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CanRisk-ClinGen: A multi-site randomised controlled trial of multifactorial risk assessment in NHS clinical genetics services

Submission date
14/12/2023

Recruitment status
Recruiting

Registration date
19/12/2023

Overall study status
Ongoing

Last Edited
16/12/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims

To provide the best care to patients who are concerned about getting breast cancer in the future, healthcare professionals must assess that person's future cancer risk. Traditionally, these risk assessments have been based on family history of cancer and, where available, the results from genetic tests that look for changes in genes linked to breast cancer. Whilst this method of assessing future risk of cancer has been used for a long time, from looking at information from hundreds of thousands of people who have developed (and not developed) cancer over many years, we now know that many other risk factors contribute to future risk. By combining information on these other risk factors alongside family history and the results of genetic testing, into a statistical model (called a multifactorial risk prediction model), a more accurate and personalised estimate of future risk is obtained.

The National Institute of Health and Care Excellence (NICE), now recommends that multifactorial risk prediction models are used to assess future cancer risk for breast cancer. To help clinicians conduct risk assessments in the clinical setting, a tool was developed called CanRisk. The CanRisk tool is available for use by all healthcare professionals. The CanRisk tool is being used within the NHS Clinical Genetics Services across the UK and varying amounts of risk factor information are being collected with people's risk being assessed at different points during the patient pathway. This means that the risk assessment may not be 1) available at the most helpful time, 2) as accurate as it could be and 3) consistent across all genetics centres.

To address this, this trial aims to test a new care pathway where 1) the risk assessment is conducted at the earliest point after referral and 2) all patients receive genetic testing to provide them with as much risk factor information as possible. To assess if this pathway provides equivalent (or better) care, and to understand the impact it has on patients and staff, it needs to be compared to the existing care pathways that are in use across the UK. The best way to compare one pathway to another is to conduct a randomised controlled trial. Within a randomised controlled trial, half of the participants who are recruited are asked to have their care on the existing pathway (they are called the control group) and half are asked to have their care on the new care pathway (they are called the intervention group).

Who can participate?
Women aged 18-75 years old who have been referred to their local NHS Clinical Genetics Service or Family History Clinic via their GP or breast services team with a family history of breast cancer

What does the study involve?
Anyone who wishes to take part in this trial must give their consent. After giving consent, participants will be randomly allocated to one of two groups (control or intervention). Each group has different tasks to complete during their participation.

For participants in the control group (existing pathway), there is one main task – completing a questionnaire as soon as they join the trial and then again at one, four and twelve months after they receive their risk category from the hospital.

For participants in the intervention group (new care pathway), there are three core tasks – 1) completing four questionnaires (the same as the control group), 2) providing information about them and their family history of cancer via our MyCanRisk app, and 3) providing a saliva sample that can be used for genetic testing.

Patients from both arms may be asked to take part in an interview to better understand their experience of their pathway.

The clinical progress of participants in both groups will be followed to see what happens to them in the longer term, beyond the scope of this trial, using databases such as the National Cancer Registration and Analysis Service (NCRAS), the Hospital Episodes Statistics (HES) and any another health record or registry that may be relevant or that might become available in the future. Participants will not need to do anything for this, other than completing the consent process.

What are the possible benefits and risks of participating?
All women, regardless of participation in the study, will have their future risk of breast cancer assessed. For those who choose to participate in the study and are allocated the control group, the same care will be given as if they had not participated. As such, there is no direct benefit to the participant. For those allocated the intervention group, participants will receive a multifactorial risk assessment which is highly personalised and may be helpful in the future when making decisions about how to reduce or manage cancer risk.

There are no medical risks involved in taking part in this trial. There are no disadvantages expected for the control group participants. For those allocated to the intervention group, there is a possibility that it may take slightly longer than usual to get the risk assessment results than on the standard pathway. However, the study is designed in a way to reduce delay as much as possible and processes will be closely monitored. There is a small chance that a repeat saliva sample may be needed if it is not possible to extract enough DNA from the first sample. As the risk assessment in the intervention group requires genetic testing, the results may have an impact on participants and their families, should a change in a cancer-causing gene be found. Support will be offered throughout the risk assessment and testing process, and after the risk assessment has been made, through the local NHS Clinical Genetics Services.

