

# Pilot study: age extension of NHS Breast Screening Programme

<b>Submission date</b> 16/01/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/07/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00890864

**Protocol serial number**  
09/H0710/2

## Study information

**Scientific Title**

# Pilot study of the feasibility and acceptability of randomising the phasing-in of the age extension of the NHS Breast Screening Programme in England

## Study objectives

Currently all women are invited for breast screening between the ages of 50 and 70. In 2007 the Cancer Reform Strategy announced that from 2012 the NHS Breast Screening Programme would be extended to cover women between the ages of 47 and 73. This means that all women will get two extra screening invitations in their lifetime. It also means that all women will get their first invitation before age 50. As capacity does not allow for full immediate roll out across the whole of England, the age extension will be phased-in with full coverage from 2012. Randomising this phasing-in would provide unbiased evidence on the extent to which it is beneficial to extend the age range for breast screening and whether an extra screen at younger or older ages is more worthwhile. To date there is no clear evidence on this as no trial has looked at the added value of one extra screen within an existing screening programme. This pilot study will assess the feasibility and acceptability of randomising the phasing-in of the age extension in six volunteer sites in different areas of England.

As of 29/05/2009 this record was updated to include amendments to the anticipated trial dates; the initial trial dates were as follows:

Initial anticipated start date: 01/03/2009

Initial anticipated end date: 31/03/2010

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added 29/05/2009: Approval obtained from Ealing and West London Research Ethics Committee in March 2009 (ref: 09/H0710/2)

## Study design

Multicentre cluster randomised study

## Primary study design

Interventional

## Study type(s)

Screening

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

Breast screening

## Interventions

As part of the routine breast screening process, the National Breast Screening System (NBSS) creates screening invitation batches of about 1,000 women spanning ages 50 - 70 years. In this pilot study the NBSS will create batches of about 1,000 women aged 47 - 73 years. These batches (clusters) will be randomly allocated to one of two groups, that is, to include ages 47 - 70 or ages 50 - 73 years, instead of, as now, 50 - 70 years. The randomisation will be done with equal (50/50) probability and no stratification. Study participants are the women aged 47 - 49 years and 71 - 73 years in the screening invitation batches that include their age group. There will be of the order of 100 such women in each batch and about 36,000 in total across the 6 pilot

sites. Women aged 50 - 70 years will be unaffected by the randomisation process as they are in the age group already eligible for routine screening, and their invitations for screening will continue as normal. Women aged 47 - 49 years who are not invited for screening as part of the pilot study may request to be screened if they live in a pilot area. Women aged over 70 are already able to request screening every 3 years.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Screening uptake among women invited for screening in the extended age groups
2. Workload associated with inviting these new age groups for screening
3. Self-referrals among women in the pilot areas aged 47 - 49 years or 71 - 73 years but who were not invited for screening

Each of the pilot sites will be studied for up to 12 months. The measurement of the primary outcomes will be ongoing from soon after the start of the study. A final analysis and interpretation of the data will be conducted at the end of the study period.

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

31/05/2010

**Eligibility****Key inclusion criteria**

Study participants will be women living in one of the six pilot areas aged 47 - 49 years or 71 - 73 years and in a screening invitation batch that includes their age group.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

Does not comply with inclusion criteria

**Date of first enrolment**

01/05/2009

**Date of final enrolment**

31/05/2010

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**NHS Cancer Screening Programmes**

Sheffield

United Kingdom

S10 3TH

## Sponsor information

**Organisation**

University of Oxford (UK)

**ROR**

<https://ror.org/052gg0110>

## Funder(s)

**Funder type**

Government

**Funder Name**

NHS Breast Screening Programme National Office (UK)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes