

Why am I Still Tired?
Adaptation, Implementation, and Evaluation of an Intervention for Cancer-Related
Fatigue.

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Preface

This thesis is manuscript-based, containing a general introduction, two studies, and a general discussion/conclusion. The main collaborators throughout have been myself, Dr. Sophie Lebel, Ph.D., C. Psych, Dr. Georden Jones, PhD, C. Psych, Dr. Jennifer Brunet, Ph.D., and Patricia Barrett, RN. For the first qualitative study, I was responsible for conducting a literature review, data transcription, analysis and interpretation, conference presentations, and writing of the manuscript. I was partially involved in the data collection as a co-facilitator for two of the focus groups, in the preparation of the ethics application, and discussion of methodology. For the second mixed-methods study, I was primarily responsible for conducting a literature review, study design and methodology, preparation of study documents (i.e., ethics review board application, consent forms, posters, informational sheets, patient and facilitator workbooks, patient resources etc.), facilitating the patient advisory board and focus groups, engaging with interest holders at the Ottawa Cancer Foundation and other organizations such as CancerCare Manitoba, Alberta Health Services, and Wellspring, participant recruitment, selection of measures, data collection, entry, and analysis, conference presentations, grant submissions, and writing of the manuscript. Each co-author's role is described below.

Dr. Sophie Lebel, Professor at the University of Ottawa and my thesis supervisor, supervised all research activities, such as the study design, methodology, ethics review board applications, selection of measures, data collection, analysis and interpretation, grant submissions, dissemination of findings, and manuscript preparation.

Dr. Jennifer Brunet, Professor at the School of Human Kinetics, Department of Health Sciences, University of Ottawa, worked as a collaborator on our first study and second study, being a co-facilitator of the focus groups, providing expert knowledge in quantitative and qualitative

research, and assisting with manuscript editing. For the second study, she provided general consultation on the physical activity portion of the CrF workbook and provided revisions of the manuscript.

Dr. Georden Jones, former colleague at the Psychosocial Oncology Lab, laid the foundation for our study through her dissertation work, including the methodology for the initial focus groups with HCP, CSP, and patients. She was involved in the first study, primarily with interpretation of data and manuscript editing.

Patricia Barrett, registered nurse and cancer coach, collaborated on the second study as a community partner representing The Ottawa Cancer Foundation. However, due to the COVID-19 pandemic which led to restructuring at the Ottawa Cancer Foundation she lost affiliation with our community partner part way through the project, however continued to advocate for the provision of the program at the Ottawa Cancer Foundation. She was involved in the conception of the CrF program, adaptation of the CrF workbook, facilitated the CrF groups, collaborated on conference presentations, and manuscript editing.

This research was approved by the local research ethics boards. Study 1 was approved by the Institutional Review Board of The Ottawa Health Science Network Research Ethics Board (Protocol #20170704-01H, 19 April 2018), the Montfort Hospital Research Ethics Office (Protocol #GJ-06-08-15, 24 September 2015), and the University of Ottawa Office of Research Ethics and Integrity (File #H12-15-26, 1 February 2016). These approvals can be found in Appendices VII-IX. Study 2 was approved by The Ottawa Health Science Network Research Ethics Board (Protocol# 20220190-01H, 8 June 2022) and the University of Ottawa Office of Research Ethics and Integrity (File# H-11-21-7124, 9 December 2021). These approvals can be found in Appendices XI & XII. This study was also registered as a clinical trial NCT05409638. Study 1 has

been accepted for publication in a peer-reviewed journal. The first study entitled “An Ideal Intervention for Cancer-Related Fatigue: Qualitative Findings from Patients, Community Partners, and Healthcare Providers” has been published as an original research article in *Current Oncology* (Rutkowski NA, Jones G, Brunet J, Lebel S., 2024). The 2nd article entitled “A brief psychoeducational intervention for cancer-related fatigue in a community context: A hybrid type-2 effectiveness-implementation randomized controlled trial pilot study” will be submitted to a peer review journal. Both these studies have been presented at national and international conferences; they are noted below.

1. **Rutkowski, N.,** Barrett, P., Lebel, S. (2024, June). *Brief intervention for cancer-related fatigue: Partnering with a patient advisory board and community partners for sustainable intervention development.* Engaging stakeholders in survivorship research to increase its reach and impact: Lessons learned from the perspective of researchers and clinicians. Symposium at CAPO 2024, Calgary, Canada.
2. **Rutkowski, N.,** Barrett-Robillard, P., Lebel, S. (2022, August). *Why am I still tired? Adaptation and implementation of an evidence-based intervention for cancer-related fatigue in a community context.* Cancer-related fatigue in a dyadic and community context: Needs assessment, intervention development, and implementation. Symposium at IPOS-CAPO 2022, Toronto, Canada.
3. **Rutkowski, N.,** Jones, G., Lebel, S. (2021, June). *An ideal intervention for cancer-related fatigue: What do patients, community providers, and healthcare providers want?* Oral presentation at the 36th Annual CAPO Virtual Conference.

General Abstract

Cancer related fatigue (CrF) is one of the most prevalent and debilitating post treatment side effects and has been reported as an long-standing unmet need for individuals living beyond cancer (Roseleur et al., 2023). CrF has been defined as a “distressing, persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Berger, Mooney, et al., 2015). Approximately a third of cancer survivors will continue to experience moderate to severe fatigue for several years post treatment (Al Maqbali et al., 2021; Kang et al., 2023). Persistent fatigue has been found to have significant adverse impacts on quality of life and contribute to high levels of disability (Jones et al., 2016). Given the prominence of CrF, guidelines for the assessment and management of CrF have been developed. In Canada, evidence-based guidelines by the Canadian Association for Psychosocial Oncology (CAPO) are available (Howell et al., 2015). Internationally, evidence-based guidelines are available from several international organizations, including European Society for Medical Oncology (ESMO) (Fabi et al., 2020), National Comprehensive Cancer Network (NCCN), (Berger, Mooney, et al., 2015) and most recently the American Society of Clinical Oncology (ASCO) (Bower et al., 2024). Guidelines suggest a variety of effective nonpharmacological interventions for the management of CrF including cognitive behavioural therapy, psychoeducation, mind-body interventions, and physical activity (Howell et al., 2015). Despite the availability of guidelines for CrF and well researched interventions that have demonstrated effectiveness implementation has been lacking (Pearson et al., 2017). Several barriers have been identified including lack of healthcare provider training and knowledge, a lack of leadership, attitudes of patients and HCP towards CrF including perceptions of treatment futility, complexity of guidelines, and inefficient referral pathways (Jones et al., 2021; Pearson et al., 2023; Thong, van Noorden, et al., 2020). This thesis’ objectives were to adapt, implement, and

evaluate an intervention for CrF in a community context using the Knowledge-to-Action framework (KTA) (Field et al., 2014), RE-AIM framework (Holtrop et al., 2021), and community and patient partnership.

Study 1 captures KTA stages of adaptation of knowledge to the local context and identification of barriers by exploring what an ideal intervention for CrF would look like from the perspectives of different interest holders and the barriers to its implementation. A total of 62 participants—16 patients, 32 healthcare providers (HCPs), and 15 community support providers (CSPs) were recruited. This needs assessment described what patients, CSPs, and HCPs wanted in an ideal intervention for CrF and the potential barriers to implementing such intervention through qualitative methodology. Data was collected via nine focus groups and four semi-structured interviews. Data was coded into themes using content analysis. Two main themes emerged around addressing CrF: *“It takes a village”* and *“This will not be easy”*. Participants discussed an intervention for CrF could be anywhere, offered by anyone and everyone, and provided early and frequently throughout the cancer experience and could include peer support, psychoeducation, physical activity, mind–body interventions, and interdisciplinary care. Patients, HCPs, and CSPs described several potential barriers to implementation, including patient barriers (i.e., patient variability, accessibility, online literacy, and overload of information) and systems barriers (i.e., costs, lack of HCP knowledge, system insufficiency, and time). This study laid the groundwork for study 2’s implementation of a patient-centered intervention for CrF in a community context by identifying a significant need for CrF programming in the local context, guiding the selection of an intervention, and preparing for anticipated barriers.

Study 2 addresses KTA stages of selection/tailoring of an intervention, monitoring knowledge use, evaluating outcomes, and sustaining knowledge use. Based on our needs

assessment, an evident knowledge to practice gap exists for CrF management in Ottawa, Canada. This pilot study employed a type-2 hybrid effectiveness-implementation design. Participants (N=50) were randomized to either an intervention group or a wait-list control, with both groups completing questionnaires at baseline, at 5 weeks, and at 2-month follow-up. Participants assigned to the intervention group received four virtual 90-minute sessions facilitated by a registered nurse/cancer coach. The CrF intervention showed promise of improvements in quality-of-life improvements on the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F-13) ($F_{2,84}=4.73, p=.015, \eta_p^2=.101$) and reduced fatigue on the Multidimensional Fatigue Inventory-20 (MFI-20) ($F_{2,84}=6.18, p=.007, \eta_p^2=.128$), compared to the wait-list control. Improvements in sleep and depression were also found. Evaluation of implementation outcomes were guided by the RE-AIM framework (Holtrop et al., 2021). The intervention was delivered with high levels of fidelity and low attrition. The intervention was found to be feasible with high satisfaction rates suggesting acceptability. Through partnership with a community organization and patient advisory board, this project was able to ensure a) end users and providers' needs were met and b) maintenance of the CrF program for individuals living with and beyond cancer who are experiencing CrF in the Ottawa region.

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List of Abbreviations

ACE: Alberta Exercise Program

ACSM: American College of Sports Medicine

ASCO: American Society for Clinical Oncology

CAPO: Canadian Association for Psychosocial Oncology

CBT: Cognitive behavioural therapy

CFIR: Consolidated Framework for Implementation Research

CIHR: Canadian Institutes of Health Research

CSP: Community support providers

CRCI: Cancer related cognitive impairment

CrF: Cancer-related fatigue

CRP: C-reactive protein

ESMO: European Society for Medical Oncology

HCP: Healthcare providers

HPA: hypothalamic-pituitary-adrenal

IL-1Ra: interleukin-1 receptor antagonist

IL-6: interleukin 6

IS: Implementation science

KT: Knowledge translation

KTA: Knowledge-to-Action

sTNF-RI/ sTNF-RII: soluble tumor necrosis factor receptor type I and II

MBSR: Mindfulness-Based Stress Reduction

mHealth: mobile health

NCCN: National Comprehensive Cancer Network

NIH: National Institute for Health

TMF: Theory, model, framework

RE-AIM: Reach, Effectiveness, Adoption, Implementation, and Maintenance

SIO: Society for Integrative Oncology

T-CaST: Theory Comparison and Selection Tool

TNF- α : tumor necrosis factor

QoL: Quality of life

General Introduction

Cancer is a disease in which an abnormal or damaged cell, resulting from a genetic change such as an error during cell division or DNA damage, has begun to multiply uncontrollably and can subsequently invade nearby tissue or spread to distant parts of the body (National Cancer Institute, 2021b). Many treatment options for cancer exist, including chemotherapy, radiation, surgery, immunotherapies, and targeted therapies. Chemotherapy is a pharmacological intervention which targets cancer's fast-growing cells, radiation uses beams of intense energy to destroy cancer cells, and surgery is used to remove solid cancer tumours. Over the last few decades many advancements have been made in cancer treatment including immunotherapies like chimeric antigen receptor t cells (CAR-T), which use components of the immune system to aid in identifying and destroying cancer cells. Further, nanoscale/nanostructure-based therapeutics, such as targeted cancer treatment, which target specific molecules such as a protein on the surface or inside a cancer cell, and gene therapy, which introduces new genes into cancer cells to trigger cell death or slow the growth of cancer cells. The goal of these treatments is to target tumor cells in a controlled manner while minimizing side effects (Arruebo et al., 2011). Cancer treatments, prognosis, and survival rates vary depending on the type of cell from which the cancer originates. For example, breast cancer develops from breast tissue and forms solid tumours while blood cancers such as lymphoma are non-solid tumours that develop from lymphocytes, a part of the immune system (Canadian Cancer Society, n.d.). For many cancers, the extent of cancer spread or progression is represented by clinical staging. Stage 0 denoting precancerous cells, stage I representing a localized tumour with no spread, stage II-III representing greater progression with possible spread to nearby organs and stage IV indicating distant spread in the body, otherwise known as metastatic cancer (Amin et al., 2017).

The incidence of cancer remains high, with approximately two in five Canadians being

diagnosed in their lifetime. Cancer is the leading cause of mortality in Canada with one in four individuals diagnosed expected to die of cancer. In 2024, an estimated 247,100 Canadians were diagnosed with cancer, with lung cancer being the most common followed by breast, prostate, and colorectal, together accounting for 47% of all new cancer cases (Brenner et al., 2024). Fortunately, the rise in curative therapies has resulted in a continued decrease in cancer mortality in Canada, however due to a growing and aging population a continued increase in estimated new cases of cancer is expected (Brenner et al., 2024). With increasing rates of new cancer diagnoses and decreased mortality, cancer has become a chronic condition with long-term implications on patients' functioning and quality of life. It is estimated that approximately 1.5 million Canadians are living with or beyond cancer 25 years after diagnosis (Canadian Cancer Statistics Advisory Committee, 2022). Many individuals living with or beyond cancer experience adverse symptoms post-treatment including depression or mood disturbance, insomnia, pain, sexual health concerns, cognitive impairment, fear of cancer recurrence, and fatigue (Schmidt et al., 2022).

In 2006, a seminal publication entitled *From Cancer Patient to Cancer Survivor: Lost in Transition* was released by the National Academy of Medicine (previously known as the Institute of Medicine) warning that greater co-ordination between active treatment and post treatment survivorship was needed or individuals were at risk of being “lost in translation” by lacking the knowledge and resources to mitigate the risk of a cancer recurrence (Institute of Medicine, National Research Council, 2006). Nearly two decades later, challenges remain in meeting the needs of individuals living with or beyond cancer. A 2022 study by Ross and colleagues evaluating the perspectives of comprehensive cancer control programs, survivors, and healthcare providers found a continued unmet informational need on healthy lifestyle, possible late and long-term side effects of cancer, and psychosocial concerns after cancer (Ross et al., 2022). The National Cancer

Institute recently developed the National Standards for Cancer Survivorship Care which continue to emphasize a need to prioritize the physical, psychological, and social unmet needs of individuals living with or beyond cancer (Mollica et al., 2024). One of the most prevalent and debilitating unmet needs reported among individuals living with or beyond cancer is cancer-related fatigue (CrF) (Kang et al., 2023; Roseleur et al., 2023).

Cancer-related Fatigue

Definition and Diagnostic Criteria.

Cancer-related fatigue (CrF) has been defined by the US National Comprehensive Cancer Network (NCCN) as a “distressing, persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Berger, Mooney, et al., 2015). CrF has been defined as multidimensional with four dimensions proposed, physical, cognitive, mental/emotional, and motivational (Keane et al., 2024). Diagnostic criteria for CrF was first proposed in 1998 (Cella et al., 1998). This criteria was published in The International Statistical Classification of Diseases and Related Human Problems 10th Revision (ICD-10) (Mitchell, 2010). Diagnostic criteria for CrF was categorized as six or more out of 11 symptoms present every day or nearly every day for a two week period, with A1 being compulsory: A1) significant fatigue, diminished energy, or increased need to rest, disproportionate to any recent change in activity level, A2) general weakness or limb heaviness, A3) diminished concentration or attention, A4) decreased motivation or interest to engage in usual activities, A5) insomnia or hypersomnia, A6) experience sleep as nonrestorative, A7) perceived struggle to overcome inactivity, A8) marked emotional reactivity to feeling fatigued, A9) difficulty completing daily tasks, A10) perceived problems with short-term memory, A11) post-exertional malaise lasting several hours, B) symptoms cause clinically significant distress or impairment in

social, occupational, or other important areas of functioning, C) there is evidence from history, physical examination, or laboratory findings that the symptoms are a consequence of cancer or cancer therapy, and D) symptoms are not primarily a consequence of comorbid psychiatric disorders such as major depression, somatization disorder, somatoform disorders, or delirium (Mitchell, 2010). A recent systematic review found that the most commonly used tool across CrF studies was the Multidimensional Fatigue Inventory (MFI-20) (Keane et al., 2024). However, as many as 58 unique measurement tools have been developed for the assessment of CrF with no consensus on the most appropriate tool or definition for CrF (Pearson et al., 2018). Measurement inconsistency and the lack of an agreed upon definition for CrF has resulted in a heterogeneity of methods and results across CrF studies, and has likely contributed to challenges in the translation of research into clinical practice (Keane et al., 2024). Consistent across several guidelines is the recommendation to use a valid intensity scale from 0-10 to measure the severity of CrF over the past 7 days, with 0 representing no fatigue and 10 representing the worse fatigue imaginable (Howell et al., 2013). The Pan Canadian Guidelines have classified scores of 1-3 as mild fatigue, scores of 4-6 as moderate fatigue, and scores of 7-10 as severe fatigue (Howell et al., 2015). Mild fatigue represents minimal fatigue symptoms and limited impact on daily functioning. Individuals experiencing moderate fatigue have more symptoms that impact daily function and cause distress, while individuals reporting severe fatigue experience more significant fatigue, impairments in daily function, need excessive rest and may experience physiological symptoms such as shortness of breath, rapid heart rate, and blood loss (Howell et al., 2015). Although these cut-off points were originally developed based on expert consensus, they have been validated through empirical studies (Wang et al., 2014).

Prevalence

CrF is consistently reported as an unmet need and continues to be a top concern for individuals living with and beyond cancer (Roseleur et al., 2023). CrF has been reported to affect between 62%-85% of patients on active cancer treatment (Thong et al., 2020; Wang et al., 2014). Fatigue has been found to have the most prominent negative impact on quality of life (QoL) compared to other commonly reported post treatment side effects such as pain and nausea/vomiting (Berger, Mooney, et al., 2015). Recent systematic reviews have reported the prevalence of moderate to severe CrF among individuals living beyond cancer is between 43% and 52%, with the rate increasing to as high as 70% when including individuals experiencing mild fatigue (Al Maqbali et al., 2021; Kang et al., 2023; Ma et al., 2020). This indicates that 4-7 out of 10 individuals living beyond cancer report being fatigued compared to 1 out of 10 in the general population (Kang et al., 2023). Kang and colleagues (2023) further examined prevalence of CrF based on severity among those who endorsed CrF and found that the prevalence of mild fatigue was 34.7%, moderate fatigue was 25.5%, and severe fatigue was 38.3% (Kang et al., 2023). Previous findings have found that approximately 30% of individuals living beyond cancer will experience moderate to severe fatigue upwards of five years post-treatment (Wang et al., 2014). CrF has been observed in nearly all cancer types and across different cancer treatments, however higher prevalence of fatigue have been reported among individuals who received chemotherapy, are on maintenance treatment (i.e., adjuvant endocrine therapy or androgen deprivation therapy), and for specific cancers such as brain tumours and lung (Kang et al., 2023; Thong et al., 2020; Wang et al., 2014). Individuals experiencing gynecological cancers reported the lowest prevalence of CrF at 3.9%. Further, women have been found to be more likely to experience CrF as well as individuals from Asian countries (Kang et al., 2023). In a longitudinal study, Reinertsen et al.

(2010) found that approximately a third of breast cancer survivors reported persistent fatigue upwards of 10 years after diagnosis. Persistent fatigue was found to be associated with psychological distress, high body mass index, and increased leukocyte count (Reinertsen et al., 2010). Among younger cancer patients (ages 19-39), one in four report feeling chronically fatigued 15 years post cancer diagnosis, with 65% reporting no change or worsening fatigue with time (Bøhn et al., 2019; Thong et al., 2020). In general, CrF was found to be more prevalent in younger cancer populations, with 85% of adolescent and young adult cancer survivors reporting experiencing fatigue in the last month, double that of age and sex-matched peers (Poort et al., 2017; Spathis et al., 2017).

Impacts of CrF on Quality of Life

Given the prevalence of CrF among individuals living with and beyond cancer, it is important to understand the impacts that CrF has on quality of life. For many individuals, CrF prevents a return to normalcy and has been found to significantly hinder the ability to return to work and education, disproportionately affecting young cancer survivors and leading to severe consequences including financial toxicity, difficulties with social reintegration, and higher rates of disability (Behringer et al., 2016; Jones et al., 2016, 2023). Behringer et al. (2016) found that among Hodgkin lymphoma survivors who reported CrF 57% had returned to work or education 5 years post diagnosis compared to 84% who did not endorse CrF. This study also found increased financial burden upwards of 9 years post diagnosis among those who reported CrF and more frequent medical consultations, suggesting more somatic distress in individuals reporting fatigue (Behringer et al., 2016). A more recent study by Jones and colleagues (2023) reported similar findings, revealing that individuals experiencing CrF were 2.72 times higher odds of being unemployed or on leave and demonstrated higher healthcare utilization with fatigue being one of

the most common presenting concerns (Jones et al., 2023). Individuals who do return to work despite fatigue experience reduced work ability and productivity, resulting in reduced working hours, poorer performance at work, and increased absenteeism (Jones et al., 2023; Tan et al., 2021). Further, breast cancer survivors who permanently did not return to work reported significantly worse quality of life compared with those who did return to work, however reduced quality of life may also be associated with higher symptom burden that prevents returning to work (Schmidt et al., 2019). To compound the financial burden, individuals experiencing CrF often experience difficulties and barriers to accessing benefits from insurers due to the ‘invisible’ and subjective nature of CrF despite extensive biomedical literature documenting its existence (Berger, Mooney, et al., 2015; Nekhlyudov et al., 2022). Younger women diagnosed with breast cancer and experiencing CrF reported worse quality of life compared to older women, with researchers proposing that younger women are likely more vulnerable to the effects of a diagnosis and treatment (Ruiz-Casado et al., 2021). Indeed, adolescent and young adults (ages 15-39) diagnosed with cancer face many unique challenges such as interruption of career development and peer/intimate relationships, fertility concerns, difficulties making independent decisions and complying with healthcare recommendations, have less developed coping strategies and support, and increased financial burden/responsibility which may increase distress during and post cancer diagnosis, contributing to lower quality of life (Patterson et al., 2015). Although CrF has profound implications on productivity and return to work, healthcare utilization, and quality of life, CrF continues to be a highly endorsed unmet need that survivors report having difficulties accessing care to manage, including barriers to asking for help or receiving help when communicating concerns to HCPs (Berger et al., 2015; Fitch et al., 2018; Jones et al., 2023; Ruiz-Casado et al., 2021).

CrF Etiology

Biological factors. The etiology of CrF is not well understood. Researchers have hypothesized numerous mechanisms that may contribute to fatigue, but with inconsistent findings across studies and cancer types this relationship remains unclear. From a biological perspective several theories have been proposed with increasing evidence that the activation of proinflammatory cytokines may play a vital role in fatigue during and after treatment. Several studies have found a positive association between increased markers of inflammation and fatigue, such as in the C-reactive protein (CRP) and *interleukin-1 receptor antagonist (IL-1Ra)* in patients undergoing radiation therapy and in the *interleukin 6 (IL-6)* in patients undergoing chemotherapy (Bower, 2014). One prominent theory is the *cytokine dysregulation hypothesis* which postulates that cancer or cancer treatment may disrupt signaling molecules that regulate immunity, inflammation, and hematopoiesis (blood cell production). Cytokines are responsible for communicating to the brain when an infection has occurred, triggering the release of inflammatory mediators, specifically interleukin (IL)-1 β , tumor necrosis factor (TNF)- α and IL-6, which induce feelings of “sickness” to conserve energy for healing. Sickness behaviour has been demonstrated in animal models and includes cluster symptoms of pain, insomnia, mood changes, lethargy, and cognitive impairment, which are often found co-occurring in individuals experiencing CrF (Bower, 2014; Kelley & Kent, 2020; O’Higgins et al., 2018; Wang & Woodruff, 2015). Higher levels of proinflammatory cytokine markers have been found in fatigued cancer patients compared to healthy controls or non-fatigued cancer patients. It is hypothesized that increased inflammation may be caused by tissue damage from chemotherapy, radiation, or a combination. Further, causal links between inflammation and fatigue have been demonstrated in animal models with high levels of pro-inflammatory cytokines resulting in observed behavioural changes such as fatigue and

reduced motivation (Dantzer et al., 2014). However, due to inconsistent findings among studies, the relationships between inflammation and fatigue remains unclear as to whether inflammation is the cause of CrF or simply exacerbates it (O'Higgins et al., 2018).

Another theory is the *hypothalamic-pituitary-adrenal (HPA) axis disruption hypothesis* which proposes that cancer or cancer treatment may disrupt the HPA axis, which regulates the body's response to stress, through changes to endocrine signals and disruptions to the negative feedback loop. Chronic exposure to proinflammatory cytokines has been found to decrease cortisol levels, impacting the circadian rhythm and causing sleep disruptions. As cortisol plays a vital role in wakefulness, energy, and sleep this disruption may contribute to feelings of tiredness and fatigue. Further, as cortisol plays a role in the regulation of immune system function and inhibits cytokine production, reduced cortisol may contribute to an overproduction of proinflammatory cytokines through a negative feedback loop, perpetuating the cycle and resulting in persistent feelings of fatigue. Further longitudinal research is needed to examine the changes in cortisol levels before, during, and after treatment in cancer populations (O'Higgins et al., 2018).

Other theories have proposed that CrF may be the result of muscle metabolism dysregulation. One such theory, the *Adenosine triphosphate dysregulation hypothesis*, stipulates that cancer or its treatment may damage the sarcoplasmic reticulum, which plays an important role in muscle contraction and relaxation, through increased calcium levels resulting in compromised muscle function and reduced physical ability. However, limited evidence for this theory is currently available (Agteresch et al., 2000; O'Higgins et al., 2018).

Biological mechanisms are likely only one contributing component to the development of CrF. CrF is believed to be multifactorial, a complex interaction of genetic risk factors, psychosocial factors, and biobehavioral factors that react with the inflammatory processes. Psychological and

biobehavioral risk factors include pre-treatment fatigue, depression, sleep disturbances, physical inactivity, difficulty coping with cancer, loneliness, and early life stress (Bower, 2014). Many of these risk factors are associated with elevated inflammatory responses, therefore cancer survivors who develop CrF may have elevated inflammatory activity prior to cancer treatment (Bower, 2014; Wang & Woodruff, 2015). These findings suggest that certain individuals may be at greater risk of developing persistent CrF after cancer treatment which may greatly impact their quality of life (Bower, 2014). Other identified risk factors for persist fatigue include pre-existing conditions of diabetes, psychotic disorders, migraines, pain, peripheral artery disease, and arthritis, as well as menopause symptoms, area-related discomfort, lymphedema, and dyspnea (Ruiz-Casado et al., 2021). Another interesting emerging risk factor is exposure to the SARS-CoV-2 virus, as individuals with a history of a COVID-19 infection were found to report higher rates of CrF and greater impacts on physical function compared with cancer survivors who did not contract the COVID-19 virus. This suggests that COVID-19 may exacerbate CrF or that post-COVID syndrome, for which fatigue is a primary symptom, may be occurring concurrently through different mechanisms or may be a differential diagnosis (Urbano Chamorro & de la Torre-Montero, 2024).

Behavioural Factors.

