

Proactive familial breast cancer risk assessment in primary care (Phase 2)

Submission date 20/12/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/09/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-identifying-women-at-increased-risk-breast-cancer-due-to-family-history>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

15872

Study information

Scientific Title

Proactive familial breast cancer risk assessment in primary care: feasibility of an optimised intervention to improve identification and care of women at risk (Phase 2)

Study objectives

Some women with relatives previously diagnosed with breast cancer may be at higher than average risk of developing breast cancer. It is important to identify these women so they can benefit from specialist services for early diagnosis and better life expectancy.

National guidelines on how to identify women at familial risk of breast cancer were issued in 2004. However, some women with a high risk, particularly younger women and those from less educated and minority backgrounds, are not being identified. In contrast, other women at average risk are inappropriately referred to specialist services.

This study aims to develop a more systematic approach to identify women's familial risk of breast cancer. The intervention will involve women completing a family history questionnaire already tested for effectiveness combined with practices using decision-making software to calculate breast cancer risk and to better target referral to specialist services. We will compare what happens now (usual care) with a proactive way of identifying women, aged 30-60, with familial breast cancer risk.

This study will:

1. Develop and refine the intervention in women aged 30-60 in primary care
2. Use a combination of different research methods to begin to understand the benefits to the NHS of using the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham 2, First MREC approval date 27/01/2014, ref: 14/EM/009

Study design

Randomised interventional; Design type: Prevention, Process of Care, Screening

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions

General practices are randomised to either the intervention arm (proactively identifying women aged 30-60 and using the decision-support software) or the control arm.

16 women recruited for focus groups 1 and 2 (8 per focus group)

Approximately 35 women from 6 control practices opportunistically identified.

Approximately 350 women from 6 intervention practices = 2100 (however this may be more or less depending on practice list size).

The interviews following the exploratory trial will involve women already recruited to the study and included in the numbers above.

6-12 GPs for interviews from the intervention group.

6-8 administrative staff for interviews.

Family History Questionnaire, This will be used with decision-making software

Follow Up Length: 8 month(s)

Study Entry : Registration and One or More Randomisations

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Proactively identify women at risk of familial breast cancer; Timepoint(s): Final analysis

Key secondary outcome(s)

1. Optimise study design for a further trial; Timepoint(s): Final analysis will identify whether this study is successful in meeting its aims
2. Streamlined referrals to specialist services; Timepoint(s): Measured through participant medical records at 6 month follow-up

Completion date

30/06/2016

Eligibility

Key inclusion criteria

Eligibility for General Practice anonymised MIQUEST searches:

General Practices in Nottinghamshire who consent to undertake anonymised database searches.

Eligibility for Focus Group 1:

Women with a family history of breast cancer and no previous referral to specialist services, identified through newspaper adverts in Nottingham newspapers. Participants will be aged between 18 to 70 years.

Eligibility for Focus Group 2:

Women identified with a family history of breast cancer with previous experience of specialist services identified through the Royal Derby Hospital. Participants will be aged between 18 to 70 years.

Eligibility criteria for patient participants for the exploratory trial and nested qualitative study:

1. Women aged between 30 and 60 years
2. Registered with a participating GP practice
3. Able to complete the family history questionnaire in English (assistance from a household member is permitted)

4. Have NO history of breast or ovarian cancer
5. Must NOT have undergone a Familial Breast Cancer Assessment at specialist services in the previous 12 months
6. Must not have participated in the focus groups

Eligible health professionals for the exploratory trial are:

Consenting GPs (principals, salaried, registrars), nurses (including nurse practitioners/practice nurses) and administration staff at the study general practices in Derbyshire.

Eligible health professionals for the nested qualitative study are:

1. Consenting GPs (principals, salaried, registrars), nurses (including nurse practitioners/practice nurses) and administration staff at the study general practices in Derbyshire.
2. Nominated lead GPs involved in providing the information or risk communication/consultation with patients from each intervention practice
3. Designated administrative staff entering the FHQ data into FaHRAS (risk assessment software); Target Gender: Male & Female; Upper Age Limit 70 no age limit or unit specified ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Exclusion criteria for General Practice undertaking the anonymised MIQUEST searches:
General Practices who do not consent to undertake anonymised database searches.

Exclusion criteria for Focus Group 1:

Women who do not have a family history of breast cancer

Women who were referred to specialist services as part of their NHS care for breast cancer /suspected breast cancer.

Exclusion criteria for Focus Group 2:

Women who do not have a family history of breast cancer

Women who were not referred to specialist services, for familial breast cancer risk, at Royal Derby Hospital.

Exclusion criteria for patient participants for the exploratory trial and nested qualitative study:

1. Women outside the age range of 30-60 years
2. Not registered with a participating practice

3. Unable to provide written informed consent
4. Unable to complete the family history questionnaire in English
5. History of breast or ovarian cancer

Exclusion criteria for Focus Group 2:

Women who do not have a family history of breast cancer

Women who were not referred to specialist services, for familial breast cancer risk, at Royal Derby Hospital.

Exclusion criteria for patient participants for the exploratory trial and nested qualitative study:

1. Women outside the age range of 30-60 years
2. Not registered with a participating practice
3. Unable to provide written informed consent
4. Unable to complete the family history questionnaire in English
5. History of breast or ovarian cancer
6. Undergone a Familial Breast Cancer Assessment at specialist services in previous 12 months
7. Must not have participated in the focus groups.
8. Patients considered by the General Practitioners to be inappropriate to recruit due to psychosocial reasons.

Exclusion criteria for health professionals for the exploratory trial and nested qualitative study are:

GPs (principals, salaried, registrars), nurses (including nurse practitioners/practice nurses) and administration staff at general practices not participating in the study.

Date of first enrolment

10/02/2014

Date of final enrolment

30/08/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Nottingham

Nottingham

United Kingdom

NG7 2RD

Sponsor information

Organisation

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Government

Funder Name

NIHR (UK) - School for Primary Care Research; Grant Codes: Project 206

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to consent not being obtained from participants for datasets to be shared. The study was set up in 2014 and sharing of datasets was not included in the ethics and R&D applications.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results		21/09/2021	21/09/2021	No	Yes