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A feasibility study of offering breast cancer risk assessment to women through general practice

Submission date
14/12/2023

Recruitment status
No longer recruiting

Registration date
19/02/2024

Overall study status
Ongoing

Last Edited
06/01/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is common in the general population. The estimated risk of being diagnosed with breast cancer over the life course is 1 in 7 (15%) for females in the UK. For women aged 30 years or above who are at increased risk of developing breast cancer there are options available to reduce this risk and help find any cancers that do develop early. These options include making changes to their lifestyle, earlier screening and medication. Some women learn about their increased risk of developing breast cancer because of other cancers in their family. Women without a family history of breast cancer can also be at increased risk. We know that there are many women who do not know that they are at increased risk and they are therefore missing out on potential options to reduce it.
The CanRisk tool combines genetic, family history, lifestyle and hormonal risk factors about women to help doctors predict each woman's future risk of developing breast cancer. CanRisk is widely used in specialist clinics with women who are known to have an increased risk, but it has not yet been implemented in general practice, where it could help identify more women who are at increased risk of developing breast cancer. Very little is known about whether and how to start using CanRisk in general practice.
The aim of this study is to assess whether it is workable to invite women to complete a CanRisk assessment and receive an estimate of their breast cancer risk through general practices, and what women and healthcare professionals think of the process.

Who can participate?
The researchers are inviting women between 40 and 50 years old who do not already know they are at increased risk of developing breast cancer, have not already been diagnosed with breast cancer, have not opted out of being contacted for research and are registered at GP practices across Cambridgeshire and Peterborough to take part in this study. If they can't find enough women within this age group, they may also invite women between 35 and 40 years old. The researchers are also asking the healthcare professionals and practice managers involved in the delivery of CanRisk assessments with patients to take part in an interview at the end of the study.

What does the study involve?
Following completion of an electronic consent form, the research team will send the participant

a questionnaire to complete electronically or by post (according to the participant's preference) and a link to MyCanRisk will be sent, which will request information about the participant and their family members to calculate breast cancer risk.
Participants will be asked if they would like to include genetic information in their assessment. If the participant agrees to include genetic information, we will send a saliva sample kit to complete with a pre-paid envelope to post it back. Once the information from MyCanRisk and the saliva sample have been processed the participant and recruiting GP practice will receive a letter from the research team with an electronic report of the risk assessment results.
Most women joining the study will be at population risk, which means they do not have an increased risk of developing breast cancer. If a participant is found to be at population risk, participants will receive the CanRisk report and a results letter including breast awareness information.
If a participant is found to be at population risk but has told us about information in the medical history that might affect their risk, or their results show they may be at moderate or high risk of developing breast cancer, they will receive the CanRisk report and a results letter and will be advised to book an appointment with their GP to discuss the results. During this appointment, the GP will talk through their risk and the options available. Some participants may be asked if we can record their appointment, this will be optional. If appropriate, they will be offered a referral to a specialist for a follow-up.
Regardless of risk results, the participant will receive links to complete follow-up questionnaires after 4 weeks, 3 and 6 months of completing the CanRisk assessment.
The researchers would also like to talk to a small number of patients individually at a later date to discuss their thoughts about the CanRisk assessment. These interviews can be online or in person at your home or at the University of Cambridge and will be recorded with participant consent.

What are the possible benefits and risks of participating?
Participants will receive an estimate of their future risk of developing breast cancer. This information may help them to decide if they would like to make lifestyle changes to reduce that risk. If they are found to be at increased risk, they will also have the opportunity to discuss their results with their GP and if appropriate will be offered a referral to specialist care to see if they are eligible for earlier screening or medication to reduce the risk of developing breast cancer.
There are no medical risks in taking part. Still, learning about the risk of developing breast cancer in the future can potentially cause anxiety. To make sure this affects participants as little as possible, we will provide them with information about local services and websites where they can find further information and support.

