RESEARCH PROTOCOL OF BREAST CANCER NAVIGATION

Full title: Enhancing cancer navigation for newly diagnosed, treated and post-treatment of people living with breast cancer in interior region of British Columbia.

Concise Title: Cancer navigation experiences of people living with breast cancer

Project Acronym: Cancer Navigation and Reported Outcomes (CNRO)

Funding: Breast Cancer Society of Canada and Thompson Rivers University

Ethics Approved: BC Cancer, Interior Health and Thompson Rivers University

RESEARCH TEAM MEMBERS

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PROJECT SUMMARY

Current cancer navigation in British Columbia is across the cancer care continuum including prevention, detection, diagnosis, treatment, and survivorship in British Columbia (Pedersen, 2011). Cancer navigation intervention 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. Cancer navigation intervention will consist of direct psychosocial and educational webinars, coordinated telephone support services, and community-based cancer care resources. A professional navigator in the cancer navigation intervention is a graduate, trained and experienced to work with people living with breast cancer to help them with their healthcare. The professional navigator will provide help and guidance across the physical, psychosocial and emotional challenges that come with a cancer diagnosis, treatment and post-treatment.

BACKGROUND INFORMATION

Cancer is the leading cause of mortality for men and women in Canada (80,152). Cancer care after treatment and completion of treatment plays a significant role in accessing health and medical care. There are variations in access to cancer care after treatment and supportive care services in suburban, rural and remote areas (Racine et al., 2022; D'Souza et al., 2021). Hence, it is important to focus on patient-reported outcomes by developing and implementing the delivery of and access to a better understanding of supportive care. This research study focuses on strategies to improve the lives of people with cancer through cancer navigation after treatment and the development of individualized care for making a difference in diagnosed, treated and survivors. Cancer wields an enormous health burden on Canadian society. The empirical evidence is undeniable: Currently, the burden of care is escalating in all national regions and across wide-ranging socio-economic categories

(Canadian Cancer Statistics, 2017). Lung, breast, colorectal and prostate cancer are the most diagnosed cancers in Canada and account for about half (48%) of all new cancer cases (Canadian Cancer Society, 2021). 2018 saw 26,735 new cancer cases in British Columbia (BC) with a cancer incidence rate of 533.6/100,000 for people representing all ages, genders, and primary cancer sites in BC (Statistics Canada, 2021). In 2020, 115,800 Canadian men were estimated to be diagnosed with cancer, with 44,100 dying from the disease; and among women, 110,000 were estimated to receive a cancer diagnosis, with 39,300 dying from it (Canadian Cancer Society, 2021).

RATIONALE

Investigating this research study is important because there is a gap in practice due to the hectic nature of meeting priorities of patient care needs and supportive care in cancer clinics, where the coordination and follow-up of care can be uneven, especially during the pandemic. (D’Souza et al., 2025). This can cause delays in treatment initiation and lack of continuation, and lead to poor patient outcomes and decreased patient satisfaction(D’Souza et al., 2024; D'Souza et al., 2023). Early findings in this region conducted by our team found that 24% of women reported not receiving adequate emotional support from their breast cancer treatment phases, and 50% of women felt they received adequate support from the health professionals present when they were diagnosed, although 20% would have liked to receive more emotional support (D'Souza et al., 2022; D’Souza et al., 2021). These findings indicated that participants in the Interior of BC had difficulty understanding, utilizing and navigating the cancer care services citing a lack of follow-up after treatment, timely coordination and organization of care after treatment.

AIMS

1. What are the barriers to, and facilitators of, accessing cancer care services in BC for people with breast cancer diagnosis, treatment and post-treatment?
2. How effective is cancer navigation in enhancing patient engagement in care and patient-reported outcomes for people living with breast cancer in BC?

Study Goals

1. Develop and evaluate a community-based intervention that will assess patients' experience with cancer navigation, with a clear intention to contextualize the experiences of equity-deserving groups.
2. Engage and share study results with key stakeholders to create a robust cancer navigation support dedicated to the improvement of cancer navigation services.

METHODOLOGY

Study Design

This study employs a Randomized Control Trial (RCT), and a mixed methods research approach. An RCT is a single-centre, parallel-group study with stratified block randomization. The purpose of the study is to utilize and evaluate an innovative Cancer Navigation Intervention (CNI) designed to improve the quality of life in the breast cancer journey consists of a tailored and interactive CNI versus a Standard Of Care (SOC) for participants with newly diagnosed breast cancer (intervention group/arm). After enrollment and informed consent are completed, participants complete a baseline survey and are electronically randomized to the intervention (CNI) or control (SOC) group/arm. The CNRO research protocol (Appendix 1) will be submitted through the harmonized ethics application to the BC Cancer, Interior Health and Thompson Rivers University research ethics board to seek approval. Recruitment, data collection and intervention will be initiated after receiving the ethics approval certificate for the research study.

DATA ANALYSIS AND MANAGEMENT

The survey will assess primary and secondary outcomes, along with selected co-variates at baseline and the end of 3 months and end of 6 months of intervention. The survey instrument will be developed in English and will be translated into the local language, if any, back-translated by an independent translator for language consistency as needed and reconciled with the original version to enhance semantic validity. The survey will be refined with inputs from the key informants and pre-tested to participants in Kamloops and Revelstoke communities to evaluate the ease of comprehension, suitability of questions, and completion issues. Process data regarding these changes will also be documented. We will produce a final survey version based on survey feedback and test the survey for clarity and translation purposes with participating community stakeholders. Content validity and internal consistency of relevance scales such as symptom distress, quality of life, and functional assessment will be assessed using Cronbach's alpha. Research assistants will survey and interview the participants.

Outcome measures and analysis

Primary outcomes will include reduced functional assessment and improved quality of life. Secondary outcomes will include increasing physical activity and improving satisfaction. A socio-demographic survey will be used to collect the demographic of people newly diagnosed with breast cancer. The demographic survey will take 5 minutes. Functional assessment of the cancer therapy scale will be used to measure health-related QOL. This instrument was developed to test health-related QOL among people with cancer diagnosis, treatment and post-treatment. Internal consistency reliability is 0.90 and the alpha coefficients of subscales range from 0.63 to 0.86. The test-retest reliability, convergent, and divergent validity are tested in different studies. The level of symptom distress and quality of life of people with cancer diagnosis, treatment and post-treatment will be assessed before surgery or adjuvant therapy and at the end of the intervention.

Knowledge translation action

The research team is dedicated to the dissemination of research findings to participants, providers, and policy-makers, and has a strong history of scientific publications. Publications from this research will be made available to the public through the National Library of Medicine PubMed Central website within one year after the date of publication. We will publish findings related to each of the study aims. The study findings and processes such as recruitment and screening and findings will be presented at professional conferences and scientific summits hosted by BC Cancer Summit, the Canadian Cancer Research Alliance, the Canadian Association of Nurses in Oncology, and the International Psycho-Oncology Society.

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