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A randomised trial of a patient-centred strategy to facilitate transition of breast cancer survivors' routine Follow-UP from specialist to primary care

Submission date 12/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/03/2007	**Overall study status** Completed	
Last Edited 07/01/2020	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
A randomised trial of a patient-centred strategy to facilitate transition of breast cancer survivors' routine Follow-UP from specialist to primary care

Acronym
FUP II

Study objectives
Our hypotheses are that Health Related Quality of Life (HRQoL) and patient satisfaction will be positively affected by the intervention to 12 months post-randomisation, and that health service outcomes will be positively affected to 24 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
In progress. 1/8 clinical centres has received ethics as of 12th December 2006.

Study design
A pragmatic multi-centre Randomised Controlled Trial (RCT).

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Breast Cancer survivorship

Interventions
We will conduct a pragmatic multi-centre Randomised Controlled Trial (RCT) with patients who have completed intensive treatment for breast cancer and are ready for transition from specialist care to routine follow-up in primary care. Patients will be randomised to receive usual care or to receive the intervention. Patients will be followed for 24 months. The trial will involve centres in Nova Scotia, Quebec, Ontario and Alberta (eight clinical centres). An economic evaluation and a knowledge translation sub-study will be conducted alongside the clinical trial.

The focus of the intervention is to facilitate the patient's transition from specialist care to follow-up by their FP. The intervention will be as consistent with usual practice as possible, so as to be generalisable to specialist cancer clinics and primary care settings in Canada. The intervention will be tailored to the specific patient and will include specially developed user friendly versions of a guideline on follow-up care both for the patient and for the FP, a follow-up care plan, an educational session with a nurse, and a supportive care resource kit.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome will be the specific Health-Related Quality of Life (HRQoL) domain of adjustment to breast cancer at 12 months using the Impact of Events Scale (IES).

Secondary outcome measures
Secondary outcomes will be:
1. Adjustment at 24 months, using other HRQL domains (including the Profile Of Moods States [POMS], the Short Form health survey [SF-36], Medical Outcomes Study [MOS], Patient Satisfaction Questionnaire 18 [PSQ 18], patient perceived preparedness for follow-up care using two questions used by Stanton and Ganz)
2. Health service outcomes include:
a. guideline adherence as measured by an index of the manoeuvres recommended
b. the extent to which patients in both arms will decline transfer to the FP
c. the extent to which patients return to the cancer centre for routine follow-up
d. follow-up visits with multiple practitioners (e.g., surgical, medical, radiation oncologist) for routine follow-up care
e. return visit to the cancer centre for Aromatase Inhibitors (AIs) according to oncologist's recommendation
f. continuity of care by using the Continuity and Coordination of Care Questionnaire which covers the key constructs relevant to continuity of care
g. the awareness of which physician is responsible for follow-up care

Overall study start date
10/01/2006

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Women diagnosed with invasive breast cancer
2. Stage I, II, or IIIa having completed primary treatment
3. There is no evidence of recurrence; and
4. Patient's surgeon agrees to transfer follow-up care to the Family Practitioner (FP)

Participant type(s)

Patient

Age group
Not Specified

Sex
Female

Target number of participants
400

Key exclusion criteria
1. Primary treatment (surgery, chemotherapy, radiotherapy) not completed at least three months previously, except for continued use of tamoxifen or an aromatase inhibitor
2. On herceptin or a potential candidate for herceptin (patients will become eligible following completion of herceptin therapy if ready for transition to primary care for routine follow-up)
3. Under investigation for possible recurrence (patients will become eligible if recurrence is ruled out)
4. Does not have a community-based FP to provide care (we will monitor the frequency with which patients are excluded because of this factor)
5. The patients' FP already has a patient enrolled in the trial (to avoid contamination)
6. Unable to comply with study protocol including completion of questionnaires
7. Previously enrolled in a study requiring ongoing follow-up by a cancer specialist; or
8. Actively followed by a cancer specialist for another primary cancer

Date of first enrolment
10/01/2006

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Canada

Study participating centre
Cancer Care Nova Scotia
Halifax
Canada
B3H 2Y9

Sponsor information

Organisation

Canadian Breast Cancer Research Alliance/National Cancer Institute of Canada

Sponsor details
10 Alcorn Avenue
Suite 200
Toronto
Canada
M4V 3B1

Sponsor type
Charity

Website
http://www.ncic.cancer.ca

Funder(s)

Funder type
Charity

Funder Name
Canadian Breast Cancer Research Alliance/National Institute of Canada (Canada)

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	01/03/2014		Yes	No