

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
Registration date 30/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/05/2012	Condition category Cancer	☐ Individual participant data

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)

Study design

Randomised controlled trial

Primary study design

Interventional

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