

# The effect of using emotive language in information about over-diagnosis in cancer screening on knowledge, attitudes and screening intentions

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<b>Registration date</b> 24/06/2015	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/08/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Although cancer screening has the potential to save lives, it may also cause harm. Research has shown that many people have difficulties understanding the concept of overdiagnosis, which is one of the main potential harms of screening. Overdiagnosis refers to the diagnosis of a cancer that would never have caused a problem during a person's lifetime; either because it was slow-growing, or because the person would have died of another cause before symptoms arose. However, cancer screening aimed at detecting aggressive cancers will also identify slow-growing cancers. Since doctors can't yet distinguish aggressive and slow-growing cancers, every cancer will be classified as aggressive, and the individual will be offered treatment (e.g. chemotherapy, radiotherapy or surgery). Given that cancer treatment is still highly invasive, drastically diminishes quality of life and is associated with secondary medical problems (e.g. heart disease, urinary incontinence, impotence), it is vital to find effective ways to communicate the potential harms of screening, so that people can make informed decisions about screening. It is possible that many people ignore the harms of screening because thinking about cancer screening makes them think about dying from cancer. Therefore, it may be that reading information on overdiagnosis, which just states the facts, may not get a similar emotional response. In this study, we would like to test whether varying the emotional content in cancer screening information about overdiagnosis could help people think more about the benefits and harms of cancer screening. We hope that this would lead to people making more informed decisions about whether or not they would like to take part in screening.

### Who can participate?

Men and women aged 40-70 who do not have a personal history of breast/prostate cancer, respectively.

### What does the study involve?

The study involves reading some information about overdiagnosis and filling out an online survey.

What are the possible benefits and risks of participating?

There is little risk for participants from taking part in the study. One benefit of taking part may be that participants learn about the benefits and harms of cancer screening.

Where is the study run from?

University College London (UCL) (UK).

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

May 2015 to August 2017.

Who is funding the study?

Cancer Research UK.

Who is the main contact?

Dr Susanne Meisel

## Contact information

### Type(s)

Public

### Contact name

Dr Susanne Meisel

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

Scientific Title

The effect of varying emotive content of cancer screening information regarding over-diagnosis on knowledge, attitudes and screening intentions: a randomised controlled trial

### **Study objectives**

The primary outcome will be components of informed choice (knowledge, attitudes and screening intentions) regarding participation in breast or prostate cancer screening, for women and men respectively. We hypothesise that a vignette aimed at activating emotional processing related to issues arising from over diagnosis will lead to greater elaboration about the benefits and harms of screening than a vignette including the same information presented in a format which activates less emotional processing, or compared with the control group who will receive breast/prostate cancer screening information currently used by the NHS.

Updated 06/08/2015:

The trial did not start because the objectives would have had limited practical application.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration

### **Study design**

Web-based single-blind three-arm individually-randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

### **Study setting(s)**

Internet/virtual

### **Study type(s)**

Other

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Understanding of over-diagnosis in cancer screening.

### **Interventions**

Following baseline measurements, participants will be randomized to:

1. A vignette explaining over-diagnosis and its consequences in an emotive writing style, including a narrative account of a person's experience of a screen-detected cancer diagnosis, or
2. To a matched vignette which is written in a more 'fact-based' style.

Women will be allocated to read a vignette about breast cancer; men to a vignette about prostate cancer. After confirming that they have read the vignette, participants will be directed to the follow-up questionnaire.

### **Intervention Type**

Behavioural

## **Primary outcome measure**

Primary outcome measures will be collected immediately after exposure to the intervention.

1. Attitudes to taking part in breast/prostate cancer screening  
2. Attitudes to participation in breast/prostate cancer screening will be measured as by Hersch and colleagues (2015), using a validated scale consisting of six items. Each item will be preceded by the statement: 'For me, taking part in breast/prostate cancer screening would be...'

2.1. (1) A bad thing – (7) not a bad thing

2.2. (1) Beneficial – (7) not beneficial

2.3. (1) Harmful – (7) not harmful

2.4. (1) A good thing – (7) a bad thing

2.5. (1) Worthwhile – (7) not worthwhile

2.6. (1) Important – (7) unimportant

In addition, we will ask two questions from Schwartz et al. (2004):

2.7. 'Do you think cancer screening for healthy people is almost always a good idea?', with response options being ('yes', 'no', 'it depends', 'not sure') and breast/prostate cancer screening could reduce my chance of dying from breast/prostate cancer', with response options being 'strongly disagree', 'disagree', 'neither agree nor disagree', 'agree', 'strongly agree'.

3. Breast/prostate cancer screening knowledge: We will assess conceptual breast/prostate cancer screening knowledge with six questions used by Hersch and colleagues (2015). Response options to all questions will be 'true', 'false', and 'not sure':

3.1. 'Women (men) who go for breast (prostate) cancer screening are more likely to be diagnosed with breast (prostate) cancer,

3.2. 'Not all breast (prostate) cancer causes illness and death';

3.3. Health professionals can't predict whether cancer detected by screening will cause harm;

3.4. One risk of screening is that sometimes cancers are detected and treated that would not have caused any problems

3.5. 'After screening, some healthy people will be unnecessarily turned into cancer patients',

3.6. 'Cancer screening finds harmless cancers more often than it prevents death'.

4. Numeric knowledge will be assessed with two questions referring to breast cancer screening and two questions referring to prostate cancer. Again response options will be 'true', 'false', 'not sure', and each correct answer will be given one point:

4.1. 'Breast cancer screening saves about one life for every 200 women who are screened'

4.2. 'For each life saved by breast cancer screening, three women are over-diagnosed' ;

4.3. 'Prostate cancer screening saves at most 1 life for every 1000 men who receive the PSA test'

4.4. '67 in every 100 prostate cancers found are not aggressive and do not cause problems if left untreated'.

5. Intention to take part in breast/prostate cancer screening: This will be assessed as by Waller and colleagues (2014): 'If you were invited to take part in breast/prostate cancer screening would you take up the offer?', with response options being 'yes, definitely'; 'yes, probably'; 'not sure'; 'probably not'; 'definitely not'.

## **Secondary outcome measures**

1. Decisional conflict: assessed using the 10-item decisional conflict scale

2. Decision satisfaction: assessed using the 10-item decision attitude scale

## **Overall study start date**

01/11/2014

## **Completion date**

30/08/2017

**Reason abandoned (if study stopped)**

Objectives no longer viable

## Eligibility

**Key inclusion criteria**

1. Men and women
2. Aged between 40-70
3. Able to give informed consent

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Both

**Target number of participants**

600

**Key exclusion criteria**

Participants with a personal history of breast/prostate cancer

**Date of first enrolment**

01/05/2015

**Date of final enrolment**

30/08/2015

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

University College London

Gower Street

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WC1E 6BT

## Sponsor information

**Organisation**

University College London

**Sponsor details**

Gower Street  
London  
England  
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**Sponsor type**

University/education

**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

**Results and Publications****Publication and dissemination plan**

Results will be published in scientific journals and conferences. In addition, we plan to disseminate research findings via social media (Twitter), 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