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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Other

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Sussex NHS Research Consortium (UK)

Results and Publications

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