

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

<b>Submission date</b> 12/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/01/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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?
<a href="#">Results article</a>	results	01/03/2014		Yes	No