

What are my options? A feasibility study of a personalized primary prevention strategy for women and men at high risk of breast and prostate cancer

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| Submission date 30/06/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 05/07/2022 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 28/01/2025 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Cancer remains the disease affecting Canadians the most. It is accepted that the easiest way to fight cancer is to stop it before it starts. Unfortunately, year after year, the number of new cancer cases keeps rising, suggesting that new primary prevention strategies are needed to reverse this trend. Recently, tailoring preventive measures to individuals' risk of cancer, needs and preferences have emerged as a highly promising strategy requiring to be implemented in real life. The goal of our research is to know whether it is feasible and acceptable to implement a primary cancer prevention strategy, encompassing an individualized action plan with support and follow-ups, in men and women at high risk of prostate and breast cancer, respectively. We also want to know how well each prevention plan correlates with relevant biological, clinical and psychosocial outcomes associated with breast and prostate cancer.

Who can participate?

High-risk women and men will be identified primarily in two sites: the Breast Diseases Center and the Department of Urologic Oncology of the CHU de Québec-Université Laval. Breast cancer-free adult women with one or more of the following characteristics will be identified: having a first-degree family history of breast cancer, personal history of breast atypical hyperplasia, an extreme breast density or being a mutation carrier in high or moderate penetrance genes. Prostate cancer-free adult men with one or more of the following characteristics will be identified: being an African-descent origin or a BCRA1/2 mutation carrier, having an elevated prostate-specific antigen or a first-degree family history of prostate cancer.

What does the study involve?

Participants will be asked to complete two online questionnaires, one at baseline and one six months after enrollment. Participants randomized in the control group will be provided with an educational booklet. Participants randomized in the intervention group will be provided with an educational booklet, an interactive decision tool and the possibility to have a free consultation with the study healthcare social worker or nurse to support them in completing the decision

tool. Both groups, control and intervention group, will be asked to consult their respective resource documents.

What are the possible benefits and risks of participating?

Participants will receive resources related to the primary prevention of cancer. There is no risk involved related to the participation in this study. The duration of participation in the project is one of the main disadvantages associated with this project. If our questions related to cancer risk are causing discomfort, anxiety, or emotions, participants will be informed that they may choose not to answer these questions. They will also be provided with contact information should they need to discuss the discomfort associated with participating in the research project.

Where is the study run from?

The study is conducted at CHU de Québec-Université Laval, a university-affiliated hospital in Québec city, Canada.

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

July 2022 to December 2025

Who is funding the study?

1. The Canadian Cancer Society (CCS) - National Office (Toronto)
2. The Canadian Institutes of Health Research (CIHR) - Breast Cancer Initiative
3. The Quebec Breast Cancer Foundation (Canada)

Who is the main contact?

Professor Hermann Nabi, Hermann.Nabi@crchudequebec.ulaval.ca

Study website

<https://pulsar.ca/en/les-projets/projet/ETUDE3PC/fiche-complete>

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

CIHR-IRSC:0674000046

Study information

Scientific Title

Personalized primary prevention of cancer: The 3PC Study

Acronym

3PC

Study objectives

1. To evaluate uptake intentions and uptake rates of each preventive option proposed to each group of individuals and their level of comfort with each option.
2. To explore the associations between actual uptake of each preventive option and biological /clinical markers linked to breast cancer or prostate cancer, as well as psychosocial outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/10/2022, Research Ethics Board of the CHU de Québec – Université Laval (10, rue de l'Espinay, Québec (Québec), Canada, G1L 3L5; +1 418-525-4444 ext. 52715; gurecherche@chudequebec.ca), ref: 2023-6315

Study design

Interventional multicenter mixed-methods pilot feasibility study using a two-arm parallel group randomized controlled trial design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Breast and prostate cancers

Interventions

After completing the online eligibility screening questionnaire, consent form and baseline questionnaire assessing sociodemographic, health-related and psychosocial variables, participants will be randomized (ratio 1:1) into either the intervention group or the control, separately for men and women. This randomization will be conducted using a computer-based system and overseen by a statistician not involved in the study. A minimization procedure will be used to ensure that the study groups are balanced according to variables related to risk profile. For women, the minimization procedure will be based on having a first-degree family history of BC, personal history of breast atypical hyperplasia, an extreme breast density, or being a mutation carrier in high (e.g. BCRA1/2) or moderate (e.g. CHECK2) penetrance genes. For men, the minimization procedure will be based on being an African-descent origin or a BCRA1/2 mutation carrier, having an elevated prostate-specific antigen, or a first-degree family history of prostate cancer.

All participants will have access to a private web portal for the total 6 months duration of the study follow up. They will be invited to consult their portal and the documents at their convenience.

Intervention group: Participants randomized in this group will receive a comprehensive 4 to 6-page educational booklet about breast or prostate cancer. This booklet will be intended to provide general information about these cancers, but also their risk factors and recommended preventive options. The booklet will be written at approximately an eighth grade reading level in order to minimize health literacy and health numeracy demands. In addition to the booklet, participants in the intervention group will receive in their web portal the Ottawa Personal Decision Guide (OPDG) partially completed. The OPDG is a widely used tool, validated in French and English, which aims to help people make informed health and lifestyle decisions. Finally, the intervention group will also be offered a 45 to 60-minute Zoom or Teams consultation with the study healthcare social worker if they need assistance to navigate through the tool.

Control group: Participants randomized in this group will receive the educational booklet via their online study portal.

Data will be collected at two occasions through online questionnaires at baseline (T1, pre-randomization) and at 6 months (T2, post-randomization).