Where is the study run from?
The study is jointly sponsored by the University of Cambridge and Cambridge University Hospitals NHS Foundation Trust. The study will be managed centrally by the University of Cambridge and locally by the participants' NHS trust.

When is the study starting and how long is it expected to run for?
August 2023 to June 2027

Who is funding the study?
Cancer Research UK

Who is the main contact?
Study inbox – cuh_canrisk-clingen@nhs.net

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-ways-to-assess-breast-cancer-risk-canrisk-clingen

Contact information

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
326139

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PPRPGM-Nov20\100002, CPMS 56802

Study information

Scientific Title
Operationalising CanRisk in NHS clinical genetics services: A multi-site randomised controlled trial

Acronym
CanRisk ClinGen V1

Study objectives
An early stratification pathway is anticipated to streamline risk profiling, give women the most comprehensive risk assessment available, and ensure that women are cared for by the right clinical service at the right time.

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/0194

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Risk of breast cancer

Interventions

Current interventions as of 16/12/2025:
This study is a multi-site randomised controlled trial set in 14 NHS Clinical Genetics services and Family History clinics in England. Women referred to their local NHS Clinical Genetics service or Family History clinic because of their family history of breast cancer will be randomised 1:1 into the control group (care in line with the standard pathway) or the intervention group (care in line with the new early stratification pathway), using stratified block randomisation.

The early stratification pathway involves women receiving an up-front risk stratification at the point of being referred to the service (after initial triage by the Clinical Genetics team but before any additional information is collected to perform a risk assessment). The risk assessment will use the CanRisk tool, which is a multi-factorial risk prediction tool for breast and ovarian cancer. The risk assessment combines information on known personal risk factors for BC (lifestyle, hormonal and clinical risk factors) as well as family history and results from genetic testing (monogenic and polygenic) to produce a risk score. The risk score can be used to place women into three risk categories defined by NICE CG164: near-population, moderate, and high risk. Information gleaned from the risk assessment will be used to triage women into the correct service (back to primary care or on to secondary or specialist care) to receive care based on that risk as normal within that service.

For participants in the control group (existing pathway), there is one main task – completing a questionnaire as soon as they join the trial and then again at one, four and twelve months after they receive their risk category from the hospital.

For participants in the intervention group (new care pathway), there are three core tasks – i) completing four questionnaires (the same as the control group), ii) providing information about them and their family history of cancer via our MyCanRisk app, and iii) providing a saliva sample that can be used for genetic testing. Some of the women who are seen in the clinical genetics clinic will be asked if they can have their healthcare consultation video recorded.

Participants from both arms may also be asked to take part in an interview to understand their experience of their pathway.

The staff who deliver the new pathway will also be asked to complete a questionnaire about their views. Some will be invited to interview to explore their experiences in more detail.

Recruitment and consent
Women meeting the eligibility criteria for the trial (identified at initial triage by a Clinical Geneticist or by the PICS team) will be invited to participate via post. To fully embed the trial within current clinical practice, the invitation to participate will be included with the family history form sent by the clinical team. In the invitation to participate, women will be asked to either a) complete the enclosed family history form to continue with the standard of care (without taking part in the trial) or b) consent to take part in the trial after reading the participant information sheet. A short electronic link (bitly) and QR code for the information sheet and the consent form, which will be hosted on REDCap, will be included in the invitation to participate.

All women who access the link to find out more information about the trial will be asked to select if they wish to participate (yes/no). Using skip logic within REDCap, those who do not wish to take part in the trial will be able to give insights for their decision via an open-ended question and multiple-choice option. Women who do wish to consent will be able to complete the full consent form. Upon completion of the consent form, participants will be sent a copy of their consent form, via email for their records. This email will also include a copy of their unique trial

ID. To avoid delay to the standard care pathway, women will be asked to consent to take part in the trial within two weeks (the letter will contain a cut-off date for consenting). Those who do not - or cannot for any reason - consent within this period will not be able to join the trial and returned to the standard pathway.

