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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	**Recruitment status**	[X] Prospectively registered
04/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2020	Cancer	

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, Ovacome). 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, Ovacome).

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
susanne.meisel@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Susanne Meisel

ORCID ID
https://orcid.org/0000-0002-5080-3050

Contact details
Health Behaviour Research Centre
University College London
1-19 Torrington Place
London
United Kingdom
WC1E 6BT
+44 (0)2076791789
susanne.meisel@ucl.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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

Key secondary outcome(s))
1. Changes in knowledge about ovarian cancer and genetic literacy
2. Decision satisfaction

Measured 1-2 weeks after the intervention.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
74 years

Sex
Female

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
United Kingdom

England

Study participating centre
Health Behaviour Research Centre, University College London
1-19 Torrington Place
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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

Funder Name
The Eve Appeal (UK)

Results and Publications

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