Several behavioural factors have been found to be associated with higher rates of CrF including physical inactivity, higher body mass index, and avoidance behaviours. Individuals living beyond cancer are less likely to meet the recommended physical activity guidelines compared to the general public (Mowls et al., 2016; Ottenbacher et al., 2015). Indeed, studies have found that cancer patients often reduce their physical activity after a cancer diagnosis, despite the recognized benefits of physical activity (Fassier et al., 2016; Littman et al., 2010). Indeed, a study

by Rommero et al. (2018) found that 79% of individuals living beyond cancer reported to have decreased their physical activity since their cancer diagnosis, identifying fatigue and pain as a barrier (Romero et al., 2018). Physical inactivity has been associated with higher CrF (Ruiz-Casado et al., 2021). While physical activity has been found to primarily improve physical fatigue symptoms, it has been found to have less impacts on affective or cognitive dimensions of fatigue in breast cancer patients undergoing chemotherapy (Schmidt et al., 2017; van Vulpen et al., 2016). Greater improvements in CrF have been found when physical activity interventions are offered post-treatment (Serdà i Ferrer et al., 2018). Engagement in any self-reported exercise has been found to be associated with lower fatigue (Schmidt et al., 2017). Potential pathways for these improvements may be related to a decrease in chronic inflammation, psychological benefits (i.e., increased self-efficacy, decreased catastrophizing, reduced mood and pain symptoms, improved sleep), and physical conditioning through improved cardiopulmonary fitness and muscle strength reducing effort required for everyday tasks (LaVoy et al., 2016). In the general population and in cancer survivors, increased physical activity has been observed to be associated with lower levels of pro-inflammatory markers such as CRP, leptin, IL-6, and TNF- α (Serdà i Ferrer et al., 2018). In breast cancer populations, studies have shown reductions in pro-inflammatory markers of IL-6, TNF- α , and IL-2 but not CRP after engaging in aerobic and/or resistance exercise (Meneses-Echávez et al., 2016). For individuals living beyond prostate cancer and undergoing androgen deprivation therapy (ADT), aerobic exercise combined with resistance training was associated with a reduction in CRP (Galvao et al., 2017). Alternative pathways proposed have been related to the HPA axis dysregulation theory. Exercise has been observed to normalize HPA axis function in early-stage breast cancer populations, indicated by increased morning salivary cortisol as opposed to higher evening cortisol observed in fatigued patients (Saxton et al., 2014). Higher body

mass index (BMI) prior to commencing cancer treatment has been associated with increased physical and cognitive fatigue post treatment (Schmidt et al., 2017). However, other studies have not found an association between CrF and BMI in women with breast cancer (Bower et al., 2018). Potential proposed pathways for the association between BMI and CrF have been that adipose tissue has been associated with higher pro-inflammatory markers and may contribute to chronic inflammation (Schmidt et al., 2017). Avoidance behaviour (i.e., avoiding activity and engaging in excessive rest) and all-or-nothing behaviour (i.e., overdoing activity and then taking prolonged rest to recover) have also been found to be associated with functional impairment and fatigue. Both behaviours may contribute to muscle deconditioning due to prolonged rest periods, resulting in muscle weakness and increased effort required to complete activities of daily living (Dirou et al., 2018; Hughes et al., 2020).

Psychological and social factors.

CrF is a complex interaction of biological, biobehavioural, and psychosocial factors. Several psychosocial risk factors have been identified that increase the probability of developing persistent CrF including early life adversity, pre-treatment fatigue and depression, coping and appraisal (i.e., catastrophizing), anxiety, loneliness, and sleep disturbances (Bower, 2014; Ruiz-Casado et al., 2021). Early life adversity (i.e., physical, sexual and emotional abuse, neglect and separation from caregivers) and being reared in poverty have been found to be predictors for the development of CrF (Bower, 2014). Women diagnosed with breast cancer who have experienced abuse or neglect as children report higher levels of CrF (Bower et al., 2018). It is believed that chronic childhood stressors can cause immune system dysregulation, increasing inflammation in the body. Indeed, the relationship between chronic childhood stressors and inflammation is well-documented, with increases in IL-6, CRP, and TNF- α proinflammatory cytokines being observed

in adults who experienced early life adversity, the same inflammatory responses identified in CrF (Baumeister et al., 2015; Bower, 2014; Kuhlman et al., 2022). Interestingly, the type of adversity has been found to be associated with different elevations in proinflammatory cytokines, with IL-6 and TNF- α being associated with physical and sexual abuse, and CRP being primarily associated with parental absence and neglect (Baumeister et al., 2015). Individuals who experienced poverty in childhood have also been noted to have elevated CRP and IL-6 in adulthood, suggesting that exposure to early chronic stressors affects long-term inflammatory transcriptome (Castagné et al., 2016). Indeed, Bower et al. (2021) examined changes in gene expression among women diagnosed with early-stage breast cancer who experienced childhood maltreatment prior to commencing cancer treatment and found increases in the classical nuclear factor-kappa B (NF- κ B) related proinflammatory signaling pathway. This pathway plays a critical role in the activation of immune responses, suggesting a broader range of immunoregulatory processes (i.e., alterations to B cell and T cell activation) being affected by early adverse experiences, which may not only predispose individuals to developing depression and fatigue but may also result in poorer health outcomes, such as greater risk of cancer recurrence/progression and mortality (Bower et al., 2020). Early life adversity may predispose individuals to increased inflammation in the body which may then be exacerbated by inflammatory changes during and after cancer treatment, resulting in persistent fatigue that may last for years after treatment completion (Bower et al., 2018). Across studies, pre-treatment fatigue has been identified as a consistent and strong predictor of CrF, suggesting that mechanisms that contribute to CrF may be pre-existing prior to cancer treatment (Bower, 2014).

Coping strategies may also play an important part in the maintenance of persistent fatigue. For example, tendencies to catastrophize, passive management strategies, and difficulties with illness adjustment have been found to be associated with CrF and may be related to the

mental/emotional dimension of CrF (Keane et al., 2024; Ruiz-Casado et al., 2021). A Canadian study by Fitch et al. (2018) found that 68% of survivors reported suffering from anxiety and fear of cancer recurrence, with many individuals not seeking help to manage these symptoms due to being told by healthcare providers these were normative emotional changes post cancer (Fitch et al., 2018). Other studies have found an association between fear of recurrence and severe fatigue, with authors hypothesizing that lingering symptoms of fatigue may exacerbate worry through catastrophizing, (as fatigue can be an early symptom of cancer/recurrence) or may serve as a constant remind of their disease, excessive worry can then worsen fatigue, perpetuating the cycle (Hall et al., 2014; Phillips et al., 2013; Trudel et al., 2024). Indeed, elevated anxiety prior to treatment has been found to predict fatigue severity (Hughes et al., 2020). Additionally, a pessimistic outlook on the future may impact survivors perceptions of their symptoms, leading to increased catastrophizing and withdrawal from social and recreational activities (Hughes et al., 2020). Intrusive thoughts and anxiety may also be connected to increased inflammation through stress pathways (i.e., HPA axis dysfunction), leading to elevated depressive symptoms, fatigue, and other sickness behaviours (Dupont et al., 2013; Hall et al., 2014). Dupont et al. (2013) found that women with breast cancer experiencing high levels of intrusive thoughts around cancer reported significantly worse fatigue, more sleep disturbances, pain, depression, and had overall poorer psychological adjustment one year post treatment (Dupont et al., 2013). Another psychosocial risk factor identified was social constraints (feeling unable to disclose cancer-related thoughts due to other's behaviours of criticism or avoidance). Social constraints was found to result in more avoidant coping and lower self-efficacy and associated with higher levels of CrF, sleep disturbances, and cognitive impairments such as inattention (Adams et al., 2017). Similarly, perceived punishing responses from others was associated with poorer functioning and fatigue

among breast cancer patients (Hughes et al., 2020). Loneliness has been associated with similar outcomes, with lonely cancer survivors experiencing higher rates of fatigue, depression, and pain compared to those reporting feeling socially-connected (Jaremka et al., 2013, 2014).

CrF Differential Diagnosis

Depression.

This section will describe the complicated relationship between depression and CrF and provide support for the inclusion of depression as an outcome in Study 2. Major depressive disorder is characterized by feelings of low mood, decreased pleasure in previously enjoyed activities, lack of energy/fatigue, poor concentration and motivation, and changes to sleep, psychomotor activity, appetite, and libido (American Psychiatric Association, 2013). Depression has been found to be associated with moderate-to-severe fatigue and a history of depression prior to treatment has been found to increase the risk of developing CrF two fold (Wang et al., 2014; Wang & Woodruff, 2015). Depression may be related to the motivational dimension of CrF (Keane et al., 2024; LaVoy et al., 2016). Further, individuals with a history of depression report significantly higher levels of emotional and mental fatigue, as opposed to physical fatigue (Bower et al., 2018). The significant overlap between CrF and depression can make distinguishing between these two constructs difficult and has resulted in theorizing that perhaps a common etiology exists which explains both depression and CrF such as a dysregulation of serotonin (5-HT) mechanisms (O'Higgins et al., 2018). However, this theory has been difficult to prove and clinical trials that have attempted to treat CrF with selective serotonin reuptake inhibitors and selective serotonin agonist have demonstrated no evidence of CrF improvement despite likely increases in 5-HT levels (Alexander et al., 2010; Morrow et al., 2003). One of these studies tested the antidepressant paroxetine and found significant reductions in depressive symptoms, but not CrF (Morrow et al.,

2003). Given these outcomes, serotonin is not believed to be a primary cause of CrF, further supporting that CrF is a separate construct from depression despite overlapping symptoms (O'Higgins et al., 2018).

Another suggested common etiology has been proinflammatory cytokines, which have been shown to play a role in the development of depression and CrF (LaVoy et al., 2016). Interestingly, studies have found that different proinflammatory cytokines may be responsible for CrF and depression. A study by Pertl and colleagues (2013) found that more severe fatigue was associated with higher concentrations of a CRP and IL-6 and that elevated levels of CRP prior to cancer treatment predicted fatigue severity but not depression, while pre and post treatment levels of kynurenine (a key regulator of the inflammatory response and energy metabolism) predicted changes in depressive symptoms (Pertl et al., 2013). Associations between CRP, IL-6, and long-term CrF continue to be documented, however a recent study found that this association disappeared when adjusting for relevant covariates such education, body mass index, physical activity, and depression, demonstrating the complex multifactorial nature of CrF (Maurer et al., 2021). Bower et al. (2011) examined whether a common underlying mechanism exists for sleep, fatigue, and depression. Conversely, this study did not find an association between CRP and fatigue, but rather between fatigue and the soluble tumor necrosis factor (TNF) receptor type II (sTNF-RII), a proinflammatory cytokine responsible for cell survival and death, and concluded that fatigue, sleep, and depression likely stem from distinct biological processes (J. E. Bower et al., 2011). More recently, Pedraz-Petrozzi et al. (2020) reported similar findings that despite great overlap, the relationship between inflammatory cytokines and fatigue symptoms are not influenced by depression and remain separate constructs (Pedraz-Petrozzi et al., 2020). IL-6 has been most consistently found to be associated with CrF and other chronic fatigue syndromes (Grossberg et

al., 2020). For example, IL-6 has been found to be associated with vegetative symptoms of depression which are characterized by reduced motivation and somatic complaints in ovarian cancer patients but not affect (i.e., sadness), and reduction in IL-6 levels post treatment were associated with reduced fatigue, vegetative depression, and disability (Lutgendorf et al., 2008; Schrepf et al., 2013). Based on these findings, inflammation may be a precipitating factor for CrF, with the interrelationship between psychological (i.e., depression) and physical factors likely perpetuating CrF by maintaining one another through a negative feedback loop, for example, CrF may disrupt social, occupational, and leisure activities which may cause/exacerbate depressive symptoms, which can in turn further worsen exhaustion and fatigue (Bower, 2014). Given documented overlap between depression and the motivational dimension of CrF and co-occurrence of depression and fatigue among cancer populations, it can be important to consider depressive symptoms as a moderator variable in CrF research studies and to examine whether therapeutic interventions improve both CrF and depressive symptoms (Lobefaro et al., 2022).

Cancer-related Cognitive Impairments.

Cancer related cognitive impairment (CRCI), often referred to as ‘chemo brain’ by patients, is another common post treatment side-effect that may overlap with the cognitive dimension of CrF and depression. CRCIs are commonly reported cognitive symptoms such as problems with memory, attention/concentration, processing speed, word finding, and executive functions (i.e., time management, decision making) (Mayo et al., 2021; Schmidt et al., 2016). These symptoms have been reported by survivors of various cancers, both solid tumors and hematological malignancies, and treatment protocols (i.e., chemotherapy, radiotherapy, and hormone therapy) (Buchbinder et al., 2018; Schmidt et al., 2016; Treanor et al., 2017). Indeed, CRCI is highly prevalent among cancer survivors affecting upwards of 65% of patients during treatment, with one

third then continuing to experience longer term cognitive impairment. In a study of 3108 survivors with various cancers, nearly half reported experiencing perceived cognitive difficulties, with higher rates being observed in younger, female, employed, separated, and lower income individuals (Schmidt et al., 2016). Similarly to CrF, pre-treatment cognitive dysfunctions have been observed, and are thought to be associated with inflammatory responses, possible hormonal changes, diminished cognitive reserve, and depression, demonstrating the complex interconnection of these symptoms (Schmidt et al., 2016). Chemotherapy is known to cause a systemic immune response, impairments in hippocampal and frontal lobe regions, reductions in grey matter density, and suppression of neurogenesis (Bai & Yu, 2021). This immune response produces increased secretions in proinflammatory cytokines that can pass through the blood-brain barrier and trigger an inflammatory response in the brain (i.e., oxidative stress, neuroinflammation) and suppress brain-derived neurotrophic factor (BDNF) expression. Indeed, CRCI has been proposed to be linked to dysregulation in BDNF, which is responsible for neurogenesis (i.e., the process that new neurons are created in the brain) and neuro plasticity, through upstream regulators such as proinflammatory cytokines (Yap et al., 2021). Studies have found associations between elevated levels of cytokines, a decline in BDNF during chemotherapy, and an elevated risk of experiencing persistent CRCI (Yap et al., 2021). Further, other studies have demonstrated that elevated levels of IL-1 β and IL-6 were associated with poorer cognitive function and increases in sTNF-RI and II with a decline in short-term visual memory in breast cancer patients (Cheung et al., 2015; Williams et al., 2018). There is a distinction between objective cognition (i.e., measured through neuropsychological testing) and cognitive complaints (i.e., patient reported). Interestingly, cognitive complaints are much more frequently endorsed, with 50% of breast cancer patients reporting cognitive complaints but only 15-25% demonstrating objective cognitive concerns

(Lange et al., 2019). Indeed, studies have demonstrated associations between reported cognitive complaints and CrF, depression, anxiety, and sleep concerns (Joly et al., 2019). Additionally, several overlapping risk factors between CrF and CRCI exist including age, trauma, depression, maladaptive coping, and socioeconomic status (Ahles & Root, 2018; Joly et al., 2019; Lange et al., 2019). It is possible that similar underlying mechanisms related to inflammation may contribute to both CrF and CRCI (Joly et al., 2019). Indeed, many interventions that reduce symptom burden of CrF have also been found to improve CRCI and other concurrent symptoms like depression and anxiety, particularly physical activity interventions which are believed to reduce proinflammatory activity and cognitive behavioural therapy (Joly et al., 2019; Lange et al., 2019; Mayo et al., 2021).

Interventions for CrF

Physical Activity.

The effects of physical activity are well document for the management of CrF (Bower et al., 2024). Individuals living with and beyond cancer who engage in physical activity experience benefits including increased aerobic capacity, muscular strength, and reduced symptoms of fatigue (Belloni et al., 2021; Dong et al., 2023; Zhang et al., 2023). Additionally, physical activity has also been associated with longer progression-free survival, reduced risk of recurrence, and decreased disease-related mortality. Indeed, a meta-analysis found that engaging in 150 minutes of moderate to vigorous intensity exercise was associated with around a 24% reduction in the risk of overall mortality among breast and colorectal populations (Schmid & Leitzmann, 2014). Among breast cancer patients undergoing primary treatment, exercise was found to have modest effects on CrF (Ehlers et al., 2020). For patients who have completed treatment, a meta-analysis by Belloni and colleagues found significant differences in CrF severity between the exercise intervention and

control groups (SMD = -0.33 ; 95% CI = $-0.43, -0.23$, $I^2 = 64\%$), with breast cancer patients demonstrating greater reductions in CrF compared to prostate cancer patients. Authors reported that exercise programs such as aerobic and resistance training across heterogeneous cancer types and treatments had a small positive impact on CrF symptoms (Belloni et al., 2021). Across studies exercise programs were found to range from 10-120 minutes, 1-6 times a week, run for between 2-52 weeks and combine moderate to high intensity exercise. However, given the variety of cancers and treatments, it was recommended by authors that exercise programs be tailored to individual patient needs, considering patients' preferences, physical and psychological needs, treatment side-effects, and work and home responsibilities (Belloni et al., 2021). In a network meta-analysis, post treatment combined aerobic and resistance exercise was found to have a significant impact on CrF and be the most effective intervention, while during active treatment combined aerobic and resistance exercise, yoga, and regular physical activity (i.e., patient's original daily activities or exercise level) were all found to improve CrF (Dong et al., 2023). Additionally, in a systematic review of systematic reviews exercise was also found to reduce CrF, however authors reported there continues to be a limited consensus on the mode, frequency, intensity, and amount of time required (Zhang et al., 2023). Indeed, individuals living beyond cancer have reported challenges with identifying an initial exercise dose, with many reporting fear due to a lack of knowledge regarding safe and appropriate intensity of exercise and engaging in trial and error to identify what works for their body, occasionally resulting in exacerbated CrF or a barrier to commencing exercise (Wechsler et al., 2023). Other studies have found that light to moderate activity achieved greater reductions in fatigue, while vigorous intensity appeared to exacerbate CrF (Serdà i Ferrer et al., 2018). Walking has found to be the preferred method of physical activity among cancer populations (Avancini et al., 2020). This may be due to the relative

ease, flexibility, and accessibility of walking, reducing barriers such as socioeconomic status (Avancini et al., 2020).

Despite the known benefits of physical activity, many individuals living with and beyond cancer are not meeting recommended guidelines for physical activity, with estimates of between 25-84% of patients being insufficiently active (Avancini et al., 2020). Current physical activity guidelines by the American College of Sports Medicine (ACSM) for cancer patients recommend a combination of 150 minutes of moderate-intense aerobic activity and strength training 2-3 times a week (Campbell et al., 2019). Many factors may contribute to difficulties maintaining a physically active lifestyle, with fatigue being a commonly cited barrier among lung cancer patients (Granger et al., 2017), advanced cancer patients (Frikket et al., 2020), and heterogeneous cancers (Ng et al., 2021). Although significant benefits exist for in-person exercise interventions and long-term cost-effectiveness of physical activity programs (Gubler-Gut et al., 2021), these interventions face many barriers to implementation in community contexts including capacity to offer physical activity programs (i.e., specialized staff, equipment, and space), possible patient costs to attend programming, lack of healthcare provider commitment to physical activity programs, and resources needed to tailor exercise support for each cancer survivor's unique needs (Belloni et al., 2021; IJsbrandt et al., 2019). Unfortunately, the global COVID-19 pandemic at the time of this study also prevented in-person programming and contributed to financial strain on the local community cancer support provider. In the current climate, offering education on physical activity guidelines, strategies to improve engagement in physical activity, and redirecting patients to existing physical activity programs may be a starting point for the management of CrF, particularly as education around CrF and the management of CrF is a recommendation in evidence-based guidelines (Howell et al., 2013). Further, this would address a gap as cancer survivors have

reported unmet informational needs on healthy lifestyle, including physical activity (Ross et al., 2022).

Psychosocial Interventions.

Apart from physical activity, several psychosocial interventions have been investigated and have shown good outcomes in the management of CrF, including cognitive behavioral therapy (CBT), Mindfulness-Based Stress Reduction (MBSR), psychoeducation, and peer support, among others (Cedenilla Ramón et al., 2023; Thong et al., 2020). Psychological interventions have been extensively investigated due to the association between severity of fatigue and psychological distress and demonstrate the same strength of evidence as exercise interventions for the management of CrF (Bower et al., 2024). Studies have demonstrated similar outcomes between physical activity and psychological interventions. In a meta-analysis by Mustian et al. of 11525 participants, similar improvements in CrF reduction were found between exercise (WES, 0.30; 95% CI, 0.25-0.36; $P < .001$) and psychological interventions (WES, 0.27; 95% CI, 0.21-0.33; $P < .001$) (Mustian et al., 2017). The average intervention length was 43 sessions over 14 weeks that lasted 60 minutes. Greater reduction in CrF were noted for early-stage disease and when offered post treatment in group-based and in-person formats. Physical activity was found to be more effective when offered during primary treatment, while a combination of exercise and psychological intervention was found most beneficial after treatment completion (Mustian et al., 2017).

MBSR similarly has shown significant outcomes in improving CrF (Xie et al., 2020). A meta-analysis of 3008 patients by Xie et al. from 2020 found that MBSR had moderate to large effects in improving CrF (SMD -0.89), depending on the cancer type with lung cancer patients experiencing greater benefits than breast cancer patients. Most studies on average offered MBSR

for 6-weeks, however greater improvements were noted for 8-week programs, offered once a week for two hours and guided by an expert. In subgroup analysis, MBSR was found to improve all dimensions of fatigue but have a small effect on the cognitive dimension of CrF (Xie et al., 2020). Further, a meta-analysis by McCloy and colleagues that looked specifically at impact of mindfulness on CrF in women with cancer, found mindfulness had a large effect (SMD -0.81) on CrF, as well as anxiety and depression, but did not significantly improve sleep or QoL (McCloy et al., 2022). The benefits of MBSR on CrF have been documented in other systematic reviews and meta-analyses (Cedenilla Ramón et al., 2023; He et al., 2020; Johns et al., 2021; Zhang et al., 2016). Indeed, in a recent Bayesian network analysis comparing several psychosocial interventions for CrF, MBSR was found to have the highest probability in alleviating CrF compared to other psychosocial interventions (Yuan et al., 2022). However, MSBR, CBT, and psychoeducational interventions were all found to be statistically significant in relieving CrF compared to a control group (Yuan et al., 2022).

Psychoeducational interventions have also shown small to moderate effect sizes on CrF. Psychoeducation may be particularly important in addressing misconceptions and distress around CrF, such as beliefs around treatment futility (Thong et al., 2020). Indeed, a meta-analysis found that psychoeducation had a moderate effect size in reducing fatigue distress (SMD -0.57 , 95% CI -1.09 to -0.05) compared to usual care. Further, small effect sizes were found for reduction in fatigue interference with daily life, general fatigue, and fatigue intensity (Bennett et al., 2016). A more recent systematic review and meta-analysis of psychoeducational interventions with cognitive behavioural components found moderate effects sizes in improving symptoms of CrF ($P = .042$; Hedges' $g = 0.38$; 95% confidence interval, 0.013 - 0.755 ; 1369 patients) (Karakuş et al., 2022). No differences were found between interventions offered individually, in group settings,

in-person, or virtually. Interventions included education on symptoms and treatment for CrF and cognitive behavioural therapy components (i.e., basic CBT principles, self-monitoring behaviour, emotions, and thoughts, relaxation exercises, problem solving, goal setting, improving coping strategies, exploration of barriers, and cognitive restructuring) and were administered by allied health providers such as nurses or psychologists, with sessions ranging from 10-270 minutes over 2-8 sessions (Karakuş et al., 2022). Psychoeducational interventions appear to be effective in the management of CrF by providing individuals living with and beyond cancer the tools and strategies to self-manage CrF (Karakuş et al., 2022). Canadian and other international guidelines for the management of CrF suggest that all patients should receive counselling and education on self-management of CrF, specifically around increasing activity levels, the multifactorial nature of fatigue, pacing, and coping with fatigue (Berger et al., 2015; Howell et al., 2015). However, knowledge gaps continue to exist, with as many as 56.4% of patients reporting feeling poorly informed about fatigue and treatment options, with some also reporting problematic beliefs such as fearing fatigue is an indicator of cancer progression (Schmidt et al., 2022). Education sessions and web-based self-management CrF interventions have been proposed as a cost-effective method to close these gaps and reduce fatigue distress (Jones et al., 2021; Schmidt, Milzer, et al., 2022).

eHealth Interventions.

As virtual interventions have resulted in comparable outcomes for psychoeducational interventions for CrF, they may offer more accessible services for individuals struggling with CrF, particularly as fatigue has been reported as a barrier to attending in-person programming and may eliminate barriers related to travel and parking costs (Spahrkäs et al., 2020; Stubblefield, 2017). Over the last few years there has been more growth and acceptance of eHealth interventions, for the self-management of chronic symptoms in patient populations (Beenhakker et al., 2022).

eHealth has been defined by the National Cancer Institute as the “use of digital technology, such as computers, mobile devices, and the Internet, to deliver and manage health care information and services” (National Cancer Institute, n.d.). These interventions may help address significant systemic barriers, reduce costs, and improve the reach of interventions (Spahrkäs et al., 2020). There have been several eHealth interventions developed for the management of CrF. Indeed, Beenhakker and colleagues conducted a scoping review of existing eHealth interventions for CrF and found 35 interventions, which varied in duration (i.e., 4 weeks to 6 months) and intensity (i.e., daily to self-paced) and included physical activity, mind-body, and psychological interventions. Most interventions were developed and evaluated in the United States. Psychological interventions were found to be primarily web-based, while physical activity interventions used an app primarily. Peer support was only present in 6 of the 35 interventions. Approximately 70% of the interventions reported significant reductions in CrF. Among psychological interventions specifically, 9/13 reported significant improvements in CrF. Psychological interventions consisted of CBT, psychoeducation, coping skills training, self-management and supportive-expressive therapy (Beenhakker et al., 2022). Further, a meta-analysis by Wang and colleagues on internet-based psychoeducational interventions among cancer patients found that eHealth interventions did have significant effects on fatigue and depression. An analysis of 427 and 462 participants, respectively, showed a significant difference between eHealth interventions and control groups for fatigue (MD -9.83 , 95% CI $(-14.63, -5.03)$, $p < 0.01$) and depression (SMD -0.58 , 95% CI $(-1.12, -0.03)$, $p = 0.04$) (Y. Wang et al., 2020). There exists less evidence for mobile health applications (mHealth) interventions effectiveness, with majority of studies focusing on usability, adoption, and acceptability of apps (Chib & Lin, 2018). For CrF, one such advancement in the management of CrF has been the Untire mobile app, a mobile application designed to help patients manage their

CrF (Tired of Cancer, 2020). The intervention was evaluated across four countries and demonstrated significant improvements in fatigue severity ($d=0.40$), fatigue interference ($d=0.35$), and overall QoL ($d=0.32$), compared to a control group (Spahrkäs et al., 2020). However, this app is no longer available in North America due to local health regulations. eHealth interventions appear to be effective in improving CrF symptoms and may offer patients more flexibility, reduce costs, and better align with patient preferences which can increase adherence and satisfaction of interventions (Beenhakker et al., 2022). Further, virtual interventions have been recommended by developers of evidence-based guidelines for CrF to help facilitate wide implementation of psychoeducational interventions for the management of CrF to address knowledge to practice gaps and provide access to education on CrF to all patients (Berger & Mooney, 2016).

Evidence-based Guidelines for CrF

Due to a growing awareness of CrF and significant amount of evidence for effective treatment options for CrF as described above, several national and international organizations have published evidence-based guidelines on the treatment and assessment of CrF, including the NCCN (Berger, Mooney, et al., 2015), the Canadian Association for Psychosocial Oncology (CAPO) (Howell et al., 2015), and more recently the European Society for Medical Oncology (ESMO) (Fabi et al., 2020) and the American Society of Clinical Oncology (ASCO)–Society for Integrative Oncology (SIO) (Bower et al., 2024). Practice guidelines are meant to inform health care providers of appropriate evidence-based treatments to ensure quality and efficiency of care and are increasingly important in treatment decisions within the financially constricted health care system (Kredo et al., 2016). Given the availability of Canadian guidelines, this summary will synthesize recommendations described by Howell and colleagues (Howell et al., 2015) and briefly compare

them to other international guidelines. These guidelines were developed for intended users in primary oncology interdisciplinary team members, such as allied health and psychology, and community practitioners like family physicians. Authors examined existing guidelines and systematic reviews published between 2009-2014 and assessed any pharmacological and non-pharmacological interventions for the assessment and management of CrF in adults. Recommendations include screening for the presence of CrF and educating all patients on fatigue, specifically how to cope and engage in more physical activity. Engaging in moderate intensity physical activity five times a week and resistance training three times a week has been recommended after cancer treatment. A referral for specialized rehabilitation is recommended for obese individuals, those who are physically inactive, or who require more tailored regimes due to treatment side-effects. No pharmacological interventions were recommended due to insufficient evidence. The following nonpharmacological interventions have been recommended: psychoeducation on the symptoms of CrF; (i.e., coping with emotions, healthy sleep, understanding fatigue, opportunity to share experiences); mind-body interventions (i.e., yoga, mindfulness); physical activity; and psychosocial interventions (i.e., cognitive behavioural therapy) (Howell et al., 2015).

