

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

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

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?
Results article	results	01/02/2005		Yes	No