

# Improving older women's knowledge and confidence to present early with breast symptoms: a randomised controlled trial of a radiographer-delivered intervention

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<b>Registration date</b> 03/10/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/06/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-ways-to-encourage-older-women-to-report-breast-symptoms>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

N/A

# Study information

## Scientific Title

Improving older women's knowledge and confidence to present early with breast symptoms: a randomised controlled trial of a radiographer-delivered intervention

## Acronym

PEP (Promoting Early Presentation)

## Study objectives

The supplementation of optimised usual care with one of two variants of a radiographer-delivered psycho-education intervention will be more effective than optimised usual care alone in improving women's knowledge and confidence to present promptly with breast symptoms.

Review of the evidence available in <http://www.ncbi.nlm.nih.gov/pubmed/15992567>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

King's College Hospital Research Ethics Committee, 18/04/2007, ref: 07/Q0703/51

## Study design

Three-arm multicentre randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Screening

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

Breast cancer

## Interventions

All three groups will receive optimised usual care, i.e., a reminder that they are no longer eligible for routine breast screening but may continue to request further breast screening themselves every three years. One group in addition will receive a radiographer-delivered booklet containing educational messages designed to increase women's knowledge and confidence to detect breast changes and to motivate them to present promptly if they discover a breast change. The third group will receive a 10-minute radiographer-delivered interview in addition to the booklet. The interview is based on the key messages of the booklet and provides the opportunity for the radiographer to reinforce and clarify the content of the booklet.

The intervention is given just once, duration 10 - 15 minutes for the interview group, 5 minutes or less for booklet-alone and optimised usual care. Follow up consists of a questionnaire sent at 1 month and another at 6 months post-intervention for all groups.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

Breast awareness, measured one month post-intervention, based on a composite measure of knowledge of non-lump breast cancer symptoms, knowledge of age-related relative risk and confidence to detect a breast change: each component (knowledge/risk/confidence) is given equal weighting and contributes one point to the total score (range 0 to 3), as follows:

1. Non-lump knowledge:

1.1. Score 1 if 5 - 9 symptoms identified

1.2. Score 0 if 0 - 4 symptoms identified

2. Relative risk:

2.1. Score 1 if identify old age group as most at risk

2.2. Score 0 if do not identify old age group as most at risk

3. Confidence:

3.1. Score 1 if check breasts at least once a week/month

3.2. Score 0 if check breasts at least once every six months or less

## Key secondary outcome(s)

Secondary measures are changes at one month and six months post intervention in:

1. Knowledge of breast cancer symptoms (score 0 - 11)

2. Knowledge of relative risk (in the next year who is most likely to get breast cancer? [response categories: a 30 year old woman/a 50 year old woman/a 70 year old woman/a woman of any age])

3. Knowledge of absolute risk (how many women will develop breast cancer in their lifetime? [response categories: 1 in 3/1 in 9/1 in 100/1 in 1000])

4. Confidence to detect a breast change (how often do you check your breasts? [response categories: at least once a week/at least once a month/at least every six months/rarely or never])

5. Breast awareness, measured six months post intervention, based on a composite measure of knowledge of non-lump breast cancer symptoms, knowledge of age-related relative risk, and confidence to detect a breast change

## Completion date

30/10/2008

## Eligibility

### Key inclusion criteria

Women aged 67 - 70 years attending National Health Service (NHS) breast screening clinics for final routine mammography

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Senior

**Sex**

Female

**Key exclusion criteria**

1. Any significant disease or disorder that affects ability to consent or participate
2. Insufficient understanding of the English language, or language difficulties
3. Participant going overseas during the six-month study period

**Date of first enrolment**

30/07/2007

**Date of final enrolment**

30/10/2008

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Guy's Campus**

London

United Kingdom

SE1 3QD

**Sponsor information****Organisation**

Institute of Psychiatry (UK)

**ROR**

<https://ror.org/0220mzb33>

**Funder(s)****Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (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

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/12/2009		Yes	No
<a href="#">Results article</a>	results	28/06/2011		Yes	No
<a href="#">Results article</a>	results	05/06/2017		Yes	No