The NCCN guidelines similarly recommend that all patients should be screened for CrF during and after completion of treatment and receive education and counseling on CrF. Many of the other recommended strategies described in the CAPO guidelines overlap with the NCCN, however the NCCN includes several more strategies for the management of CrF. In addition to the recommendations above, the NCCN recommends implementing energy conservation strategies, using distraction to cope, meaning-making, massage therapy, supportive expressive therapies, nutritional consults, CBT for sleep, and the possible use of pharmacological therapies such as

psychostimulants such as methylphenidate (Berger et al., 2015). Guidelines developed by ESMO continue to echo the same recommendations for healthcare providers to screen, educate, and provide guidance on how to manage CrF throughout the cancer experience. The ESMO guidelines concur with the CAPO guidelines that there continues to be insufficient evidence for the use of pharmacological interventions and do not recommend the use of corticosteroids, acetylcholinesterase inhibitors, eszopiclone, megestrol acetate, melatonin, or selective serotonin reuptake inhibitors in the management of CrF. However, consensus was not reached on psychostimulants or Wisconsin ginseng with panel members divided on the potential benefits. The ESMO guidelines recommend psychoeducation, CBT, MBSR, and yoga (Fabi et al., 2020). The most recent guidelines by the ASCO-SIO recommended the following as strongly supported by the literature for the management of CrF: physical activity, CBT, MBSR, tai chi or qigong, yoga and do not recommend the use of modafinil or armodafinil. Psychoeducation and ginseng demonstrated moderate evidence and continue to be recommended. Routine use of psychostimulants, such as methylphenidate, L-carnitine, and antidepressants was not recommended (Bower et al., 2024). Across all guidelines physical activity, CBT, psychoeducation, MBSR, and yoga were recommended for the management of CrF. Despite the existence of these guidelines for nearly a decade and many randomized controlled trials demonstrating effective interventions for the management of CrF for over two decades, limited progress has been made in implementing these recommendations into clinical practice, leaving individuals living beyond cancer limited options to manage their CrF (Agbejule et al., 2021; Pearson et al., 2017).

Implementation Gaps

Evidence-based guidelines require immense efforts and costs to develop and are intended to decrease variation in practice, improve quality of care, and improve effectiveness, however less

emphasis is placed on their translation and usability in clinical practice (Kredo et al., 2016). Studies have reported non-compliance rates to clinical practice guidelines can be as high as 70% among clinicians, meaning various clinical practice guidelines encounter parallel challenges and do not necessarily translate to improvements in patient care or outcomes (Barth et al., 2016; Bierbaum et al., 2020; Cnossen et al., 2021; Liu et al., 2021; Romiti et al., 2021; Ryan et al., 2020). Adherence may vary depending on the recommendation, with higher compliance found for recommendations within clinical practice guidelines that are strongly supported by evidence (i.e., level one evidence), and reduced compliance for consensus-based or low evidence recommendations (In et al., 2012). Some identified barriers to non-compliance include a lack of awareness, familiarity, agreement with content, and knowledge, confidence, or skills to carry out recommendations, as well as external barriers such as time, resources, educational materials, staff, and costs (Barth et al., 2016). Clinical guidelines for CrF have faced similar challenges. Despite the availability of evidence-based guidelines for CrF over the last several years, implementation of these guidelines into clinical practice continues to be lacking (Agbejule et al., 2021; Berger & Mooney, 2016; Jones et al., 2021; Pearson et al., 2017; Pearson et al., 2023).

To understand why clinical practice guidelines for CrF are experiencing difficulties with adherence, Pearson and colleagues interviewed healthcare providers. Healthcare providers reported that the current state of the CAPO guidelines for CrF lacked clinical utility, describing the recommendations as a ‘complex intervention’, which required multiple disciplines, numerous fatigue management interventions, and extensive assessments (Pearson et al., 2017). Indeed, complexity and rigidity of various clinical practice guidelines has been previously cited as a significant barrier to uptake and adherence (Barth et al., 2016; Bierbaum et al., 2020). Building on these findings, Pearson and colleagues examined the barriers and enablers to implementing the

CAPO fatigue guidelines in Australia and found that limited time was the most critical and consistent barrier. Another significant barrier identified was a lack of healthcare provider knowledge or resources to address CrF. Enablers consisted of incorporating fatigue screening into routine symptom screening, creating accessible training for clinicians, and creation of clinician friendly practice tools. For patients, barriers to self-advocacy included reduced motivation and energy and feeling their fatigue was not prioritized. Patient enablers consisted of tailoring interventions to patient's needs, using telehealth to increase accessibility, and involving caregivers (Pearson et al., 2023). Notably studies have found that 87% of healthcare providers reported they had limited knowledge of CrF despite a median of a decade working in oncology care, suggesting a significant gap in training and education opportunities around CrF (Pearson et al., 2023). Many healthcare providers require further training and education on CrF treatment and management in order to adequately meet the needs of individuals experiencing CrF (Pearson et al., 2017). Indeed, a recent Canadian study by Jones and colleagues examining underlying mechanisms impacting CrF guideline implementation found that healthcare providers' lack of knowledge and resources coupled with systemic barriers (i.e., time, inefficient pathways) and a breakdown in patient-provider communication contributed to the "perfect storm", resulting in inadequate management of CrF (Jones et al., 2021).

Looking at the broader picture of CrF intervention implementation, Agbejule and colleagues conducted a systematic scoping review of CrF intervention implementation studies and found only six studies, half of which were guided by an implementation model or framework. This clearly demonstrates a significant gap between effective CrF interventions, which have a substantial body of evidence and their availability in routine care (Agbejule et al., 2021). Given challenges with implementation in public settings such as hospitals and given that survivorship

care is often transitioned to primary care and community, CrF interventions may be more accessible and maintainable in community settings (Agbejule et al., 2021). Currently in Canada, a national CrF psychoeducation program is offered virtually through a community organization called Wellspring (Wellspring, n.d.). The program was created by Wellspring and has not presently been evaluated but does reference the CAPO guidelines in their description (Wellspring, n.d.). The program covers understanding fatigue, lifestyle approaches, nutrition, and exercise (Wellspring, n.d.). In Ontario, the first and only interdisciplinary clinic called Cancer Fatigue Services has launched recently in Toronto specializing in the treatment of CrF (Cancer Fatigue Services, 2024). In Alberta, the Alberta Exercise Program (ACE), a free 12-week exercise program, is offered to individuals who may be experiencing CrF (McNeely et al., 2019; Suderman et al., 2020). The ACE program has prioritized large scale implementation across the province of Alberta to serve more individuals throughout the province and rural communities (McNeely et al., 2022).

Implementation of physical activity guidelines by the ACSM for cancer patients have also experienced similar challenges (Campbell et al., 2019). Less than 50% of healthcare providers regularly promoted physical activity to patients, citing similar barriers such as lack of time, knowledge/training, inefficient exercise referral pathways, and limited availability of programs (Hardcastle et al., 2018). Indeed, a Canadian study by Nadler et al. found that 80% of clinicians were not aware of Canada's physical activity guidelines or when and how to refer patients to exercise programs (Nadler et al., 2017). Further, a study by Hardcastle et al. found that 60% of exercise prescribed did not match current guidelines, and only 25% of oncologists referred patients to an exercise specialist and 6% referred patients to an exercise program (Hardcastle et al., 2018). A recent study by Ng and colleagues on exercise barriers and adherence reported that 86% of cancer patients reported being counselled on the benefits of exercise by their physician, but not

necessarily the duration or amount recommended. The authors found reduced adherence among women, those with higher symptom burden, and those who found exercise unenjoyable (Ng et al., 2021). Importantly, 80% of patients were found to be willing to start an exercise program designed for cancer patients, suggesting a high need and interest in exercise programming (Avancini et al., 2020). Additionally, patients reported a preference to be informed about programming from their oncologist, which is concerning given the findings described above (Avancini et al., 2020). Adherence to existing exercise programs for individuals living with or beyond cancer has also been a challenge. Factors that have been found to contribute to adherence of exercise programs include providing interventions closer to patient's homes, leveraging family support, and increasing exercise motivation through tailored feedback and coaching (Ormel et al., 2018). Other barriers to physical activity programs include programs not being tailored to patient needs, healthcare provider lack of knowledge, inappropriate settings and time of program delivery, lack of capacity, and not involving family physicians in cancer care (IJsbrandy et al., 2019). Travel distance has been identified as a significant barrier to face-to-face programming in general, predicting worse adherence and lower enrollment in exercise programming and rehabilitation in cancer and other health populations (Hayton et al., 2013; Stubblefield, 2017). There is an evident knowledge-to-practice gap that is preventing individuals living with and beyond cancer from accessing services that could provide tools to better manage CrF. Knowledge translation strategies have been shown to enhance dissemination into practice and may be critical to implementing clinical practice guidelines for CrF into real-world settings (Agbejule et al., 2021; Glasgow & Estabrooks, 2018).

Knowledge Translation Strategies

Knowledge translation (KT) has been defined by the Canadian Institutes of Health

Research (CIHR) as “a dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products, and strengthen the healthcare system” (Government of Canada, 2020). It has been estimated that it may take as long as 17 years for effective clinical practices to translate into routine care, with half of evidence-based practice never being implemented. This poses a significant problem due to the associated costs and resources to healthcare systems, researchers, funding agencies, as well as patients who do not benefit from advancements in care (Kirchner et al., 2020). There has been increased recognition in the benefits of using implementation theories, models, or frameworks (TMF) to improve research into clinical practice, when applied meaningfully throughout the project rather than retrospectively (Moullin et al., 2020). However, meaningful application and selection of a TMF can be a daunting task. Within the field of KT research, there continues to be a lack of consistent terminology with over 100 terms used to describe the concept of KT, such as knowledge transfer and uptake, research utilization, and implementation science (IS) (McKibbon et al., 2010). KT and IS are overlapping concepts but IS is considered a subset of KT, specifically the study of methods that promote the uptake of research into practice (Esmail et al., 2020). To further complicate the field, selection of an appropriate KT TMF is difficult, as there are currently over 150 TMF which continue to evolve based on application to different fields and little evidence-informed guidance available for how to select a TMF (Strifler et al., 2018). Indeed, the difficulty with selection of an appropriate TMF is a central issue in implementation science and compounded by the considerable overlap between the different KT theoretical approaches (Martinez et al., 2014).

As KT is a relatively new field still in development, there continues to be a lack of rigorous research on the effectiveness of KT strategies (Powell et al., 2014; Wensing & Grol, 2019). Birken

et al. created the Theory Comparison and Selection Tool (T-CaST) to aid in navigating the selection process, however this tool has been described as complex using 16 specific criteria to justify selection (Birken et al., 2018; Esmail et al., 2020). One of the key criteria's described in the T-CaST is the extent interest holders are able to understand a TMF, apply it and operationalize it, as well as interest holders' familiarity with the TMF (Birken et al., 2018). A recent scoping review by Esmail and colleagues has distilled KT TMF down to 36 TMF that are full-spectrum (i.e., across the implementation spectrum from planning to sustainability) and recommended these TMF be used in research, with the hope of better directing the KT field to build a theoretical foundation for KT science (Esmail et al., 2020). Lynch and colleagues' created a pragmatic guide to selecting a theoretical approach and emphasized "goodness-of-fit" as an important consideration in the selection process (Lynch et al., 2018). To aid in the selection process, Nilsen and colleagues categorized KT TMF into five categories. These five categories are 1) process models, 2) determinant frameworks, 3) classic theories, 4), implementation theories, 5) evaluation frameworks (Nilsen, 2015). These categories were used by Esmail and colleagues when categorizing the 36 full-spectrum TMF (Esmail et al., 2020). For the purposes of this thesis, a process model that guides the process of translating research into practice and an evaluation framework (i.e., which assesses a specific aspects of implementation that could be evaluated to determine success) were seen to be the most appropriate, as opposed to a determinant framework (i.e., which tries to understand influences on implementation), a classic theory (i.e., theories that originate from external fields like psychology or sociology, such as theory of diffusion), or an implementation theory (i.e., which aid in understanding an aspect of implementation) (Nilsen, 2015).

The following frameworks were considered for selection: Consolidated Framework for

Implementation Research (CFIR), the Knowledge-to-Action Model (KTA), and RE-AIM. The CFIR framework was considered when deciding on a guiding framework. The framework is composed of five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process (Damschroder et al., 2009). Despite being frequently cited, Kirk et al. (2016) found that many studies reporting using the framework applied it sub optimally. Further, the framework has primarily been used within organizations and post-implementation to examine the ways the implementation was successful or unsuccessful (Kirk et al., 2016). The framework has been found to be best suited for large scale complex organizational change, such as implementing clinical practice guidelines across multiple healthcare settings (Breimaier et al., 2015). The CFIR framework may be appropriate in the future for wider scale implementation of the CrF intervention and the KTA model was selected for this project instead.

Knowledge-to-Action Framework

The KTA framework, developed in Canada by Graham and colleagues in the 2000s, is a process model that guides translating research into practice (Esmail et al., 2020; Graham et al., 2006). It was created with the intention to provide conceptual clarity in response to the multiplicity of terminology and TMFs in the KT field. The framework was created from 31 planned action theories of which ten have been empirically tested. The framework has several strengths including consideration for local context and culture, promoting active collaboration between researchers and knowledge users, being easily understandable yet comprehensive, and used extensively in health care implementation (Field et al., 2014; Graham et al., 2006). The KTA framework consists of several interacting phases: a) identify problem, determine the know/do gap, & identify, review, select knowledge, b) adapt knowledge to local context, c) assess barriers/facilitators to knowledge use, d) select, tailor, implement intervention, e) monitor knowledge use, f) evaluate outcomes, and

g) sustain knowledge use. The phases are flexible and can be carried out in order or simultaneously, however involvement of interest holders and tailoring the intervention to the needs of end-users is critical (Graham et al., 2006). Within cancer populations, the KTA framework has been used for example to examine decision-making among cancer registries to improve healthcare outcomes (Stirling et al., 2024) and to assess barriers and facilitators to the implementation of clinical practice guidelines for the assessment and management of lymphedema (Campione et al., 2023). In Canada it has been used to guide the implementation of a training session to improve healthcare providers knowledge of CrF guidelines (Jones et al., 2020) and to co-create a yoga program for women diagnosed with gynecologic cancers (Price et al., 2024).

Despite being one of the most used frameworks in literature, presently there are no theoretical approaches that have been agreed-upon or any empirical evidence demonstrating the advantage of one approach over others (Lynch et al., 2018). The KTA framework was found to be the most appropriate for this dissertation given its practicality, comprehensive yet flexible phases that provided guidance on the planning of the implementation, intuitiveness of the framework and ease of use for interest holders, being a full spectrum model (Esmail et al., 2020), and the small scale of this project (i.e., one institution, one healthcare provider vs large scale organizational implementation). Further, the KTA framework is endorsed and used by CIHR (Government of Canada, 2016) and has been used by other health organizations such as the National Institute for Health (NIH) and Care for South Yorkshire (Field et al., 2014). In addition, the KTA framework was recently recommended by the SIO and ASCO to aid in the translation of evidence based guidelines for anxiety and depression in adults with cancer (Carlson et al., 2023). Lastly, it was also chosen for continuity and consistency as this work built on previous work by Jones et al. who utilized the KTA framework in their exploration of CrF implementation gaps in the Canadian

context (Jones et al., 2020, 2021). The KTA model helped to plan, structure, and guide the progression of the project (see Appendix. I for a description of how each stage was incorporated).

RE-AIM

In addition to the KTA framework, RE-AIM was selected as an evaluation framework to guide the evaluation of specific aspects of implementation for study two. The RE-AIM framework captures reach, effectiveness, adoption, implementation, and maintenance, and captures both individual levels and ecologic levels (i.e., staff, setting, systems, and policy) of implementation (Holtrop et al., 2021). The RE-AIM framework has become one of the most frequently used frameworks for the evaluation of implementation in public health, behavioural science, and implementation science, and has been recommended by larger scale health organization like the NIH (Glasgow et al., 2019; Holtrop et al., 2021). Like other frameworks, RE-AIM is often sub-optimally applied to research with the adoption and maintenance dimensions being the least frequently reported in the literature, and reach and implementation being the most commonly reported (D’Lima et al., 2022; Glasgow et al., 2022; Holtrop et al., 2021). This has resulted in the RE-AIM framework evolving and emphasizing a more pragmatic application of the model which allows researchers to select which dimensions to prioritize and which to exclude, ideally with justification (D’Lima et al., 2022). Some reported challenges of using RE-AIM have been distinguishing between the reach and adoption dimensions and identifying appropriate evaluation measures (D’Lima et al., 2022). Among cancer populations, RE-AIM has been used in the evaluation of a psychosocial distress screening program funded by the National Cancer Institute (Lazenby et al., 2019), the implementation of a community-based exercise program for cancer survivors (Covington et al., 2018), and the implementation of psychosocial interventions for pain management among breast cancer patients (Cox-Martin et al., 2023). RE-AIM was selected for its

practical application, extensive use in diverse healthcare settings and cancer populations, being a full spectrum framework (Esmail et al., 2020), and for providing comprehensive guidance on evaluating implementation (Glasgow et al., 2022). This framework helped inform what implementation outcomes to collect during data collection and guided the reporting of implementation outcomes in study two (See Appendix II. for a figure of how the framework was used).

Hybrid Implementation Design

Effectiveness-implementation hybrid designs were created in hopes of addressing science-to-service gaps and accelerating the translation of research into practice by blending clinical effectiveness research with implementation research (Curran et al., 2012). Three types of hybrid designs exist, Type I, Type II, and Type III which all focus on a dual approach but to varying degrees. Type I tests clinical interventions impact on relevant outcomes while observing and collecting implementation outcomes. Specifically, Type I are early clinical effectiveness trials that incorporate some assessment of implementation outcomes. An example is the “Coordinated Anxiety Learning and Management (CALM)-study which conducted a large scale RCT with 1004 patients while assessing barriers/facilitators to delivering the intervention (Roy-Byrne et al., 2010). Type II prioritizes both clinical effectiveness and implementation outcomes equally. In Type II designs, evaluation of effectiveness is more liberal, not requiring necessarily a randomized trial or strongly powered design, but rather at least one outcome measure, focusing more on pragmatic “real world” delivery, and addressing knowledge to practice gaps. This design can be used when there is strong “indirect” efficacy or effectiveness data for an intervention, such as in this case, meta-analysis and systematic reviews, and evidence-based guidelines on psychoeducational interventions for the management of CrF (Berger et al., 2015; Bower et al., 2024; Howell et al.,

2015; Karakuş et al., 2022). Further, there is also reasoning to collect outcomes measures such as significant adaptations to the interventions are needed or it is being offered in a new setting/format. An example of a Type II design from McGill University Health Centre is the Lost & Found program, the program's goal was to identify and contact out-of-care patients who were living with HIV (Cox et al., 2020). Type III evaluates implementation outcomes while observing and collecting the impact of a clinical intervention on relevant outcomes (Curran et al., 2012). Type III designs are conducted once there is sufficient evidence that a program is clinically effective, justifying the costs associated with implementation across settings, and assessing the effectiveness of an intervention in less controlled conditions. An example of a Type III design is the large-scale randomized implementation of evidence-based practices (i.e., ensuring that care is patient-centered, only using necessary medications, identifying depression/delirium, and promoting safe movement) to create an age-friendly health system for veterans (Piazza et al., 2023).

To help guide the selection of the type of hybrid effectiveness-implementation, developers of the design proposed four guiding questions: 1) What is the nature of the effectiveness data on your intervention of interest?, 2) How much do you expect the intervention will need to be adapted for where you want to study/use it?, 3) How much do you already know about implementation determinants for the intervention in your context of interest?, and 4) How ready are you to evaluate a “real world” implementation strategy or package of strategies?. Based on these questions, type II was selected as the most appropriate given the guiding recommendations under each question. See Appendix III for full guiding questions. Justification for this choice included significant adaptations were needed to the intervention but a strong body of evidence existed for the effectiveness of psychoeducational interventions for CrF, including recommendations by several national and international practice guidelines, a needs assessment evaluating anticipated barriers

was conducted prior to this study, and the program was ready for real world implementation using the KTA framework (Curran et al., 2022; Howell et al., 2015).

Hybrid designs have been used in cancer populations to facilitate change and close the knowledge-to-practice gap; however, it appears primarily for exercise-based interventions and health policy changes such as cancer screening (Beidas et al., 2014; Hassine et al., 2022; McNeely et al., 2019). In Canada, McNeely and colleagues have published a hybrid protocol for the evaluation of a community-based exercise program for individuals living beyond cancer which was implemented across several settings and cities in Alberta, Canada (McNeely et al., 2019). Their primary effectiveness outcome was meeting or exceeding 150 min of moderate intensity exercise at one year follow-up and their implementation outcomes were guided by the RE-AIM framework (McNeely et al., 2019). Another example is a study by Beidas et al., who used a hybrid Type 1 effectiveness-implementation trial to evaluate an evidence-based exercise intervention for breast cancer survivors. Researchers reported a successful implementation that retained clinical effectiveness, but noted several barriers including physical therapists dissatisfaction with group formats, long-term costs of sustaining the program, and referral inefficiencies that require follow-up (Beidas et al., 2014). Recently, hybrid designs have also been used for changing practice in cervical cancer screening (Hassine et al., 2022), shared decision-making for lung cancer screening (Khanna et al., 2022), and prehabilitation in head and neck cancer patients (Wagoner et al., 2023). Hybrid designs have also been used in other health populations such as chronic pain (Midboe et al., 2024) and primary care settings (Cully et al., 2012). Hybrid effectiveness designs have been proposed as a solution in addressing the large knowledge-to-practice gaps for CrF (Pearson et al., 2023).

The Current Research

The overall objective of this project was to adapt an intervention for CrF within the local community context. To meet this goal, two studies were conducted. The first study was a needs assessment and consisted of focus groups and interviews with healthcare providers (HCP), community support providers (CSP), and patients. The objectives of the first study was to explore key interest holders' (patients, HCPs, CSPs) perceptions on what ideal program for CrF could look like and explore the barriers to implementation of an intervention for CrF in the local context. The KTA framework was used to guide overall implementation efforts, such as selection/tailoring, evaluating and monitoring outcomes, and sustaining knowledge use. Study one focused on two specific stages of the KTA model: *adaptation of knowledge to the local context and identification of barriers*. The results of Study 1 served as a guide for adapting an intervention to the local context and considering identified desired components of an intervention and potential barriers to implementation. The second study consisted of adaptation, implementation, and evaluation of an intervention for CrF in partnership with a community organization and patient advisory board. KTA framework was used to inform and guide the project and captured the remaining stages of the KTA model, including *selection/tailoring of intervention, monitoring knowledge use, evaluating outcomes, and sustaining knowledge use*. The RE-AIM framework was used to evaluate the implementation efforts. This study assessed acceptability and feasibility of a 4-week virtual psychoeducational program for CrF. Study one was supported by members of Montfort Hospital, the Ottawa Cancer Foundation, and Psychosocial Oncology Program at the Ottawa Hospital, General Campus. The second study involved a partnership with the Ottawa Cancer Foundation and a patient advisory board which consisted of members from the Ottawa Cancer Foundation and the Patient and Family Advisory Board from the Ottawa Hospital. As mentioned previously, all

required ethics approvals were obtained from associated institutions (See Appendices VII-IX & XI-XII).

Rationale for current studies

Study 1

The manuscript entitled “An Ideal Intervention for Cancer-Related Fatigue: Qualitative Findings from Patients, Community Partners, and Healthcare Providers” is a qualitative study with 62 participants (16 patients, 32 HCP, and 14 CSP). The study explored desired components of an intervention for CrF in the local context of Ottawa, Canada from the perspective of patients, HCPs, and CSPs, as well as the anticipated barriers to the implementation of an intervention for CrF. The goal of this study was to assess the need for CrF programming, gain an understanding of possible barriers to implementation in a local context, and lay the groundwork for the implementation of a program for the management of CrF. This study was published in Current Oncology, the full reference is as follows: Rutkowski NA, Jones G, Brunet J, Lebel S. (2024). An Ideal Intervention for Cancer-Related Fatigue: Qualitative Findings from Patients, Community Partners, and Healthcare Providers. *Curr Oncol.* 31(8):4357-4368.

Study 2

Based on the results of Study 1 there was an evident unmet need and desire for programming to address CrF in the local context from patients, HCPs, and CSPs. Anticipated barriers were considered during the implementation, including costs, offering virtual programming and collaboration with patients on content delivery to increase accessibility, offering the program after treatment completion to decrease informational overload, collaborating with a community partner to mitigate systemic barriers, and creating detailed descriptions to help navigate the online

resources to reduce difficulties with online literacy. Additionally, barriers identified were further evaluated in Study 2 through questionnaires and focus groups. The manuscript entitled “A brief psychoeducational intervention for cancer-related fatigue in a community context: A hybrid type-2 effectiveness-implementation randomized controlled trial pilot study” describes the adaptation and implementation of a 4-week virtual program for CrF in collaboration with a community partner and patient advisory board. The goal of this hybrid type-II pilot study was to determine the feasibility and acceptability of the CrF program, assessing both implementation and preliminary effectiveness outcomes simultaneously. Despite significant adaptations to the CrF program from the original program published in Fillion et al. (Fillion et al., 2008), a substantial body of evidence existed for psychoeducational interventions in the management of CrF that justified accelerated implementation into a community context through the use of a hybrid 2 design (Curran et al., 2022; Howell et al., 2015). The study resulted in the successful implementation of a virtual program for CrF, that continues to be maintained within the local context and was found to be both feasible and acceptable.

Study One

An Ideal Intervention for Cancer-Related Fatigue: Qualitative Findings from Patients, Community Partners, and Healthcare Providers

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Abstract

Patients consistently rate cancer-related fatigue (CrF) as the most prevalent and debilitating symptom. CrF is an important but often neglected patient concern, partly due to barriers to implementing evidence-based interventions. This study explored what an ideal intervention for CrF would look like from the perspectives of different stakeholders and the barriers to its implementation. Three participant populations were recruited: healthcare providers (HCPs; n=32), community support providers (CSPs; n=14), and cancer patients (n=16). Data were collected via nine focus groups and four semi-structured interviews. Data was coded into themes using content analysis. Two main themes emerged around addressing CrF: “It takes a village” and “This will not be easy”. Participants discussed an intervention for CrF could be anywhere, offered by anyone and everyone, and provided early and frequently throughout the cancer experience and could include peer support, psychoeducation, physical activity, mind-body interventions, and interdisciplinary care. Patients, HCPs, and CSPs described several potential barriers to implementation, including patient barriers (i.e., patient variability, accessibility, online literacy, and overload of information) and systems barriers (i.e., costs, lack of HCP knowledge, system insufficiency, and time). As CrF is a common post treatment symptom, it is imperative to offer patients adequate support to manage CrF. This study lays the groundwork for implementation of a patient-centered intervention for CrF in Canada and possibly elsewhere.

Keywords: Cancer-related fatigue, qualitative, patient-centered care, intervention, implementation, survivorship

An Ideal Intervention for Cancer-Related Fatigue: Qualitative Findings from Patients, Community Partners, and Healthcare Providers

Cancer-related fatigue (CrF) has been defined as a “distressing, persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Berger, Mooney, et al., 2015). Patients diagnosed with various cancers consistently rate fatigue as the most prevalent and debilitating symptom (A. Hall et al., 2013). Approximately, 30% of patients living beyond cancer will experience moderate to severe fatigue that persists years after treatment cessation (Al Maqbali et al., 2021; Wang et al., 2014). CrF has been found to impact quality of life, contributing to significant socioeconomic losses, disability, isolation, and increased healthcare utilization (Jones et al., 2016, 2023).

Due to a growing awareness of CrF and its burden, several organizations have published evidence-based guidelines for its assessment and treatment, including the National Comprehensive Cancer Network (NCCN) (Berger, Mooney, et al., 2015), Canadian Association for Psychosocial Oncology (CAPO) (Howell et al., 2015), and more recently the European Society for Medical Oncology (ESMO) (Fabi et al., 2020). Guidelines for CrF are relatively consistent and recommend systematic screening for fatigue and interventions including psychoeducation, psychosocial interventions (i.e., cognitive behavioural therapy), physical activity, and supportive expressive therapies. Despite the availability of these guidelines for several years, the dissemination and implementation of evidence-based CrF guidelines continues to be lacking (James et al., 2015; Jones et al., 2021; Pearson et al., 2015).

In Australia, healthcare providers (HCP) have reported that the current state of the CAPO guidelines on CrF lack clinical utility (Pearson et al., 2017). Presently, the CAPO guidelines contain a plethora of information on possible patient self-management strategies but offer little

guidance on how HCPs can support patients in making recommended behavioural changes (e.g., physical activity) (Agbejule et al., 2023; Howell et al., 2015). For these reasons, implementation of these guidelines remains problematic in hospital and community settings, resulting in HCP recommending strategies lacking empirical support (e.g., rest) (Hilarius et al., 2011) or recommending evidence-based strategies infrequently (Schmidt et al., 2021). In 2023, a self-management support practice framework was published to provide practical guidance on addressing CrF to address HCPs' concerns (Agbejule et al., 2023). To increase implementation of treatment strategies for CrF, several strategies have been proposed including leveraging information and communications technologies, prioritizing interventions ready for adaption to local contexts, and creating standardized manuals (Berger et al., 2015).

