







# MAMMO-50: mammographic surveillance in breast cancer patients aged 50 years and over

<b>Submission date</b> 26/02/2014	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
<b>Registration date</b> 26/02/2014	<b>Overall study status</b> Ongoing	 Protocol added
<b>Last Edited</b> 23/05/2023	<b>Condition category</b> Cancer	 SAP not yet added
		 Results not yet expected
		 Raw data not yet expected
		 Study ongoing and record not updated in last year

## Plain English Summary

<http://www.cancerresearchuk.org/about-cancer/trials/This-trial-looking-follow-up-mammograms-women-over-50-who-have-had-breast-cancer>

## Study website

<http://www2.warwick.ac.uk/fac/med/research/hscience/ctu/trials/cancer/mammo50>

## Contact information

### Type(s)

Scientific

### Contact name

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### Type(s)

Scientific

### Contact name

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**Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**

16250

**Study information****Scientific Title**

MAMMO-50: mammographic surveillance in breast cancer patients aged 50 years and over: a randomised controlled trial

**Acronym**

MAMMO-50

**Study hypothesis**

The Government's Cancer Reform Strategy recommends breast cancer patients be supported in self-care and have personalised risk-adjusted follow-up to meet their needs. As young age is a strong predictor of invasive and non-invasive 'second' breast cancer (i.e., recurrence on treated side or new cancer in opposite breast), current NICE 2009 guidance recommends patients diagnosed up to 50 years have mammograms annually. For those patients aged 50 or older at diagnosis, there is no clear evidence or consensus amongst specialists on risk factors to advise the optimum frequency or duration of follow-up mammograms.

Type of breast surgery (mastectomy or conservation) does not affect long-term survival. However, 3 years after diagnosis, second breast cancers are found less frequently by mammography in mastectomy patients than those patients who have had conservation surgery. Early detection of second cancers or metastasis is more likely to occur via patient self-examination between mammograms than by specialist clinic visit. A patients ability to self-check

and report concerns could be improved by alternative follow-up regimens including questionnaires and/or contact with nurses GPs, radiographers or internet access. There have been no randomised controlled trials in this setting.

In order to provide sound evidence for future management, this clinical trial aims to establish if patients aged 50 years or over can be identified who require less frequent mammographic surveillance whilst investigating alternative methods of follow-up.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

First MREC approval date 11/12/2013, ref: 13/WM/0419

### **Study design**

Randomised; Interventional and Observational; Design type: Treatment, Cohort 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 to request a patient information sheet

### **Condition**

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

### **Interventions**

For the purposes of MAMMO-50, centres will utilise digital imaging in line with the national roll-out of digital screening mammography in 2010. Digital mammography offers advantages in terms of image quality, increased sensitivity in important subgroups (e.g., women with dense breasts) and reduced examination time that permits a greater opportunity for patient contact with the radiographer or breast care nurse. It is also reported to deliver significantly less radiation than conventional mammography.

In addition to the mammogram, eligible patients will be asked to complete the MAMMO-50 patient questionnaire booklet, delivered at the time of their mammogram or clinical follow-up, which will include questions on their general health, health resource use and adherence to prescribed maintenance therapy such as Tamoxifen or Arimidex.

In addition the patient and public Involvement (PPI) component of the study will evaluate adequacy of current information offered as standard to patients as well as effective ways of

collecting quality of life data for those patients consenting to be part of the QoL and/or qualitative sub-studies.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. Disease-specific survival
2. Cost effectiveness

The first Mammo-50 patient questionnaire booklet, which will include general questions, Health Resource Use forms and EQ-5D-5L, must be given to patients after written consent is obtained but prior to randomisation. Further Mammo-50 patient questionnaire booklets will be administered around the time of scheduled mammograms, i.e. annually from randomisation for more frequent mammogram schedule and 2 or 3 years for the less frequent mammogram schedule, up to 10 years post curative surgery.

## **Secondary outcome measures**

1. Recurrence (time to recurrence, type of recurrence and features of recurrence plus new primary in ipsilateral breast and new primary in contralateral breast) using questionnaire and data linkage. The NCIN lead registry for breast cancer will match the MAMMO-50 cohort against the national cancer registration database at 3-yearly intervals for 3 years (3, 6 and 9 years after randomisation). Details of recurrent breast cancers (local, regional and distant) will be provided as will dates and causes of death where appropriate. The histological characteristics of ipsilateral breast tumour recurrences (IBTR) and contralateral new primaries will be recorded and the Nottingham Prognostic Index (NPI) calculated and compared to the NPI of the original tumour. These characteristics will include invasive and in situ tumour size, histological grade, histological type, vascular invasion status, ER, PR and HER-2 status, in those tumours treated by immediate surgical resection. Nodal status will be recorded in those who have a further nodal procedure. In tumours treated with systemic therapy and no surgery (this is common if metastatic disease is found at the time of recurrence) tumour type and grade and receptor status will be ascertained from the diagnostic core biopsy and lesion size estimated from imaging
2. Number of referrals back to the hospital system
3. Long-term survival (20 years post-surgery) using ONS flagging

## **Overall study start date**

01/09/2013

## **Overall study end date**

30/09/2025

## **Eligibility**

### **Participant inclusion criteria**

1. Female, age  $\geq 50$  at initial cancer diagnosis
2. Excised invasive breast cancer with local treatment completed
3. Three years post curative surgery date
4. Written informed consent for the study

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

Planned Sample Size: 7000; UK Sample Size: 7000; Description: Main trial: 5000 patients; Observational cohort: 1000 patients

**Total final enrolment**

6150

**Participant exclusion criteria**

1. Breast cancer recurrence, new breast cancer primary or any new malignancies
2. Previous diagnosis of malignancy unless managed by surgical treatment only and disease free for 10 years or previous basal cell carcinoma of skin, cervical intraepithelial neoplasia or in situ ductal carcinoma of the breast treated with surgery only

**Recruitment start date**

01/09/2013

**Recruitment end date**

30/09/2018

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Warwick Medical School Clinical Trials Unit**

Coventry

United Kingdom

CV4 7AL

**Study participating centre**

**115 participating centres**

United Kingdom

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# Sponsor information

## Organisation

University of Warwick (UK)

## Sponsor details

Warwick Medical School  
Coventry  
England  
United Kingdom  
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## Sponsor type

University/education

## ROR

<https://ror.org/01a77tt86>

# Funder(s)

## Funder type

Government

## Funder Name

Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Added 12/05/2021: Protocol at <https://www.journalslibrary.nihr.ac.uk/programmes/hta/112503>

/#/

Added 23/05/2023: Intended dates of publication for primary analysis is 31/03/2024 and for long-term follow-up analysis is 31/03/2026.

### **Intention to publish date**

31/03/2026

### **Individual participant data (IPD) sharing plan**

Data collected within the Mammo-50 trial will be made available to researchers whose full proposal for their use of the data has been approved by the Mammo-50 Trial Management Group and whose research group includes a qualified statistician. Any requests for access to the trial data should be sent to the Chief Investigator, Professor Janet Dunn, who will inform the data custodian, the University of Warwick. Please send requests via email to mammo-50@warwick.ac.uk. Each data sharing request should include the purpose, scope, data items requested, analysis plan, acknowledgement of the trial management team and evidence of appropriate ethical approvals. Requestors who are granted access to the data will be required to complete a data-sharing agreement, which will be signed by the requester, sponsor and principal investigator(s). We anticipate that data sharing will be possible after the publication of the primary endpoint of the trial and will remain available up to 5 years from the end of the trial.

### **IPD sharing plan summary**

Available on request

### **Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Protocol file</a>	version 4.0	07/07/2021	23/05/2023	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No