ISRCTN10220433 https://doi.org/10.1186/ISRCTN10220433

Cancer navigation experiences of people living with breast cancer

Submission date
25/01/2025

Recruitment status
Recruiting

Registration date
28/01/2025

Overall study status
Ongoing

Last Edited
08/07/2025

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 study is being conducted by Dr. Melba D'Souza from the School of Nursing at Thompson Rivers University. The aim is to understand the perspectives and experiences of people with breast cancer in Kamloops and Revelstoke, British Columbia. The study focuses on cancer care navigation, education, and support over six months.

Who can participate?
You can participate if you are 19 years or older, can read and write in English or any other language, and have been diagnosed with breast cancer at any stage. This includes those currently undergoing treatment or who have completed treatment.

What does the study involve?
Participants will receive cancer care navigation, education, and support for six months. Your information will help researchers prepare reports, workshops, and publications. The findings will be shared with participants, community stakeholders, and at academic conferences.

What are the possible benefits and risks of participating?
Benefits include receiving a $25 CAD electronic gift card for groceries and the opportunity to share your experiences, which may help others. There are no significant risks, but participation is voluntary, and you can withdraw at any time until March 30, 2025.

Where is the study run from?
Thompson Rivers University (Canada)

When is the study starting and how long is it expected to run for?
June 2022 to June 2027

Who is funding the study?
Breast Cancer Canada

Who is the main contact?
The main contact for the study is Dr. Melba D'Souza. You can reach her via email at mdsouza@tru.ca.

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Melba D'Souza

ORCID ID
https://orcid.org/0000-0002-3156-0663

Contact details
Thompson Rivers University, School of Nursing, 805 TRU Way, 840 College Drive
Kamloops
Canada
V2C 0C8
+1 6047516672
mdsouza@tru.ca

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
BCSCGrant#2022-005-R

Study information

Scientific Title
Enhancing cancer navigation for newly diagnosed, treated and post-treatment of people living with breast cancer in interior region of British Columbia

Acronym
CNRO

Study objectives
H01: Participants in the intervention arm will have a higher rate of high-quality decisions in the breast cancer journey such as accurate knowledge and a higher rate of values concordant decisions as measured by the Breast Cancer Navigation Survey (BCNS), Participant Satisfaction with Navigation Scale (PSNS) and Satisfaction with Interpersonal Relationship (SIPR).
H02. Participants in the intervention arm will report a more positive appraisal of the breast cancer journey such as preparedness, deliberation and satisfaction as determined by the Breast Cancer Navigation Interview (BCNI).

H03: Participants in the intervention arm will have a higher health-related quality of life in the breast cancer journey as assessed by the COST-FACIT and FACT-B outcome measures.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/04/2023, University of British Columbia - BC Cancer Research Ethics Board (UBC BC Cancer Research Ethics Board Fairmont Medical Building 750 West Broadway, Suite 1315, Vancouver British Columbia, V5Z 1J3, Canada; +1-250-852-7122; tlawrie@tru.ca), ref: H22-03105

Study design
Implementation science randomized controlled design and mixed methods design

Primary study design
Interventional

Study type(s)
Other, Quality of life, Efficacy

Health condition(s) or problem(s) studied
Breast cancer diagnosis, treatment and post-treatment

Interventions
Randomized controlled trial method
A mixed research method and a pilot and feasibility randomized controlled trial (RCT) design will be used. This mixed method and RCT will involve developing and implementing a cancer navigation intervention with testing and evaluation to assess reported outcomes. This pilot randomized control trial (RCT) design includes testing the effect of a Cancer Navigation Intervention(CNI) consisting of direct psychosocial and educational webinars, coordinated telephone support service, and community-based cancer care resources compared with standard care alone among people living with a breast cancer diagnosis, treatment and post-treatment.