The present study aimed to build on findings of a previous study (Jones et al., 2021) that assessed knowledge of and barriers of implementation of the CAPO guidelines. In 2021, Jones et al. found professionals' lack of knowledge and resources along with systemic barriers and breakdowns in communication between patients and providers contributed to the lack of CrF guideline implementation. The purpose of this study was to examine these stakeholders' perspectives on what an ideal CrF intervention could consist of in the local context using the Knowledge-to-Action (KTA) framework (Graham et al., 2006; Straus et al., 2013) – a model that aids in knowledge creation and practical application. Owing to its purpose, this study focused on two specific stages of the KTA model: *adaptation of knowledge to the local context* and *identification of barriers*. This knowledge will ultimately guide the application of the remaining KTA stages (i.e., selection/tailoring of intervention, monitoring knowledge use, evaluating outcomes, and sustaining knowledge use) in the implementation and evaluation of an intervention for CrF in Ottawa, Canada.

Methods

Participants

This study employed a phenomenological approach (Creswell & Poth, 2017) in which individuals best positioned to speak on CrF were selected to participate including: patients experiencing CrF, HCPs, and community support providers (CSPs) who worked with patients experiencing CrF. Inclusion criteria for patients, HCPs, and CSPs were to: (a) speak English or French; (b) be aged 18-85 years; and (c) be diagnosed with cancer/have experience working with cancer patients. Patients were recruited from hospital and community settings, HCPs were recruited from two local hospitals, and CSPs were recruited via cancer community centres in Ottawa, Canada.

Protocol

This study is a part of a larger mixed methods study that evaluated knowledge of CrF guidelines and assessment and treatment of CrF in clinical practice (Jones et al., 2021). A qualitative research design with focus-groups was selected to allow the exploration and understanding of participants' wants and perceived barriers for implementing an intervention for CrF in Ottawa, Canada. Participants were grouped in separate focus groups. Due to scheduling issues, however, individual interviews with physicians were undertaken. Recruitment and data collection began in July 2016 and was completed in May 2019 once data saturation was reached when analyzing the data for Jones et al.'s study (Jones et al., 2021). Research Ethics certificates were received from all institutions from which participants were recruited (protocol numbers: #GJ-06-08-15, #H12-15-26 and #20170704-01H). Participants provided written informed consent and completed demographic questionnaires before the focus groups or interviews began. Focus groups were conducted in-person and facilitated by pairs of female investigators experienced in

psychosocial oncology, a clinical psychologist (S.L.), physical activity researcher (J.B.) and two clinical psychology graduate students (G.J. and N.R.). G.J. conducted three individual interviews by phone and one in-person. Focus groups were video/audio recorded and interviews were audio recorded only. All audio recordings were transcribed verbatim and imported into NVivo12 software (QSR International Pty Ltd, 2018) for analysis. The average focus group length was 90 minutes with patients and 60 minutes with HCPs and CSPs. The average interview length was 20 minutes with HCP-physicians. This study is reported according to standards for reporting qualitative research (Braun & Clarke, 2006). See Appendix IV for the standards for reporting qualitative research.

Measures

Quantitative measures. A brief questionnaire was administered to participants to gather medical, sociodemographic information, and years of experience working in oncology for HCPs and CSPs.

Qualitative interview. Separate semi-structured interview guides were developed to facilitate the patient and professional (HCP, CSP) focus groups and interviews. For the present study, questions pertaining to what would constitute an ideal intervention for CrF and anticipated barriers to implementation were explored. See Appendices V & VI for interview guides.

Analyses

Qualitative analyses

To determine what stakeholders believed would be an ideal intervention for CrF, thematic content analysis was performed by N.R. on the data using NVivo12 software (QSR International Pty Ltd, 2018). N.R. adopted an interpretive phenomenological researcher stance, acting as a bridge between the researchers' and participants' horizons of significance. Her reflexive stance

was guided by her experience as a cancer survivor and her clinical and research training in psychosocial oncology (Frechette et al., 2020; Olmos-Vega et al., 2022). Adhering to Braun and Clarke's methods (Braun & Clarke, 2006), inductive data analysis began by becoming acquainted with the data through a first reading of all transcripts, followed by generating codes for pertinent features of the data that aligned with the current study. After this, themes and sub-themes were generated from existing codes and each theme was reviewed to ensure information coded was appropriate for the theme. Then, sub-themes and themes were defined and labeled. Last, exemplar quotes were located to provide support for conclusions. Triangulation was performed to look for similarities and differences between patients', HCPs', and CSPs' viewpoints within themes (Carter et al., 2014). Thirty percent of the focus groups were double coded by a second coder. Themes were discussed until consensus was reached.

Results

Participants

A total of 62 participants were recruited—16 patients, 32 HCPs, and 14 CSPs. The 16 patients were divided into three focus groups (two in English [$n=5$ & $n=4$], one in French [$n=7$]). Focus groups took place at the Ottawa Hospital and Montfort hospital, refreshments were provided, and cost of parking was reimbursed. Four HCP focus groups were conducted—one with members of an interdisciplinary breast cancer team (French $n=4$), one with members of an interdisciplinary psychosocial oncology team ($n=8$), one group of oncology nurses ($n=10$), and one group of radiation technicians ($n=10$), at their respected hospitals of employment. Three individual interviews were conducted with HCP-physicians over the telephone and one in-person. Two CSP focus groups ($n=7$ & $n=7$) were conducted and hosted at two community cancer support centers in Ottawa. See Table 1 for an overview of the patients', HCPs', and CSPs' characteristics.

Themes

Two overarching themes emerged from the data around addressing CrF: ‘It takes a village’ and ‘This will not be easy’. For the first theme, participants discussed provider, timing and location of the intervention (anywhere, offered by anyone and everyone, and provided early and frequently through the cancer experience) and the components of an intervention they wanted (education, physical activity, mind-body, interdisciplinary care, and co-ordination of care). For the second theme, patients, HCPs, and CSPs described several potential barriers to implementation, including patient barriers (i.e., patient variability, accessibility, online literacy, and overload of information) and systems barriers (i.e., costs, lack of HCP knowledge, system insufficiency, and time).

Theme 1: ‘It takes a village’

Provider, Timing and Location of the Intervention

Participants described the program could be located anywhere so long as it was accessible, well-located, welcoming, and provided centralized services. In the words of a patient: *“I don't care where I go. It doesn't matter to me, as long as [the programming] is good when I get there”* and a HCP stated *“I think it's really important that these [services] are offered closer to home.”*

A subtheme of anyone and everyone, early and frequently emerged where participants described that people from many disciplines or peers could provide education on fatigue and emphasized the importance of it being someone who has first contact or regular contact with the patient. A HCP described: *“I think the first person that sees them should give them something because even by the time they can see their social worker it's often too late. It needs to be caught before it happens...”* and a CSP added: *“I think it would be a multitude of different people that*

could speak to the different aspects [of CrF]. Participants discussed the importance of educating patients about fatigue early on and frequently due to difficulty processing information at diagnosis. A CSP described discussing fatigue: *“I think the earlier the better...early and often...knowing why [fatigue]is there always makes you cope with things better.”* And in the words of a patient: *“But for me it's more important to know ahead of time and not knowing that I would have the fatigue I did not prepare for it. And I would have done things differently...”*

Desired Components of an Intervention

Participants spoke to the importance of peer support, not feeling so alone, and normalizing the experience of fatigue. In the words of a HCP: *“If they could talk about fatigue, normalize it, and it's to be expected and if people share their challenges about going back to work...”* and a patient added: *“There should be one afternoon a week where everyone could meet and talk about the fatigue. Whether it's an exercise session...or 20 minutes of socializing. Because you won't feel as isolated...”*

Participants recommended educating patients as well as HCPs on CrF. In the words of a CSP and patient, respectively: *“When I think of unmet needs for clients, I think a huge one is education around CrF. And knowing "What can I do?"”* and *“Maybe if someone sat down and talked about the fatigue. Because no one really talked to me about it.”* Participants expressed wanting information on the connection between fatigue and other symptoms such as mood, strategies to manage fatigue, information that CrF is common prior to treatment, and recommendations of strategies to manage and communicate about CrF.

Patients, HCPs, and CSPs discussed in-person supervised exercise sessions; believing these would enhance patients' motivation for physical activity and reduce isolation through contact and support from others experiencing CrF (if group-based). In the words of one patient: *“Kind of*

a support group, but not with the structure where everybody sits down in a circle and talks. I want it to be dynamic, you need to be pushed a little bit to exercise.” Participants suggested yoga, walking, or running groups and offered that, depending on the activity, these could be led by peers to increase sustainability by reducing costs. Additionally, cognitive behavioural therapy elements were raised by CSPs such as identifying and addressing individual barriers to physical activity. A CSP explained: *“For somebody to say, “you should walk 30 minutes” that’s fine but the next question is well “why aren’t you doing that?” So, what is that barrier? Is it because you think you don’t have time? Okay well let’s talk about that...”*

Participants also raised mind-body interventions, such as mindfulness, meditation, art therapy, and stress reduction. CSPs expressed the use of mindfulness as a facilitator of behavioural change through patient empowerment, increased agency, and acceptance. A CSP explained: *“For a lot of people, a mindfulness-based approach as a part of intervention—that is very empowering and helpful. I mean not only is the whole piece of being in the moment and meditating energy-giving, it also engenders more self-awareness.”*

Participants described the need for interdisciplinary care and patient-centric integrative approach, wherein an intervention addresses the multifactorial nature of CrF through an interdisciplinary team. A patient described: *“I think first off it should be integrative. Here is the patient, here is your medical team, here is your psychosocial oncology contact, here is your physician, here is your nutritionist, here is your radiation-oncologist. And we are your team.”* A HCP adds: *“In a perfect world, we go back to having a group where we have an [Occupational Therapist] and a [Physio Therapist] and a dietician and maybe a social worker or a psychologist involved in counselling.”*

Participants discussed a desire for co-ordination of care, describing a lack of integration

of services and a need for greater communication between hospitals, community partners, and patients, particularly around what services are available for patients. Patients and HCPs expressed that ideally there would be someone following patients who could provide regular check-ups and guidance. A patient described: *“Someone who can get in touch with you. Like that call that I got from [the hospital] really gave me a lift of “Wow, they didn’t just forget about me!” It was three months later and “How are you doing? Do you need anything? Is there a service that you’re looking for?”.*

Theme 2: ‘This will not be easy’

Patient Barriers

The accessibility subtheme captured barriers to offering an intervention that would be accessible for all (e.g., rural communities, individuals with lower socioeconomic status). Participants identified barriers such as difficulties with attending an intervention in person due to distance, financial restraints (i.e., cost of parking or interventions/services), and symptom interference. A CSP suggested: *“Offering [the intervention] somewhere that is accessible – like free parking and all that”.* A cancer patient further explained how post-treatment symptoms interfered with in-person programs, *“I live in the middle of nowhere...but I think part of my brain fog is also time management and recognizing how long things take, getting ready and out the door on time is really difficult for me.”*

Online literacy subtheme captured concerns that patients may find online interventions challenging due to potential limited online literacy. As one patient reported: *“Being of different age than 90% of the people in here, I’m not comfortable with the internet...”*

The subtheme of information overload described how HCPs and CSPs felt that patients were overwhelmed and overloaded with information during their cancer trajectory, which made it

challenging for them to take in new information. As one HCP shared, *“it can be like a deer in the headlights. I’ve had patients actually say sometimes it’s like support overload... you need this, you need to do this, how about you go here?”*

Participants also raised concerns over patient variability that captured differences between patients regarding motivation, willingness to implement change, self-efficacy, level of family support, education level, language barriers, and personality (i.e., shyness) that could impact their ability to engage in a CrF intervention successfully. An HCP explained *“Sometimes it’s their mentality. They feel like they just have to go home and deal with [the fatigue], they don’t really think there’s a way to try to solve the issue”*, while a CSP added that patients are *“not necessarily used to in North America taking control of [their] own health and having to do things, [they] may have to change [their] diet or might have to exercise, these things aren’t easy to do...there’s no pill to fix CrF.”*

Systems Barriers

There were several systems barriers raised to implementing an intervention for CrF, including cost, lack of knowledge, system inefficiencies, and time constraints. Participants expressed concerns related to hospital administration, funding, and procedures that made it difficult to get referrals for patients or justify services that may be deemed “non-essential” such as for CrF. Participants also expressed difficulty with collaboration and having patients referred to different programming. See table 2 for additional illustrative quotes.

Discussion

This study summarized the perspectives of stakeholders on what an ideal CrF intervention could consist of in the local context in Ottawa, Canada. The two themes that emerged from the

data ('It takes a village' and 'This will not be easy') capture the recognized importance and impact of fatigue while also acknowledging there are many personal and systemic barriers that make implementing CrF interventions challenging. Participants expressed a CrF intervention could be facilitated by anyone and everyone, housed anywhere, and offered early and frequently through the cancer experience, which may speak to the level of need for CrF programming and resources in the local context. Peer support was discussed as an important component of CrF programming. Several interventions for CrF were raised including education, physical activity, mind-body, interdisciplinary care, and co-ordination of care. The perceptions of HCP, CSP, and patients may help direct much-needed efforts in implementing programming and resources for CrF in Ottawa and elsewhere.

Based on insights from our larger study (Jones et al., 2021) and in accordance with other studies (Pearson et al., 2023), CrF guideline implementation continues to be lacking due to a lack of HCP knowledge around CrF and a break down in patient-provider communication, leading to patients being dissatisfied with care for CrF. In our study, participants indicated that any HCP could facilitate CrF management and that an intervention should be offered early and frequently across the cancer experience. The CAPO guidelines do recommend early and thorough evaluation of fatigue, education on CrF for all patients, and continued follow-up, yet this poses a significant challenge due to the lack of education, clinically useful resources, and training opportunities for HCPs around CrF (Howell et al., 2015; Pearson et al., 2023). Indeed, a recent study found that 87% of HCPs rated having limited or moderate expertise with CrF despite years of practice (Pearson et al., 2023). It may therefore be paramount to prioritize HCP education on CrF. Another consideration is the lack of leadership around fatigue which may be resulting in a diffusion of

responsibility among HCPs (Spring et al., 2019), as well as a lack of prioritization at organizational and policy levels (Pearson et al., 2023).

Participants expressed an intervention for CrF could be offered anywhere (i.e., community or hospital) so long as it was accessible. However, patients experience many barriers to face-to-face programming as detailed in this study and reported in the literature with a long commute time being the most commonly cited barrier, as well as experiencing fatigue, which warrant consideration (Stubblefield, 2017). A virtual CrF intervention may be best positioned to reduce significant barriers like accessibility, costs, informational overload, and time constraints but may exclude patients who feel uncomfortable with technology. Additionally, eHealth interventions may offer more flexibility for components such as intensity and duration of an intervention, and be better personalized to patient variability and information presented, thereby being more likely to maintain patient motivation, satisfaction, and adherence (Beenhakker et al., 2022). Indeed, in 2022 Beenhakker et al. (2022) have published an overview of 35 existing CrF interventions and the variations of patient preferences among these interventions which may help guide patients or practitioners in selecting an appropriate eHealth program (Beenhakker et al., 2022). Further, based on participants' perceptions, programming with peer support should be offered when possible as it appears to contribute to a sense of normalcy and connection. Social support has also been found to facilitate physical activity motivation, an important evidence-based recommendation for CrF (McDonough et al., 2021). In-person exercise sessions may be a component of interdisciplinary care and offer inherent social support.

Importantly, participants expressed interest in education around CrF which may indicate an unmet informational need around CrF. Indeed, a recent study found that only 23% of patients were informed of treatment options for CrF. Further, most patients in the study indicated they

needed to initiate the conversation around fatigue with HCPs as opposed to HCPs inquiring about CrF (Harrington et al., 2022). This may speak to the lack of dissemination of various resources that have been available for several years, including published educational booklets by Cancer Care Ontario in 2016 (Cancer Care Ontario, 2016), Alberta Health services in 2017 (Alberta Health Services, n.d.), and Eastern Health in 2018 (Eastern Health, 2018). Many of these resources also contain video education for patients, as well as other international resources (American Cancer Society, 2020; Cancer Council Victoria, 2023; National Cancer Institute, 2021a). Given that existing resources and evidence-based treatments have been created, organizations may wish to focus on adaptation and practitioner education around available resources for CrF as a cost-effective step to begin to address this unmet information need. A virtual psychoeducation intervention on the management CrF may be a beneficial and cost-effective approach to the management of CrF; psychoeducation interventions have shown to significantly improve the management of CrF among people living beyond cancer (Corbett et al., 2019), especially when offered in a group setting and incorporating cognitive behavioural therapy (Hausmann et al., 2022).

Participants raised the benefits of case coordinator. Navigation services have been found to improve adherence to surveillance appointments, decision making, satisfaction with care, and quality of life; however, limited evidence has been found that they improve CrF (Chan et al., 2023). Several systems barriers were noted in our study that have been found by other studies (Pearson et al., 2017; Pearson et al., 2023). It is evident that to increase the implementation of CrF guidelines significant policy changes are needed, including increased funding, protected education time for HCP, improved care pathways, and prioritization of CrF within organizations.

Limitations

The data were collected prior to the COVID-19 pandemic, which may have altered patients, HCPs, and CSPs perceptions on what may be an ideal intervention specially regarding virtual or in-person settings. Further, the data was collected in Ottawa, Canada from participants who are Caucasian/White from higher socioeconomical backgrounds and well-educated. This may limit the transferability of the results.

Conclusion and future directions

This study emphasizes the critical need for CrF programming and implementation of evidence-based treatment. Future studies should prioritize effectiveness-implementation studies that accelerate the development of clinically useful resources and are adapted to local settings. Virtual CrF interventions may be best positioned to reduce barriers to accessing critical support to managing CrF, and organizations may wish to prioritize education and adaptation of existing CrF resources and programs. Lastly, policy changes are needed to address significant systems barriers like costs, system inefficiencies, and time constraints.

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Table 1. Socio-Demographic Information

Patients		
	Mean (M)	SD
Age	55.56	10.30
Time since diagnosis (years)	5.31	2.55
Time since treatment completion (years)	3.13	1.92
	N (%)	
Gender		
Man	7 (43.8%)	
Women	9 (56.3%)	
Language		
English	6 (37.5%)	
French	10 (62.5%)	
Employment		
Full-time	3 (18.8%)	
Part-time	3 (18.8%)	
No	10 (62.5%)	
Born in Canada		
Yes	16 (100%)	
Ethnicity		
Caucasian/White	16 (100%)	
Diagnosis		
Prostate	2 (12.5%)	
Breast	8 (50%)	
Colorectal	1 (6.3%)	
Stomach	1 (6.3%)	
Multiple	3 (18.8%)	
Colon	1 (6.3%)	
Chemotherapy		
Yes	8 (50%)	
Radiation		
Yes	10 (62.5%)	
Surgery		
Yes	10 (62.5%)	
Income (CAD\$)		
<40,000	4 (25%)	
40 000 – 59 999	2 (12.5%)	
60 000-79 999	1 (6.3%)	
80 000 – 99 999	1 (6.3%)	
100 000 – 150 000	6 (37.5%)	
> 150 000	1 (6.3%)	
Don't know	1 (6.3%)	
Healthcare providers		

	<u>M</u>	<u>SD</u>
Age	42.06	9.75
Work experience (years)	11.05	8.21
	<u>N (%)</u>	
Gender		
Man	5 (15.6%)	
Women	27 (84.4 %)	
Title		
Radiation technician	10 (31.3%)	
Registered nurse	10 (31.3%)	
Social worker	4 (12.5%)	
Psychologist	2 (6.3%)	
Radiation oncologist	2 (6.3%)	
Dietician	1 (3.1%)	
Surgeon	1 (3.1%)	
Palliative care physician	1 (3.1%)	
Physiotherapist	1 (3.1%)	
Community support providers		
	<u>M</u>	<u>SD</u>
Age	43.86	11.20
Work experience (years)	3.93	3.13
	<u>N (%)</u>	
Gender		
Man	2 (14.3%)	
Women	12 (85.7%)	
Title		
Cancer coach	7 (50%)	
Hypnotherapist	1 (7.1%)	
Natural Chinese medicine	1 (7.1%)	
Registered massage therapist	1 (7.1%)	
Naturopathic doctor	1 (7.1%)	
Yoga therapist	1 (7.1%)	
Manager	1 (7.1%)	
Research fellow	1 (7.1%)	

Table 2. Qualitative excerpts from patients, community support providers, and healthcare providers

Theme	Subtheme	Quote
Provider, timing and location of the intervention	Anywhere	<i>"It's not one or the other [referring to community or hospital] ...I think it could be in any location, but I think it's that education piece..." –CSP"</i> <i>"Accessible, for everybody." –Patient</i>
	Anyone and Everyone, Early and Frequently	<i>"I think if it was something that was part of their regular medical practice." –CSP</i> <i>"I think the doctors and everybody that we need to see in the medical field. They need to be more aware of how fatigue affects us. I think they take it too lightly... it's a ball floating and no one really grabs it." –Patient</i>
Desired components of an intervention	Peer Support	<i>"Maybe there's an opportunity to have like a peer-to-peer advocacy group, [for] people who have lived with fatigue, and are living with it..." –Patient</i> <i>"If I had talked to other people dealing with the fatigue maybe I wouldn't be so anxious and stressed and feeling like what's happening to me..." –Patient</i>
	Education on CrF	<i>"I think that intervention or education as we've brought up is a huge piece of reassurance around what they're coping with, and then to have the intervention - it should be holistic, it should talk about all the different things they can do, you know exercise, nutrition. How stress, how brain fog, how all these things impact their energy levels and what they can do about that." –CSP</i>
	Physical Activity	<i>"If we could offer like an exercise class, that's very basic, you could get a bunch of people and do it together." –HCP</i>
	Mind-Body	<i>"The neat thing about mindfulness is that I think it's a strategy that could be multi-modal. Like it could cover other aspects of difficulty with cancer too. But I think in terms of fatigue it is a useful intervention." –CSP</i>
	Interdisciplinary Care	<i>"From my point of view, I just want to mention too that having a little bit of a better interdisciplinary team." –HCP</i>
	Co-ordination of Care	<i>"A resource person, capable of, as I said earlier, sensitivity, being able to situate, being able to listen..." –Patient</i>
Patient Barriers	Accessibility	<i>"I find that there's a lot of resources but there's no follow through to get to them...especially a patient coming from a rural setting" –HCP</i>
	Online Literacy	<i>"A lot of them are older. So webinars might be a challenge for them." –CSP</i> <i>"...those of us that are older and our patients are even older, we can't just google the problem and solve it or go to a YouTube video." –HCP</i>

	Information Overload	<i>"I personally I try to tailor my techniques and everything to their education level like use simpler words, shorter sentences, etc. But sometimes it's just too much for them, and then you give them a piece of paper and then it's just too much and overwhelming."</i> – HCP
	Patient Variability	<i>"Because we can recommend everything until we're blue in the face but if the patient doesn't want to do it... or if they're not interested or if it's not what they like..."</i> –HCP <i>"There'll be people who are perhaps shy and don't want to work in a group and will individually go online".</i> –CSP
System Barriers	Cost	<i>"I understand it from a financial perspective, we just can't keep everything here at the hospital and we tell the patient what they can do. And we hope that they do it. But in some cases, they won't unless they're being guided to do it."</i> –HCP <i>"I just worry that in a hospital system an [intervention for CrF] will be seen as something that is non-essential and will get moved out very quickly."</i> –HCP <i>"There's what 300 cancer charities, we're all fighting over donor dollars..."</i> –CSP
	Lack of Knowledge	<i>"Fatigue was such a profound symptom for patients later on. So, I think health care provider education or lack of is a barrier."</i> – HCP
	System Inefficiencies	<i>"We have to refer patients for many things, and I know sometimes people say that process isn't complicated. But when there are 10 or 20 things to refer for, the simpler it is the more likely we are to think about it and use it."</i> –HCP <i>"We work really hard to partner but there is a challenge in that...we know oncologists say to their patients, they're not allowed to refer directly to any specific organization."</i> –CSP
	Time Constraints	<i>"Well, not just that I think it's more time to figure things out. It's time with a person. You know, we don't have time..."</i> –HCP

Study Two

A brief psychoeducational intervention for cancer-related fatigue in a community context: A hybrid type-2 effectiveness-implementation randomized controlled trial pilot study

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Abstract

Cancer-related fatigue (CrF) affects a third of individuals living with and beyond cancer. Evidence-based practice guidelines recommend psychoeducational and lifestyle interventions (among others) to help reduce the burden of CrF; yet the implementation of such interventions continues to be a challenge. **Aim:** This study aimed to evaluate the clinical and implementation outcomes of a brief virtual psychoeducational intervention for CrF in a community context. **Methods:** This single-centre, non-blinded two-armed wait-list control randomized controlled trial pilot employed a type-2 hybrid effectiveness-implementation design. Self-selected participants (N=50) were randomized 1:1 to either an intervention group (n=25) or a wait-list control (n=25), with both groups completing questionnaires at baseline (week 0), after implementation (week 5), and at follow-up (week 13). Participants assigned to the intervention group received four virtual 90-minute sessions facilitated by a registered nurse/cancer coach. Clinical outcomes on the primary outcome measure of CrF were quantified using a repeated measures ANOVA analysis. Evaluation of implementation outcomes were guided by the RE-AIM framework. **Results:** Between December 2021—February 2023, 50 adults were enrolled (recruitment rate: 45%; M age = 54 years, 95% women). A total of 36 (82%) participants completed questionnaires at all three timepoints. Program adherence rate was 89% (32/26). Compared to controls, intention to treat analysis (intervention n=23, wait-list n=21) showed reduced CrF (MFI-20: $F_{2,84}=6.18$, $p=.007$, $\eta_p^2=.128$ & FACIT-F-13: $F_{2,84}=4.73$, $p=.015$, $\eta_p^2=.101$). The intervention was delivered with high levels of fidelity, received high satisfaction ratings, and was found to be feasible and acceptable. No adverse effects reported.

Conclusions: This pilot study offers insight into the real-world implementation and preliminary clinical outcomes of a brief virtual psychoeducational intervention for CrF and other patient-reported outcomes, laying the groundwork for larger scale implementation and evaluation.

Trial registration Clinical Trials NCT05409638.

Funding: Implementation grant from the University of Ottawa

Keywords: Cancer-related fatigue, implementation science, acceptability, survivorship, hybrid effectiveness-implementation designs, cognitive behavioural therapy

A brief psychoeducational intervention for cancer-related fatigue in a community context: A hybrid type-2 effectiveness-implementation randomized controlled trial pilot study

Cancer-related fatigue (CrF) is a prevalent and debilitating side effect of cancer or cancer treatment, affecting approximately 30% of individuals living with or beyond cancer (Al Maqbali et al., 2021). Persistent fatigue has significant adverse impacts on quality of life, return to work, and social reintegration, and contributes to high levels of disability (Jones et al., 2016, 2023). Psychoeducational interventions, physical activity, mind-body interventions, and cognitive behavioural therapy have been found to reduce the symptom burden of CrF (Belloni et al., 2021; Corbett et al., 2019; Thong et al., 2020; Xie et al., 2020; Yuan et al., 2022). Accordingly, numerous international guidelines recommend such interventions (Berger et al., 2015; Bower et al., 2024; Fabi et al., 2020; Howell et al., 2015).

Implementation of evidence-based practice guidelines for the management of CrF has remained challenging (Pearson et al., 2023) despite a strong body of evidence demonstrating the benefits of non-pharmacological interventions for CrF (Mustian et al., 2017; Thong et al., 2020; Yuan et al., 2022). Studies report difficulties with implementation due to a lack of healthcare provider knowledge and resources (Jones et al., 2021), a lack of leadership, persistent beliefs that fatigue is normal and needs to be accepted among patients and healthcare providers (Thong et al., 2020), complexity of clinical guidelines, and inefficient referral pathways (Pearson et al., 2023), resulting in inadequate support services for CrF. However, only a handful of studies have engaged end-users to develop interventions. This is surprising as involving interest holders and patients in the planning, development, implementation, and evaluation of interventions may lead to more feasibility, acceptability, and long-term implementation of interventions for CrF (Wandersman et al., 2008).

One example of engaging interest holders early on is a needs assessment conducted between 2016-2019 to gather patients', healthcare providers', and community support providers' perspectives on desired components of an intervention for CrF and barriers to its implementation in the local context. Participants reported that an intervention for CrF could be facilitated by anyone and everyone (within allied health/medical disciplines or cancer peers), could rely on in-person or virtual modes of delivery, and be offered early and frequently through the cancer experience (Rutkowski et al., 2024). This likely speaks to the significant gap in programming and resources for CrF in Canada, despite Canadian guidelines for the assessment and management of CrF being published since 2015 (Howell et al., 2015). Indeed, a study by Harrington et al. (2022) found that only 23% percent of individuals experiencing CrF reported being informed of treatments by a healthcare provider possibly contributing to patients reporting feeling poorly informed about CrF (Schmidt et al., 2021). Healthcare providers have also acknowledged not addressing CrF proactively with their patients and often discussing only physical activity when providing recommendations due to a lack of knowledge of other effective treatment options for CrF (Martin et al., 2021).

