ISRCTN15749766 https://doi.org/10.1186/ISRCTN15749766

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

Submission date
30/06/2022

Recruitment status
No longer recruiting

Registration date
05/07/2022

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact information

Type(s)
Principal investigator

Contact name
Prof Hermann Nabi

ORCID ID
https://orcid.org/0000-0002-7832-0413

Contact details
1050 chemin Ste-Foy, Room J0-01
Québec
Canada
G1S 4L8
+1 4185254444 ext.82800
Hermann.Nabi@crchudequebec.ulaval.ca

Type(s)
Public, Scientific

Contact name
Dr Asma Boubaker

Contact details
1050 chemin Ste-Foy, Room J0-04
Québec
Canada
G1S 4L8
+1 4185254444 ext.82721
asma.boubaker@crchudequebec.ulaval.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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 made 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.

Key secondary outcome(s))
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.

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.

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

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 - Welcome to the Canadian Institutes of Health Research, 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

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes