

# Improving the referral process for familial breast cancer genetic counselling: an evaluation of complementary interventions

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

HTA 94/14/20

# Study information

## Scientific Title

### Study objectives

The NHS needs to identify cost-effective approaches to managing the increased demand for genetic counselling for familial cancers, particularly in the primary care setting. Using familial breast cancer as a model, this study aims to evaluate two separate, but complementary, interventions using randomised controlled trials: the first designed to improve the process of deciding to refer from primary care to specialist services, the second to cope with referred women in a cost-effective way in the community. In the first trial, general practices in Grampian will be randomised to receive specific educational input for a member of their staff, along with specific decision-support software, or to no intervention (control): outcomes will relate to appropriateness of referrals and patient understanding, In the second trial, based in Grampian and Wales, referred women will be randomised either to see a community-based genetics outreach nurse or to the current, specialist service: comparisons will be made of psychological outcomes and retention of risk information, and service acceptability to patients and professionals. An economic evaluation is an integral component of each trial.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Cancer (neoplasms): Breast

## **Interventions**

Trial 1:

1. Receive specific educational input for a member of their staff, along with specific decision-support software
2. Standard care.

Trial 2: Referred women will be randomised to see

1. A community-based genetics outreach nurse
2. Remain on current specialist service

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

Not provided at time of registration

## **Secondary outcome measures**

Not provided at time of registration

## **Overall study start date**

01/02/1998

## **Completion date**

31/08/2002

# **Eligibility**

## **Key inclusion criteria**

Women with familial breast cancer in need of genetic counselling

## **Participant type(s)**

Patient

## **Age group**

Not Specified

## **Sex**

Female

## **Target number of participants**

Not provided at time of registration

## **Key exclusion criteria**

Not provided at time of registration

## **Date of first enrolment**

01/02/1998

**Date of final enrolment**

31/08/2002

## **Locations**

**Countries of recruitment**

Canada

United Kingdom

**Study participating centre**

Department of Epidemiology & Community Medicine

Ontario

Canada

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## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**ROR**

<https://ror.org/03sbpja79>

## **Funder(s)**

**Funder type**

Government

### Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

## 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	01/02/2005		Yes	No