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Evaluation of a clinical service to support the uptake of breast cancer prevention medications by women at increased risk of the disease

Submission date
21/04/2024

Recruitment status
Recruiting

Registration date
02/05/2024

Overall study status
Ongoing

Last Edited
25/06/2025

Condition category
Cancer

[_] 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
This health services research will evaluate the implementation of an innovative, clinical intervention aimed at increasing the proportion of eligible Australian women who receive medications to prevent breast cancer. It is estimated that almost 50% of the 20,000 new breast cancers diagnosed in Australia each year occur in the 20% to 25% of women who are at moderate or high risk for the disease, based on their risk factors. Many of these cancers are preventable. A daily tablet, taken for 3-5 years, reduces breast cancer risk by 30%-60%, and guidelines confirm they are a standard of care. Yet previous research identified that few Australian women at increased risk of breast cancer are offered these medications and there is a lack of a medical workforce capable of, and willing to, discuss and initiate the prescription of these medications. An intervention, the Preventing Cancer with Medications (PCMed) Service, has been developed to address this evidence-implementation gap in service provision. This consultative telehealth service will initiate breast cancer prevention medications and support women and their clinicians throughout the total treatment period. The implementation research proposed here will assess the effectiveness, acceptability, feasibility, deliverability and cost of this Service.

Who can participate?
Women aged between 20-70 years old who have a risk of breast cancer of at least 20% over their remaining lifetime, or a risk of at least 5% over the next 10 years, and no history of invasive breast cancer, ductal carcinoma in situ (DCIS) or bilateral mastectomy.

What does the study involve?
This research will collect information about women who attend particular clinics that see woman at increased risk of cancer. Additional information will be collected on women who attend the PCMed Service. Shortly after the PCMed appointment/s, a woman will be sent an invitation to complete a brief questionnaire asking about their experience with the PCMed service. This questionnaire takes about 5 minutes to complete. Some women may be contacted after the questionnaire is received to participate in a telephone interview to help gain a deeper understanding of their experience. This interview will take about 20 minutes.

What are the possible benefits and risks of participating?
Women who attend the Service will receive personalised information about their breast cancer risk and about medications to reduce this risk. There are no medical risks in taking part in this study. The questions in the PCMed Service questionnaire and those asked during the telephone calls are unlikely to cause distress. During the telephone interview, if participants do not wish to answer a question, they can ask the interviewer to move on or stop the interview immediately. If participants become upset or distressed as a result of their participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided at no cost and by qualified staff who are not members of the research team.

Where is the study run from?
The Peter MacCallum Cancer Centre

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

Who is funding the study?
1. Tour De Cure
2. Peter MacCallum Cancer Centre

Who is the main contact?
Professor Kelly Phillips, Kelly.Phillips@petermac.org

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PMC101142

Study information

Scientific Title
Supporting uptake of risk-reducing medications and minimising treatment discontinuation: a process evaluation

Study objectives
The Preventing Cancer with Medications (PCMed) Service will be associated with an increase in the uptake of risk-reducing medications compared with historical controls, and the PCMed Service will be feasible, well-adopted, delivered with fidelity, and acceptable to clients and clinicians.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2023, Peter MacCallum Cancer Centre Human Research Ethics Committee (EC00235). (305 Grattan Street, Melbourne, 3000, Australia; +61 3 85595000; ethics@peteramc.org), ref: HREC/101142/PMCC

Study design
Single-centre interventional non-randomized implementation pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice, Hospital, Internet/virtual, Medical and other records, Telephone

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Prevention of breast cancer in clients at increased risk

Interventions
The study is a single-site study to evaluate the novel Preventing Cancer with Medications (PCMed) Service (the intervention) situated at the Peter MacCallum Cancer Centre in Melbourne, Australia. This consultative telehealth service is co-led by a nurse practitioner and medical oncologist and is for women who are at increased risk of breast cancer and who may be interested in taking medications to lower this risk. These medications will be referred to as risk-reducing medications and the women at increased risk of breast cancer will be referred to as women or clients.

Eligible clients attending the PCMed Service receive a personalised discussion of their breast cancer risk, the names and mechanism of action of risk-reducing medication/s that are potentially appropriate for the client; the potential absolute risk reduction if risk-reducing medications are taken; and other benefits and side effects of the medication/s.

For clients who indicate a desire to start a risk-reducing medication a prescription is provided, and an appointment is booked in eight to ten weeks to assess for toxicities. For clients who are undecided on whether to take risk-reducing medications and want to consider the issue further, a second consultation is offered. Clients who do not want to take risk-reducing medications, or for whom medications are not appropriate, are discharged back to the care of their referring clinician and/or their General Practitioner (GP).