Assignment of interventions
Following the completion of the three baseline survey forms, the study will randomize participants into one of the two arms as described: intervention or control. The randomization is stratified by age at the survey (18-35 years; 36-55, and above 55 years) and location/ site (Kamloops and Revelstoke) to certify equal proportions of the participants by these factors in both arms. Random allocations within strata are computer generated through the survey software OneDrive, the lead statistician on this research team coded the OneDrive project to be able to randomize the participants once age and location were entered into specific fields. Once a participant consented to the study and finished the baseline survey forms, they are randomized by the research assistant who would log into OneDrive, type in age and location site, and then click the randomization button. After randomization occurs, the participant will be emailed the told which group they have been randomized into with tailored directions for the next steps of the study. The randomization is computer-generated and is performed by using permuted blocks (size=5), An independent research member in the project carries out the randomization to ensure the blinding of the research team. The sequence of randomization is determined by the participant’s identification number, which they receive after signing the informed consent. Participants are randomized in a 1:1 ratio between intervention and control arms.

Cancer navigation intervention

Cancer navigation intervention (CNI) in this research project is used to guide people living with breast cancer through diagnosis, treatment and post-treatment to have a better quality of life. CN intervention is defined as navigation processes directed by a qualified professional navigator who supports and guides people with a breast cancer diagnosis, treatment, and post-treatment for educational, emotional and navigational needs. CN intervention is structured around three components: direct psychosocial and educational webinars, coordinated telephone support service, and community-based cancer care resources provided by a professional navigator, overseen by the Principal investigator. A professional navigator in the CN intervention is a qualified, trained and experienced person who works with people living with breast cancer to help them with their healthcare. The professional navigator will provide guidance across the physical, psychosocial and emotional challenges that come with a cancer diagnosis, treatment and post-treatment. CN intervention for people with a breast cancer diagnosis, treatment, and post-treatment will be pilot-tested at baseline prior to study initiation in a BC interior region. The intervention will consist of interrelated activities that will cover the intervention pilot including psycho-educational webinars, telephone helpline support and cancer care resources. The CN intervention for people with cancer diagnosis, treatment and post-treatment will be pilot-tested one month prior to study initiation in a BC interior region. In this research study, the intervention group will receive the professional and cancer navigation support module consisting of a personal log to identify needs and establish personal and health goals, creating an action plan to achieve the established goals, regular check-ins and an opportunity for discussion with people with cancer diagnosis, treatment and post-treatment transition to survivor, explore different services and resources, and put into practice the knowledge and skills learned during their participation. Professional check-ins will take place by telephone calls once in 2 weeks based on preference and needs. A goal review form will be used to evaluate patient progress and determine any needs for adjustment. These cancer navigation modules and webinars are individualized one-to-one meetings or patients can choose to participate in group sessions which allows them to learn from their professional navigator in committing and reaching their goals.

Intervention group

CN intervention will be delivered in face-to-face mode to individual participants with breast cancer diagnosis, treatment, and post-treatment phases. The participants in the Intervention group will dedicate 15 minutes biweekly for 3 months and 6 months for telephone calls, 45 minutes for an interactive teaching-learning and a 30-minute webinar session and 50 minutes for a participant interview, a total of 5 hours. Participants randomized to the intervention group and the standard group will standard care. The resources shared with the participants in the Cancer Navigation Intervention are the following: Cancer Education Module, Community Virtual Support, BC Cancer. Provincial Health Services Authority, and Community Resources.

Control group

The comparison in this study is a Standard Of Care (SOC) version of the education. This SOC version offers similar content but without the tailored and interactive features of the CNI version. It is designed to mirror typical self-navigated education available to participants with a diagnosis of breast cancer. Participants can navigate the information using the electronic book organized linearly. To avoid conflicts with the information given during the CNI, a communication sheet has been made. This document contains guidelines on which information the professional navigators can provide on common topics discussed during the CNI. The resources shared with the participants in the Standards Of Care are the following Breast cancer

and you: A guide for people living with breast cancer, Never too young: psychosocial information and support for young women with breast cancer, and Understanding treatment for breast cancer. Canadian Cancer Society.

