ISRCTN60569158 https://doi.org/10.1186/ISRCTN60569158

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

Registration date
25/04/2003

Overall study status
Completed

Last Edited
30/05/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Brenda Wilson

Contact details
Department of Epidemiology & Community Medicine
University of Ottawa
451 Smyth Road
Ottawa
Ontario
Canada
K1H 8M5
+1 613 562 5800 x8261
bwilson@uottawa.ca

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/08/2002

Eligibility

Key inclusion criteria
Women with familial breast cancer in need of genetic counselling

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Female

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
United Kingdom

Canada

Study participating centre
Department of Epidemiology & Community Medicine
Ontario
Canada
K1H 8M5

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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