Where is the study run from?
University of Cambridge and Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2023 to April 2026

Who is funding the study?
Cancer Research UK

Who is the main contact?
CanRisk-GP study team, cuh.canrisk-gp@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Juliet Usher-Smith

Contact details
Dept of Public Health and Primary Care
University of Cambridge
East Forvie Building
Cambridge
United Kingdom
CB1 0SZ
+44 (0)1223748693
jau20@medschl.cam.ac.uk

Type(s)
Public, Scientific

Contact name
Dr Cambridge University Hospitals CanRisk-GP study team

Contact details
-
Cambridge
United Kingdom
-
None available
cuh.canrisk-gp@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
326051

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56100, IRAS 326051

Study information

Scientific Title
CanRisk-GP: a feasibility study of incorporating multifactorial breast cancer risk assessment into general practice

Acronym
CanRisk-GP

Study objectives
This is a feasibility study aiming to assess the uptake and acceptability of all stages of proactive multifactorial breast cancer risk assessment using CanRisk within general practice from the perspective of women and healthcare professionals, to measure the psychological and behavioural impact of such risk assessment on women and to collect data to enable estimation of the cost of delivering proactive multifactorial breast cancer risk assessment using CanRisk within general practice.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/10/2023, East of England – Cambridge Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048285; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0199

Study design
Non-randomized cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
The CanRisk-GP research study is a pragmatic multicentre feasibility study of proactive multifactorial breast cancer risk assessment within general practice (GP), which will take place within 5 to 8 GP practices in the East of England.

GP practice recruitment will be supported by the Clinical Research Network (CRN) Eastern which will approach practices across the East of England that refer all patients with a family history of breast cancer to Cambridge University Hospital NHS Foundation Trust. Practices will be recruited from different areas to maximise participant sociodemographic and ethnic diversity. Practices that agree to take part will sign an Organisation Information Document acting as a participating site agreement. Reasons for practices declining to take part in the study will be collected where possible.

Eligible women will be identified through searches of the electronic health records at General Practices. The searches have been developed alongside the CRN East of England IT Specialist and will be conducted by members of staff within each General Practice. Depending on the population size of the practices taking part in the study, either all or a random sample of those women who meet the eligibility criteria will be invited to take part in the study. Those invited will be sent an invitation letter with the participant information sheet also enclosed and a reminder invitation letter 2-4 weeks later. For those who agree to be contacted via mobile

phone, we will also be sending a primer text message alerting them of the study. The invitation pack includes all the details for participants to contact the study team if necessary and complete the informed consent online.

Participants consenting to take part in this study will be:

Completing some questionnaires and MyCanRisk
After completing the consent form, the research team will send out a questionnaire to complete electronically. The questionnaire will include multiple choice questions about the participants and their background, ask them about thoughts about breast cancer and risk more generally, as well as their health and wellbeing. Participants will also receive a link to MyCanRisk, which will ask them for information about themselves and their families to calculate the participants' breast cancer risk. As this is also completed electronically, they can save it and come back to it as many times as they need.

Completing a saliva sample kit at home (optional)
Participants will be asked if they would like to include genetic information in their assessment. Most of the genetic code is the same between individuals. However, there are small differences between each of us. These differences are present from birth and do not change throughout a person's life. Some of these differences increase the risk of developing breast cancer and some of them decrease the risk of developing breast cancer. By looking at all the small differences, the researchers can calculate participants' breast cancer risk polygenic score. Combining this polygenic score with the information collected via MyCanRisk will enable the research team to make a more accurate estimate of participants' risk of developing breast cancer.
If participants agree to include genetic information in their assessment, they will receive a saliva sample kit at their preferred address. The research team will send them a pre-paid envelope that participants can use to post it back for processing. Once the information from MyCanRisk and the saliva sample have been processed, participants and their GP practice will receive a letter from the research team with an electronic report of their risk assessment results.

Receiving the risk assessment results
Most women joining the study will be at population risk, which means they do not have an increased risk of developing breast cancer. If participants are found to be at population risk, they will receive their CanRisk report and a results letter including breast awareness information. This is in line with NICE guidelines. Women in this group will not need to see the GP.
If participants are found to be at population risk but have told us about information in their medical history that might affect their risk or their results show they are at moderate or high risk of developing breast cancer, they will receive their CanRisk report and a results letter and will be advised to book an appointment with their GP to discuss the results. This appointment will take place no longer than 3 weeks after participants contact their GP practice. Appointments will have a normal duration of up to 15 minutes. During the appointment, GPs will talk through the participants' risk and what they can do about it. If appropriate, participants will be offered a referral to a specialist for a follow-up.

Completing some follow-up questionnaires:
Regardless of the risk results, participants will receive links to complete follow-up questionnaires after 1, 3 and 6 months of completing the CanRisk assessment. The questionnaires will include multiple choice questions about their thoughts on the result of the risk assessment, breast cancer and risk more generally, as well as their health and wellbeing.