Jones et al. (2021) identified two key barriers to the implementation of evidence-based guidelines. Firstly, there was a gap in healthcare provider knowledge and resources which were exacerbated by systemic issues (e.g., lack of time and funding constraints). Secondly, there was a break-down in provider-patient communication which resulted in patients feeling discouraged and not reporting symptoms of fatigue (Jones et al., 2021). Rutkowski et al. (2024) also reported several barriers impeding implementation of CrF interventions in the local context, which they categorized as *patient-related* (e.g., difficulties with accessibility, online literacy, informational overload, varying levels of patient motivation and self-efficacy) and *systemic* (e.g., cost, lack of

knowledge, system inefficiencies, and time constraints). Researchers have suggested possible solutions, such as utilizing telehealth, curating accessible and practical CrF resources for healthcare providers, and prioritizing hybrid designs to increase the implementation of interventions for CrF (Pearson et al., 2023). Hybrid designs have the objective of examining both outcomes from the implementation and intervention. A type II hybrid design prioritizes implementation and clinical outcomes equally, which can provide the opportunity to accelerate implementation into real-world settings while evaluating clinical outcomes and may help address some of the implementation challenges facing CrF interventions (Landes et al., 2019).

Given the context presented, a type-2 hybrid effectiveness-implementation randomized controlled trial pilot study was conducted to implement a brief allied health practitioner-led virtual psychoeducational intervention into a community context. The purpose of this study was to evaluate the implementation and clinical outcomes of this intervention simultaneously compared to a wait-list control group. Implementation outcomes were reach, adoption, preliminary effectiveness, implementation, and maintenance in accordance with the RE-AIM framework (Glasgow et al., 1999, 2019). Intervention adaptation and implementation was guided by the Knowledge to Action (KTA) framework (Graham et al., 2006) following a needs assessment and evaluation of barriers conducted in the local context (Rutkowski et al., 2024). In addition to the primary clinical outcome of CrF, secondary clinical outcomes included anxiety, sleep, depression, and physical activity because of their documented associations with CrF (Belloni et al., 2021; So et al., 2021) and self-efficacy which has been found to predict behaviour change (Thornton et al., 2021). The study hypotheses were the following: 1) The intervention and study design would be feasible and acceptable in a community context; 2) Participants in the intervention group would

have lower scores on the primary outcome of fatigue (MFI-20), higher on the FACIT-13, and lower on secondary measures of CrF compared to the wait-list controls.

Methods

Study Design & Randomization

This 1:1 randomized controlled trial (RCT) pilot used a type-2 hybrid effectiveness-implementation design (Curran et al., 2012; Landes et al., 2019) to compare a brief psychoeducational intervention for CrF to a wait-list control group in a community support provider setting in Ottawa, Canada. In this design, equal weight is given to clinical and implementation outcomes of an intervention. This design is appropriate when there is scientific evidence supporting a psychoeducational intervention for CrF but significant barriers to implementation in routine care exists (or are anticipated) (Curran et al., 2012; Johnson et al., 2020). The inclusion criteria included adults of both sexes a) at least 18 years of age, b) received a cancer diagnosis, c) completed primary cancer treatment, d) self-identified as experiencing CrF, e) not experiencing any unmanaged/undermanaged mental health disorder, and f) fluent in English. Inclusion criteria were assessed during a telephone intake. After agreeing to participate in the study and signing a written informed consent, participants were randomized to either the intervention or wait-list control group. The pilot RCT was approved and monitored by the University of Ottawa (#H-11-21-7124) and the Ottawa Health Science Network (#20220190-01H) research ethics boards. Recruitment began in December 2021 and participant follow-up assessments were completed by February 2023. The trial was registered as a clinical trial NCT05409638 in June 2022. This manuscript follows the Consolidated Standards of Reporting Trials (CONSORT) recommendations (Schulz et al., 2010).

The overarching project was guided and planned using the KTA framework (Graham et al., 2006), with *adaptation of knowledge to the local context* and *identification of barriers* presented in Rutkowski et al. (2024). The pilot RCT was built on these previous findings and captures the KTA stages of *selection/tailoring of intervention*, *monitoring knowledge use*, *evaluating outcomes*, and *sustaining knowledge use* (See Appendix I for a visual of how the KTA model was used). The RE-AIM framework was used to further guide the evaluation of this implementation. The RE-AIM framework captures reach (i.e., whether the target population has been reached), effectiveness (i.e., impact of intervention on outcomes), adoption (i.e., the portion of individuals from an organization who can deliver the program), implementation (i.e., consistency of delivery, costs) and maintenance (i.e., the extent the program becomes a part of routine care) (Glasgow et al., 2019). However, considering the pilot nature of this study, effectiveness of the program cannot be established, instead preliminary clinical outcomes will be presented.

Randomization and Blinding

Eligible participants were randomly assigned to either a brief 4-week virtual intervention for CrF or wait-listed for the next scheduled CrF group (on average scheduled 8-10 weeks later). Randomization was conducted once enough participants (n=15-20) were recruited to fill the intervention and wait-list groups. This process was repeated 3 times to create 4 groups. The allocation ratio was 1:1 and was performed by SL using an online virtual randomization program. Participants then received an email from NR notifying them of their group assignment and asked to complete baseline measures. Due to the nature of the study, it was not possible to blind the participants or those responsible for delivering the intervention to group assignments.

Community Partnership and Patient Advisory Board

The researchers leading the pilot RCT partnered with a local community cancer support provider, a non-profit organization that offers programming for individuals living with and beyond cancer in the Ottawa region. Members of the research team and community interest holders engaged in collaborative decision making during the design to meet the needs of the organization during the adaptation and implementation of the CrF program (see Appendix X for the program logic model). In addition, a patient advisory board was created. The board was comprised of two men and two women (ages: 18, 35, 45, and 58 years) with lived experiences of CrF and varied cancer histories. Members were recruited from the Ottawa Cancer Foundation and the Ottawa Hospital Patient and Family Advisory Council (see Appendix XIII for terms of reference for the patient advisory board). Members of the board met with the research team six times between May 2021 and November 2021. The patient advisory board provided feedback on the intervention (i.e., content, patient workbook), plans for implementation and evaluation (e.g., recruitment strategies, data collection methods), and received updates as the research study progressed (see Appendix XIV for full timeline and summary of feedback).

Sample/Participants

Participants were recruited primarily in the community through social media, community allied healthcare provider referrals (i.e., psychologists, cancer coaches), family health team newsletters, and local cancer support groups. Other recruitment strategies included posters at the largest cancer centre and referrals from hospital staff. Adults were asked to contact the research team by email; those who did were emailed additional information on the pilot RCT, an informed consent form, and asked to provide their availability for a telephone call with the lead researcher, NR, to review the consent form and assess eligibility. Participants were asked to sign a separate

written consent form if they wished to participate in the focus groups (See Appendices XVIII-XXI for recruitment and consent forms).

Intervention

The CrF program is a brief manualized psychoeducational intervention delivered virtually over four 90-minute weekly sessions. The program was adapted from a brief in-person 4-week intervention for CrF originally designed and evaluated with a RCT with 94 breast cancer participants by Fillion et al. (2008) in Quebec City, Canada (Fillion et al., 2008). Dr. Lise Fillion provided the original therapist and patient manuals and consented to allow authors to use her CrF program as a structure for the program adaptation (L. Fillion, personal communication, December 10, 2020). See Appendix XV for a visual of the original workbook provided by Dr. Fillion. The program by Fillion et al. was selected in collaboration with the community partner who requested a) a group-based intervention and b) a shorter intervention of 4 weeks to ensure feasibility. The intervention offered several advantages including access to original materials, it was developed and evaluated based on the Canadian context, was a desired format and length and incorporated several desired components (i.e., education on fatigue, mindfulness components, physical activity components, & peer support) healthcare providers, patients, and community support providers had described during a needs assessment (Rutkowski et al., 2024). In addition, it combined psychoeducation, cognitive behavioral therapy, and physical activity, for which significant empirical evidence exists in the management of CrF (Mustian et al., 2017; Thong et al., 2020; Yuan et al., 2022). The authors translated the workbook from French to English, updated information on CrF, added new content (i.e., cognitive defusion), developed a clinician manual, accompanying presentation slides, and new participant workbook to help structure and facilitate

the intervention (see Appendices XVI & XVII for the progression of the workbook and final version).

The 4 group-based intervention sessions covered: (1) psychoeducation on CrF (i.e., contributing factors, CBT model of fatigue), self-monitoring, and progressive muscle relaxation, (2) sleep hygiene, physical activity, self-compassion, and activity pacing, (3) link between emotions and thoughts, ABC model of emotions, and challenging unhelpful thoughts, and (4) thinking traps, importance of social support, consolidation, and setting personal goals. In addition to the group sessions, participants were encouraged to complete weekly homework (See Table 2. for more detailed description of the program or contact corresponding author to access program materials).

Intervention Provider and Training

Four sessions were facilitated by a registered nurse who had additional training and work experience as a cancer coach and group facilitator. Due to the small scale of the partner organization as well as the COVID-19 pandemic which resulted in staff reductions, one registered nurse was trained to deliver the program, compared to the planned 3 to 5 therapists before the pandemic. Group facilitator training was self-led by reviewing the comprehensive therapist manual, additional readings provided by researchers to support learning, and supervision with NR and SL. Supervision was provided on an as needed basis but at least once per group. All sessions were video recorded for review by the research team for fidelity throughout the trial (See Appendix XXXII for fidelity checklist); any adaptations made during the intervention's implementation were documented, and attendance was documented by group facilitator. Feedback was provided on an ongoing basis to the group facilitator based on the video recordings, satisfaction surveys, and verbal feedback from participants provided during focus groups.

Implementation Outcomes

Reach, defined as the number and representativeness of individuals willing to participate in a program, was calculated by the percentage of participants who contacted the research team divided by the total number of participants who registered and were randomized to the intervention group. Furthermore, the representativeness of the participants was analyzed based on sociodemographic and medical data. Recruitment and the source of referral was collected during baseline surveys and/or telephone screening. Adults were asked for reasons for not participating when possible. Methods for preliminary clinical outcomes for *Effectiveness*, defined as the impact of an intervention on important individual outcomes, are described in the next section. Additionally, participants were asked in the satisfaction survey about the perceived effectiveness of the program. *Adoption*, defined as the number of settings willing to initiate a program, was reported by the percentage of sites approached and in agreement to initiate the program. *Implementation*, defined as consistency and adherence to intervention delivery, included: fidelity, costs, adaptations, feasibility, and acceptability. For fidelity, half of the recorded sessions were randomly selected for a fidelity assessment. The program developer, NR, and a research assistant rated sessions for adherence based on a fidelity checklist developed by the research team which captured the manualized provision of the intervention for each session (see Appendix XXXII for fidelity checklist). For costs, costs were estimated based on national salaries for allied health providers and reported hours of preparation by the facilitator. For adaptations, all adaptations to the intervention during and after the study were recorded. Feasibility was assessed by intervention attendance, which was collected weekly by the group facilitator, ability to recruit participants within the timeframe, and survey completion. To promote participation, participants were phoned by NR to remind them of the program commencing if they had not arrived at the first session

and/or aid with any technological difficulties accessing the program during the first session. Acceptability was determined by the drop-out rate, an anonymous Likert-based satisfaction survey separate from the outcome measure questionnaire and optional focus group completed after the intervention to provide feedback on experience in the program (See Appendix XXXI for focus group semi-structured interview guide). Lastly, for maintenance, the research team maintained contact with the community support provider around the status of the program, any adaptations, ongoing evaluation efforts, and the number of groups offered yearly (Glasgow et al., 2019).

Measures

Clinical Outcome Procedures. To assess the effects of the intervention, one primary and five secondary clinical outcomes were assessed via questionnaires administered at baseline (before the intervention; T1), 5-weeks from baseline (after the intervention; T2), and 13 weeks after the intervention (T3).

Primary outcome. Fatigue was measured with the Functional Assessment of Chronic Illness Therapy-Fatigue Short Form (FACIT-F-13) and the Multidimensional Fatigue Inventory (MFI-20). The FACIT-F-13 is a 13 item questionnaire that assesses self-report fatigue and its impact on quality of life (Yellen et al., 1997). The FACIT-F-13 has been found to have excellent internal consistency, test re-test reliability, and places minimal burden on cancer populations to complete (Amarsheda & Bhise, 2022). Several items are reversed scored and the total score, ranging from 0-52, is calculated by summing all 13 items. Higher scores indicated better overall health and quality of life. Severe fatigue is defined by a score under 30 (Eek et al., 2021). See Appendix XXII for the FACIT-F-13. The MFI-20 is a 20 item questionnaire and evaluates five dimensions of fatigue: general, physical, reduced motivation, reduced activity, and mental fatigue (Smets et al., 1996). Total score ranging from 20-100 is calculated by summing items. Higher scores represent

more acute levels and burden of fatigue. For the purpose of this study, the total MFI-20 score was used. See Appendix XXIV for the MFI-20.

Secondary outcomes. The PROMIS Self-Efficacy for Managing Chronic Conditions-Short Form (PROMIS-SE) was used to measure self-efficacy. PROMIS-SE summed scores are transformed into a t-score. A t-score of 50 (SD 10) represents the average self-efficacy in populations with chronic health conditions (Gruber-Baldini et al., 2017; Lee et al., 2021). The Insomnia Severity Scale (ISI) was used to assess for insomnia (Savard et al., 2005). A score of 15 is recommended as the optimal cut-off for detecting clinical insomnia. A score between 8-14 indicates the patient is likely experiencing sleep difficulties (Savard et al., 2005). The PHQ-9 was used to assess depression. Scores range from 0-27, with 0-4 representing none or minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression, and 20-27 severe depression (Hinz et al., 2016). GAD-7 was used to assess anxiety (Esser et al., 2018). Scores range from 0-21, with 0-4 representing minimal anxiety, 5-9 mild anxiety, 10-14 moderate anxiety, and 15-21 severe anxiety. The Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) was used to assess physical activity. A score of ≤ 14 represents insufficiently active/sedentary, 14-23 represents moderately active, and a score of ≥ 24 represents active (Amireault et al., 2015). All measures been shown to have general valid scores among cancer populations (Amireault et al., 2015; Esser et al., 2018; Gruber-Baldini et al., 2017; Hinz et al., 2016; Savard et al., 2005). See Appendices XXV-XXII for secondary measures.

Additional measures. Participants completed a sociodemographic and medical history questionnaire at T1. This data was used to describe the sample and evaluate the representativeness of participants (see Appendix XXII for the sociodemographic questionnaire). An evaluation measure was adapted from the community partner to collect overall participant satisfaction and

implementation outcomes related to costs, barriers to access, and perceived effectiveness (See Appendix XXIX for measure).

Data Analyses

Data was examined for outliers and to determine data distribution. Outliers greater than ± 1.96 z-score were winsorized to the next extreme value. After confirmation of normality and homoscedasticity, a mixed analysis of variance (ANOVA) was performed for repeated measures in SPSS26 to evaluate the group by time interaction effect on fatigue and secondary outcomes. The means and standard deviations are presented in Table 3 and 4. Analysis was completed for both intention-to-treat and pre protocol (i.e., participants who completed questionnaires at all 3 timepoints as intended by protocol). For intention-to-treat, missing data were imputed by the last observation carried forward as advised by a statistical consultant (Twisk et al., 2020). For singular missing data, the mean of collected data was multiplied by the number of questions in the measure. Statistical significance was considered with an alpha of 5% ($p < 0.05$). Effect sizes were calculated using partial eta square (small effect size: 0.01, medium: 0.06, and large: 0.14) (Richardson, 2011). Cohen's D was calculated by hand by converting standard error (SE) into standard deviation (SD) from the pairwise comparisons data.

Focus groups were transcribed and analyzed in NVivo 14 software using thematic content analysis. Following Braun and Clarke's (2006) methods, data analysis began with reviewing all transcripts to become familiar with the data. This was followed by generating codes for relevant themes that emerged from the data. Subsequently, themes and sub-themes were developed from the codes, with each theme being carefully examined to ensure the coded information was appropriate. Next, the sub-themes and themes were clearly defined and labeled. Finally, representative quotes were identified to support the conclusions drawn (Braun & Clarke, 2006).

N.R. employed a phenomenological researcher stance, allowing her interpretation to be guided by her experience as a cancer survivor with lived experience of cancer-related fatigue, a clinician working with cancer populations, and a psychosocial oncology researcher (Frechette et al., 2020; Olmos-Vega et al., 2022).

Sample Size

Sample size calculations were based on the primary outcome (FACIT-F-13). G*power was used to calculate 80% statistical power at the $\alpha=.05$ level to detect small to medium effect sizes ($f=0.20$), as reported in the literature for psychoeducational interventions effects on fatigue (Karakuş et al., 2022). The minimal sample size was determined to be 42 participants; accounting for a 15% attrition rate, 50 participants were recruited. Post hoc power analysis was calculated and indicated a power of 82% to detect between-group differences with the sample size of 44 for intention-to-treat and a power of 73% for a sample of 36 for the per protocol analysis.

Results

Of 112 cancer survivors who contacted the research team, 50 (45%) were enrolled in the trial and randomized, while 13 were excluded and 49 declined to participate after receiving more information (See Figure 1 for additional information). The two groups did not differ significantly in sociodemographic or medical characteristics (see Table 1). The mean age of participants was 54 years ($SD=11.97$). The sample consisted primarily of White, university-educated, female participants and half had been diagnosed with breast cancer. The results are reported following the RE-AIM framework (See Appendix II for a figure of RE-AIM outcomes).

Implementation Outcomes

Reach

The enrollment rate was 45%. Participants who enrolled in the study reported high baseline levels of physical activity. In the Amireault et al. (2015) study which validated the GSLTPAQ in breast cancer survivors, 34% of participants' scores on the GSLTPAQ indicated they were active. In this study nearly half (48%) of participants reported to be active at baseline (See Table 3 for baseline scores). Recruited participants reported average self-efficacy, compared to others with chronic conditions (Health Measures, 2023). Within our sample, 84% were from the Ottawa region or surrounding rural area. Recruitment strategies were successful in reaching participants within the Ottawa region primarily through local cancer support groups and social media and less successful through hospital posters and staff. Reasons for not participating included time, other health issues, no longer being interested, and scheduling conflict particularly for younger participants as the intervention was offered during working hours. Furthermore, the representativeness of the participants was analyzed based on sociodemographic and medical data.

Preliminary Clinical Outcomes for Effectiveness

Intention-to-treat analysis showed preliminary evidence of improvements in quality of life on the FACIT-F-13 ($F_{2,84}=4.73, p=.015, \eta_p^2=.101$) and a reduction in self-reported fatigue on the MFI-20 ($F_{2,84}=6.18, p=.007, \eta_p^2=.128$) (see Table 2 and Figures 2 & 3). The results suggest the intervention may have moderate effects improving quality of life and reducing the symptom burden of fatigue. Significant moderate effects were additionally observed for depression ($F_{2,84}=3.67, p=0.044, \eta_p^2=.080$) and sleep ($F_{2,84}=3.98, p=0.022, \eta_p^2=.087$) outcomes, suggesting the program may positively impact mood and improve sleep. No significant differences were found between groups for physical activity, anxiety, or self-efficacy. In the pre-protocol analysis, depression and sleep outcomes did not reach statistical significance but fatigue outcomes remained

significant (see Table 3). See Table 5 for pairwise comparisons between each time point and Cohen's D effect sizes.

Adoption

Half of the 2 sites contacted were willing to participate in the development and delivery of the CrF intervention. The largest local cancer centre was initially approached as an interest holder and expressed interest, however declined due to a lack of resources and staff, citing the intervention would likely be unsustainable in the public setting. As this study was conducted during the COVID-19 pandemic and was a pilot study, we partnered with one local cancer community support provider to adapt the intervention and train staff. Adoption was made easier with interest holders' involvement from conception of the project who shared their needs, including wants of a shorter intervention of 4 weeks delivered in a group format, a standalone workbook for participants, presentation slides for the facilitator, and later in the study, assistance to facilitate the group (i.e., monitor chat, assist with technological issues).

Implementation

Fidelity. An allied health professional delivered four CrF groups between February 2022—February 2023. The average fidelity rating was 92%, suggesting the intervention was delivered as intended.

Cost. Based on our small-scale implementation, we would estimate the costs of implementing this intervention virtually in a community or hospital setting to be approximately \$2015. The cost break down is as follows: 10 hours allocated for self-led training and review of materials, 2 hours for group preparation, and 8 hours for group facilitation (adjusted for 120-minute sessions), totaling 20 hours at \$90 CAD an hour for an allied healthcare provider and \$215

for a yearly Zoom healthcare subscription. Costs would likely reduce to \$1025 for subsequent groups totaling 9 hours (8 for group facilitation and 1 hour of preparation time), costing approximately \$85 per participant in a group of 12 or \$51.25 for a group of 20.

For a hybrid delivery of the program, costs would likely double to \$3822. The cost break down is as follows: 10 hours allocated for self-led training and review of materials, 2 hours for group preparation, and 8 hours for group facilitation (adjusted for 120-minute sessions), totaling 40 hours at \$90 CAD an hour for two allied healthcare providers, \$215 for a yearly Zoom healthcare subscription, and approximately \$7 for electricity for 8 hours. Other costs not included here would be cost of a room rental if a center does not have one available to them.

Only 12% of participants in our study were unwilling to pay for an intervention if there would be a fee associated with the program, while 40% expressed a preference to pay less than \$50 (see Table 6), which could make the intervention self-sustaining for a group of 25 participants. However other costs may need to be considered such as space which may vary in costs if offering in-person, purchasing hybrid facilitating equipment, printing costs if wishing to supply the workbook (approximately \$40 per one booklet printed in colour and \$28 for a black or white version), or costs associated with local adaptation, research or program evaluation.

Adaptations. The patient advisory board provided detailed feedback throughout the development of the workbook and content, including wording, presentation, suggestions to increase accessibility for individuals experiencing vision impairment (i.e., larger font, contrasting colours), language barriers and lower reading levels (i.e., simpler language, less text), and additional examples for homework activities. During the study, only minor adaptations were made to the intervention materials based on feedback from participants during focus groups, including creation of fillable workbook forms, a printer friendly version of the workbook, and the addition

of a volunteer to aid the facilitator. However, after study completion, the program was changed to a hybrid format and increased from 90 to 120 minutes to allow for more group discussion, based on feedback from participants and the facilitator.

Feasibility. The study observed a high attendance rate with 89% (32/36) of participants completing all 4 sessions of the group. For survey completion, 36/44 (82%) completed all measures across the three time points. The study was able to recruit between 15-20 participants for each group session scheduled. These results suggest high feasibility for trial retention and intervention adherence.

Acceptability. Participants were asked to complete an anonymous satisfaction survey after completion of the intervention, which was completed by half of participants (n=25). Overall, 14 (56%) participants reported the program was very effective or extremely effective at meeting their needs, 9 (36%) reported it was moderately effective at meeting their needs, 22 (88%) reported they were satisfied or very satisfied with the program, and with 22 (88%) reporting they would recommend the program to others experiencing CrF. However, only 10 (40%) agreed or strongly agreed the 4-week program was the appropriate length (See Table 6). Suggestions for improvement from the survey and focus groups included longer sessions, more opportunities for discussion, extending the length of the program, and offering the program in the evening to accommodate individuals who work. The program experienced a low attrition rate with only 2 participants dropping out, one due to a family emergency and one for an unknown reason. Another participant was excluded from the study and seen individually due to severe cognitive impairment. These results suggest acceptability of the program.

In addition to the optional satisfaction survey, participants were invited to participate in focus groups to provide feedback on the program. Four focus groups with between 2-4 participants

were held (N=11) and 3 individual interviews (N=3). Themes emerged of “Benefits and takeaways of the program”, “Satisfaction”, and “Challenges and Suggested Improvements”. For “Benefits and takeaways of the program”, several subthemes emerged including: *accessibility, referencing resource materials, building awareness and knowledge, learning from peers, making changes, normalization and shared experience*. For “Challenges and Suggested Improvements”, subthemes included: *longer program desired, more time for connection and sharing, informational overload, downfalls of virtual, timing of the program, and group dynamics and mismanaged expectations*. See Table 7 for qualitative excerpts for each theme and subtheme.

Maintenance

Two years after implementation, the program continues to be offered by the community support provider. It has been offered twice since the completion of the study and has continued to collect participant satisfaction outcomes which indicate high rates of satisfaction among participants. The program was changed by the community partner to be offered in a hybrid format (virtual and in-person) and increased from 90 minutes to 120 minutes to allow more time for group discussion based on participant feedback. The intervention is planned to be offered twice yearly. Additional staff have been trained to offer the program to ensure long-term sustainability. The program has experienced high enrollment numbers with approximately 25 participants enrolled in each group (approximately half attending in person). See Appendix XXXIII for additional outcomes on program satisfaction collected by community partner.

Discussion

This study used the KTA framework and a hybrid type-2 implementation-effectiveness randomized design to implement a brief 4-week psychoeducational intervention for CrF in a

community context. This design provided an opportunity to partner with providers and end-users to prioritize their needs, which may have contributed to higher satisfaction among end-users, community partners, and facilitated longer term implementation (Johnson et al., 2020; Landes et al., 2019; Pearson et al., 2023). Psychoeducational interventions effectiveness for CrF has been well documented in the literature and may provide an opportunity for accessible and cost-effective programming for individuals struggling with CrF (Fabi et al., 2020; Howell et al., 2015; Thong et al., 2020; Yuan et al., 2022). In line with our hypothesis and similar studies (Karakuş et al., 2022), this study's preliminary clinical outcomes suggest the CrF psychoeducational intervention may have a moderate impacts on fatigue, sleep, and mood. The intervention was successfully implemented within a community context and demonstrated being feasible and acceptable with the limited sample.

Evidence-based guidelines for CrF and strong empirical evidence for the management of CrF have been well established, resulting in an important shift to 'real-world' implementation of interventions into cancer care (Pearson et al., 2023). However, this process has been slow with only six studies recently having been identified as evaluating the implementation of interventions for CrF (Agbejule et al., 2021). Significant barriers and challenges to the implementation of interventions for CrF have been reported including lack of knowledge among healthcare providers, costs, and time constraints (Jones et al., 2021; Pearson et al., 2023; Pearson et al., 2017; Rutkowski et al., 2024). This study employed a knowledge translation strategy that involved interest holders in the design and delivery of the CrF program (i.e., patient advisory board, community partners, and end-users). Through careful consideration, planning, partnership, and patient involvement, a successful implementation of an intervention for CrF in a community context was achieved. Prior studies have recommended the creation of user-friendly resources and materials for CrF

programming due to time constraints among busy healthcare providers (Pearson et al., 2023). Patient centered materials were created with the guidance of a patient advisory board and community partner to ensure end-users and facilitator needs were met. Providers offered input on additional necessary materials to aid with the facilitation of the group, ensuring ease, and comfort during group provision. A prior needs assessment helped guided the selection of an intervention and anticipate and plan for barriers in the local context (Rutkowski et al., 2024).

A local cancer center that is part of an academic hospital was approached initially in this study, however due to concerns over costs and human resources they were unable to commit to the long-term maintenance of the intervention. Given the significant challenges with healthcare provider knowledge, cost, and time in public settings, it may be perhaps more sustainable to continue to implement CrF programming in community contexts, as has been done for exercise interventions for cancer populations (McNeely et al., 2022). The Alberta Cancer Exercise (ACE) program in Alberta, Canada is another example of prioritizing implementation and effectiveness through hybrid designs (McNeely et al., 2019). Engaging and partnering with local community cancer support providers may be a possible solution and was found to be effective and beneficial for this study. However, community cancer support providers also face challenges with funding which may place some costs on patients to ensure sustainability. Costs have been identified as a significant barrier to CrF programming, however costs have often been unreported in CrF implementation studies despite being critical to a program's long term sustainability (Agbejule et al., 2021). The cost of offering the virtual psychoeducational intervention was approximately \$51 CAD per person for a 20-person group, with participants indicating they would be open to paying a small fee to participate. If divided between patients and centers, it may help the program remain self-sustaining.

