

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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| Submission date 06/08/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/10/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/06/2017 | Condition category Cancer | <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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

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 measure

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

Secondary outcome measures

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

Overall study start date

30/07/2007

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

Age group

Senior

Sex

Female

Target number of participants

714

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

England

United Kingdom

Study participating centre

Guy's Campus

London

United Kingdom

SE1 3QD

Sponsor information

Organisation

Institute of Psychiatry (UK)

Sponsor details

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Sponsor type

University/education

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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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 03/12/2009 | | Yes | No |
| Results article | results | 28/06/2011 | | Yes | No |
| Results article | results | 05/06/2017 | | Yes | No |