

Evaluating the uptake and impact of an adapted breast cancer risk assessment pathway in primary care amongst South Asian and Black women

Submission date 17/07/2026	Recruitment status Recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 14/10/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Breast cancer is the most common cancer affecting women in the UK. Some women have a higher chance of developing breast cancer because of a combination of factors, including their family history, lifestyle, hormonal factors and genetic factors. However, many women under 50 do not know that they may be at increased risk.

The PREVENT-Breast study is looking at whether offering women a breast cancer risk assessment through their GP practice can help identify women who may be at increased risk of breast cancer. The study is particularly focused on South Asian and Black women, as previous research has shown that these groups are less likely to take up breast cancer risk assessment. The aim is to find out whether taking part in breast cancer risk assessment is acceptable and useful to women.

Who can participate?

Women may be eligible to take part if they:

- are aged 40–49 years
- were assigned female at birth
- are registered with a participating GP practice
- are recorded in their GP records as being of South Asian or Black ethnic background

Women cannot take part if, for example, they have previously had breast or ovarian cancer, have previously been tested for a high-risk breast cancer genetic mutation, or have already taken part in certain related studies. The research team will check eligibility before women are enrolled.

What does the study involve?

Women who are eligible will receive an invitation from their GP practice. If they decide to take part, they will first complete an online consent form and a short questionnaire.

They will then complete an online breast cancer risk assessment called MyCanRisk. This asks about factors such as family history, lifestyle and hormonal factors. Participants will also be

offered the option of providing a saliva sample. This is optional. If they agree, the sample will be used to look at common genetic factors associated with breast cancer risk. Women who do not wish to provide a saliva sample can still take part in the study and have their risk estimated using the other information they provide.

The information collected will be used to calculate an individual estimate of breast cancer risk using the CanRisk tool. Participants will receive their results, together with information about breast awareness. Women whose results indicate a moderate or high risk will be offered the opportunity to discuss their results with their GP and/or be referred to appropriate specialist services.

Participants will also be asked to complete follow-up questionnaires approximately 1 month and 3 months after receiving their risk assessment. These will ask about their understanding of their risk, their experience of the study, and whether the risk assessment has affected their views or behaviour.

Participants will be invited to take part in an optional interview about their experience of the study. Interviews can take place online or in person, depending on the participant's preference.

What are the possible benefits and risks of participating?

There may be no direct benefit from taking part in the research. However, participants may benefit from learning more about their individual risk of developing breast cancer. If their assessment shows that they are at increased risk, they may be offered further discussion or referral for appropriate risk management, such as enhanced breast screening or specialist assessment.

Taking part may also help researchers understand how breast cancer risk assessment can be made more accessible and acceptable to South Asian and Black women and may help improve services in the future.

The study involves some time and effort, including completing questionnaires and the MyCanRisk assessment and, if chosen, providing a saliva sample. Some of the questions ask about family history and cancer risk, and thinking about these issues or receiving information about personal breast cancer risk may cause some women to feel worried or uncomfortable. The study specifically measures cancer-related worry and the psychological impact of risk assessment as part of its follow-up.

If a participant takes part in an interview, they can stop the interview at any time or choose not to answer a particular question. Although distress is not expected, information and support procedures are in place should a participant become uncomfortable.

Taking part is voluntary, and participants can withdraw from the study at any time.

Where is the study run from?

The study is being run through GP practices in Cambridgeshire and Peterborough and Manchester. It is expected to involve approximately 6–9 GP practices across these areas.

The study is led by researchers at the University of Cambridge and the University of Manchester. The sponsors are the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust.

When is the study starting and how long is it expected to run for?

Participant recruitment at each participating practice will continue for up to four months or until 120 women have been recruited.

Participants will then be followed for at least 3 months after receiving their risk assessment, with some information from health records collected up to 6 months after the assessment. Therefore, an individual participant's involvement is expected to extend over several months, although the overall study will run for longer to allow recruitment and follow-up across all participating GP practices.

Who is funding the study?

The study is funded by Cancer Research UK International Alliance for Cancer Early Detection (ACED). Additional support is provided through the National Institute for Health and Care Research (NIHR) Manchester Biomedical Research Centre for some members of the research team.

Who is the main contact?

If you have questions about the study, you can contact the research team:

Cambridge: Amy Lafont, Study Co-ordinator, University of Cambridge, asg55@cam.ac.uk

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Additional identifiers

Integrated Research Application System (IRAS)

363469

Central Portfolio Management System (CPMS)

72076

Grant code

EDDAMC-2023/100004

Study information

Scientific Title

PREVENT-Breast: Evaluating the uptake and impact of an adapted breast cancer risk assessment pathway in primary care amongst South Asian and Black women

Acronym

PREVENT-Breast

Study objectives

The PREVENT-Breast study is looking at whether offering women a breast cancer risk assessment through their GP practice can help identify women who may be at increased risk of breast cancer. The study is particularly focused on South Asian and Black women, as previous research has shown that these groups are less likely to take up breast cancer risk assessment. Secondary aims are:

1. To assess the acceptability of proactive multifactorial breast cancer risk assessment pathway offered through general practices amongst South-Asian and Black women aged 40-49 years and GPs involved in the consultations with women
2. To describe the distribution of risk and socio-demographic characteristics amongst women accepting and completing risk-assessment to those declining risk-assessment
3. To collect data on pathway resources, healthcare system workload and workflow, and wider societal impact in both the non-adapted and adapted arm to inform estimates of the cost of delivering proactive multifactorial breast cancer risk assessment using CanRisk through general practices

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/08/2026, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 26/NE/0136

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Screening, Prevention, Complex Intervention

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Participants consenting to take part in this study will be asked to do the following activities:

Completing some questionnaires and MyCanRisk

After completing the eligibility questions and consent form, the research team will send a baseline 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 information about themselves and their family 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 risk 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 across all the small differences, we 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 kit will include a pre-paid envelope for sample return.