Limitations

One of the limitations of this study was that participants were asked to complete baseline measures after randomization, potentially introducing bias. As well, there was higher attrition for the wait-list control group. Individuals who self-selected for the study reported high baseline levels of physical activity, suggesting these individuals were already taking active measures to manage their fatigue prior to enrollment. This may highlight a challenge of recruiting individuals who would likely benefit more from an intervention for CrF and are struggling to initiate behavioural change. Another challenge was sampling as the sample consisted primarily of White, well educated, high socioeconomic status, women with a history of breast cancer, which may limit generalizability of findings. This is a significant limitation and weakness in the recruitment for this study, as CrF is found across genders, cancer types, and diverse individuals. Indeed, a recent meta-analysis reported that moderate to severe fatigue levels were highest in data from Asia (Kang et al., 2023). Clinical outcome results should be interpreted with caution due to the small sample size, particularly as partial eta squared can overestimate effects sizes in small samples, and these outcomes will need to be replicated in a larger RCT.

Future directions

Based on participant feedback, session length was increased from 90 minutes to 120 minutes to allow for more group discussion and cohesion; as this change was made after study completion, evaluation of this longer duration is warranted. It may be important to consider offering different times for the intervention to accommodate younger individuals experiencing CrF, as this was noted several times as a barrier by those of working age. Cancer centres and community support providers may have shifted back to in-person programming, such as the community partner on this project, therefore evaluation of a hybrid or in-person provision of the

intervention may be beneficial to continue to meet the evolving needs and preferences of cancer survivors. In future studies, it may be beneficial to explore recruitment strategies to increase enrollment and explore reasons for nonparticipation of marginalized/diverse groups and men.

Conclusion

A brief group-based psychoeducational intervention for CrF appears to be a feasible and acceptable intervention in a community context with the limited sample. Early and ongoing involvement of a patient advisory board and community partner may help to ensure an intervention meets the needs of end users and providers. A hybrid type-2 effectiveness-implementation design provided an opportunity to tailor the intervention to the real world while assessing implementation and clinical outcomes simultaneously. Overall, offering a brief psychoeducational program for CrF shows promise in being a cost-effective way to reduce the symptom burden of fatigue and address an important unmet need among individuals living with and beyond cancer.

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Table 1. Sociodemographic and Medical Characteristics of Participants

Characteristics	Total (N=44) No. (%)	Control (N=21) No. (%)	Intervention (N=23) No. (%)	P
Age, M (SD)	54.10 (11.97)	56.14 (13.12)	52.22 (10.75)	.282
Gender				
Female	42 (95)	21 (100)	21 (91)	
Male	2 (5)		2 (9)	
Race				
White	41 (93.2)	20 (95.2)	21 (91.3)	.912
Non-White	3 (6.8)	1 (4.8)	2 (8.6)	
Education				
High School	1 (2.3)		1 (4.3)	.689
College/Technical	8 (18.2)	4 (19)	4 (17.4)	
University or Graduate	35 (79.5)	17 (77)	18 (78.3)	
Marital Status				
Married or living with partner	32 (72.7)	17 (81)	15 (65.2)	.808
Single, divorced, separated, or widowed	12 (27.3)	4 (19)	8 (34.8)	
Income				
<\$40,000	4 (9.3)		4 (17.3)	.206
\$41,000-60,000	6 (14)	3 (14.3)	3 (13)	
\$61,000-80,000	5 (11.6)	3 (14.3)	2 (8.7)	
\$81,000-100,000	4 (9.3)	2 (9.5)	2 (8.7)	
>\$100,000	14 (32.5)	7 (33.3)	7 (30.4)	
Prefer not to disclose	10 (23.3)	6 (28.6)	4 (17.4)	
Cancer Type				
Breast	24 (54.5)	11 (52.4)	13 (56.5)	.644
Blood	5 (11.4)	2 (9.5)	3 (13)	
Gynecological	5 (11.4)	3 (14.3)	2 (13)	
Other	10 (22.7)	5 (23.8)	5 (17.5)	
Cancer Stage				
0/I	14 (33.3)	6 (28.6)	8 (34.8)	.840
II	11 (26.2)	6 (28.6)	5 (21.7)	
III	11 (26.2)	5 (23.8)	6 (26.1)	
IV	6 (14.3)	3 (14.3)	3 (13)	
Prior cancer diagnosis				
Yes	9 (20.5)	4 (19)	5 (21.7)	.830
No	35 (79.5)	17 (81)	18 (78.3)	
Months since treatment completion				
<6 months	23 (52.2)	12 (57.1)	11 (47.8)	.967
<1 year	5 (11.4)	3 (14.3)	2 (8.7)	
1 year+ (range 1-7+ years)	16 (36.4)	6 (28.6)	10 (43.5)	
Currently taking medication				
Yes	8 (18.2)	3 (14.3)	5 (21.7)	.533
No	36 (81.8)	18 (85.7)	18 (78.3)	
Other chronic illness				
Yes	16 (37.2)	10 (47.6)	6 (26.1)	.176
No	27 (62.8)	11 (52.4)	16 (69.6)	
History of insomnia				
Yes	14 (33.3)	7 (33.3)	7 (30.4)	1.00
No	28 (66.6)	14 (66.7)	14 (60.9)	
History of depression				
Yes	18 (41.9)	10 (47.6)	8 (35.8)	.466
No	25 (58.1)	11 (52.4)	14 (60.9)	

Location				
Ottawa/Gatineau	27 (62.8)	13 (61.9)	14 (60.8)	.707
Rural community outside of Ottawa	9 (20.9)	6 (28.6)	3 (13)	
Other	7 (16.3)	2 (9.5)	5 (21.7)	

Note. The sum of individual counts may not add up to the total number of participants because of missing information for certain variables.

Table 2. Description of CrF program session content**Session One**

Psychoeducation on the dimensions of CRF (i.e., physical, emotional, cognitive), possible causes of CRF (i.e., emotions, cognitive distortions, sleep, etc.), CBT model of fatigue, and tools for behavioural change (i.e., building awareness through self-monitoring & progressive muscle relaxation).

Homework: Self-monitoring of fatigue, sleep, and relaxation. Practicing progressive muscle relaxation once per day for 20 minutes.

Session Two

Psychoeducation on sleep hygiene, boom and bust cycle, importance of physical activity, exercise guidelines, time management, & goal setting (i.e., SMART goals). Tools learned include self-compassion, physical activity goal setting, and activity pacing.

Homework: Self-monitoring fatigue, sleep, relaxation. Setting a SMART goal for physical activity and completing it. Practicing progressive muscle relaxation once per day for 20 minutes.

Session Three

Psychoeducation on the relationship between thoughts and emotions, the ABC of emotion (i.e., A=Activating Event, B=Belief, & C=Consequence), purpose of emotions, risk factors/vulnerability for stronger emotions, the vicious cycle of negative emotions and how to break that cycle. Tools learned include the ABC Model of emotions and challenging thoughts.

Homework: Self-monitoring of fatigue, sleep, relaxation & physical activity (setting goals). Continuation of physical activity goal. Completing the ABC of emotions worksheet. Practicing progressive muscle relaxation once per day for 20 minutes.

Session Four

Psychoeducation on cognitive distortions, distancing from unhelpful thoughts, the importance of social support, review of the CBT model of fatigue, integration of knowledge, and reflection. Tools include cognitive defusion and setting personal goals.

Homework: Setting personal goals for relaxation, physical activity, ABC's of emotion and social support. Continue practicing progressive muscle relaxation, physical activity and distancing from unhelpful thoughts.

Table 3. Intention-to-treat analysis for primary and secondary outcomes

	Baseline	5 weeks	13 weeks	<i>Time*</i> <i>Group</i>		
	Mean (SD)	Mean (SD)	Mean (SD)	<i>F</i>	<i>P</i>	η^2_p
Primary Outcomes						
FACIT-F-13						
Wait-list (N=21)	25.62 (6.90)	23.45 (7.81)	25.45 (7.80)	4.73	0.015*	0.101
Intervention (N=23)	22.91 (7.61)	24.31 (7.78)	28.04 (8.29)			
MFI-20						
Wait-list	68.29 (12.65)	64.90 (14.08)	63.46 (14.08)	6.18	0.007*	0.128
Intervention	73.37 (11.69)	62.78 (14.32)	58.82 (14.18)			
Secondary Outcomes						
GAD-7						
Wait-list	8.05 (5.73)	6.57 (5.75)	5.94 (4.79)	0.51	0.599	0.012
Intervention	9.04 (5.60)	6.78 (5.70)	6.01 (4.14)			
PHQ-9						
Wait-list	10.19 (5.09)	8.33 (3.69)	8.52 (4.06)	3.67	0.044*	0.080
Intervention	12.30 (4.61)	8.00 (4.91)	7.70 (4.81)			
ISI						
Wait-list	12.43 (5.10)	10.66 (5.46)	10.56 (4.41)	3.98	0.022*	0.087
Intervention	15.22 (7.02)	12.19 (6.99)	10.39 (6.63)			
PROMIS-SE						
Wait-list	42.35 (6.78)	44.74 (7.32)	45.27 (9.14)	1.26	0.286	0.029
Intervention	40.34 (6.39)	43.33 (4.64)	46.11 (8.53)			
GSLTPAQ						
Wait-list	29.55 (20.23)	29.81 (17.27)	32.21 (20.76)	0.90	0.389	0.021
Intervention	30.80 (19.23)	36.65 (21.28)	38.52 (23.85)			

Table 4. Pre protocol analysis for primary and secondary outcomes

	Baseline	5 weeks	13 weeks	<i>Time*</i> <i>Group</i>		
	Mean (SD)	Mean (SD)	Mean (SD)	<i>F</i>	<i>P</i>	η_p^2
Primary Outcomes						
FACIT-F-13						
Wait-list (N=17)	24.94 (7.13)	22.38 (7.92)	24.85 (8.17)	5.95	0.005*	0.149
Intervention (N=19)	22.47 (7.06)	24.63 (7.70)	29.16 (7.90)			
MFI-20						
Wait-list	69.71 (12.27)	65.71 (14.09)	63.92 (14.17)	4.44	0.023*	0.115
Intervention	72.24 (12.23)	61.89 (14.65)	57.11 (14.02)			
Secondary Outcomes						
GAD-7						
Wait-list	7.88 (5.41)	6.35 (5.50)	5.51 (4.13)	0.172	0.842	0.343
Intervention	8.21 (5.56)	6.16 (5.91)	5.23 (3.85)			
PHQ-9						
Wait-list	10.06 (4.62)	8.29 (3.57)	8.53 (4.03)	2.85	0.079	0.077
Intervention	11.47 (4.50)	7.42 (4.86)	7.05 (4.67)			
ISI						
Wait-list	13 (5.18)	10.87 (5.79)	10.75 (4.55)	2.80	0.068	0.076
Intervention	14.63 (7.49)	11.81 (7.37)	9.63 (6.75)			
PROMIS-SE						
Wait-list	41.44 (5.16)	44.29 (7.31)	44.30 (8.97)	1.51	0.230	0.043
Intervention	41.05 (6.13)	44.03 (4.63)	47.25 (8.82)			
GSLTPAQ						
Wait-list	29.66 (20.34)	29.94 (16.37)	33.09 (21.02)	0.552	0.537	0.016
Intervention	29.08 (17.89)	35.00 (19.37)	37.26 (22.89)			

Table 5. Pairwise comparisons and effect sizes for primary and secondary outcomes

Primary Outcomes		Mean Difference (95% CI)	<i>Cohen's D</i>	<i>P</i>
FACIT-F-13	T1 & T2	.39 (-1.39, 2.16)	0.07	.662
	T2 & T3	-2.87 (-4.33, -1.40)	-0.60	.000*
	T1 & T3	-2.48 (-4.52, -.45)	-0.37	.018*
MFI-20	T1 & T2	6.99 (4.01, 9.96)	.71	.000*
	T2 & T3	2.70 (.66, 4.75)	.40	.011*
	T1 & T3	9.69 (6.21, 13.17)	.85	.000*
Secondary Outcomes				
GAD-7	T1 & T2	1.90 (.86, 2.88)	.56	.001*
	T2 & T3	.70 (-.24, 1.64)	.23	.141
	T1 & T3	2.57 (1.56, 3.58)	.77	.001*
PHQ-9	T1 & T2	3.08 (1.89, 4.27)	0.79	.000*
	T2 & T3	.06 (.40, .89)	0.02	.888
	T1 & T3	3.14 (1.70, 4.57)	0.66	.000*
ISI	T1 & T2	2.40 (1.31, 3.49)	0.67	.000*
	T2 & T3	.95 (-.03, 1.92)	0.30	.056
	T1 & T3	3.35 (2.23, 4.47)	0.91	.000*
PROMIS-SE	T1 & T2	-2.689 (-4.35, -1.03)	-0.49	.002*
	T2 & T3	-1.65 (-3.44, .14)	-0.28	.069
	T1 & T3	-4.34 (-6.58, -2.10)	-0.59	.000*
GSLTPAQ	T1 & T2	-3.06 (-6.40, .29)	-0.28	.072

T2 & T3	-2.14 (-6.91, 2.64)	-0.14	.371
T1 & T3	-5.19 (-10.70, .32)	-0.29	.064

Table 6. Implementation outcomes for the cancer-related fatigue program

	N (%)
Overall satisfaction with the program	
Very satisfied	14 (56)
Satisfied	8 (32)
Neither satisfied nor dissatisfied	1 (4)
Dissatisfied	2 (8)
The program was an appropriate length (i.e., 4 weeks)	
Disagree	8 (32)
Neither agree nor disagree	7 (28)
Agree/Strongly Agree	10 (40)
Would you recommend this program to other cancer survivors?	
Yes	22 (88)
No	3 (12)
Ideal timing for the program to be offered	
Upon diagnosis	5 (20)
During treatment	2 (8)
After treatment	17 (68)
Preference for program being offered virtually	
Neither agree nor disagree	6 (24)
Agree	5 (20)
Strongly Agree	14 (56)
Impact of income on ability to access services after treatment	
Yes	3 (6.8)
Somewhat	9 (20.5)
No	31 (70.5)
If you had to pay to attend this group, would it affect your decision to participate?	
Yes	8 (18.2)
Maybe	25 (56.8)
No	10 (22.7)
Ideal cost of the program	
<\$50	10 (40)
\$50-75	7 (28)
\$75-100	3 (12)
\$100-150	2 (8)
Unwilling to pay	3 (12)
Comfort with technology	
Yes	26 (59.1)
Somewhat	17 (38.6)
Experienced barriers accessing this program	
Yes	1 (2.3)
No	42 (95.5)
<i>Note.</i> HCP = Health care providers	

Table 7. Qualitative excerpts from focus groups after completion of the CrF Program

Theme	Subtheme	Quote
Benefits and takeaways from the program	Accessibility	<i>“I think when it's virtual, it's much easier to not skip it. And I think for the most part, everybody, almost everyone showed up every week” -Individual Interview</i>
		<i>“You don't have to worry about parking. I don't have to drive. I don't really have to be concerned about being late or getting stuck in traffic... you don't have to worry about the weather...my immune system was more compromised, then I wouldn't have to worry about someone in the room, maybe making me sick unintentionally” -Individual Interview</i>
		<i>“We're getting people from other regions and other areas that would not have made the physical trip if we were doing something face-to-face...I think you would have a really hard time insisting that people come face to face once a week for a two-hour session. People would probably fall off...” –Fall Focus Group 1</i>
		<i>“And it would be very draining for me, energy wise. So having it virtual it's very good in that respect.” –Winter Focus Group</i>
		<i>“I returned to work probably a lot faster than I ought to have, but I could do [the program] because it was virtual...” –Fall Focus Group 2</i>
	Referencing Resource Materials	<i>“I'm looking forward to going back through the stuff a little bit more slowly and carefully. And I think you don't have to remember everything that was said during the discussion because you have the resources. I thought it was excellent. And as I said, like so comprehensive, like a wide variety of areas that were covered that are related to fatigue –Fall Focus Group</i>
		<i>“Certainly, the workbook was invaluable to be able to go back and read again or clarify something that you wanted to understand a little better.” – Spring Focus Group</i>
	Building awareness and knowledge	<i>“I hadn't really thought about the emotions, like managing your emotions honestly, like obviously, we all have lots of emotions, whether we're going through chemo or not. But I didn't really think about that in terms of impacting fatigue. That was a big one for me”. –Fall Focus Group 1</i>
		<i>“I think to me the first step is just being aware of stuff...more aware of my sleep habits and being more aware of the amount of exercise I am or am not getting.” –Fall Focus Group 1</i>
		<i>“And the knowledge built on itself. So, we understood it better as we went along, and I found that very helpful.” –Winter Focus Group</i>

	<i>"I really like connecting fatigue to all the other issues that we're dealing with from treatment. Basically, the brain fog, the sleep issues, pain in some cases, anxiety, neuropathy, all the things that sort of pulled it all together for me. We've been dealing with a lot of those things separately."—Winter Focus Group</i>
Learning from Peers	<i>"Some of the other participants were giving examples of what they've done or not done or experienced. And I found that to be sometimes equally as insightful as the course itself." — Individual Interview</i>
Making Changes	<i>"For me, the biggest takeaway was towards the end, the statement that said, is this thought helping me move closer to the life I want? Or is it moving me farther away? And that's the first time I've heard that and that really hit home to me..."—Winter Focus Group</i> <i>"That's what this course has done for me because I am now committed to doing that walking, which I wasn't."—Spring Focus Group</i> <i>These new little pieces that you gave us. I've been trying different ones, like when I've woken up in the middle of the night or if I'm struggling to go to sleep, and I found those very helpful—Fall Focus Group 1</i>
Normalization	<i>"I think just having that information and knowing that what I'm experiencing is normal and finding strategies to help with it and knowing that it's never going to be perfect."—Individual Interview</i>
Shared Experience	<i>I really like this group for including people with all different kinds of cancers...it's kind of good to know that there are other people with other cancers that are experiencing the same thing. —Fall Focus Group 1</i> <i>"Just hearing other people's stories and recognizing very much you're not alone."—Individual Interview</i> <i>"Realizing the shared experience among people that had very different cancer journeys, and we're also on different stages of their journey... I sit here in the house alone and it's easy to forget that other people are going through the exact same thing. So that that was that kind of solidarity, was very encouraging. — Individual Interview</i>
Satisfaction	<i>"I thought it was incredibly comprehensive, it covered a lot of variety of different kinds of approaches and strategies for dealing with fatigue, which I thought was fantastic...it's not just useful for people with fatigue, but for well really anyone —Fall Focus Group 1</i> <i>"Generally, I thoroughly enjoyed it. I thought [facilitator] did a terrific job presenting it. I felt all the information was really interesting. So generally, a very positive experience. —Spring Focus Group</i>

Challenges and Suggested Improvements	Longer Program Desired	<i>"The thoughts that I had were a two-hour session. And I know that some people probably would find two hours tiring because we're experiencing fatigue. But I think if you have at least a 10-minute break in the middle it would probably be OK"</i> –Fall Focus Group 1 <i>"And I would like the program to be longer. It's so short and sweet... We learned a lot but may not be able to grasp these skills in that time frame"</i> –Fall Focus Group 2 <i>"I almost think it was too much for a four-week program. I feel it should be six weeks"</i>—Spring Focus Group
	More time for connection and sharing	<i>"My biggest feedback is the discussion part. I think that was really shortened and I think there was a lot of value for us in the conversations"</i> –Fall Focus Group 1 <i>"I felt the debriefs were a little too short at the start of each week...but it was just that there might have been a greater chance to share experiences and learn from others or help others"</i> –Winter Focus Group <i>"...just have shorter information sessions because there are certain things maybe some of us would have wanted to talk more about, but there just wasn't that much time."</i> –Individual interview
	Information overload	<i>I 100% understand that when there's so much good info sharing it, I think it was like almost overwhelming."</i> –Fall Focus Group 1 <i>"I just found it all too much to remember."</i> –Spring Focus Group <i>"I had a really hard time when it ended trying to even just keep track of what it was, I was supposed to be doing...And so I'm not even sure I really remembered so much of the program".</i> – Winter Focus Group
	Downfalls of Virtual	<i>"...Just the not having the human interaction...like as much as it can be a positive but it's also a negative. You do feel the energy of a group when you're in a group setting, [not] when you're looking at a zoom..."</i>—Spring Focus Group <i>"...however, that social connection and those informal moments, you don't get those online"</i> –Individual Interview
	Timing of the Program	<i>"I think when you're a younger person with cancer. You already feel a bit isolated and a bit lonely...and then when you find out all those great programs for us, but you can't attend them because it's during the day when you have your kids, [or] when you have to go back to work because you haven't retired yet. It's kind of just makes it that much more isolating..."</i> –Individual Interview <i>"Hearing [about the program] in September and going, why the hell was this not available to me when I really needed it? Now it's just confirming stuff that I did or could have done more of...so I was dealing with my own personal frustration on the</i>

	<i>timing of it.” –Fall Focus Group 1</i>
Group dynamics and mismanaged expectations	<i>“I think that one of the biggest challenges for me was just with the diversity of experiences and cancers. I find, like there was often an interest from participants in going down a rabbit hole. And in our group, I think it was like gynecological cancers...it kind of started to almost feel like an oppression Olympic of who had the worst cancer or the worst prognosis.”</i> <i>–Individual Interview</i> <i>“When people started to kind of talk about things that were there were important to them and stuff like that...that's really good, but we've got to get on to this next thing. We've got to get on to this next thing... I could see in her eyes that she wasn't intending to be dismissive but that's what was happening...”</i> <i>–Fall Focus Group 2</i>

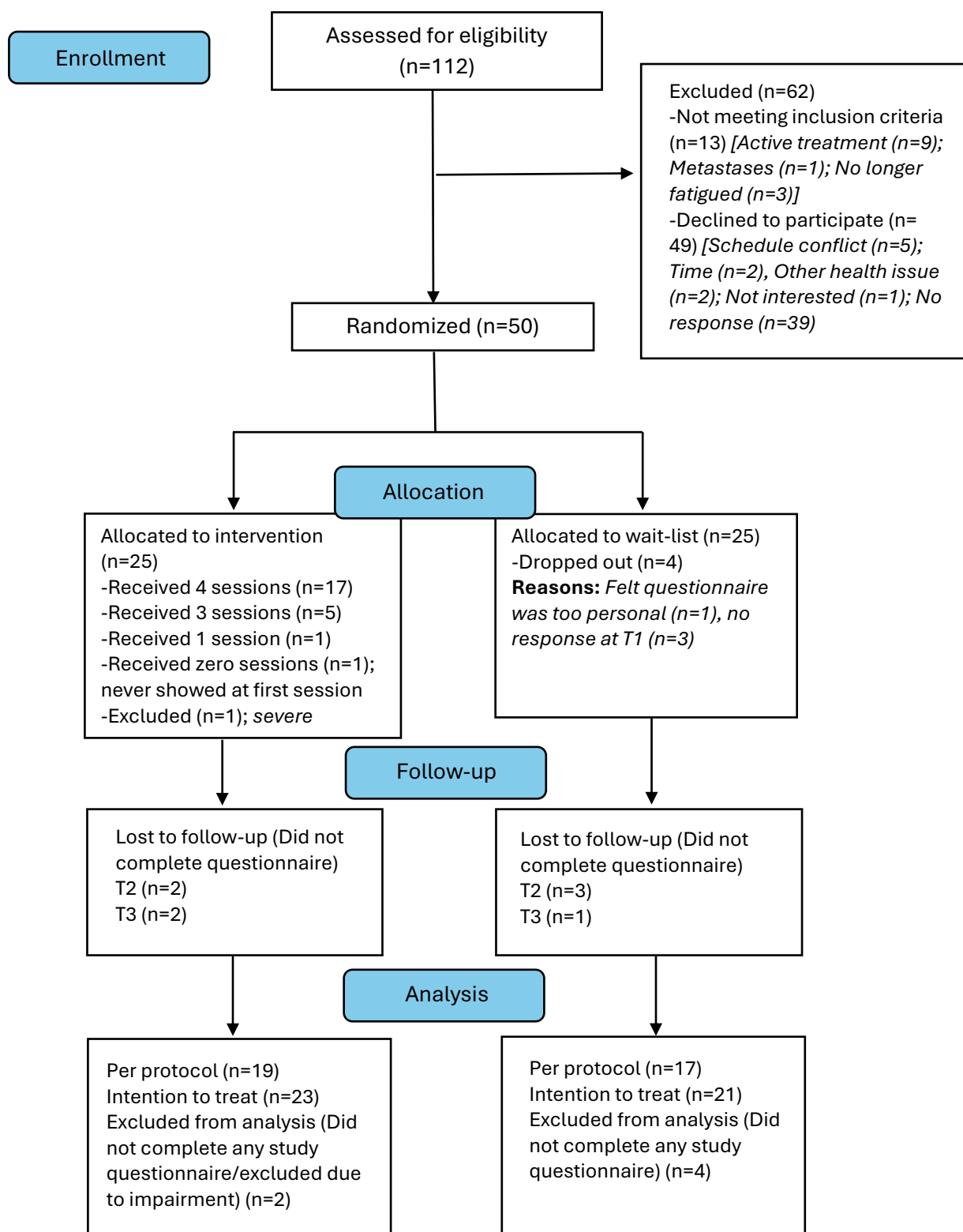
Figure 1. Consort Diagram

Figure 2. FACIT-F-13 scores change over time between intervention and control groups for intention-to-treat analysis

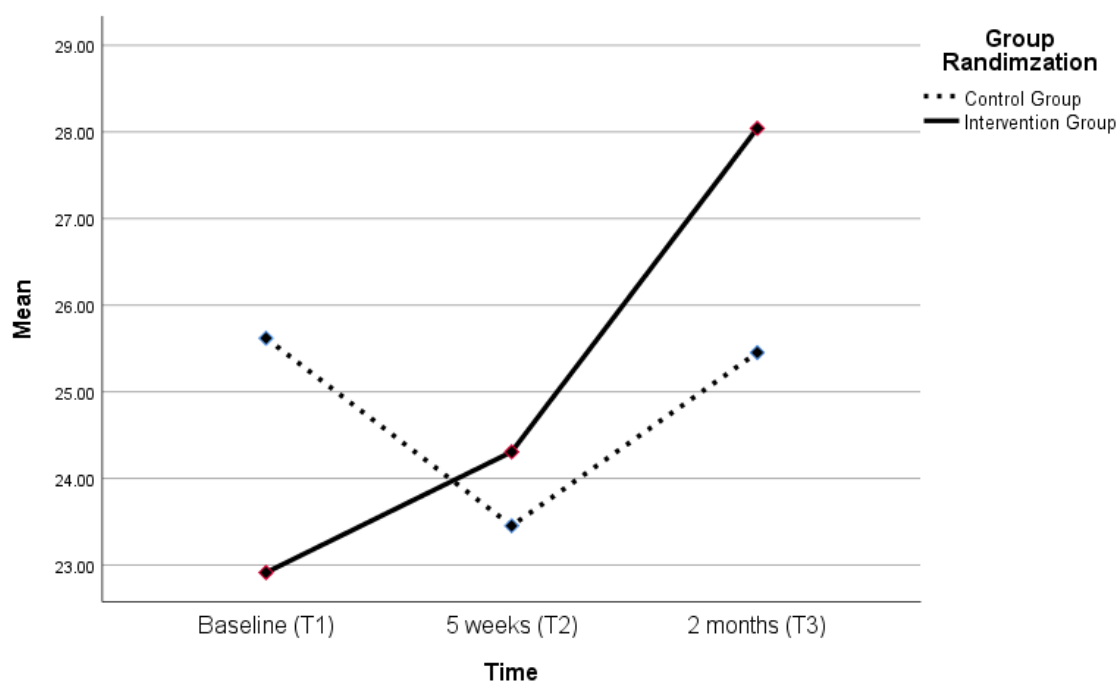
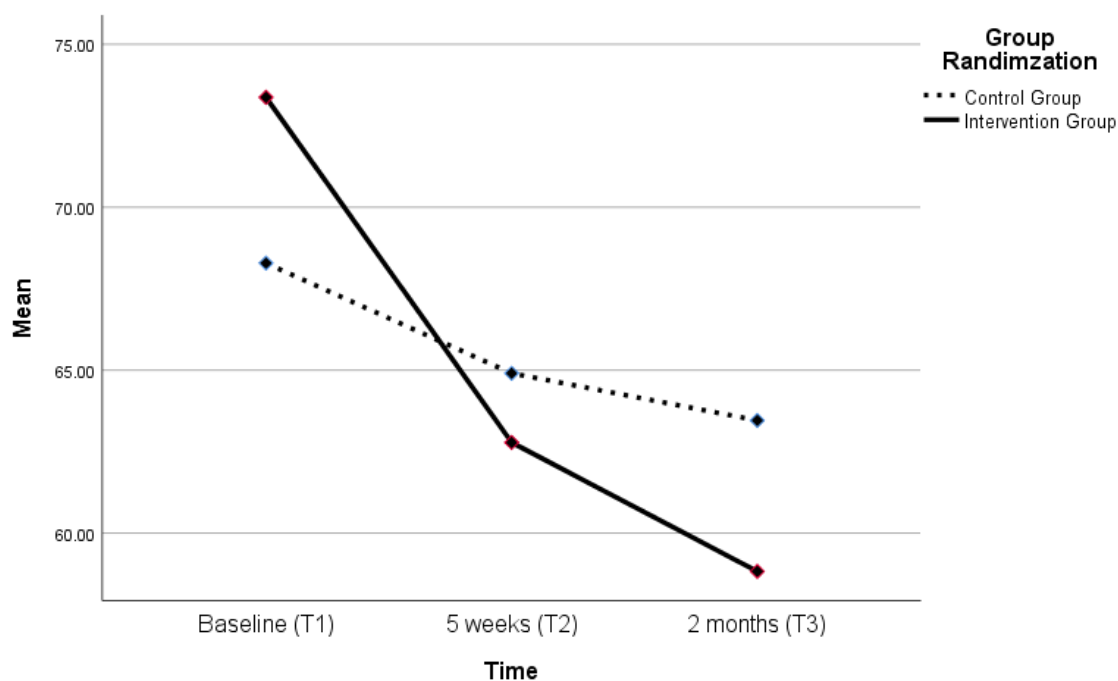


Figure 3. MFI-20 scores change over time between intervention and control groups for intention-to-treat analysis



General Discussion

Thesis Rationale

CrF is a prevalent post treatment side-effect that affects approximately a third of individuals living with and beyond cancer, impacting patients' quality of life, mental well-being, social integration, and return to work (Al Maqbali et al., 2021; Jones et al., 2016, 2023). Despite the significant impacts of CrF on individuals, the availability of evidence-based guidelines for its management and a significant body of literature on several effective treatment options, limited support services are available for individuals experiencing CrF in Canada (Berger & Mooney, 2016; Howell et al., 2015; Jones et al., 2021). Implementation of interventions for the management of CrF have been lacking due to several identified barriers including lack of HCP knowledge, time constraints, costs, inefficient referral pathways, complex guidelines, and lack of user-friendly materials, among others (Jones et al., 2021; Pearson et al., 2023; Pearson et al., 2017; Rutkowski et al., 2024). A greater understanding of barriers to implementation of CrF assessment and management has been achieved over that last few years, however little research to date has focused on the implementation of interventions for the management of CrF that would directly benefit individuals experiencing fatigue (Agbejule et al., 2021; Pearson et al., 2023). Indeed, a recent study by Agbejule et al. (2021) found that only 6 studies have examined implementing interventions for CrF prior to 2020. This thesis' manuscripts used the KTA framework and engaged interest holders, a community cancer support provider, and patients to improve the implementation of a program for the management of CrF in a community context in Ottawa, Canada. The first study aimed to address KTA stages of *adaptation to local context* and *assessment of barriers* through qualitative methods (Graham et al., 2006). The perspectives of HCPs, CSPs, and patients (N=62) were gathered on the desired components of an intervention for CrF in the region and anticipated barriers

to its implementation and patient enrollment. The second study addressed the remaining KTA framework stages, including *selection/tailoring of an intervention to the local context*, *monitoring knowledge use*, *evaluation of outcomes*, and *sustaining knowledge use*. An intervention was adapted and implemented into the local context, shaped by feedback from providers and end-users, and evaluated implementation and clinical outcomes simultaneously through a hybrid effectiveness-implementation design. This general discussion will focus on reviewing the findings of these two studies, integrating these findings into current literature, and discussing the studies' limitations, behavioural change techniques, clinical implications, and future directions.

Study 1: Review of objectives and hypotheses

The manuscript entitled “An Ideal Intervention for Cancer-Related Fatigue: Qualitative Findings from Patients, Community Partners, and Healthcare Providers” is a qualitative study with 62 participants (16 patients, 32 healthcare providers [HCP], and 14 community support providers [CSP]). The goal of this study was to explore key interest holders' perceptions on desired components of a CrF intervention in the local context, addressing the KTA stage of *adaptation to local context*, and anticipated barriers to its implementation, addressing the KTA stage of *assessment of barriers*. This study was exploratory and phenomenological in nature; therefore, data guided the formation of themes, and no specific hypotheses were formed prior to analysis.

Study 1: Main Findings

This study found two overarching themes of “It takes a village” and “This will not be easy”. For the first theme, participants discussed provider, timing, and location of the intervention (anywhere, offered by anyone and everyone, and provided early and frequently through the cancer experience) and the components of an intervention they wanted (education, peer support, physical

activity, mind-body, interdisciplinary care, and co-ordination of care). For the second theme, patients, HCPs, and CSPs described several potential barriers to implementation, including patient barriers (i.e., patient variability, accessibility, online literacy, and overload of information) and systems barriers (i.e., costs, lack of HCP knowledge, system insufficiency, and time constraints). Overall findings suggested an unmet need for CrF programming and resources in the local context and provided guidance for what interest holders and patients were looking for in an intervention for CrF, as well as anticipated barriers for consideration.

The results of this study helped guide the remaining KTA action cycle. When deliberating on the *selection/tailoring of an intervention to the local context* with the community support provider, a group-based intervention was selected to allow for peer support that incorporated many of the reported desired components, including psychoeducation on fatigue, physical activity, and mind-body components (i.e., progressive muscle relaxation, cognitive defusion strategies like leaves on the stream). It was not possible to provide interdisciplinary care or co-ordination of care due to significant costs and difficulties with long-term sustainability. To address the accessibility barrier, the program was offered virtually and free of charge. As the program has begun to be offered in person, the community support provider is centrally located, offers free parking, and agreed to continue offering a virtual option to ensure accessibility. Further, the workbook was revised by the patient advisory board to ensure it was accessible for those with visual impairments (i.e., large font), fatigue and brain fog (i.e., short texts), and written simply for individuals with lower education or for whom English is a second language. To decrease the barrier of online literacy, a step-by-step document was created detailing how to navigate the workbook and resources. Additionally, the facilitator would open the virtual space early to provide support with technological issues and provide support after the session if needed to navigate the online

workbook. The lead researcher would also phone participants if late for the first session to aid with any difficulties logging on. To reduce overload of information, it was decided to offer the program to individuals once they have completed their treatment. Patient variability was a challenge as self-selected participants demonstrated high physical activity; therefore, this barrier will require more consideration and forethought for future studies. It was decided to partner with a community support provider as the public hospital cited similar system barriers identified in this needs assessment to implementation in their setting. However, to increase HCP knowledge around CrF, the information sheet for this study included the definition of CrF, references to clinical guidelines and effective treatments, and prevalence of CrF (Appendix XIX). Researchers also met with several interest holders at the local hospital to inform them of the availability of the CrF program and presented to several local cancer support groups.

Study 2: Review of objectives and hypotheses

The second manuscript entitled “A brief psychoeducational intervention for cancer-related fatigue in a community context: A hybrid type-2 effectiveness-implementation randomized controlled trial pilot study” presents the results of a pilot implementation and evaluation of a brief 4-week virtual intervention for CrF in a community context. The objective of this study was to examine clinical and implementation outcomes through a hybrid type II implementation-effectiveness randomized controlled trial pilot design. This study addressed KTA stages of *selection/tailoring of intervention, monitoring knowledge use, evaluating outcomes, and sustaining knowledge use* (Graham et al., 2006; Straus et al., 2013) and used the RE-AIM framework to evaluate outcomes of the implementation (Glasgow et al., 2019).

Study 2: Main Findings

The study's main findings were as follows 1) It was feasible to recruit participants within the study timeline; however it was challenging to recruit men, diverse populations, and individuals with cancer histories other than breast. Participants found it feasible to complete questionnaire packages across the three timepoints and the program experienced a high attendance rate with 89% of participants completing all 4 sessions. The study demonstrated high acceptability with a low dropout rate and high satisfaction ratings on the survey with 88% of participants reporting being satisfied or very satisfied with the program. 2) Participants in the intervention compared to the wait-list control group demonstrated statistically significant reduction in CrF on MFI-20 and a reduction in fatigues' impact on daily life on the FACIT-F-13 as hypothesized, however participants were on average still in the severely fatigued range for the FACIT-F-13. Longer-term follow-up is warranted to observe whether these possible improvements are maintained or improve further as participants practice strategies and possibly engage more in physical activity. 3) Participants in the intervention group compared to wait-list control showed evidence of a reduction in sleep and mood concerns in the intention to treat analysis but this result was not maintained in the pre protocol analysis. A larger sample size may be needed to determine the effects on these secondary outcomes. No significant difference was found for the remaining secondary outcomes (i.e., physical activity, self-efficacy, anxiety). 4) Implementation costs were found to be reasonable, approximately \$51 per participant for a group of 20. 5) The program was administered with a 92% fidelity rating, suggesting the intervention was administered as intended. 6) The KTA model provided an important framework that helped guide the implementation of this study and partnership with interest holders and patients likely contributed to high satisfaction ratings and long-term adoption and maintenance of the program. Overall, results suggest a brief 4-week virtual intervention in a community context is feasible and acceptable, KT strategies and partnership may

help address the knowledge to practice gap for CrF reducing barriers to implementation, and the intervention may be helpful in improving CrF, sleep, and depression, however a larger trial is necessary to replicate these findings.

Integration of Findings

Together, these studies highlight the possibility of addressing knowledge to practice gaps using the KTA framework and partnership with end-users to successfully implement a program for CrF in a community context, despite existing barriers. The difficulty of translating guidelines into practice is not limited to CrF. The ACSM has published clinical practice guidelines in 2010 (updated in 2019) for the prescription and delivery of exercise interventions in cancer populations which include the management of fatigue, however similar challenges exist to its translation into practice (Campbell et al., 2019; Schmitz et al., 2010). A study conducted at a cancer centre in Hamilton, Ontario in 2017 found that 80% of oncology care providers were not aware of exercise guidelines (Nadler et al., 2017). Further, similar barriers were identified to exercise guideline implementation including lack of knowledge on when or who to refer to exercise programs, organizational-level factors such as costs, and lack of time (Czosnek et al., 2021; Nadler et al., 2017). Yet, of note is that the ACSM has placed more consideration into its knowledge translation through the creation of the Move through Cancer registry that connects individuals in America with local exercise programs (American College of Sports Medicine, 2019) and researchers in the field began using hybrid designs over a decade ago (Beidas et al., 2014).

There continues to be an emphasize on demonstrating the efficacy of interventions through highly controlled research settings, that are well-funded and have the resources to provide extensive training to staff, which do not accurately reflect the real life conditions or barriers in healthcare or community settings (Czosnek et al., 2020). Indeed, many publications on CrF

continue to emphasize the need for more translation of research findings into practice, yet little has been done to move in this direction, instead more publications on the efficacy of already well-established interventions for CrF continue to be produced (Berger & Mooney, 2016; Pearson et al., 2017). Which begs the question of what the purpose of conducting such research is if it seldom becomes available to those who would benefit from it and does not result in improvements to existing clinical practice. In Canada, some researchers have moved towards more pragmatic study designs, such as using hybrid effectiveness-implementation designs (Curran et al., 2022). For example, the Alberta Exercise Program has prioritized widescale implementation in the province of Alberta using a hybrid design (McNeely et al., 2019). Costs have also been reported as a significant barrier, both for patients and for organizations. Studies implementing exercise programs have reported improved sustainability when providing services in the community free of charge (Czosnek et al., 2021).

Based on this study, hybrid designs and implementation models that incorporate community partners and patients in the process may help create programs that meet end-users needs and are more suited for real world implementation. Particularly, as researchers may create patient and provider materials that are too complex or do not consider accessibility for end-users, similarly to concerns expressed around the CrF clinical practice guidelines (Pearson et al., 2017). The creation of user-friendly materials has been suggested as strategy to increase the implementation of programming for CrF (Pearson et al., 2023). Partnership with a patient advisory board was instrumental in shaping the program and program materials to ensure their accessibility and applicability to individuals living with and beyond cancer. Further, the use of the KTA and RE-AIM framework provided guidance and consideration of the sustainability of the program from conception. From a research standpoint, it provided the forethought of what implementation

measures to collect, which are often reported or considered after study completion. The KTA model also promoted adaptation to local context, which encouraged us to have early conversations with community partners and cancer centres on what would be required in the short-term and long-term to sustain the program. This resulted in the largest cancer center in the area to recognize and acknowledge they would not have the capacity to house the intervention in the long-term, past the study period. The overarching goal of this project was to ensure that a program would remain accessible to the community after the completion of the research study, particularly as community members and providers played a vital role in the adaptation and implementation of the program.

Thesis Limitations

This thesis has several limitations that are worth noting. Firstly, we did not maintain a patient advisory board from the beginning of Study 1 until the end of Study 2. The patient advisory board was formed after the completion of Study 1 and served until recruitment began for Study 2. Patient engagement in research has been found to result in better quality research and improved health outcomes (Warren et al., 2020). Having a consistent patient advisory board across the span of this thesis would have allowed for a true partnership with patients, giving equal power to patients to shape their care through participating in greater research related decision-making. This could have been achieved by allowing patient partners to participate fully in the research design planning process, reviewing and interpretation of qualitative and quantitative outcomes, reviewing and approving final manuscripts, and receiving co-authorship. This would have aligned more strongly with participatory action research methodology (Cornish et al., 2023). Additionally, sampling methods comprised of convenience and self-selection, which may have introduced sampling and participation bias and limited generalizability of these studies (Elston, 2021). Despite efforts to recruit diverse samples, both samples were compromised of primarily White, highly

educated, high socioeconomic status (a third reporting incomes of 100k and above) women, half of whom had been diagnosed with breast cancer.

For Study 1, unfortunately general practitioners who play a significant role in the long-term management of cancer-related symptoms, and hospital administrators, who may have had greater insights into systemic barriers and possible enablers to improving intervention implementation, were absent from focus groups due to difficulties with recruitment of these groups. Inclusion of these interest holders may have provided important perspectives and a deeper understanding of barriers/enablers to intervention implementation in the local context. Hospital administrators may have been better able to speak to the higher-level barriers of implementing CrF programming within the public system. Further, participants were not presented with the CrF clinical practice guidelines to review prior to being asked to discuss their ideal intervention for CrF programming. However, fortunately many of the desired components participants reported were in line with practice guidelines for CrF, apart from co-ordination of care. However, provision of guidelines may have provided more focused discussion on programming and ensured discussion remained aligned with practice guidelines. Lastly, this study did not follow up with focus group participants to provide them the opportunity to review transcripts or themes. This would have allowed participants to reflect on quotations and themes and provide elaborations to deepen insight (Braun & Clarke, 2024).

For Study 2, as this was a pilot trial, the intervention and wait-list control group were small (n=23 and n=21, respectively). Therefore, results need to be replicated in a larger clinical trial. This study had a short follow-up of 2-month post intervention, longer term follow-up may be beneficial to conduct during a larger trial as health behavioural change (i.e., increasing physical activity) can take time (Conner & Norman, 2017) and given the association between physical

deconditioning and CrF (Dirou et al., 2018), improvements to CrF may be more prominent after a longer follow-up period if participants maintain increased activity and cognitive behavioural strategies. Secondly, the study did not examine in depth the reasons individuals declined to participate. For assessment of *Reach*, the RE-AIM framework suggests qualitative methods to understand reach and recruitment (Holtrop et al., 2021). One of the identified barriers to participation in Study 1 was patient variability (i.e., motivation), in Study 2 participants who enrolled demonstrated high levels of engagement in physical activity, suggesting difficulties with recruitment related to patient variability as anticipated in Study 1. This will be an important implementation outcome to further explore the reasons participants enrolled in the study and how to engage individuals who did not self-select and may be experiencing lower self-efficacy or motivation for behavioural change. Thirdly, this study used self-reported data with no objective measure of physical activity such as wearable activity device. Self-report measures can result in high subjectivity and low accuracy due to the social desirability/approval and reporting bias (Adams et al., 2005; Duan et al., 2021). Indeed, participants reported an average of 29 units at baseline for physical activity on the Godin Leisure Time Exercise Questionnaire in the sample, 24 units or more signifies active, which may suggest inflated responses. Another limitation related to this bias, is that this pilot study was not blinded, and participants were aware of research outcomes such as CrF and physical activity, which may have affected their behaviour or subjective reports on measures. Further, although randomization was conducted by a co-author, group allocation was not concealed from the research team nor during data analysis which may have increased the risk of confirmation bias. Next, no clinical cut-off or screening tool for CrF was used to establish eligibility for the study, participants self-identified as experiencing CrF and self-selected into the study. This was done to capture more organic program enrollment and as part of real-world

implementation; however, this may have reduced the replicability of the study. However, the average baseline FACIT-F-13 scores for both intervention and wait-list groups were under 30, indicating participants who enrolled were experiencing severe fatigue (Eek et al., 2021).

Thesis Strengths

This thesis offers an original contribution to research by being the first to implement and evaluate an intervention for CrF in Canada. Although another virtual intervention for CrF is available through a national community support provider, Wellspring, this intervention has not been formerly evaluated, it does not contain evidence-based cognitive behavioral therapy components, nor has it been developed in collaboration with interest holders and patients to ensure it is meeting the needs of end-users. Given limited literature aimed at addressing real world implementation and evaluation of CrF programming, this thesis addresses an important gap and demonstrates the benefits of utilizing a KT strategy to guide implementation and evaluation from conception of the research study. The use of the KTA framework likely contributed to the acceptability, adoption, and maintenance of the program within the local community context. Indeed, research has found that KT research implementing evidence-based practice that was co-produced with end-users was more likely to succeed, meet the specific needs of end-users, and be maintained in routine practice, as well as foster future collaboration (Heaton et al., 2015). The overall findings of these studies suggest that despite significant long-standing gaps in the management of CrF, programming to address patients' unmet needs around CrF is possible with the use of KT strategies and partnership with community partners and patients.

This thesis has several strengths including the engagement of a community interest holders across the two studies. The community support provider that was partnered with for Study 2 was also a participant in the focus groups in Study 1. Another strength was that this thesis incorporated

all the stages of the KTA action cycle, utilizing the KT strategy from conception of the research work. Study 1's use of qualitative methods allowed for a deeper understanding of perspectives from multiple interest holder groups. These perspectives were integral in adapting a program to the local context and offered the opportunity to providers and patients to shape CrF programming in their community. For Study 2, this thesis' use of hybrid implementation-effectiveness design allowed for a wealth of information to be collected and provided accelerated implementation of a program that directly benefits individuals living with and beyond cancer, especially given significant existing evidence to support psychoeducational interventions in the management of CrF (Karakuş et al., 2022). Further, measures selected for this study have been validated with cancer populations. This study included partnership with a local community support provider and a patient advisory board, which resulted in the adaptation of a program that met providers and patients' specific needs. Further, the program has continued to be offered due to ongoing engagement, advocacy, and support between researchers and the community partner. The patient advisory board comprised of a group of white men and women of varying ages and cancer experiences, that provided invaluable guidance on the adaptation of patient materials for the program. Lastly, the percentage of missing data among completed questionnaires was low, suggesting questionnaires were manageable and did not overly burden participants.

Behavioural Change Techniques

The CrF program incorporated several behavioural change techniques (BCTs) including education, which may help to normalize CrF, goal setting whereby participants set personalized, measurable activity goals; action planning, which facilitated detailed planning around when, where, and how to engage in physical activity; and barrier identification, which helped participants anticipate and manage barriers to physical activity. The intervention also integrated self-monitoring of behavior, supported through activity logs, fatigue, sleep, and relaxation tracking,

and weekly homework review. Lastly, social support was embedded through peer discussion and sharing of successes and challenges of behavioural goals weekly with the group (Bohlen et al., 2020). These BCTs have been found to enhance motivation, self-efficacy, and long-term behavior maintenance (Hardcastle et al., 2018), aligning with evidence-based practices for managing cancer-related fatigue through physical activity and psychosocial interventions like cognitive-behavioural therapy and psychoeducation (Berger et al., 2015; Mustian et al., 2017).

Theoretically, two behaviour models may help inform BCT for the CrF intervention including the Information-Motivation-Behavioral Skills (IMB) model and the Health Action Process Approach (HAPA), two complementary models that offer insight into behavior change processes. The IMB model, originating from HIV medication adherence research, explains health behavior change through the interaction of three key components: information, motivation, and behavioral skills. The model postulates that individuals need accurate and relevant knowledge about the benefits of changing their behavior, personal and social motivation to engage in the behavioural change, and the self-efficacy to carry out the change effectively. All three components are considered necessary for initiating and maintaining behavior change (Fisher & Fisher, 1992). The IMB model has been applied to physical activity and chronic disease self-management in cancer populations. Indeed, a study by Wang et al. (2019) used the IMB model to explain variance in exercise adherence among post treatment breast cancer patients (Wang et al., 2019). Authors found that behavioural skills (i.e., self-efficacy) had the greatest impact on exercise adherence and recommended tailored functional exercises be taught to patients, a component currently lacking from the CrF program. They additionally found that increasing knowledge around the benefits of functional movement could lead to increased motivation (Wang et al., 2019). Applying the IMB model to the CrF program, the program provides information on the benefits of behavioural change

for fatigue (i.e., physical activity, sleep, & cognitive behavioural therapy) and the rationale based on the literature, offers social motivation through peer support and a community that is actively working towards managing their fatigue, and practical skills that can help build patient's self-efficacy in managing their fatigue symptoms such as goal setting and strategies for emotion regulation.

The HAPA model is a stage-based theory of health behavior change that distinguishes between a motivational phase, where individuals form intentions to act, and a volitional phase, where they plan, initiate, and maintain the behavior. In the motivational phase, individuals form intentions to change based on their perceived risk, expected benefits of the behavior, and confidence in their ability to perform it. In the volitional phase, strategies such as action planning, anticipating barriers, and maintaining self-efficacy help translate those intentions into consistent, long-term behavior (Schwarzer, 2008). The HAPA model has been used to predict behavioural change in breast cancer populations around physical activity (Hardcastle et al., 2018; Sequeira et al., 2023). The CrF program does include majority of the components of the HAPA model, apart from task self-efficacy for physical activity (i.e., modeling or guided practice of physical activity to facilitate confidence). This may be a potential area of improvement for the CrF program, especially as an in-person exercise component was a part of the original study by Fillion and colleagues (Fillion et al., 2008). Future studies may consider using the HAPA model to evaluate patients' challenges in maintaining behavioural change, as many patients may have intentions to change behaviour but have difficulty implementing and sustaining the necessary changes (Schwarzer, 2008).

Study 2 did not find any significant behavioural changes for physical activity nor increases in self-efficacy, implying perhaps that goal setting, action planning, and barrier identification may

not have been the drivers of reductions in reported fatigue levels and that improvements or consideration of the above-mentioned models during refinement of the intervention may be necessary to further improve outcomes. Generally, a meta-analysis by Tang et al (2019) reported that interventions with a variety of BCTs were found to be more effective for increasing and maintaining physical activity, as different approaches may work for different patients (Tang et al., 2019). The CrF program does offer a variety of BCTs that may offer participants flexibility in selecting the ones that work for them. Of note, half of our sample already engaged in an active lifestyle, which may further emphasize the need to broaden recruitment to reach individuals who may significantly benefit from BCT and incorporating more physical activity into their routine. Based on qualitative data from study 2, several beneficial BCTs were discussed by participants. Participants shared that social support and learning from their peers was an important component of the intervention, as well as a way to normalize fatigue. Participants also mentioned building awareness which is likely related to self-monitoring of behaviour and education around fatigue and fatigue management strategies. Additionally, participants reported making behavioural changes such as beginning to walk or changing sleep habits. No formal assessment of barriers to behavioural change was measured in study 2, which may be an important future consideration, as self-monitoring may have been impacted by common cognitive concerns reported by cancer survivors (Joly et al., 2019). Further, participants may not have set realistic physical activity goals as they did not receive individualized feedback on their goals (McEwan et al., 2016).

Additionally, future studies may wish to assess which BCTs may have played a significant role in the reduction of fatigue with the CrF intervention. This may be done by comparing the CrF intervention group with different control groups. For example, a supportive expressive group for fatigue which provides social support but no other behavioural change techniques, and a group

where the CrF intervention is offered individually, providing several BCTs but no social support component. This may help shed light on whether social support is an integral part of change observed in the reduced fatigue outcomes in study 2. Future studies may additionally wish to incorporate in-person exercise sessions, which have been found to have the greatest reduction in fatigue when paired with cognitive behavioural therapy/psychoeducational interventions (Mustian et al., 2017). Another consideration may be the inclusion of caregivers in the programming to help support patient's physical activity goals, as studies have found greater outcomes when a patient and caregiver complete physical activity together (Yamada et al., 2021). Lastly, it may be beneficial to assess readiness for behaviour change pre and post intervention.

Clinical Implications

As incidence of cancer continues to increase and individuals are living longer with cancer-related side-effects impacting their quality of life, proper and timely management of these symptoms is imperative. Effective symptom management may improve reintegration into work/leisure and improve overall wellbeing (Jones et al., 2016, 2023). Despite the 2006 seminal work by the Institute of Medicine identifying significant gaps in survivorship care, there continues to be much work needed around improving the quality of life of individuals living with and beyond cancer (Institute of Medicine, National Research Council, 2006; Ross et al., 2022). The lack of implementation of evidence-based guidelines is a disservice to patients, funding organizations, and researchers who dedicate significant time into the development and evaluation of effective treatments to improve symptom burden among cancer populations. Improvements to timely access to resources and programs for symptom management are necessary. Unfortunately, many programs, even if found efficacious, cease to exist after completion of evaluation, leaving patients reporting unmet needs around their post cancer care (Ross et al., 2022). KT strategies can be an

effective tool for collaborative and sustainable implementation of evidence based clinical guidelines for CrF (Heaton et al., 2015).

Presently, limited research exists on the implementation and evaluation of interventions for CrF (Agbejule et al., 2021). This thesis provides preliminary evidence for the benefits of using KT strategies and hybrid implementation-effectiveness designs in the implementation and evaluation of CrF programming. This work contributes to addressing the significant knowledge to practice gaps that exist in the management of CrF in Canada, offering individuals living with CrF access to support services to gain tools and knowledge to reduce symptom burden of CrF. The hybrid implementation-effectiveness design allowed for accelerated access to programming that aligned with evidence-based guidelines and addressed unmet informational needs for patients, as evident by findings in Study 1 and reported in the literature (Jones et al., 2021; Roseleur et al., 2023; Ross et al., 2022). Hybrid designs offer the opportunity to increase access to services which have already demonstrated efficacy in the literature, while larger more time intensive randomized controlled trials can be conducted to further determine effectiveness for the specific program (Johnson et al., 2020). This is the first study to our knowledge to use hybrid effectiveness design in the implementation of CrF programming. Hybrid designs have been used in the implementation of physical activity guidelines for cancer populations (Beidas et al., 2014; McNeely et al., 2022) and have recently been recommended to help enhance program implementation for CrF (Pearson et al., 2023).

In the current healthcare climate in Canada, community cancer support providers may be a more viable options for the management of cancer-related symptoms and wellness. Public systems experience significant barriers, such as time constraints and costs, that impact their ability to provide programming as well as limit the opportunity to train staff to facilitate programming.

To address these barriers, significant changes to the public system would need to occur, including advocating for increased funding, prioritizing CrF at organizational and policy levels, dedicating resources and time to train staff, and improving screening and care pathways for CrF. Implementation of cost-effective psychoeducational programs in the community may provide a stepped care solution that reduces pressure on the public system. In addition, co-producing programming and resources with end-users provides an opportunity for patients and providers to shape the care they receive and provide, improving implementation outcomes. Longer term outcomes of CrF programming implementation could include improved satisfaction with care, improved return to work and reduced disability, and lower healthcare utilization (Jones et al., 2023).

Future Directions

Psychosocial oncology research may need to prioritize the implementation of existing evidence into practice to ensure patients living with and beyond cancer benefit from advancements in care. Improvement to the implementation and dissemination of CrF practice guidelines is necessary to ensure individuals living with and beyond cancer receive evidence-based treatment that has proven to be effective in the management of CrF, thereby improving patient access to important supports, addressing unmet needs, and reducing the burden of fatigue. Given limited programming for CrF across Canada, future directions could include multi-site implementation and a large scale randomized controlled trial to determine effectiveness. For example, it may be interesting to compare this psychoeducational program to the CrF virtual program currently being offered by Wellspring. Further, to increase accessibility ideally the program would be adapted back to French and perhaps other languages through international collaboration, similar to programs such as the Fear of Cancer Recurrence Therapy (FORT) (Etapé et al., 2023).

