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Out of Hours Study: the effect of weekend and out-of-hours appointments on attendance rates at breast screening

Submission date 20/10/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/10/2009	**Overall study status** Completed	
Last Edited 06/01/2014	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cptu.co.uk/outofhours

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A multicentre randomised controlled study of the effect of weekend and out-of-hours appointments on attendance rates at breast screening

Acronym
OOHS

Study objectives
The primary purpose of the study is to discover whether the offer of weekend or out of hours screening appointments alters attendance rates, and if so, which is better, working hours appointments, weekday evening appointments or weekend appointments.

Women in Manchester and Bristol who are due a routine breast screening appointment will be randomised to trial arms, in which they will receive letters inviting them to an appointment in weekday working hours, an evening, a Saturday, or working hours with the option to change to an evening or Saturday. The measured endpoints for comparison will be overall attendance rates and attendance at first offered appointment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Outer North East London Research Ethics Committee (REC) approved on the 15th March 2009 (ref: 09/H0701/96)

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 and prevention

Interventions
There are no trial drugs or treatments associated with this trial.

Women who are due to be invited for breast screening in Manchester and Bristol will be allocated, based on month of birth, to one of 6 groups. These will then be randomised in a ratio of 3:1:1:1 to the following conditions:
1. Usual invitation letter to a routine screening appointment within working hours
2. Invitation letter to a routine screening appointment within working hours, but with the option of changing to an appointment on a weekend or on a weekday evening
3. Invitation letter to a weekday evening screening appointment
4. Invitation letter to a weekend appointment

The time taken between sending letters and initial appointment is 5 weeks, if appointments are changed then those within 120 days will be counted. Therefore the maximum length of time the patient could be in the study is 155 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Attendance rate. Comparison will be made between the two major arms of the study, those with a working hours appointment offered, and those with an evening or weekend appointment. Attendance is defined as attending a screening appointment either at the time originally offered, or at an alternative appointment time within 120 days of the original. Data capture will include the appointment date and time offered, and the appointment date and time actually attended (if any).

Secondary outcome measures
1. Whether the invitee attended the first appointment offered, measured by whether the radiographer records on the NBSS system database that the patient attended the original appointment (5 weeks after the invitation letter was sent out)
2. Comparison of the attendance rates between the four groups for subsets of the invitees. In particular, we shall evaluate the effect of the non-standard appointments at prevalence screen and by age group, but will also look at effects on incidence screens, previous attenders and previous non-attenders. This will be assessed using the attendance data collected from the primary outcome, and compared between the patient subsets.

Overall study start date
01/01/2010

Completion date
01/01/2011

Eligibility

Key inclusion criteria
All women (aged 47-73 at Manchester, 50-70 at Bristol, the age range which is eligible for the screening programme at these sites) scheduled for invitation in batches to their next breast screening appointment by the participating centres.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
18,000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cancer Research UK Centre for Epidemiology, Mathematics and Statistics
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Sponsor information

Organisation

Queen Mary University of London (UK)

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Sponsor type
University/education

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

ROR
https://ror.org/026zzn846

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	06/08/2013		Yes	No