

# 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?

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

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WC1E 6BT

**Sponsor information****Organisation**

University College London

**Sponsor details**

Gower Street

London

England

United Kingdom

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**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?
<a href="#">Results article</a>	results	16/11/2017		Yes	No