Collecting baseline data
After completing the consent form, all participants will be able to immediately complete the baseline questionnaire, via an embedded link at the end of the REDCap consent form. Those participants who do not wish to complete the baseline questionnaire straight after consenting will be able to via a link within the email that contains a copy of the consent. In every questionnaire, women will be asked to include or confirm their unique trial ID; this will be contained/repeated in all correspondence (the code will be automatically included in the questionnaire for those who complete it straight after consent). To not delay patients' care, women will be given a maximum of 17 days to complete the baseline questionnaire following consent (a date for the completion of the baseline questionnaire will be included in the email that contains the link). Women will be contacted once by email to remind them to complete the questionnaire within this time; those who do not/cannot complete the baseline questionnaire within this time will be withdrawn from the trial and returned to the standard pathway.

Collecting the risk factor information (intervention group only)
After participants have been randomised into the control or intervention groups, participants in the intervention group will be emailed a link to complete MyCanRisk, which asks for information on risk factors, family history, and supplementary information about family members who have had cancer(s). Once the participant has completed MyCanRisk, the encrypted information will be returned to a nhs.net email account and decrypted by a member of the research team.

Collecting the saliva sample (intervention group only)
Upon the completion of MyCanRisk, participants will be mailed a home test kit to provide a saliva sample with a cover letter. The saliva sample will be used to complete both types of genetic tests (gene panel and PRS). Alongside the test kit, participants will receive a link to a set of digital pre-test information, comprising 15 static screens of written information and schematics which aim to provide the same information delivered within a standard genetic counselling appointment. This pre-test information has been co-designed with patient public partners and extensively tested elsewhere. Participants will be asked to engage with the pre-test information, then complete the saliva sample (according to the instructions in the kit) and return it in the post to the trial team based at Strangeways Research Laboratory in a pre-paid /addressed envelope.

Communicating the outcome (intervention group only)
The local service or clinic will communicate the risk assessment to patients. All letters will include a copy of the CanRisk report and will be copied to their GP. Women without a pathogenic variant will be sent a letter containing information about their risk category and what to do next. Women at moderate and high risk with no pathogenic variant who may be eligible for additional breast screening will be referred to the relevant service by the clinical genetics team.

Women with a pathogenic variant will be sent a letter telling them their risk category (including the information about having a pathogenic variant) and inviting them to see a Clinical Geneticist /Genetic Counsellor in the clinic, where they will be asked to undergo confirmatory NHS testing. Whilst they are waiting for their appointment, they will be able to contact the clinical genetics team with any questions. The letter will inform women that as they may also be eligible for additional breast screening, they will be referred to the relevant service by the clinical genetics team.

Video recording of a follow-up appointment (intervention group only)
Before attending the clinic (face-to-face or virtual), a purposive sample of 20 participants will be sent an invitation letter, information sheet and a consent form to allow for their consultation to be video recorded. Participants will only be invited to participate if the healthcare professional that they are due to see in the clinic has read the information sheet and consented to have their consultations recorded. Where both the healthcare professional and participant consent to having the consultation recorded, the consultation will be recorded via the standard clinical videoconferencing software where available (if a virtual clinic) or on a static camera in the clinic room (if a face-to-face clinic).

Follow-up (control and intervention groups)
Participants in the control group will be sent follow-up questionnaires at 1, 4 and 12 months following the date of their closing letter. Participants in the intervention group will be sent follow-up questionnaires at 1, 4 and 12 months following the date of the clinical letter detailing the results of their risk assessment. In every questionnaire, women will be asked to include their unique identifier; this will be contained/repeated in all correspondence.

Qualitative interviews (control and intervention groups)
A purposeful sample (based on age and risk category) of between 24 and 30 participants from the intervention group and 15 participants from the control group will be invited to take part in an audio-recorded semi-structured interview, which may last up to 60 minutes. After reading the participant information sheet and giving informed consent, the interview will explore women's lived experience of the pathway (standard of care OR early stratification), including questions specifically focusing on its acceptability. All interviews will be audio recorded and transcribed verbatim.

