

Personalised risk information and its impact on informed choice and intention to undergo colonoscopy in the Scottish Bowel Screening Programme

Submission date 01/12/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/12/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/10/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This early phase study aims to assess what patient responses would be if they were given personalised risk information about their chances of having colorectal (bowel) cancer. In Scotland the existing bowel screening test (the guaiac Faecal Occult Blood test) is being replaced by a new test, called the Faecal Immunochemical Test (FIT), which requires a single stool sample. This test is easier to do and also gives more accurate information about an individual's risk of having colorectal cancer, based on their age and sex. The aim of this study is to test whether giving individuals personalised information on their risk of colorectal cancer, would help them to decide what is best for them, when weighed up alongside the risks of having further investigation via a colonoscopy (i.e. a test where a tiny camera is inserted into the bowel to check for anything which is out of the ordinary). It will also assess whether this would lead to more or fewer people deciding to have a colonoscopy and aims to find out the best way of presenting this information, so that people can fully understand it.

Who can participate?

Adults aged 50-74 registered on the Scottish Bowel Screening database.

What does the study involve?

Participants are randomised to one of three groups to receive information about their risk of cancer following a hypothetical result for detected faecal haemoglobin concentration (amount of blood in their stool sample), based on their age, gender and faecal haemoglobin concentration: 1) personalised risk information in numeric form (e.g. 1 in 100), 2) personalised information described as 'high', 'medium' or 'low' risk, and 3) as a 'positive' test result, as is currently given to people. The best methods to present this information is determined by this study, with the help of members of the public, two of who are part of the project team. Each participant is sent the information by letter and asked to say whether or not they would intend

to take up the offer of a colonoscopy for each level of risk. The groups are compared on whether or not their decision was based on a sound understanding of the information (informed choice), whether or not they intend to have a colonoscopy, and how satisfied they are with their decision.

What are the possible benefits and risks of participating?

The presented information is hypothetical i.e. it does not involve actual results from participants' tests but consists of imaginary examples, and so harms to people taking part will be limited. There are no individual benefits but the study will help us to assess whether giving people personalised risk information could improve cancer detection, increase patient satisfaction and save lives.

Where is the study run from?

Ninewells Hospital, Dundee (UK)

When is study starting and how long is it expected to run for?

August 2017 to July 2019

Who is funding the study?

Chief Scientist Office, Scotland (UK)

Who is the main contact?

Dr Jayne Digby

jayne.digby@nhs.net

Contact information

Type(s)

Public

Contact name

Dr Jayne Digby

Contact details

Division of Cancer Research

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Dundee

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

PErsonalised Risk Information for Colorectal Cancer Screening: How does personalised risk information versus the current 'positive' result letter impact on informed choice and intention to undergo colonoscopy in the Scottish Bowel Screening Programme?

Acronym

PERICCS

Study objectives

The aims of this study are:

1. To determine whether providing personal risk information can lead to fully informed choice in uptake of colonoscopy
2. To assess the effects of providing personal risk information on intention to take up an offer of colonoscopy and thus obtain indicative results to inform a larger RCT to estimate impact on current service levels
3. To compare estimated uptake of colonoscopy between different methods of presenting risk information after FIT i.e. personalised numerical score, personalised category and positive /negative cut-off
4. To assess participants' responses to receiving personal risk information, including knowledge, attitudes to screening and risk, and emotional responses including anxiety

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval is being sought from the East of Scotland Research Ethics Service.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Colorectal cancer screening

Interventions

Prospective participants are approached, by letter, to ask if they would give consent to participate in a survey to assess their response to an offer of colonoscopy in relation to an estimated personalised risk of having cancer. They are also asked whether or not they would consent to a possible follow-up telephone call. A full patient information sheet and a return slip for written consent are provided. Data on screening history (i.e. previous participation/failure to participate/been offered a colonoscopy) is collected at the time of sampling, as these strongly predict screening uptake.