Intervention Type
Behavioural

Primary outcome(s)
1. Breast Cancer Navigation is measured using the Breast Cancer Navigation Survey (BCNS) at 3 months, and 6 months
2. Participant Satisfaction with Navigation is measured using the Participant Satisfaction with Navigation Scale (PSNS) at 3 months, and 6 months
3. Satisfaction with Interpersonal Relationships is measured using the Satisfaction with Interpersonal Relationships (SIPR) at 3 months, and 6 months
4. Perspectives of Diagnosis and Treatment are measured using the Breast Cancer Navigation Interview at 6 months
5. Feasibility, Acceptability, and Satisfaction are measured using the Breast Cancer Navigation Interview at 6 months

Key secondary outcome(s))
1. Health-Related Quality of Life is measured using the Functional Assessment of Cancer Therapy – Breast (FACT-B) at baseline
2. Cost is measured using the COST-FACIT Version 2 at baseline

Completion date
22/06/2027

Eligibility

Key inclusion criteria
1. People aged above 18 years (19 years and older)
2. People who are able to read, understand, and write in English or any other languages
3. People with a diagnosis of breast cancer at all stages
4. People eligible for treatment
5. People post-treatment
6. People with operable cases of breast cancer
7. People who are undergoing conserving breast cancer surgeries
8. People who are undergoing breast cancer adjuvant chemotherapy or radiation therapy

Participant type(s)
Patient, Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
19 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. People with advanced breast cancer and metastasis to other organs such as brain, bone, liver
2. People with concurrent malignancies
3. People with secondary cancers
4. Neonates, infants, and children less than 19 years
5. People with self-reported severe, undiagnosed, and untreated psychiatric or cognitive problems preventing informed consent

Date of first enrolment
27/07/2023

Date of final enrolment
21/07/2026

Locations

Countries of recruitment
Canada

Study participating centre
BC Cancer Provincial Health Services Authority
BC Cancer, Kamloops Cancer Centre, Royal Inland Hospital
311 Columbia Street
Kamloops
Canada
V2C 2T1

Study participating centre
Rae Fawcett Breast Health Clinic
Royal Inland Hospital, 311 Columbia Street
Kamloops
Canada
V2C 2T1

Study participating centre
Queen Victoria Hospital
1200 Newlands Road

Revelstoke
Canada
V0E 2S0

Study participating centre
Royal Inland Hospital
311 Columbia St
Kamloops
Canada
V2C 2T1

Study participating centre
Nicola Valley Hospital and Health Centre
3451 Voght St
Merritt
Canada
V1K 1H6

Study participating centre
100 Mile District General Hospital
555 Cedar Ave
100 Mile House
Canada
V0K 2E1

Sponsor information

Organisation
Thompson Rivers University

ROR
https://ror.org/01v9wj339

Funder(s)

Funder type
Research organisation

Funder Name
Breast Cancer Canada

Alternative Name(s)
Breast Cancer Society of Canada, The Breast Cancer Society of Canada, Breast Cancer Soc., BreastCancerSociety, Cancer du sein Canada, La Société du cancer du sein du Canada, Société du cancer du sein du Canada, , BCC

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The individual participant data or personal information is protected by our privacy law in BC. This law is called the Freedom of Information and Protection of Privacy Act (FIPPA). We are collecting your information under section 26 (e) of FIPPA.
All paper or electronic research data will be encrypted or password-protected and any copies of data will be kept in a secure computer and a locked cabinet at TRU. Digital electronic data files will be encrypted and stored in a password-protected computer on servers located in TRU. Data will be shared over a secure TRU-shared OneDrive granting access only to the principal investigator, co-investigator and/ or research assistant. After the study is completed, the coded data will be retained for future research use and available on the institutional data repository. For online data, the researcher will store the data in a secured TRU cloud and locally on the TRU encrypted computer and include the disclaimer in the consent form.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, 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	version 4	27/12/2024	28/01/2025	No	Yes
Protocol file		27/01/2025	28/01/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes