

Evaluation of service development in the NHS Breast Screening Programme

Submission date 06/05/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-see-how-well-encouraging-older-woman-report-breast-cancer-symptoms-works>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9553

Study information

Scientific Title

Evaluation of service development in the NHS Breast Screening Programme: an intervention to promote early presentation in older women with breast cancer

Acronym

Evaluation of promoting early presentation service development

Study objectives

This study relates to a pilot of the implementation of a health promotion intervention to promote early presentation in older women with breast cancer. The intervention (the Promoting Early Presentation (PEP) Intervention) is delivered by a health professional to a woman aged 67+ attending for screening, after she has had her mammogram, and takes about 10 minutes. The aim of the PEP intervention is to equip women with the knowledge, skills, confidence and motivation to present promptly to their GPs on discovering breast symptoms, and thereby improve survival. The NHS Cancer Screening Programme has funded the pilot to offer the PEP Intervention to every woman attending for the current final round of screening (at age 67-70) in a number of breast screening services.

This study will evaluate this pilot in terms of health outcomes. The PEP Intervention has already been evaluated in a randomised controlled trial: it increases breast cancer awareness more than fourfold after two years compared with usual care. This evaluation is not intended, therefore, to determine the efficacy of the PEP Intervention itself, rather to measure the impact of the policy of offering the PEP Intervention to all eligible women on health outcomes in the routine clinical practice setting.

The main health outcome of interest is breast cancer awareness, measured before and after the pilot. To strengthen the design we will also measure breast cancer awareness at the same time in services not offering the PEP Intervention. This will provide the evidence needed to support decision making on whether the PEP Intervention should be implemented across the whole NHS Breast Screening Programme in England. This work is aligned with the National Awareness and Early Diagnosis Initiative (NAEDI).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee, First MREC approval date 16/11/2010, REC reference number 10/H0304/90

Study design

Non-randomised; Interventional; Design type: Prevention

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions

The main health outcome of interest is breast cancer awareness. Approaching 2500 women will allow us to detect a 5% percentage point difference (equivalent to just over a doubling) in the proportion who are breast cancer aware between implementation and comparison services with 90% power (assuming baseline proportion breast cancer aware of 4%, questionnaire response of 60%, 2-sided significance tests and significance level of 5%).

PEP Intervention : The PEP intervention is a scripted ten-minute one-to-one interaction between a screening radiographer (or screening assistant practitioner) and an older woman supported by a booklet, designed to be delivered during a routine appointment on the NHS Breast Screening Programme.

Follow Up Length: 48 month(s); Study Entry: Registration only

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Breast cancer awareness; Timepoint(s): Baseline, 6 months and 12 months

Secondary outcome measures

1. Cancer registrations; Timepoint(s): Yearly for 4 years post recruitment
2. General practitioner (GP) attendance; Timepoint(s): Baseline, 6 months and 12 months
3. Symptomatic breast clinic attendance; Timepoint(s): 3 years post recruitment

Overall study start date

31/03/2011

Completion date

30/03/2012

Eligibility**Key inclusion criteria**

1. Women who were born in 1941, 1942 or 1943, attending for routine mammogram during 2011 at the breast screening services where the PEP Intervention is implemented (the implementation services)
2. Women who were born in 1941, 1942 or 1943, attending for routine mammogram during 2011 at the two breast screening services where the PEP Intervention is not implemented (the comparison services)

Target Gender: Female; Upper Age Limit 70 years; Lower Age Limit 67 years

Participant type(s)

Patient

Age group

Senior

Sex

Female

Target number of participants

Planned Sample Size: 2500; UK Sample Size: 2500

Key exclusion criteria

1. Significant cognitive impairment
2. Insufficient understanding of the English language or language difficulties
3. Women presenting at their appointment with a breast symptom

Date of first enrolment

10/05/2011

Date of final enrolment

30/03/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Promoting Early Presentation Group

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Institute of Psychiatry (UK)

Sponsor details

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Government

Funder Name

NHS Cancer Screening Programme (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	01/01/2012		Yes	No

[Plain English results](#)

25/10/2022

No

Yes