ISRCTN99273117 https://doi.org/10.1186/ISRCTN99273117

# A trial investigating the impact of medication review on breast cancer patients in a pharmacy technician led outpatient clinic.

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| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>10/05/2012 | **Condition category**<br>Cancer | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0283156787

# Study information

## Scientific Title

## Study objectives
To assess whether the introduction of a pharmacy technician led outpatient clinic for breast cancer patients at Worthing Hospital results in an improved level of patient understanding about their chemotherapy support medication. A pharmacy technician clinic will be implemented, the research study will therefore primarily report any benefits of this clinic.

Please note that as of 16/09/10 this record has been updated to include information missing at the time of registration. All information has been taken from the published results paper listed in the publications section below.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Added 16/09/10:
1. West Sussex Local Research Ethics Committee approved on the 23rd of November 2004 (ref: 04/Q1911/45)
2. The Sussex NHS Research Consortium approved on the 6th of January 2005 (ref: 0457/WASH /2004)

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Other

## 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

## Interventions

Randomisation into a research or control arm:
Group A: attend pharmacy outpatient clinic
Group B: usual care

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Level of patient understanding:
The chief investigator (HR) interviewed each consented patient using a standard question set, asking the patient to explain what each of their support medications was for and how they used it. Assessments were recorded as an overall rating of the subject's understanding on a Likert scale from 1=very poor to 5=very good, plus a drug-specific score derived from marks awarded for various pieces of information: drug name (+2); indication (+2); dose frequency (+2); dose duration (+1); dose (+1). Thus the maximum score per drug was 8 and the minimum 0. The average score per drug was also calculated. Assessments were conducted prior to randomisation; the chief investigator was blind during subsequent, post-randomisation assessments.

### Secondary outcome measures
Added 16/09/10:
1. The numbers of patients experiencing delays in receiving their chemotherapy
2. The numbers of patients requiring chemotherapy dose reductions
3. Numbers of patients having potential drug interactions between GP prescribed medication and chemotherapy or chemotherapy support medication
4. The number of chemotherapy support medication items supplied per patient
5. The average cost of chemotherapy support medication supplied per patient
6. The numbers and costs of chemotherapy support medication not supplied
7. The average amount of pharmacy time per patient spent resolving medication issues
8. The numbers of patients requiring a prescription intervention at the point of dispensing

### Overall study start date
06/01/2005

### Completion date
08/03/2006

## Eligibility

### Key inclusion criteria
1. 140 patients being treated for breast cancer and receiving chemotherapy.
2. 18 years and above

### Participant type(s)
Patient

### Age group

Adult

**Lower age limit**
18 Years

**Sex**
Female

**Target number of participants**
140

**Key exclusion criteria**
Does not match inclusion criteria

**Date of first enrolment**
06/01/2005

**Date of final enrolment**
08/03/2006

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Worthing & Southlands Hospitals NHS Trust**
Worthing
United Kingdom
BN11 2DH

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
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SW1A 2NL
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### Sponsor type
Government

### Website
http://www.dh.gov.uk/Home/fs/en

## Funder(s)

### Funder type
Government

### Funder Name
Sussex NHS Research Consortium (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 | 12/03/2007 | | Yes | No |