Following all consultations, clients, and their referring (and other relevant doctors) will receive a written summary of the consultation and relevant information from peak cancer care organisations about risk-reducing medications.

A hotline telephone service is available for women on risk-reducing medications, their referring clinicians and GPs for emergent concerns. An additional consultation can be arranged as required.

This study will have a retrospective and a prospective component.

Retrospective Component of the Study
The retrospective component will comprise women (historical controls) who have attended the Peter MacCallum Cancer Centre (PMCC) Specialty Clinics that routinely sees women at increased risk of breast cancer and where the clients may be provided information on risk management

strategies. These clinics are subsequently referred to as “Catchment Clinics” and the consultations are referred to as “Risk Management Consultations”.

Historical controls will be identified using PMCC hospital databases and electronic medical records. These will be consecutive eligible clients who attended the catchment clinics in the same months of the year (but in the year prior) as the prospective cohort to ensure study results are not biased by seasonal variation in the uptake of risk-reducing medications. Data will include information on demographics, catchment clinic details, whether risk-reducing medications were discussed and whether the woman had commenced risk-reducing medications 12 months after her last risk management consultation. These data will provide information on the uptake of risk-reducing medications before the implementation of the PCMed Service.

Prospective Component of the Study
Clients
Consecutive eligible clients who attend Catchment Clinics from the commencement of the study will be identified using PMCC hospital databases and electronic medical records.

Eligible clients from catchment clinics who do not attend the PCMed Service will have data extracted from medical records including information on demographics, catchment clinic details, whether risk-reducing medications were discussed, whether the PCMed Service was discussed, and whether they were referred to the PCMed Service, reason for declining referral, and if clients were taking risk-reducing medications 12 months after attendance at the catchment clinic. These data will provide information on the uptake of risk-reducing medications after implementation of the PCMed Service compared to the historical controls. It is also essential that the number of eligible women coming through these catchment clinics is known so that the proportion that subsequently attends the PCMed Service can be calculated to inform how well-adopted the PCMed Service is.

Consecutive eligible clients who are referred to the PCMed Service (regardless of referring clinic or doctor) will be invited to participate in an active follow-up component of the study. Consenting clients will have additional data collected including medical information to further assess breast cancer risk and appropriateness for risk-reducing medications, whether the woman indicated an interest in taking risk-reducing medications, whether a prescription for medications was accepted, and the type of medication recommended and prescribed. These clients will also be sent a brief questionnaire and receive two phone calls. A subset will be invited to participate in an interview.

Client Questionnaire
The brief questionnaire is sent to consenting clients 1 to 2 weeks following the consultation where the decision is made whether they want to take risk-reducing medications. The questionnaire consists of eight questions constructed from the Theoretical Framework for Acceptability and takes approximately five minutes to complete.

Client Interviews
A subset of clients who have completed the questionnaire will be invited to participate in a telephone interview to further understand their perception of the Service.

Follow-up Telephone Calls at 6 and 12 months
Clients will receive a phone call 6 months after the PCMed consultation (when a decision is made whether to take risk-reducing medications) and 12 months after the catchment clinic consultation. Data will be collected regarding the use of risk-reducing medications when commenced (if relevant), if commenced where they ceased, reason for ceasing, reason for not

taking up medications, intent to use in the future, or if no intention to use then the reason for not intending to use medications.

Administrative Data Collection
Data will be extracted and recorded to assess the feasibility, fidelity and cost of the Service including, the mode of delivery of the consultation (i.e. telehealth vs face-to-face vs telephone), attending clinician (nurse practitioner vs medical oncologist), duration of consultations, how many consultations required before a prescription was written, number or failed to attend consultations and reason for this, additional consultations required and calls to hotline and reason for these.

Clinicians
Eligible Clinicians who i) saw eligible women in the catchment clinics (whether or not they referred any client to the PCMed Service) and who are still working at these clinics at the end of the study period and ii) any referring doctors external to the catchment clinics who referred women to the PCMed Service will be invited to participate in the study.

Clinician Questionnaire
Clinicians will be invited to complete a brief questionnaire based on the Theoretical Framework of Acceptability (TFA) at the end of the study period.

Clinician Interviews
A subset of clinicians will be invited to participate in interviews regarding their experience of the Service). Recruitment of this subset will be stratified using purposive sampling to include a cross-section of clinicians including clinic type, speciality, age, and sex.

Research Journal
A formal research journal will be kept by the nurse practitioner informed by the FRAME fidelity framework and the COM-B behaviour change framework. Influences on the Service and the nurse practitioner role will be recorded alongside changes to the PCMed Service Process and the rationale for the change. Any unintended consequences of the implementation of the PCMed Service will be documented.

Intervention Type
Behavioural

Primary outcome measure
Use of risk-reducing medications measured using data documented in the medical records or self-reported at 12 months after a Risk Management Consultation

Secondary outcome measures
Current secondary outcome measures as of 25/10/2024:

The following secondary outcome measures are assessed using data recorded in medical and study records and by self-reporting at the end of the study unless specified:
1. Adoption of the PCMed Service measured using the attendance by women at the PCMed Service within 6 months following a documented discussion on the PCMed Service at the relevant catchment clinic.
2. Use of risk-reducing medications by clients measured by self-report at 6-months after the PCMed Service consultation where a decision was made.
3. Reason for not using risk-reducing medications measured by self-report at 6 months after the

PCMed Service consultation where a decision was made.
4. Acceptability of the PCMed Service by clients measured using a brief questionnaire based on the theoretical framework of acceptability at 2 to 3 weeks following the PCMed Service consultation where a decision was made, and a telephone interview following the last planned PCMed Service consultation.
5. Acceptability of the PCMed Service by clinicians measured using a questionnaire and a telephone interview (based on the Theoretical Framework of Acceptability) at the end of the study recruitment period.

6. Feasibility and fidelity of the PCMed service intervention will be assessed using the following variables at the end of the study:
6.1. The number of consultations conducted by telehealth vs face-to-face vs telephone as recorded in the medical record at the time of the consultation.
6.2. Attending clinician type for each appointment (nurse practitioner and/or medical oncologist) as recorded in the medical record at the time of the consultation.
6.3. Duration of every consultation as measured using a stopwatch and recorded at the time of each consultation.
6.4. Number of consultations required before a prescription is written measured by the number of consultations a client has attended at the time a prescription is written for risk-reducing medications, or a client is discharged.
6.5. Number of clients who failed to attend the post-prescription consultation and the reason for the failure to attend measured by non-attendance of a booked post-prescription consultation by clients and the self-reported reason by clients for the failure to attend within 7 days of the event.
6.6. Number of additional post-prescription consultations required measured by any consultation that occurs in addition to the one planned post prescription consultation.
6.7. Telephone hotline use measured by the recorded number of calls received to the hotline telephone, the duration of each phone call as recorded at the time of the call, caller type (client, clinician, GP), and the self-reported reason for the call recorded at the time of the event.
6.8. Factors that influence 6.1 to 6.7 above including age, socioeconomic status (SEIFA), marital status, education level, indigenous status, country of birth (Australia/not Australia), need for interpreter, referral source and referring clinician type, name of medication commenced (if any) as sourced from the medical record.
6.9. Unintended consequences of the PCMed Service intervention as recorded in the research journal by nurse practitioner at the time of the event/s over the study period.
7. The cost of the intervention will be assessed using the following variables at the end of the study:
7.1. Funding received per woman who uses risk-reducing medications measured using activity-based funding with data extracted from the PMCC Reporting System
7.2. Funding received per woman attending the PCMed Service measured using activity-based funding with data extracted from the PMCC Reporting System
7.3. Cost of the PCMed Service per woman who uses risk-reducing medications measured through micro-costings (inventory of resources required for service delivery) collected at the time-of-service event with data extracted from medical records at the end of the study period and salaries measured as per Awards and Enterprise Agreements
7.4. Cost per woman attending the PCMed Service measured through micro-costings (inventory of resources required for service delivery) collected at the time of a service event with data extracted from study records at the end of the study period and salaries measured as per Awards and Enterprise Agreements
7.5. Difference between 7.1. and 7.3.
7.6. Difference between 7.2. and 7.4.

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Previous secondary outcome measures:

The following secondary outcome measures are assessed using data recorded in medical and study records and by self-reporting at the end of the study unless specified:
1. Adoption of the PCMed Service measured using the attendance by women at the PCMed Service within 6 months following a documented discussion on the PCMed Service at the relevant catchment clinic
2. Use of risk-reducing medications by clients measured by self-report at 6-months after the PCMed Service consultation where a decision was made
3. Reason for not using risk-reducing medications measured by self-report at 6 months after the PCMed Service consultation where a decision was made
4. Acceptability of the PCMed Service by clients measured using a brief questionnaire based on the theoretical framework of acceptability at 2 to 3 weeks following the PCMed Service consultation where a decision was made
5. Acceptability of the PCMed Service by clinicians measured using a questionnaire (based on the Theoretical Framework of Acceptability) at the end of the study recruitment period

