Innovative ways of following up early breast cancer patients: The experience of the *iBreast* Trial Development Group

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Background

Breast cancer is the most common cancer in women in the UK with around 45,000 new cases reported in 2005, representing around 31% of all cancers in women (www.cancerresearchuk.org). Survival is steadily improving. The latest figures for England show that an average of 76% of women diagnosed with breast cancer in 1993 to 1995 were alive five years later (DOH 2002). This constitutes a considerable burden to the NHS and to cancer services in particular, not only in terms of diagnosis and treatment but in terms of follow-up. Several pilot studies have attempted to compare hospital versus alternative follow-up using GP-led, nurse led or radiographer led models but these were underpowered to detect disease driven endpoints such as disease free survival.

Objectives

•To determine whether alternative follow-up methods are equivalent to traditional specialist hospital based follow-up.

•To determine whether alternative follow-up methods are equivalent or better than traditional methods for perception of living with cancer in terms of anxiety and quality of life.

iBreast Trial design

Newly diagnosed early breast cancer patients can be registered at the MDT as candidate for *iBreast* trial and flagged with the WMCIU.

Eligibility: Patients with early invasive breast cancer having completed curative treatment and at the point of discussing follow-up options.

Randomisation must be within 3 years post diagnosis.

Randomisation stratified by: NPI risk (<3.4, 3.4-5.4, >5.4), ER status, HER 2 status, vascular invasion, type of curative treatment

RANDOMIZE
N=8000

Standard hospital follow-up with annual clinical examination, mammography and questionnaire up to 5 years post diagnosis .
(n= 4000)

Immediate discharge to alternative follow-up with annual mammography and questionnaire up to 5 years post diagnosis
(n= 4000)

5 years post diagnosis:
Annual mammograms up to 10 years post discharge with an annual questionnaire.

Flagged with WMCIU for annual follow-up.

Outcomes

Primary:	Disease free survival
	Recurrence (time to and severity of)
	Psychological assessment
	Health economics
Secondary:	Compliance with hormone therapy
	Number of referrals back into hospital and other service effects
	Acquisition of outcome data
	Molecular pathology and biomarkers
	Long-term survival

Methods – design and data collection

- Patients will be randomised to alternative follow-up methods including radiographer, GP or nurse contact verses the traditional hospital specialist clinic visit.
- Psychological assessment data will be collected annually by means of questionnaires and all patients will have an annual mammogram.
- Data will be collected from hospital records for the duration of the study and from cancer registry data linkage for long-term survival.
- Data on use of GP services and number of return visits to the hospital will be recorded as part of an evaluation of the effect of alternative follow-up on use of NHS resources and other outcomes such as problems with medication side effects, compliance of maintenance therapy and how these issues are resolved in alternative follow-up.
- Linking databases through primary and secondary care would enable patients to be tracked and their additional treatments and outcomes recorded. Innovative ways of following up breast cancer patients by linking databases would be beneficial to both patients and the health service.

Conclusion

•*i*Breast trial involving 8000 early breast cancer patients aims to use WMCIU for registration and flagging.

•Data linkage through primary and secondary care would enable trial patients to be monitored outside of standard hospital visits.

•Innovative ways of following iBreast patients will be piloted as part of the trial.

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