End of trial questionnaires (staff)
All staff who have been involved in delivering the early stratification (clinical and administrative) across all recruiting sites will be invited to complete an online questionnaire via Qualtrics. After reading the participant information sheet and completing the consent form, staff will be able to anonymously complete the short questionnaire, focusing on the acceptability of the early stratification pathway, and their views on the potential implementation of the pathway into mainstream NHS Clinical Genetics Services.

Qualitative interviews (staff)
All staff (clinical and administrative) will be asked if they are also happy to take part in a 60-minute-long semi-structured interview and 20 will be purposively selected to participate based on job role and level of involvement in the pathway. After reading the participant information sheet and giving informed consent, the interviews (face-to-face or remote) will explore their experience of using the early stratification pathway, their views on the acceptability of the pathway, and their perspectives on if/when/how this pathway could be incorporated into standard clinical practice. All interviews will be audio recorded and transcribed verbatim.

Previous interventions:
This study is a multi-site randomised controlled trial set in 10 NHS Clinical Genetics services in England. Women referred to their local NHS Clinical Genetics service because of their family history of breast cancer will be randomised 1:1 into the control group (care in line with the standard pathway) or the intervention group (care in line with the new early stratification pathway), using stratified block randomisation.

The early stratification pathway involves women receiving an up-front risk stratification at the point of being referred to the service (after initial triage by the Clinical Genetics team but before any additional information is collected to perform a risk assessment). The risk assessment will use the CanRisk tool, which is a multi-factorial risk prediction tool for breast and ovarian cancer. The risk assessment combines information on known personal risk factors for BC (lifestyle, hormonal and clinical risk factors) as well as family history and results from genetic testing (monogenic and polygenic) to produce a risk score. The risk score can be used to place women into three risk categories defined by NICE CG164: near-population, moderate, and high risk. Information gleaned from the risk assessment will be used to triage women into the correct service (back to primary care or on to secondary or specialist care) to receive care based on that risk as normal within that service.

For participants in the control group (existing pathway), there is one main task – completing a questionnaire as soon as they join the trial and then again at one, four and twelve months after they receive their risk category from the hospital. Some people in the control group will be asked to take part in an interview to better understand what their experience is of the existing pathway.

For participants in the intervention group (new care pathway), there are three core tasks – i) completing four questionnaires (the same as the control group), ii) providing information about them and their family history of cancer via our MyCanRisk app, and iii) providing a saliva sample that can be used for genetic testing. Some of the women who are seen in the clinical genetics clinic will be asked if they can have their healthcare consultation video recorded. Some people in the intervention group will be asked to take part in an interview to better understand what their experience is of the new care pathway.

The staff who deliver the new pathway will also be asked to complete a questionnaire about their views. Some will be invited to interview to explore their experiences in more detail.

Recruitment and consent
Women meeting the eligibility criteria for the trial (identified at initial triage by a Clinical Geneticist or by the PICS team) will be invited to participate via post. To fully embed the trial within current clinical practice, the invitation to participate will be included with the family history form sent by the clinical team. In the invitation to participate, women will be asked to either a) complete the enclosed family history form to continue with the standard of care (without taking part in the trial) or b) consent to take part in the trial after reading the participant information sheet. A short electronic link (bitly) and QR code for the information sheet and the consent form, which will be hosted on Qualtrics, will be included in the invitation to participate.

All women who access the link to find out more information about the trial will be asked to select if they wish to participate (yes/no). Using skip logic within Qualtrics, those who do not wish to take part in the trial will be able to give insights for their decision via an open-ended question and multiple-choice option. Women who do wish to consent will be able to complete the full consent form. Upon completion of the consent form, participants will be sent a copy of their consent form, via email for their records. This email will also include a copy of their unique trial ID. To avoid delay to the standard care pathway, women will be asked to consent to take part in the trial within one week (the letter will contain a cut-off date for consenting). Those who do not - or cannot for any reason - consent within this period will not be able to join the trial and returned to the standard pathway.

Collecting baseline data
After completing the consent form, all participants will be able to immediately complete the baseline questionnaire, via an embedded link at the end of the Qualtrics consent form. Those participants who do not wish to complete the baseline questionnaire straight after consenting will be able to via a link within the email that contains a copy of the consent. In every questionnaire, women will be asked to include or confirm their unique trial ID; This will be contained/repeated in all correspondence (the code will be automatically included in the questionnaire for those who complete it straight after consent). As with the consent process, to not delay the standard care pathway, women will be asked to complete the baseline questionnaire within two weeks of the initial invitation letter, to continue with the trial (a date for the completion of the baseline questionnaire will be included in the email that contains the link). Women will be contacted once by email to remind them to complete the questionnaire within this time, those who do not/cannot complete the baseline questionnaire within this time will be withdrawn from the trial and returned to the standard pathway.

Collecting the risk factor information (intervention group only)
After participants have been randomised into the control or intervention groups, participants in the intervention group will be sent a link (via email) to complete MyCanRisk. Once the participant has completed MyCanRisk, including the risk factor information, their family history, and the supplementary information about family members who have had cancer(s), the encrypted information will be returned to a nhs.net email account and decrypted by a member of the research team.

Collecting the saliva sample (intervention group only)
Upon the completion of MyCanRisk, participants will be sent (via post) a home test kit to provide a saliva sample and a cover letter. The saliva sample will be used to complete both types of genetic tests (gene panel and PRS). Alongside the test kit, participants will receive a link to a set of digital pre-test information, comprising 15 static screens of written information and schematics which aim to provide the same information delivered within a standard genetic counselling appointment. This pre-test information has been co-designed with patient public partners and extensively tested elsewhere. Participants will be asked to engage with the pre-test information, then complete the saliva sample (according to the instructions in the kit) and return it in the post to the trial team based at Strangeways Research Laboratory in a pre-paid /addressed envelope.

Communicating the outcome (intervention group only)
We will write to all participants informing them of the results of their risk assessment. All letters will include a copy of the CanRisk report and will be copied to their GP. Women without a pathogenic variant will be sent a letter containing information about their risk category and what to do next. Women at moderate and high risk with no pathogenic variant who may be eligible for additional breast screening will be referred to the relevant service by the clinical genetics team.

Women with a pathogenic variant will be sent a letter telling them their risk category (including the information about having a pathogenic variant) and inviting them to see a Clinical Geneticist /Genetic Counsellor in the clinic, where they will be asked to undergo confirmatory NHS testing. Whilst they are waiting for their appointment, they will be able to contact the clinical genetics team with any questions. The letter will inform women that as they may also be eligible for additional breast screening, they will be referred to the relevant service by the clinical genetics team.

Video recording of a follow-up appointment (intervention group only)
Before attending the clinic (face-to-face or virtual), a purposive sample of 20 participants will be sent an invitation letter, information sheet and a consent form to allow for their consultation to be video recorded. Participants will only be invited to participate if the healthcare professional that they are due to see in the clinic has read the information sheet and consented to have their consultations recorded. Where both the healthcare professional and participant consent to having the consultation recorded, the consultation will be recorded via the standard clinical videoconferencing software where available (if a virtual clinic) or on a static camera in the clinic room (if a face-to-face clinic).

Follow-up (control and intervention groups)
Participants in the control group will be sent follow-up questionnaires at 1, 4 and 12 months following the date of their closing letter. Participants in the intervention group will be sent follow-up questionnaires at 1, 4 and 12 months following the date of the clinical letter detailing the results of their risk assessment. In every questionnaire, women will be asked to include their unique identifier; this will be contained/repeated in all correspondence.