Intervention Type

Behavioural

Primary outcome measure

Measured at 6 months post-randomization through an online questionnaire:

1. Intentions to uptake primary preventive measures for breast cancer or prostate cancer: For the intervention group, the question « Based on what you know right now, how likely do you think you are to take each of the following prevention options for breast cancer (or prostate cancer) recommended to you? » will be asked. For the control group, the question « Based on what you know right now, how likely do you think you are to take one of the following breast cancer (or prostate cancer) prevention measure » will be asked. A five-point Likert-type response scale will be used for these questions.
2. Actual uptake of primary preventive measures for breast cancer or prostate cancer: « Have you made a decision about whether or not you are going to take any of the prevention options for breast cancer (or prostate cancer) recommended to you? » or « Have you made a decision about whether or not you are going to take any of the prevention measures for breast cancer (or prostate cancer)? » Those who respond that they made a decision will be asked « Did you actually take the option or the measure? And how? », those who did not make a decision will be asked « How close are you to making a decision? »
3. Decision regret: Both groups will be asked to complete the French or English version of the Decision Regret Scale (Brehaut, Medical Decision Making, 2003). This scale comprises 5 statements for which respondents are selecting a number from 1 (Strongly Agree) to 5 (Strongly Disagree) that best indicates their level of agreement. Scores are converted on a scale of 0 to 100 with a score of 0 meaning no regret and a score of 100 meaning high regret.

Secondary outcome measures

Collected through online questionnaires at two time points: baseline (pre-randomization) and 6 months post-randomization.

1. Feasibility of the study: Participation rates, appropriateness of randomization process, number of participants who use the study materials, and completion of data collection tools will be tracked throughout the study.
2. Feasibility and acceptability of the intervention: The acceptability of the intervention will be measured at T2 by assessing the satisfaction of participants with the intervention materials. Semi-structured interviews will be used to elicit participants' perspectives regarding the intervention.
3. Clinical and biological measures: Upon consent, levels of PSA in men and breast density in women will be extracted from participants' medical charts at T2, whether or not participants have taken preventive measures. The acceptability for participants to provide a blood specimen at follow-up (T2) to assess inflammatory markers, insulin like growth factor, steroid hormones, metabolites levels and DNA methylation will be tested and whether some of these measures could be linked to the uptake of preventive measures status will be explored.

Overall study start date

01/07/2022

Completion date

31/12/2025

Eligibility

Key inclusion criteria

Breast cancer-free adult women with one or more of the following characteristics :

1. Having a first-degree family history of breast cancer
2. Personal history of breast atypical hyperplasia
3. An extreme breast density
4. Being a mutation carrier in high or moderate penetrance genes.

Prostate cancer-free adult men with one or more of the following characteristics :

1. Being an African-descent origin
2. Being a BCRA1/2 mutation carrier
3. Having an elevated prostate-specific antigen.
4. Having a first-degree family history of prostate cancer.

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

A sample size of 60 high-risk women, 30 per arm, and 60 high-risk men, 30 per arm, will be recruited.

Key exclusion criteria

1. Personal history of any cancer
2. Participation in a clinical study on primary prevention of breast cancer and prostate cancer
3. Engaged in a decision-making process regarding breast cancer and prostate cancer preventive measures

Date of first enrolment

15/09/2023

Date of final enrolment

30/06/2024

Locations

Countries of recruitment

Canada

Study participating centre

CHU de Québec-Université Laval, Saint-Sacrement Hospital, Breast Diseases Center
1050 chemin Ste-Foy

Québec
Canada
G1S 4L8

Study participating centre

CHU de Québec-Université Laval, Hôtel-Dieu de Québec, Department of urologic oncology
11, Côte du Palais
Québec
Canada
G1R 2J6

Sponsor information

Organisation

CHU de Québec-Université Laval

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://www.chudequebec.ca/accueil.aspx>

Funder(s)

Funder type

Charity

Funder Name

Canadian Cancer Society

Alternative Name(s)

Canadian Cancer Society – Ontario, Société canadienne du cancer, CCS, SCC

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Canada

Funder Name

Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Fondation du cancer du sein du Québec

Alternative Name(s)

Quebec Breast Cancer Foundation, Fondation cancer du sein du Québec, Fond cancer du sein, FCSQ, QBCF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Canada

Results and Publications

Publication and dissemination plan

For researchers, we will use traditional dissemination strategies, including publications in relevant peer-reviewed journals related to implementation science, oncology, and health services research, prevention and public health. In addition, to foster debate and engage with potential collaborators, we will present study results and lessons learned at relevant conferences and workshops (e.g., BRCA meeting in Montreal, Canadian Association for Health Services and Policy Research annual conference, Canadian Cancer Research Conference). We will also share our reports using free public repositories such as Open Science Framework and ResearchGate. The dissemination of this project will start with the publication of the protocol. For knowledge users and stakeholders, we will use a number of strategies to disseminate our work. Summary briefs presenting a synthesis of evidence and observations from the study team will be disseminated to study participants at the end of the study. The summary briefs will also be posted on our social media platforms and published in institutional newsletters (e.g., le Chuchoteur at the CHU de Québec-Université Laval) to inform patients, the general population and other health professionals about the study findings. In addition, results will be disseminated among local and regional public health units, organizations involved in breast and prostate cancer prevention and early detection, and among those conducting breast and prostate cancer prevention and early detection research. Feedbacks that will be received from these dissemination activities will inform the development of an actionable implementation framework for our prevention strategy. This is important given that our research team includes several clinicians with the capacity to influence breast and prostate cancer services and prevention organization in Quebec.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date