

How does giving a little vs. a lot of information about screening for ovarian cancer based on genetic risk assessment influence thoughts and feelings about taking part in ovarian cancer genetic testing and screening?

Submission date 04/03/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Despite progress in early detection and treatment for many cancers, ovarian cancer (OC) remains a leading cause of cancer death in women. The absence of a distinct 'pre-cancerous' stage combined with non-specific symptoms such as bloating and back pain makes timely detection challenging. A novel research programme (PROMISE, jointly funded by CRUK and The Eve Appeal) is currently under way to test whether a 'personalized' approach to ovarian cancer screening (which includes assessment of genetic risk markers alongside biomarkers and epidemiological data) could improve current risk prediction approaches; making population-based screening for ovarian cancer feasible. One important aspect of the research is to discover how to best convey the potential benefits and risks of the programme to women to help them make an informed decision about participating in the PROMISE programme.

Who can participate?

All women aged 18-74 who are able to give informed consent and who have not been diagnosed with ovarian cancer

What does the study involve?

The study is run over the Internet. Participants are randomly allocated into one of two groups and are asked to visit one of two versions of the website informing about PROMISE. Here, they find information about ovarian cancer, genetic testing and PROMISE. Participants are instructed to browse the website at their leisure, and to make a hypothetical decision whether or not they'd like to take part in PROMISE. Participants are asked questions about ovarian cancer and genetic testing before and after visiting the website. They are also asked about their thoughts and feelings about taking part in PROMISE after they visited the website.

What are the possible benefits and risks of participating?

Participants get information about ovarian cancer and its symptoms. Participants also learn about potential benefits and harms of ovarian cancer screening. This may be helpful in current and future related health decision making. In addition, participants are referred to trusted sources to find out further information should they wish to do so (e.g. CRUK; The Eve Appeal, Ovacom). Thinking about cancer may be upsetting for some people. Full information is provided about ovarian cancer at the end of the study and participants are referred to trusted sources to find out further information should they wish to do so (e.g. CRUK; Eve Appeal, Ovacom).

Where is the study run from?

The Health Behaviour Research Centre, University College London, London (UK)

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

April 2015 to September 2016

Who is funding the study?

The study is jointly funded by Cancer Research UK and The Eve Appeal

Who is the main contact?

Dr Susanne Meisel

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The impact of brief vs. extended information about personalized, risk-stratified ovarian cancer screening based on genetic risk assessment on intentions to participate in risk-stratified ovarian cancer screening: study protocol for a randomised controlled trial

Study objectives

This study will test the impact of information format (brief vs. extended) on hypothetical uptake of risk-stratified OC screening based on genetic risk, genetic literacy and knowledge about OC, and decision satisfaction in a web-based randomized controlled trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Web-based single-centre open individually randomized controlled trial, 1:1 group allocation

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

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

Ovarian cancer screening

Interventions

We will create two versions of a website outlining information about OC risk, genetic testing and the risk-stratification programme (PROMISE) for the purpose of this study. With the exception of content length, all components of the website (layout, overarching themes, and decision aid) will be standardised.

1. Intervention group ('brief' information)

Following baseline measurements, participants randomized to access the 'brief' version of the website will be invited to browse the website at their leisure. They can access each component of the website in the order they prefer. At any point, they can choose to access the decision aid which aims to help them to make a hypothetical decision about participation in PROMISE in line with their personal values.

2. Control group ('extended' information)

The extended version of the website is based on information given to patients attending clinical genetics services; resembling a 'usual care' arm of the trial. Following baseline measurements, participants randomized to the 'extended' version of the website will also be invited to browse the website at their leisure. Identical to the intervention group, they can also access each component of the website in the order they prefer, and they can choose to access the decision aid at any point.

Intervention Type

Behavioural

Primary outcome measure

Intention to participate in personalized-risk stratified OC screening, measured 1-2 weeks after the intervention

Secondary outcome measures

1. Changes in knowledge about ovarian cancer and genetic literacy
2. Decision satisfaction

Measured 1-2 weeks after the intervention.

Overall study start date

01/04/2015

Completion date

30/09/2016

Eligibility

Key inclusion criteria

1. Women
2. Aged 18-74
3. Able to give informed consent
4. No personal history of ovarian cancer

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

74 Years

Sex

Female

Target number of participants

600

Key exclusion criteria

1. Women not able to give informed consent
2. Personal history of ovarian cancer

Date of first enrolment

01/05/2015

Date of final enrolment

30/08/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Health Behaviour Research Centre, University College London

1-19 Torrington Place

London

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Sponsor information**Organisation**

University College London

Sponsor details

Gower Street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

Website

<http://www.ucl.ac.uk>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

The Eve Appeal (UK)

Results and Publications

Publication and dissemination plan

Findings from the current study will form the basis for the PROMISE feasibility study website. Results from this study will be published in peer-reviewed scientific journals and at conferences. In addition, research findings will be disseminated via social media (Twitter), the HBRC blog and news outlets. These should be accessible for participants.

Intention to publish date**Individual participant data (IPD) sharing plan**

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/11/2017		Yes	No