Receiving the risk assessment results

- Once the information from MyCanRisk and the saliva sample have been processed (if provided), participants and their GP practice will receive a letter from the research team with a report of their risk assessment results (CanRisk report).

- Most women joining the study will be at near-population level risk, which means they do not have an increased risk of developing breast cancer. If participants are found to be at near-population level 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 their GP.

- If participants are found to be at near-population level 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 online follow-up questionnaires at 1-month and 3-months after receiving their risk results. 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.

Patient interviews (optional):

Participants will be asked at the beginning of the study whether they would like to take part in an individual interview to discuss their thoughts about the CanRisk assessment. We will aim to talk to a small number of patients. The conversation can last for up to 1 hour and the details will be arranged with each participant to accommodate to 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/University of Manchester. With the participant's agreement, we will audio record the interview.

GPs interviews (optional):

A sub-set of GPs involved with consultations with patients at above population level risk will be invited to take part in semi-structured interviews to learn about their views on the pathway, the training provided, the CanRisk output, and challenges experienced during the consultations with patients. As with the patient interviews these will take place at a convenient time and place and will be audio recorded.

Dissemination

All members of the research team will be involved in helping to compile the reports and papers, and to disseminate the findings. These findings will be disseminated via presentations at national and international conferences related to cancer and primary care research and practice. The findings will also be presented for publication in journals that will reach these audiences. We will provide a lay summary of the findings for study participants.

Study Timetable

Our aim is to have recruitment running from November 2026 to February 2027. The end of the study will be six months after the last participant has received their estimated risk. This is a tight timeline that requires participants to complete the various steps in the study within specific time windows. We have made this clear in the relevant participant documentation, and will send reminders accordingly.

Intervention Type

Other

Primary outcome(s)

1. Proportion of women who consent to take part in the study measured using study level data on consent at baseline, completion of recruitment

Key secondary outcome(s)

1. Proportion of eligible women invited in each practice who consent to take part, with and without polygenic risk score, measured using aggregate-level data from GP practices and study-level consent data at baseline and completion of recruitment
2. Proportion of women completing each stage of the breast cancer risk assessment pathway measured using study-level data on consent, baseline questionnaire completion, completion of the MyCanRisk risk factors questionnaire, and return of saliva sampling kits throughout recruitment and study participation through to follow-up
3. Acceptability of the proactive multifactorial breast cancer risk assessment pathway among participants measured using participant questionnaires and interviews at baseline, 1 month post-risk assessment, and 3 months post-risk assessment, with interviews conducted throughout the pathway
4. Acceptability of the proactive multifactorial breast cancer risk assessment pathway among healthcare professionals involved in delivery measured using GP interviews post-risk assessment
5. Distribution of risk and socio-demographic characteristics among women accepting risk assessment measured using CanRisk risk estimates for participants and assessments completed in clinical genetics or secondary care, where applicable, at completion of risk assessment and following assessment in clinical genetics or secondary care, where applicable
6. Costs and workload associated with delivery of the proactive multifactorial risk assessment within both the non-adapted and adapted pathways, and wider societal impacts, measured using

participant questionnaires and electronic health records at baseline, 1 month post-risk assessment, 3 months post-risk assessment, and 6 months post-risk assessment for electronic health record data extraction

Completion date

31/08/2027

Eligibility

Key inclusion criteria

1. Female sex as defined at birth
2. Aged 40-49 years at the time of invitation
3. Registered with a participating general practice (Cambridgeshire and Peterborough, or Manchester)
4. Identified in their medical records as South Asian or Black ethnic background

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

40 Years

Upper age limit

49 Years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Have an entry in their medical records showing a personal history of breast or ovarian cancer
2. Have an entry in their medical records showing a previous diagnosis of metastatic cancer or entry on the palliative care register
3. Have an entry in their medical records showing they have given prior notification of dissent to research
4. Self-report that they have previously been tested for a high-risk mutation for breast cancer
5. Self-report that they have already participated in the CanRisk-GP or BCAN-RAY studies
6. Self-report that they have undergone or are undergoing hormonal treatment for gender reassignment

Date of first enrolment

01/09/2026

Date of final enrolment

28/02/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

tbc

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England

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Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

ROR

<https://ror.org/04v54gj93>

Funder(s)

Funder type

Government

Funder Name

Cancer Research UK

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

Once the study has ended, the datasets generated during and/or analysed during the study will be stored in a publicly available repository (<https://www.repository.cam.ac.uk>) and within the Cancer Research UK Alliance Data Centre. Data will be stored for 100 years. Anonymised quantitative study (including MyCan Risk and study questionnaires) and qualitative data (anonymised interview transcripts) will be shared. Consent from participants to share data publicly has been obtained. 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