Qualitative interviews (control and intervention groups)
A purposeful sample (based on age and risk category) of between 24 and 30 participants from the intervention group and 15 participants from the control group will be invited to take part in an audio-recorded semi-structured interview, which may last up to 60 minutes. After reading the participant information sheet and giving informed consent, the interview will explore women's lived experience of the pathway (standard of care OR early stratification), including questions specifically focusing on its acceptability. All interviews will be audio recorded and transcribed verbatim.

End of trial questionnaires (staff)
All staff who have been involved in delivering the early stratification (clinical and administrative) across all recruiting sites will be invited to complete an online questionnaire via Qualtrics. After reading the participant information sheet and completing the consent form, staff will be able to anonymously complete the short questionnaire, focusing on the acceptability of the early stratification pathway, and their views on the potential implementation of the pathway into mainstream NHS Clinical Genetics Services.

Qualitative interviews (staff)
All staff (clinical and administrative) will be asked if they are also happy to take part in a 60-minute-long semi-structured interview and 20 will be purposively selected to participate based on job role and level of involvement in the pathway. After reading the participant information sheet and giving informed consent, the interviews (face-to-face or remote) will explore their experience of using the early stratification pathway, their views on the acceptability of the pathway, and their perspectives on if/when/how this pathway could be incorporated into standard clinical practice. All interviews will be audio recorded and transcribed verbatim.

Intervention Type
Mixed

Primary outcome(s)
Differences in risk distribution measured using the CanRisk risk score

Key secondary outcome(s))

1. Uptake of available risk management interventions measured using outcome data provided by sites at the end of follow-up
2. Planned uptake of available risk management interventions measured using outcome data provided by sites at the end of follow-up
3. Psychosocial impact measured using questionnaires at baseline, 1, 4 and 12 months from the date of the risk score letter
4. Uptake of genetic testing in the intervention group measured using saliva samples provided by participants following the completion of MyCanRisk
5. Amount and completeness of information added to MyCanRisk in the intervention group measured using MyCanRisk data provided by participants at the time of completing MyCanRisk
6. Impact of confirming cancer diagnoses listed for family members within the family history section of MyCanRisk measured by comparing CanRisk score before and after cancer confirmations
7. Role of multifactorial risk assessment within the genetic counselling appointment measured using recordings of appointments following receipt of risk score
8. Acceptability of the early stratification pathway to patients and healthcare professionals measured using recruitment rates and questionnaires throughout the study
9. Cost-utility and cost-consequences of using the early stratification pathway measured using questionnaires completed at baseline, 1, 4 and 12 months and outcome data provided by sites

Completion date
14/02/2027

Eligibility

Key inclusion criteria
1. Female
2. Aged 18-75 years
3. Referred with a family history of breast cancer; able to give informed consent
4. Referred with a family history of breast cancer
5. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Previous diagnosis and treatment for breast cancer
2. Known pathogenic variant in BRCA1, BRCA2, PALB2, ATM, CHEK2, RAD51C, RAD51D, BARD1 within their family
3. Previously undergone diagnostic genetic testing for BRCA1, BRCA2, PALB2, ATM, CHEK2, RAD51C, RAD51D, BARD1
4. Previously undergone multifactorial risk assessment (using CanRisk or another tool) incorporating risk factors, family history and genetic testing
5. Previously undergone risk-reducing surgery, has already participated in the CanRisk-GP study
6. Known pathogenic variant in BRCA1, BRCA2, PALB2, ATM, CHEK2, RAD51C, RAD51D, BARD1, within their family
7. Previously undergone diagnostic genetic testing for BRCA1, BRCA2, PALB2, ATM, CHEK2, RAD51C, RAD51D, BARD1
8. Previously undergone multifactorial risk assessment (using CanRisk or another tool (e.g. IBIS Breast Cancer Risk Evaluation Tool)) incorporating risk factors, family history and genetic testing (panel +/- PRS)
9. Previously undergone risk-reducing surgery (RRM/RRBSO)

Date of first enrolment
14/08/2024

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge
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Study participating centre
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Cambridge Biomedical Campus
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Study participating centre
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HA1 3UJ

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Study participating centre

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Study participating centre
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Manchester
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Study participating centre
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M8 5RB

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

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

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. 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 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes