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

Submission date 20/12/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 20/12/2013	**Overall study status** Completed	
Last Edited 21/09/2021	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
10/02/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 2163; UK Sample Size: 2163

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
England

United Kingdom

Study participating centre
University of Nottingham
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Sponsor information

Organisation
University of Nottingham (UK)

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Sponsor type
University/education

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/03/2019

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