Consenting participants are randomised to one of 3 treatment groups:

1. Numerical (i.e. a personalised numerical-based risk assessment (e.g. a 1 in X risk) related to hypothetical test result and age and gender)
2. Categorical (as treatment group 1) but this would be categorised as 'Low', 'Medium' and 'High' risk
3. Positive cut-off (i.e. as current practice that is i.e. a positive or negative test result, based on the current cut-off of 2% positivity).

Randomisation with minimisation on variables related to risk (i.e. age, SIMD, gender) is carried out via MINIM software. Consenting participants are posted the study questionnaires, the personalised risk scenarios and the current explanatory information on colonoscopy, which describes the bowel preparation, the performance of the procedure and the attendant risks.

Each treatment arm is presented with hypothetical scenarios relating to different levels of risk of CRC and asked to rate their intention of attending a colonoscopy if they received that result following an actual FIT. Three scenarios, relating to low, medium and high risk for colorectal cancer are presented in groups 1 and 2; by definition group 3 has only one possible scenario i.e. a positive result.

Intervention Type

Behavioural

Primary outcome measure

1. Intention to take up the offer of colonoscopy, as a proxy for behaviour, will be measured on a Likert-type scale from 1 (low intention) to 7 (strongly intend) at a single time point on return of the study questionnaire
2. Informed choice in cancer screening is measured using a questionnaire adapted from a Smith et al measure at a single time point on return of the study questionnaire

Secondary outcome measures

1. Participants feeling informed about their decisions is measured using the Decisional Conflict Scale, Informed Choice subscale (3 items) at a single time point on return of the study questionnaire
2. Anxiety is measured using the State Trait Anxiety Inventory at a single time point on return of the study questionnaire
3. Ease of understanding and acceptability of the presentation of risk information measured using in the questionnaire using Likert-type questions scored on a 7-point scale from "strongly agree" to "strongly disagree" at a single time point on return of the study questionnaire

Overall study start date

01/08/2017

Completion date

31/07/2019

Eligibility

Key inclusion criteria

Any adult registered on the Scottish Bowel Screening database aged 50-74.

Participant type(s)

Other

Age group

Adult

Sex

Both

Target number of participants

We aim to recruit 300 adults. An $n=300$ (100 in each group) will have 83.7% power of detecting a 1 point increase in knowledge (intervention versus control), and a 2 point difference in attitudes (based on existing study means/SDs 8,11), using a one-way ANOVA. A pilot sample of 60-100 per group is recommended to provide an estimate of an event rate (e.g. screening uptake); so a sample of 300 would provide an indicative effect size of colonoscopy uptake for a future full-scale study. We would send out 1,440 invitations, from whom we conservatively expect to get around 360 replies (25%); we expect a further 20% attrition between consent and questionnaire return, giving a final $n=300$. In the event that we do not hit our target of 360 replies to the first letter, a second wave of invitation letters would be sent out (the number of these would be based on actual response to and the deficit from the first invitation).

Total final enrolment

308

Key exclusion criteria

Being currently treated for cancer.

Date of first enrolment

01/08/2018

Date of final enrolment

31/01/2019

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre**Ninewells Hospital**

James Arrott Drive

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

Co-Sponsorship from University of Dundee and NHS Tayside

Sponsor details

TASC (Tayside Medical Science Centre)

Ninewells Hospital & Medical School

TASC Research & Development Office

Residency Block

Level 3

George Pirie Way

Dundee

United Kingdom

DD1 9SY

Sponsor type

Research organisation

ROR

<https://ror.org/000ywep40>

Funder(s)

Funder type

Government

Funder Name

Chief Scientist Office

Alternative Name(s)

CSO

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Our wide-reaching dissemination policy will include regular briefing papers, a dedicated website, dissemination seminars, presentation of findings at international conferences and in peer-reviewed journals. Two patient and public involvement (PPI) members will be involved in the dissemination process. We will publish our protocol in advance of trial recruitment e.g. in BMC Public Health.

Intention to publish date

31/07/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Jayne Digby, jaynedigby@nhs.net

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/04/2019		Yes	No
Results article	results	20/10/2020	22/10/2020	Yes	No