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Pilot study: age extension of NHS Breast Screening Programme

Submission date 16/01/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/02/2009	**Overall study status** Completed	
Last Edited 31/07/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cancerscreening.nhs.uk/breastscreen/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00890864

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

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
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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2009

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

Age group
Adult

Sex
Female

Target number of participants
36,000

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
England

United Kingdom

Study participating centre
NHS Cancer Screening Programmes
Sheffield
United Kingdom
S10 3TH

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details

c/o Heather House
Clinical Trials and Research Governance
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NHS Breast Screening Programme National Office (UK)

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	01/01/2011		Yes	No