Additional (optional) research activities:

Interviews
The researchers will aim to talk to a small number of patients individually at a later date to discuss their thoughts about the CanRisk assessment. Participants will be asked at the beginning of the study whether they would like to take part in this. The conversation can last for up to 1 hour and the details will be arranged with each participant to accommodate their preferences and availability as much as possible. The conversation can be online or in person at the participant's home or at the University of Cambridge. With the participant's agreement, the researchers will audio record the interview.

Video recording of consultations
The researchers will aim to video and audio record a small number of appointments. Patients and GPs will be able to decide before the consultation if they are happy for the appointment to be recorded. If they decide they would prefer not to have the appointment recorded, the appointment will not be affected in any way and participants will still be able to take part in the study. If the appointment is recorded, participants will be asked again after the consultation if they are still happy for the recording to be used as part of our research. Participants can say no at that point, and the researchers will delete the recording.

Intervention Type
Other

Primary outcome(s)
Uptake of multifactorial breast cancer risk assessment, including the proportion of those invited who consent and the proportion of those invited who complete the breast cancer risk assessment, with or without the inclusion of the polygenic risk score. Measured from recruitment data and completion of MyCanRisk and return of saliva sampling kits for genetic analysis at baseline.

Key secondary outcome(s))
1. Distribution of breast cancer risk measured using CanRisk risk score generated at baseline and following further clinical assessment where applicable
2. Identification of women at moderate and high risk of breast cancer, including the proportion of registered women aged 40-49 years at participating practices who are at moderate or high risk of breast cancer after assessment in secondary/tertiary care compared with the proportion of women aged 40-49 years at moderate or high risk of breast cancer after referral to secondary /tertiary care at non-participating practices across Cambridgeshire and Peterborough and compared with the proportion of registered women aged 40-49 years at participating practices in the 12 months prior to the study. Measured using data on referrals to secondary/tertiary care from across Cambridgeshire and Peterborough during the study and from participating practices for the 12 months before the study start.
3. Uptake of risk-reducing interventions measured using GP appointment, referral and outcome data collected at end of study
4. The amount of information collected through MyCanRisk measured using MyCanRisk completion at baseline
5. Psychological and behavioural impact of multifactorial breast cancer risk assessment, measured through participant questionnaires including measures of cancer worry (the Lerman cancer worry scale-R, the short-form of the STAI and the EQ-5D-5L) at baseline, 4 weeks, 3 months and 6 months
6. Acceptability of the pathway, including response rates and completion of questionnaires, measured through participant questionnaires incorporating elements of the theoretical framework of acceptability at baseline, 4 weeks, and 3 months and 6 months, healthcare

professional questionnaires incorporating the NoMAD checklist at end of study, and participant and healthcare professional interviews throughout the study, and observation of GP appointment for women above population-level risk
7. Response rates and completion of questionnaires at baseline, 4 weeks, 3 months and 6 months
8. Costs and workload associated with the delivery of proactive multifactorial risk assessment, measured through participant questionnaires at 4 weeks, 3 months and 6 months, observation of GP appointments for women above-population level risk and participant outcome data collected at the end of the study

Completion date
30/04/2026

Eligibility

Key inclusion criteria
1. Aged 40-49 years
2. Registered with a participating general practice
3. Capacity to consent
4. English speaker

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
49 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Personal history of breast or ovarian cancer
2. Known high-risk gene mutation
3. Previous diagnosis of metastatic cancer or entry on the palliative care register
4. Prior notification of dissent to research
5. Lack of capacity to consent
6. Non-English speaker

Date of first enrolment

01/07/2024

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Not provided at time of registration
-
NO COUNTRY SPECIFIED, assuming England
England
-

Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: PPRPGM-Nov20\100002

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
After the results have been analysed and published by the research team, anonymised quantitative data arising from the MyCanRisk app and trial questionnaires will be stored in and made publicly available through the University of Cambridge repository (https://www.repository.cam.ac.uk/). Qualitative data (anonymised transcripts from the interviews and consultations) will be available to researchers upon request through the University of Cambridge repository (https://www.repository.cam.ac.uk/). Researchers will be required to complete a Data Access Agreement that will indicate the criteria for data access and conditions for research use and will incorporate privacy and confidentiality standards to ensure data security.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/11/2025	06/01/2026	Yes	No