6. Feasibility and fidelity of the PCMed service intervention will be assessed using the following variables at the end of the study:
6.1. The number of consultations conducted by telehealth vs face-to-face vs telephone as recorded in the medical record at the time of the consultation
6.2. Attending clinician type for each appointment (nurse practitioner and/or medical oncologist) as recorded in the medical record at the time of the consultation
6.3. Duration of every consultation as measured using a stopwatch and recorded at the time of each consultation
6.4. Number of consultations required before a prescription is written measured by the number of consultations a client has attended at the time a prescription is written for risk-reducing medications, or a client is discharged.
6.5. Number of clients who failed to attend the post-prescription consultation and the reason for the failure to attend measured by non-attendance of a booked post-prescription consultation by clients and the self-reported reason by clients for the failure to attend within 7 days of the event
6.6. Number of additional post-prescription consultations required measured by any consultation that occurs in addition to the one planned post prescription consultation
6.7. Telephone hotline use measured by the recorded number of calls received to the hotline telephone, the duration of each phone call as recorded at the time of the call, caller type (client, clinician, GP), and the self-reported reason for the call recorded at the time of the event.
6.8. Factors that influence 6.1 to 6.7 above including age, socioeconomic status (SEIFA), marital status, education level, indigenous status, country of birth (Australia/not Australia), need for interpreter, referral source and referring clinician type, name of medication commenced (if any) as sourced from the medical record.
6.9. Unintended consequences of the PCMed Service intervention as recorded in the research journal by nurse practitioner at the time of the event/s over the study period.
7. The cost of the intervention will be assessed using the following variables at the end of the study:
7.1. Funding received per woman who uses risk-reducing medications measured using activity-based funding with data extracted from the PMCC Reporting System
7.2. Funding received per woman attending the PCMed Service measured using activity-based funding with data extracted from the PMCC Reporting System
7.3. Cost of the PCMed Service per woman who uses risk-reducing medications measured through micro-costings (inventory of resources required for service delivery) collected at the time-of-service event with data extracted from medical records at the end of the study period

and salaries measured as per Awards and Enterprise Agreements
7.4. Cost per woman attending the PCMed Service measured through micro-costings (inventory of resources required for service delivery) collected at the time of a service event with data extracted from study records at the end of the study period and salaries measured as per Awards and Enterprise Agreements
7.5. Difference between 7.1. and 7.3.
7.6. Difference between 7.2. and 7.4.

Overall study start date
07/02/2023

Completion date
30/10/2026

Eligibility

Key inclusion criteria
Eligibility criteria for clients:
1. Female
2. Age between 20 and 70 years old
3. Residual lifetime breast cancer risk of at least 20% or a 10-year risk of at least 5%, or history of lobular carcinoma in situ (LCIS) or atypical hyperplasia, or previous thoracic irradiation
4. Does not require germline genetic testing to further clarify the risk
5. Does not carry a pathogenic variant in a high-risk breast cancer predisposition gene and is not an untested 1st-degree relative for carriers
6. No history of invasive breast cancer or ductal carcinoma in situ (DCIS)
7. No history of bilateral mastectomy
8. No prior or current use of breast cancer prevention medications

Eligibility for clinicians:
Clinicians working in clinics from which eligible clients could be referred

Participant type(s)
Patient, Health professional

Age group
Mixed

Lower age limit
20 Years

Upper age limit
70 Years

Sex
Female

Target number of participants

Historical Cohort 100 women. The prospective cohort of clients is to be determined based on uptake in the historical controls. Clinicians to be determined based on the number of clinicians working in catchment clinics at the end of the study period

Key exclusion criteria
Not meeting the inclusion criteria

Date of first enrolment
14/11/2023

Date of final enrolment
30/10/2025

Locations

Countries of recruitment
Australia

Study participating centre
Peter MacCallum Cancer Centre
305 Grattan Street
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Sponsor information

Organisation
Peter MacCallum Cancer Centre

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Clinical Research Development and Operations, 305 Grattan Street
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Sponsor type
Hospital/treatment centre

Website
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ROR

https://ror.org/02a8bt934

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Peter MacCallum Cancer Centre

Alternative Name(s)
Peter Mac

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Australia

Funder Name
Tour De Cure

Results and Publications

Publication and dissemination plan
Study results will be presented at scientific meetings and published in peer-reviewed journals.

Intention to publish date
30/10/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available due to no participant consent to do so.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	06/09/2023	01/05/2024	No	Yes

Protocol file	version 4	08/08/2024	26/02/2025	No	No
Protocol article		18/06/2025	24/06/2025	Yes	No
Protocol file	version 5	06/03/2025	25/06/2025	No	No