is exclusively related to participation in an interview for the research project and is completely independent of participation or not in the Bowel Screening programme.
In the questionnaire and interview, participants will be asked to answer questions about colorectal cancer and colorectal cancer screening. They might face emotional issues while thinking about a sensitive issue such as cancer. They will be free not to answer some questions. In addition, they will be free to withdraw their participation at any time without justification. If they feel that they would like to talk to someone about some of the issues it raises, the research team will be happy to recommend someone to them.

Where is the study run from?
The study is run from the National Screening Service, based in Dublin. The research team is based at the University of Galway (Ireland)

When is the study starting and how long is it expected to run for?
February 2022 to May 2023

Who is funding the study?
Irish Cancer Society (Ireland)

Who is the main contact?
Dr Alice Le Bonniec, alice.lebonniec@universityofgalway.ie

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Alice Le Bonniec

### ORCID ID
https://orcid.org/0000-0001-9916-8038

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
The CRITICALS project: CReation of an Innovative inTervention for Improving ColorectAL cancer Screening

### Acronym
CRITICALS

### Study objectives
The materials developed as part of the CRITICALS intervention to invite eligible people to participate in colorectal cancer screening will be evaluated as more acceptable and will increase screening uptake compared to the materials currently used.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 24/06/2022, University of Galway Research Ethics Committee (University of Galway, University Road, Galway, Ireland; +353 (0)91 493757; ethics@nuigalway.ie), ref: 2022.05.005

### Study design
Interventional single-center randomized small pilot

### Primary study design
Interventional

### Study type(s)
Screening

### Health condition(s) or problem(s) studied
Participation in colorectal cancer screening in general population

### Interventions
Two workshops were organized with key stakeholders to develop an intervention to encourage people to request the colorectal cancer screening kit when they are invited to take part by mail. Based on workshops results, the CRITICALS intervention was developed, which comprises two elements:
1. A new invitation letter, re-worded to be easier to understand and more appealing than the current letter;
2. A new leaflet (to be sent with the invitation), shorter than the current leaflet and highlighting

key information. This new leaflet also includes narratives from people having experienced screening and from a general practitioner. In addition, it includes prompts to encourage people to request the screening kit immediately, avoid postponement or procrastination which the literature suggests usually leads to non-participation in screening.

To test the feasibility and acceptability of the intervention, a mixed-methods feasibility study is conducted with participants randomly selected from the National Screening Service database. This study will include interviews and questionnaires with members of the public who have received the intervention material (vs a control group having received the usual invitation) to assess the acceptability of the materials, screening intention and subsequent screening behaviour.

Method of randomisation
The National Screening Service has managed the random allocation of eligible clients to the study. The research team at the University of Galway does not have sight of the demographic details of the participants nor of the details of the randomisation. The invitations to participate in the study were mailed from the National Screening Service system as screening invitations (with the intervention).

### Intervention Type
Behavioural

### Primary outcome(s)
Screening behaviour is measured by comparing the percentage of people who participated in screening in the control group vs the intervention group. This data will be provided by the National Screening Service 3 months after the intervention.

### Key secondary outcome(s))
All outcomes are measured at baseline:
1. Acceptability of the invitation letter to participate in screening and information leaflet, measured by five items with a scale from 1 to 5
2. Capability, opportunity and motivation are measured with a validated questionnaire - six items, scale from 1 to 10 (COM-B questionnaire)
3. Already participated in bowel cancer screening assessed using one item, Yes/No
4. Already called the Freephone to request the screening kit, assessed using one item, Yes/No
5. Already received the screening kit, assessed using one item, Yes/No
6. Intention to participate in screening, assessed using one item, scale from 1 "Definitely will" to 5 "Definitely will not"
7. Knowledge regarding bowel cancer and screening assessed using four questions, measure of the number of correct and incorrect answers
8. The acceptability of the materials and the views and perceptions of the BowelScreen programme, assessed using an optional interview after completing the questionnaire

### Completion date
01/05/2023

## Eligibility

### Key inclusion criteria

The inclusion criteria were developed in line with the BowelScreen inclusion criteria:
1. Adults aged 60 years old
2. Newly invited to participate in screening

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. People who are already involved in the screening programme (previously invited/ participated in colorectal screening)
2. People who have been diagnosed with colorectal cancer
3. People who are not competent English speakers and/or do not comprehend spoken or written English

### Date of first enrolment
20/10/2022

### Date of final enrolment
01/04/2023

## Locations

### Countries of recruitment
Ireland

### Study participating centre
### National Screening Service
Kings Inn House
200 Parnell St
Rotunda
Dublin
Ireland
D01 A3Y8

## Sponsor information

**Organisation**
National University of Ireland, Galway

**ROR**
https://ror.org/03bea9k73

# Funder(s)

**Funder type**
Charity

**Funder Name**
Irish Cancer Society

**Alternative Name(s)**

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
Ireland

# Results and Publications

**Individual participant data (IPD) sharing plan**
The dataset generated and analysed during the current study will be stored in a non-publicly available repository (secured One Drive).
The dataset generated and analysed during the current study will be available upon request from Alice Le Bonniec (alice.lebonniec@universityofgalway.ie).

The type of data that will be shared: not currently known
Timing for availability: not currently known
Whether consent from participants was required and obtained: Consent from participants was required and obtained before accessing the questionnaire.
Comments on data anonymization: Questionnaires do not collect any data that could identify the participant. If participants wish to leave their contact details to be contacted for an interview, they are invited to fill out another form, whose data will be treated separately. Interviews will be transcribed for analysis purposes. All information that could potentially identify participants or other individuals will be removed during recording transcription. All participants will be assigned an identification number which will be used during the analysis

process and in the publication of the study results.
Any ethical or legal restrictions: no
Any additional comments: no

## IPD sharing plan summary

Stored in non-publicly available repository, Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |