

Invitation reminder study

Submission date 22/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/05/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Breast screening saves lives by detecting cancer earlier, which can make treatment more effective. This reduction in cancer deaths depends partially on women regularly attending their three-yearly routine screening appointments. Even though many women who do not attend will have made an informed decision, others will be in favour of screening but may have simply forgotten about the appointment. Womens attendance at breast screening should be based on decisions about the likely benefits and risks of screening rather than on whether they remember their appointment. We are therefore carrying out a study to investigate whether a reminder letter sent by post to arrive close to a womans screening appointment increases attendance and whether this approach is cost-effective.

Who can participate?

Women living in Bolton, Bury and Rochdale, South Lancashire, and Liverpool will be entered into the study when they are invited to their routine three-yearly screening appointment.

What does the study involve?

One half of the women invited to their routine screening receive a reminder letter around two days before the screening appointment in addition to the normal invitation letter. The other group with only receive the standard invitation letter without any reminders.

What are the possible benefits and risks of participating?

This reminder letter was produced following consultation, including with lay people, to ensure that it contains only accurate information, and is non-coercive in tone. Women in the reminder group of the study who are in favour of screening but may have simply forgotten about the appointment will be reminded to either attend the appointment or call in and re-book. We do not anticipate any risks that may adversely affect the participants as a result of taking part in the trial.

Where is the study run from?

Centre for Cancer Prevention (CCP) at Barts and The London, Queen Mary University of London, UK

When is study starting and how long is it expected to run for?

November 2012 to December 2013

Who is funding the study?
National Health Service (NHS) - Cancer Screening Services

Who is the main contact?
Prof. Stephen Duffy
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Contact information

Type(s)
Scientific

Contact name
Prof Stephen Duffy

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A randomised controlled trial of the effect of a breast screening appointment reminder letter on population uptake

Study objectives
The aim of this study is to investigate whether sending an appointment reminder letter to women invited for routine breast screening improve appointment attendance.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised controlled trial

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 cancer screening

Interventions

Women in the intervention arm will be sent a reminder letter by post approximately seven days before their screening appointment.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

An increase in attendance within 30 days of the first offered appointment

Secondary outcome measures

Attendance within 90 days of the first offered appointment, secondly, within 180 days of the date the episode was opened, and thirdly, at the date and time of the first offered appointment.

Subgroup analyses will be performed and the cost per additional attendance will be calculated.

Overall study start date

01/11/2012

Completion date

31/12/2013

Eligibility

Key inclusion criteria

All women scheduled for invitation to their next breast screening appointment in Liverpool, South Lancashire, and Bolton, Bury and Rochdale.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

20,000 (10,000 in each arm)

Key exclusion criteria

1. Self referrals
2. Early re-calls
3. Women who are invited because of a higher risk of breast cancer
4. Women who have cancelled their appointment before the letter extract is generated and who do not re-book at a later stage are excluded as they will never appear in any of the letter extracts.

Date of first enrolment

01/11/2012

Date of final enrolment

31/12/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Queen Mary University of London

London

United Kingdom

EC1M 6BQ

Sponsor information

Organisation

Queen Mary University of London (UK)

Sponsor details

Joint R&D Office

5 Walden Street

London

England

United Kingdom

E1 2EF

+44 (0)20 7882 7260

sponsorsrep@bartshealth.nhs.uk

Sponsor type

University/education

Website

<http://www.bartsandthelondon.nhs.uk/our-services/research-and-development/>

ROR

<https://ror.org/026zzn846>

Funder(s)

Funder type

Government

Funder Name

NHS Cancer Screening Programmes (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	19/01/2016		Yes	No