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

Submission date
06/08/2007

Recruitment status
No longer recruiting

Registration date
03/10/2007

Overall study status
Completed

Last Edited
07/06/2017

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Dr Lindsay Forbes

Contact details
Guy's Campus
9th Floor, Capital House
42 Weston Street
London
United Kingdom
SE1 3QD
+44 (0)20 7848 6216
lindsay.forbes@kcl.ac.uk

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
King's College London
De Crespigny Park
London
England
United Kingdom
SE5 8AF
+44 (0)20 7848 0675
gill.lambert@iop.kcl.ac.uk

Sponsor type
University/education

Website
http://www.iop.kcl.ac.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, 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