

# Evaluation of service development in the NHS Breast Screening Programme

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

### Protocol serial number

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

## **Primary study design**

Interventional

## **Study design**

Non-randomised; Interventional; Design type: Prevention

## **Study type(s)**

Screening

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

Female

**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**

United Kingdom

England

**Study participating centre**

Promoting Early Presentation Group

London

United Kingdom

SE1 7EH

**Sponsor information****Organisation**

Institute of Psychiatry (UK)

**ROR**

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

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

Government

**Funder Name**

NHS Cancer Screening Programme (UK)

# Results and Publications

## 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? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | results | 01/01/2012   |            | Yes            | No              |
| <a href="#">Plain English results</a> |         |              | 25/10/2022 | No             | Yes             |