Additionally, other adaptations may include a version specifically for adolescent and young adults diagnosed with cancer who are likely most impacted by CrF due to their life stage (Poort et al., 2017). Collection of longitudinal data may be informative to determine whether patients engaged in behavioural change and whether these changes were maintained long term. Further, it would be of interest to collect qualitative data on the types of behavioural or lifestyle changes individuals who engage in the program continued to implement months after program completion. As programming returns to in-person, evaluation of hybrid and in-person provision of the CrF program will be necessary. It may be interesting to compare outcomes between in-person and virtual services to evaluate whether differences exist, as peer support was identified as an important component of desired programming for CrF. Future research would benefit from exploring how to engage adults who may be more sedentary or have less motivation through more robust qualitative methods to understand the reach of the program.

In order to address other gaps in knowledge around CrF, community engagement through presentations at local cancer support groups, most recently at the local Prostate cancer support group in January 2025, are an on-going initiative we are engaging in to promote more knowledge around CrF and promote the CrF program to men, as this was a significant limitation in our study. Lack of HCP knowledge has been identified as a barrier; therefore, ongoing education and efforts are needed to inform local HCP of the availability of a program for CrF in the Ottawa region and elsewhere. Another step may be the creation of education class around the management of CrF for healthcare providers and the creation of a one-session education way-finding class that can be offered at cancer centres to help patient navigate to existing programming and resources for CrF locally. This may improve co-ordination of care and provide patients with timely information on CrF, as significant false beliefs continue to be present around CrF, such as fears around fatigue

being a sign of treatment failure or cancer progression. During discussions with the community support provider, they expressed an interest in materials and recorded video sessions being available through a webpage to accommodate patients who do not wish to engage in a group. Another possibility will be the creation of a webpage to house recorded sessions to increase accessibility of the program.

In conclusion, the results of these studies demonstrate that practice gaps and significant barriers to clinical guideline implementation for the management of CrF continue to exist, however these challenges can be overcome using KT strategies, partnership with community support providers, and patients, to ensure programming is available and meets the needs of providers and patients. This methodology ensures that the time and effort of community partners and patient place into research, creates a lasting impact in their community for other individuals experiencing CrF. It is hoped that future research efforts will focus on providing greater access and dissemination of effective interventions for CrF, thereby improving the quality of life and care of individuals living with or beyond cancer struggling with CrF across Canada.

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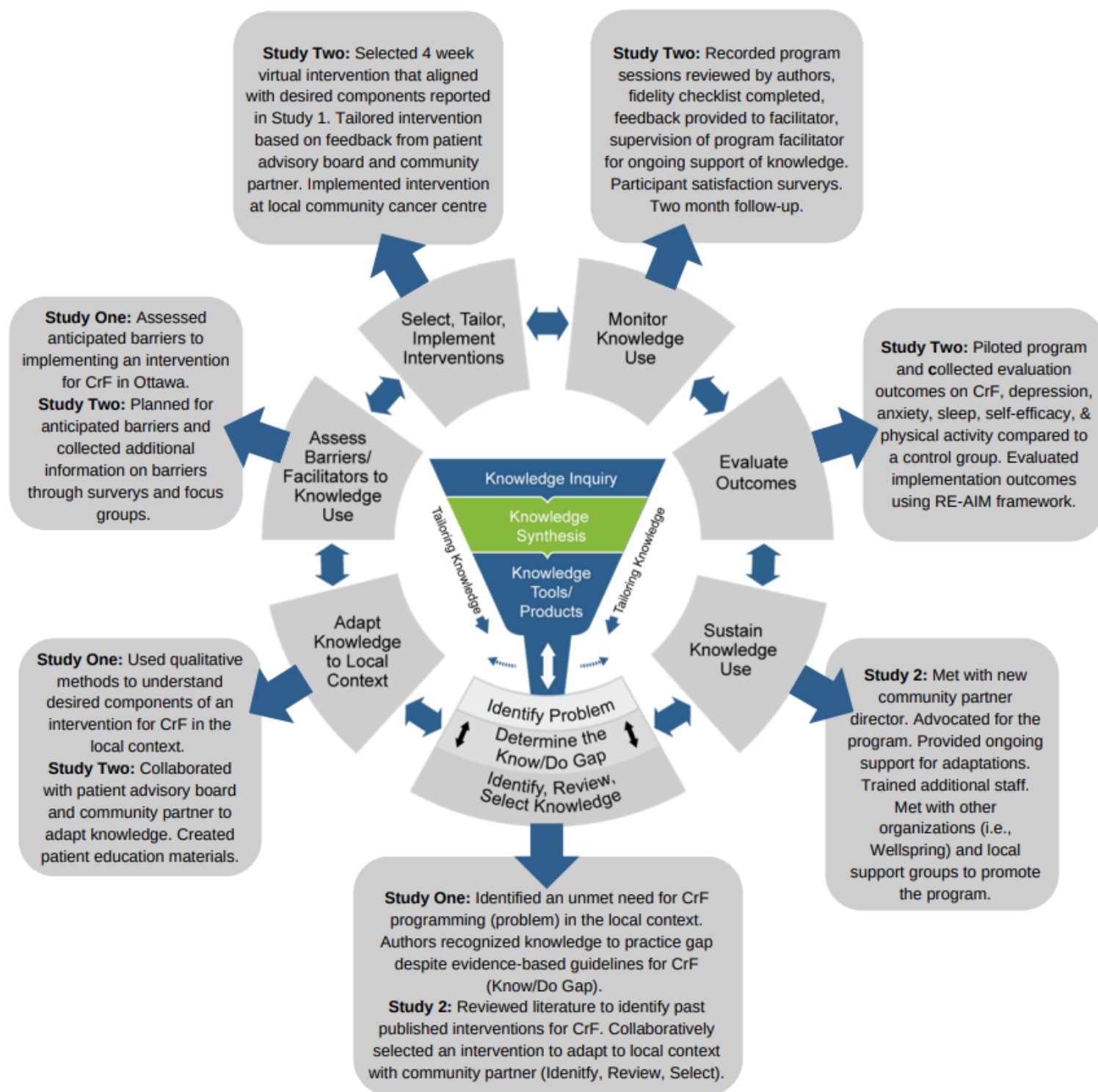
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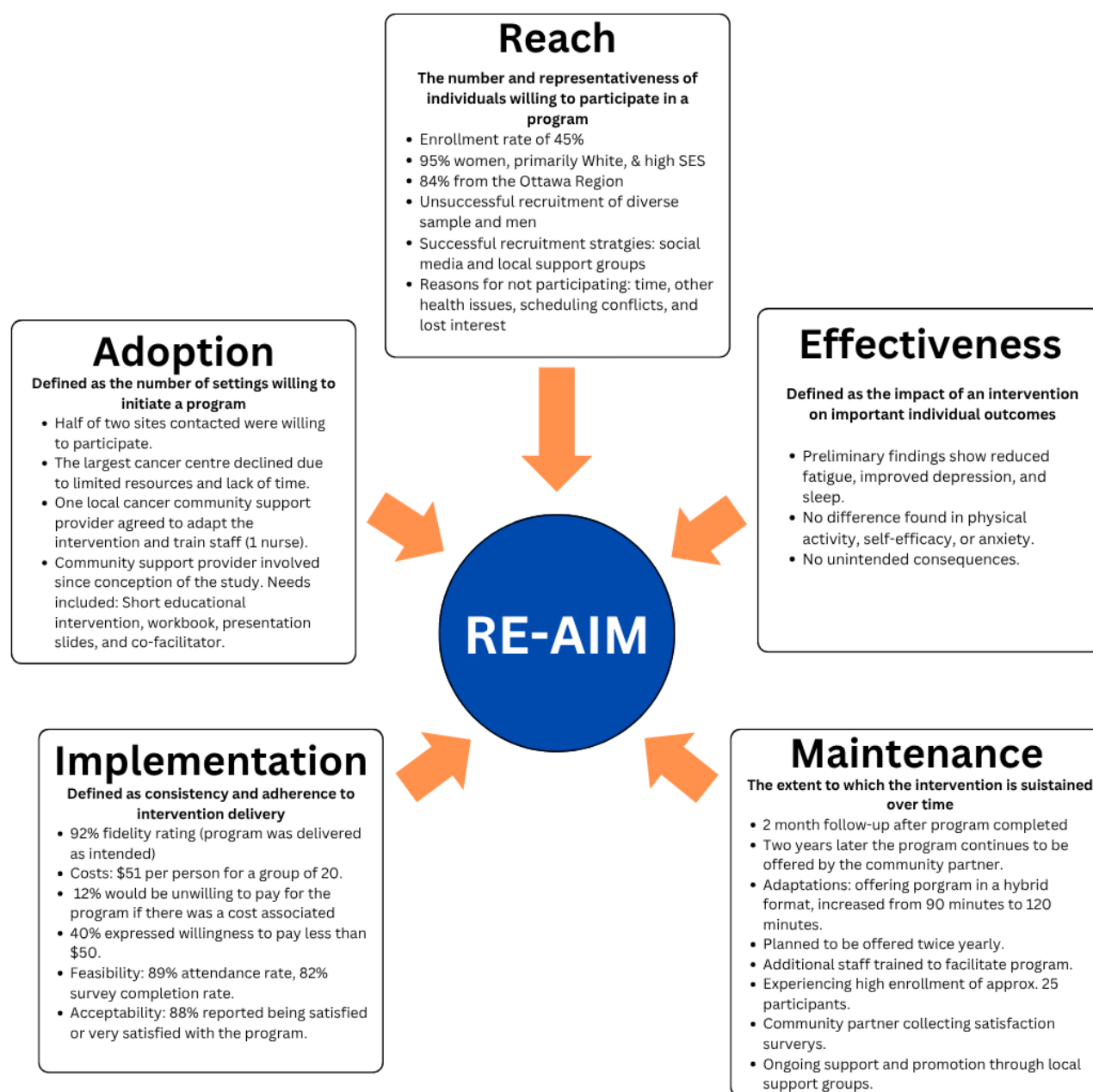
Appendices

Appendix I. Figure of Knowledge to Action Framework Model



Original Source: Graham ID, Logan J, Harrison MB, Straus SE, Tetroe J, Caswell W, et al. Lost in knowledge translation: time for a map? J Contin Educ Health Prof. 2006;26(1):13-24.

Appendix II. Figure of RE-AIM Framework for Study 2



Ory, M. G., Altpeter, M., Belza, B., Helduser, J., Zhang, C., & Smith, M. L. (2015). Perceived Utility of the RE-AIM Framework for Health Promotion/Disease Prevention Initiatives for Older Adults: A Case Study from the U.S. Evidence-Based Disease Prevention Initiative.

Appendix III. Guiding Questions for deciding on the type of Hybrid-Effectiveness Design

1. What is the nature of the effectiveness data on your intervention of interest?
 - Very-to-moderately strong, especially if not a lot of intervention adaptation needs to take place? Consider type 3 or type 2 depending on how much you expect the intervention will need to be adapted (Question 2).
 - Mixed results? Missing (strong) effectiveness data? Consider types 1 or 2.
2. How much do you expect the intervention will need to be adapted for where you want to study/use it?
 - A little? Consider type 2 or 3, including adaptation process as a step in an implementation-focused project.
 - A lot? Consider focusing on effectiveness in a type 1 or type 2.
3. How much do you already know about implementation determinants for the intervention in your context of interest?
 - Not much? If you also need to focus on effectiveness data, consider type 1.
 - If the effectiveness data are strong, and you know enough already to develop/select a strategy or package of strategies to evaluate? Consider type 2 or 3.
4. How ready are you to evaluate a “real world” implementation strategy or package of strategies?
 - Not ready? A type 1 is indicated, where you collect information on implementation determinants to help you prepare for developing strategies later.
 - Ready, and you need to focus as well on effectiveness of the intervention (Question 1)? Consider a type 2.
 - Ready, and your effectiveness data are strong (Question 1) and you don't need to adapt a lot (Question 2)? Consider a type 3.

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Curran GM, Landes SJ, McBain SA, Pyne JM, Smith JD, Fernandez ME, Chambers DA, Mittman BS. Reflections on 10 years of effectiveness-implementation hybrid studies. *Front Health Serv.* 2022 Dec 8;2:1053496.

1. What is the nature of the effectiveness data on your intervention of interest?

- Presently there is a large body of evidence for the effectiveness of psychoeducational interventions on CrF, including several evidence-based guidelines. Consider Type 3 or 2.

2. How much do you expect the intervention will need to be adapted for where you want to study/use it?

- Significant adaptations are needed due to outdated information and patient materials. Further, the original intervention included in-person tailored physical activity, due to several limitations this was not possible in this study. Further

adaptations are needed to the local setting with a patient advisory board and in collaboration with a community partner. Consider Type 1 or 2.

3. How much do you already know about implementation determinants for the intervention context of interest?

- Focus groups completed with patients, healthcare providers, and community support providers to explore anticipated barriers to implementation. Small scale implementation within one local community cancer centre guided by the KTA model. Consider Type 2 or 3.

4. How ready are you to evaluate a “real world” implementation strategy or package of strategies?

- Ready for real-world implementation given the significant knowledge to practice gap. Community partner committed and prepared to offer and train staff to deliver the program. Given the strong body of evidence for psychoeducational interventions for CrF, major adaptations required, an implementation model selected (KTA Model), and readiness for “real world” implementation a Type 2 design is likely best suited.

Study 1

Appendix IV. Standards for Reporting Qualitative Research for Qualitative Research

Standards for Reporting Qualitative Research (SRQR)*

<http://www.equator-network.org/reporting-guidelines/srqr/>

Page/line no(s).

Title and abstract

Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	Pg. 1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Pg. 2

Introduction

Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	Pg. 3; line: 58-78
Purpose or research question - Purpose of the study and specific objectives or questions	Pg. 3; line:80-91

Methods

Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	Pg. 4; line 96-98
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Pg. 4; line: 115-118, 137
Context - Setting/site and salient contextual factors; rationale**	Pg. 4; lines 105-122
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	Pg. 4; line: 96-98; 110-112
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Pg. 4; line: 112-113

Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	Pg. 4; Line: 110-113; 115-122
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Pg 4; line 125-132
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Pg. 5; line 149-159, Pg 13. Table 1
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	Pg 4; line 119-120
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	Pg. 4; line; 136-146
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	Pg 5; line 143-146

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Pg 5-7; lines 169-272
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Pg 5-7; lines 169-272; pg. 15-16; Table 2

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Pg. 8; lines 274-333
Limitations - Trustworthiness and limitations of findings	Pg. 9; lines 335-340

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Pg 1; line 28
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Pg. 1; lines: 25-27

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
DOI: 10.1097/ACM.0000000000000388

Appendix V. Patient Interview Guide

Opening word:

- The group leaders will introduce themselves and will present the objective of the focus group: To explore patients' experiences with cancer-related fatigue (CRF)
- The group leaders will ensure that all participants still consent to participate in the study and to being voice-recorded and to be filmed
- Group leaders will explain that they are responsible for the confidentiality and the anonymity of the participants and will ask the participants to ensure the confidentiality of the others in the group

CRF questions for patients:

1. Can you briefly describe your experience with CRF?
2. Can you explain what motivated you to report or withhold your CRF from any or all of your health care providers?
3. Has your health care provider assessed your CRF?
 - *Probe: How did they do this?*
 - *Probe: Did they ask you questions about your CRF? Like what?*
 - *Probe: Did they do blood tests? Do you recall discussing the results of these blood tests?*
 - *When did this happen?*
4. Have you ever received information to manage your CRF?
 - *Probe: Who provided you with this information?*
 - *Probe: When did they do this?*
 - *Probe: How helpful was this to you?*
5. Have you ever received strategies to manage your CRF?
 - *Probe: Who provided you with these strategies?*
 - *Probe: When did they do this?*
 - *Probe: How helpful was this to you?*
6. How and when would you have liked information and strategies to be given to you?
7. What do you do to manage your CRF?
8. What would an ideal approach to help manage your CRF look like?
 - *Probe: We know that some things like physical activity, energy conservation (i.e., pacing yourself with periods of relaxation between periods of activity) as well as psychotherapy that can help you change unhelpful thoughts about feeling fatigued are useful to help manage CRF. Would you see yourself doing any of these things?*
9. What might get in the way of continuing with the recommendations for the management of CRF after the treatment ends?

• *Probe: What might make it easier?*

10. Who do you think should be responsible for helping you manage your CRF? Where should you receive assistance to manage your CRF? And at what point in the cancer journey would you have liked to first receive assistance?

11. Is there anything you would like to add about CRF and your experience with it?

Appendix VI. HCP and CSP Interview Guide

Opening word:

- The group leaders will present themselves and will present the objective of the focus group
- The group leaders will ensure that all participants still consent to participating in the study and to being filmed
- Group leaders will explain that they are responsible for the confidentiality and the anonymity of the participants and will ask the participants to ensure the confidentiality of the others in the group

CRF questions for HCPs:

1. What is your understanding of the components of CRF or how would you define CRF?
 - *What is your understanding of the impact of CRF?*
2. In your experience, how often and at what point do patients report CRF?
 - *Probe: When do you feel CRF is more prevalent?*
3. How often do you actively assess patients for CRF in your practice and how do you do this?
 - *Probe: Do you ask questions? Do you run specific tests? Which ones?*
4. What do you want to rule out in patients with CRF before you recommend self-care strategies?
5. What treatment(s) for CRF do you recommend to your patients?
 - *Probe: Why do you recommend these? What informs your recommendations?*
 - *Probe: Do you vary your recommendations based on the patient's trajectory in their cancer journey (i.e. active treatment, end of life, survivorship)? What do you recommend for patients newly diagnosed with cancer? What about those on treatment? What about for pts who have just completed tx? And finally what do you suggest in patients who are in well-follow-up/survivorship?*
 - *Probe: Do you recommend physical activity, CBT, energy conservation strategies?*
6. Can you describe your level of familiarity with the CAPO/NCCN/CCO/COSTAR guidelines on CRF?
7. If we wanted to improve the way we manage CRF, what would be an ideal assessment and intervention plan?
 - *Probe: Who do you think should provide patients with this assistance?*
 - *Probe: Where should patients receive this assistance?*
 - *Probe: How should patients receive this assistance? (e.g., face-to-face, online)*
8. What barriers do you experience in practice for the assessment and intervention for CRF? What barriers do you think patients experience? How could they be avoided?
9. What could be done to ensure the assessment and management of CRF is sustainably done in the future?
10. Do you have any further comments or suggestions about CRF?

Appendix VII. University of Ottawa Research Ethics Approval for Study 1

File Number: H12-15-26

Date (mm/dd/yyyy): 02/01/2016



Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

Certificate of Ethics Approval**Health Sciences and Science REB****Principal Investigator / Supervisor / Co-investigator(s) / Student(s)**

<u>First Name</u>	<u>Last Name</u>	<u>Affiliation</u>	<u>Role</u>
Sophie	Lebel	Social Sciences / Psychology	Principal Investigator
Jennifer	Brunet	Health Sciences / Human Kinetics	Co-investigator

File Number: H12-15-26**Type of Project:** Professor

Title: An Intervention for the Management of Cancer Related Fatigue: What do Patients, Health Care Providers and Community Partners have to say?

Approval Date (mm/dd/yyyy)	Expiry Date (mm/dd/yyyy)	Approval Type
02/01/2016	01/31/2017	Ia

(Ia: Approval, Ib: Approval for initial stage only)

Special Conditions / Comments:

N/A

File Number: H12-15-26

Date (mm/dd/yyyy): 02/01/2016



Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

This is to confirm that the University of Ottawa Research Ethics Board identified above, which operates in accordance with the Tri-Council Policy Statement and other applicable laws and regulations in Ontario, has examined and approved the application for ethical approval for the above named research project as of the Ethics Approval Date indicated for the period above and subject to the conditions listed the section above entitled "Special Conditions / Comments".

During the course of the study the protocol may not be modified without prior written approval from the REB except when necessary to remove participants from immediate endangerment or when the modification(s) pertain to only administrative or logistical components of the study (e.g. change of telephone number). Investigators must also promptly alert the REB of any changes which increase the risk to participant(s), any changes which considerably affect the conduct of the project, all unanticipated and harmful events that occur, and new information that may negatively affect the conduct of the project and safety of the participant(s). Modifications to the project, information/consent documentation, and/or recruitment documentation, should be submitted to this office for approval using the "Modification to research project" form available at: <http://research.uottawa.ca/ethics/submissions-and-reviews>.

Please submit an annual status report to the Protocol Officer 4 weeks before the above-referenced expiry date to either close the file or request a renewal of ethics approval. This document can be found at: <http://research.uottawa.ca/ethics/submissions-and-reviews>.

If you have any questions, please do not hesitate to contact the Ethics Office at extension 5387 or by e-mail at: ethics@uOttawa.ca.

Appendix VIII. Montfort Hospital Research Ethics Approval and Modification



Affilié à l'Université d'Ottawa | Affiliated with the University of Ottawa

Approbation éthique d'une demande de modification Comité d'éthique de la recherche de l'Hôpital Montfort (CÉR)

Le 18 juin 2019

Chercheuse principale :

Sophie Lebel
École de Psychologie, Université d'Ottawa
Institut du Savoir Montfort (ISM)
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Co-chercheuse :

Jennifer Brunet
École des Sciences de l'activité physique
Université d'Ottawa
jennifer.brunet@uottawa.ca

Titre du projet : « An Intervention for the Management of Cancer related Fatigue: What do Patients, Health Care Providers and Community Partners Have to Say. »

Numéro du dossier : GJ-06-08-15

En conformité avec la dernière édition de l'Énoncé de politique des trois conseils — Éthique de la recherche avec des êtres humains (ÉPTC 2), le Bureau d'éthique de la recherche (BÉR) de l'Hôpital Montfort vous informe que votre demande de modification soumise le 14 et complétée le 17 juin 2019 pour le projet mentionné ci-dessus a été **évaluée** et **approuvée** en comité délégué par le président du CÉR ou son délégué. Les décisions prises au sujet des dossiers évalués en comité délégué ou évaluation administrative sont ratifiées par le comité lors de sa prochaine réunion plénière. Les modifications approuvées touchent les éléments et documents suivants :

- **Changement à l'équipe de recherche :** ajout de Mlle Nicole Rutkowski, en tant qu'assistante de recherche.

Le CÉR a également reçu les documents suivants en lien avec les modifications ci-dessus:

- L'entente de confidentialité signée par Mlle Rutkowski pour le projet de recherche ainsi que son certificat EPTC2.

Le CÉR de l'Hôpital Montfort est constitué et exerce ses activités d'une manière conforme aux Bonnes pratiques cliniques : directives consolidées, du Conseil international sur l'harmonisation des exigences techniques relatives à l'homologation des produits pharmaceutiques à usage humain (CIH-BPC E6), à la Partie C, Titre 5, du Règlement sur les aliments et drogues et aux règlements applicables, à la partie 4 du Règlement sur les produits de santé naturels; à la partie 3 du Règlement sur les instruments médicaux, au « Code of Federal Regulations » des États-Unis, à la Loi ontarienne de 2004 sur la protection des renseignements personnels sur la santé, de même qu'aux lois et règlements applicables en Ontario. Le CÉR de Montfort est enregistré auprès du *Department of Health and Human Services (DHHS)* et de l'*Office for Human Research Protection (OHRP)* aux États-Unis.

Votre certificat d'approbation éthique valide jusqu'au **14 décembre 2019** couvre ces modifications.

713 Montréal, Ottawa, ON: K1K 0T2
 ☎ 613-746-4621
 📠 613-746-4914
www.hopitalmontfort.com



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Si vous avez des questions, vous pouvez communiquer avec le bureau d'éthique de la recherche (BÉR) de l'Hôpital Montfort au 613-746-4621 poste 2221 ou par courriel à ethique@montfort.on.ca.

Appendix IX. Ottawa Health Science Network Research Ethics Approval



**Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du
Réseau de science de la santé d'Ottawa**

Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311
<http://www.ohn.ca/ohn-reb>

Friday, April 5, 2019

Dr. Cheryl Harris
Ottawa Hospital Cancer Centre - General Campus
Psychosocial Oncology Program
501 Smyth Rd, Box 918
Ottawa, ON
K1H 8L6

Dear Dr. Harris:

RE: Protocol# - 20170704-01H Cancer-related fatigue: What do patients, healthcare professionals, and community partners have to say?

Renewal Expiry Date - Sunday, April 5, 2020

I am pleased to inform you that your Annual Renewal Request was reviewed by the Ottawa Health Science Network Research Ethics Board (OHSN-REB) and is approved. No changes, amendments or addenda may be made in the protocol or the consent forms without the OHSN-REB's review and approval.

This renewal is approved as of: April 05, 2019.

Renewal is valid for a period of one year. If the study is to continue beyond the expiry date noted above, a Continuing Review Form should be submitted to the REB, in hardcopy. All annual renewal requests, regardless of review type (i.e., full board or delegated), must now be submitted according to the full board meeting submission deadlines AND at least 30 days prior to the expiry date of the study to prevent a lapse in approval. If the study is completed by this date, a Study Closure Form should be submitted.

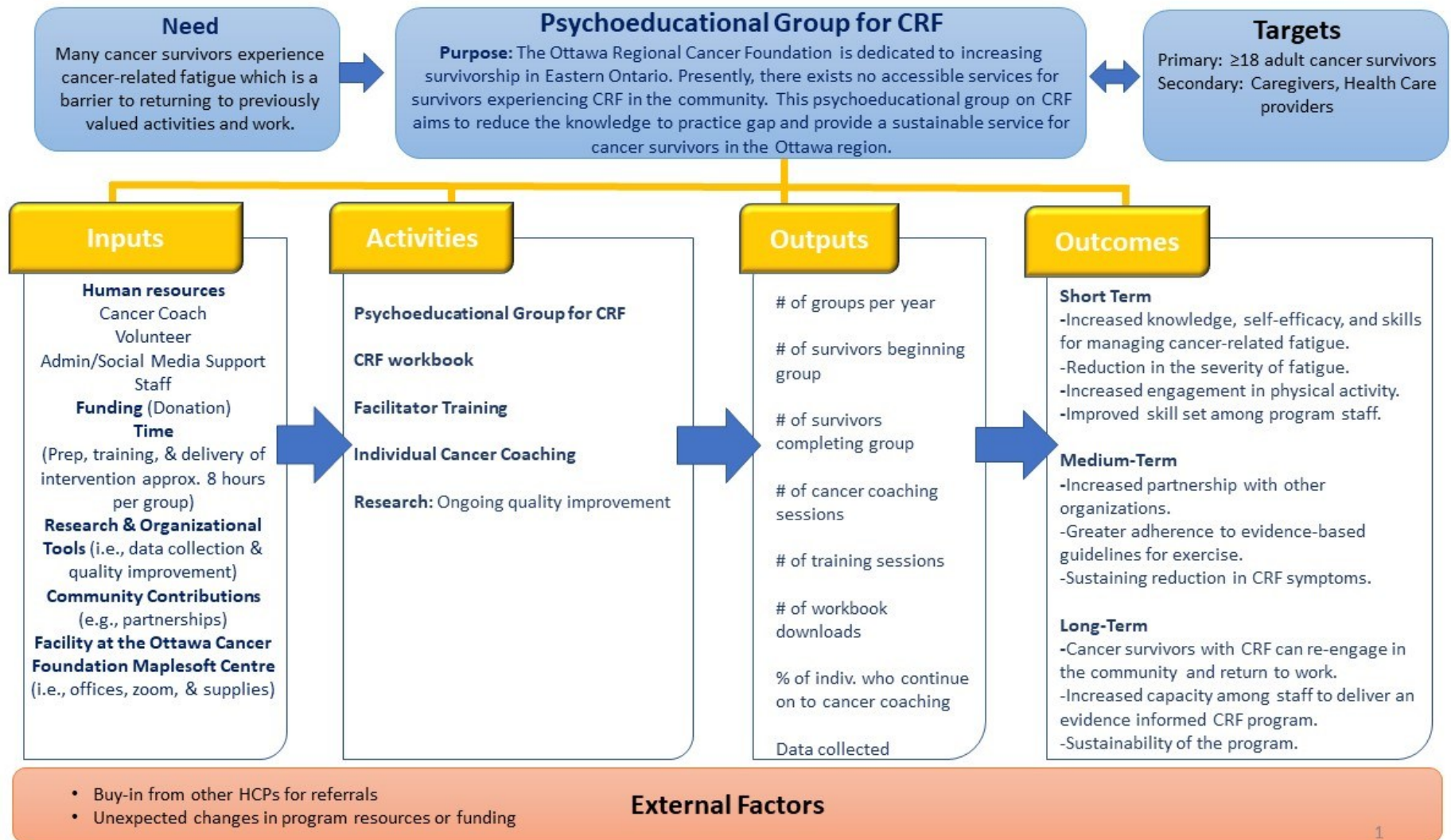
The consent forms currently approved for use by the REB are:

- English and French Informed Consent Form for Patients, dated November 08, 2018
- English and French Informed Consent Form for Healthcare Providers, dated November 08, 2018

The OHSN-REB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Integrated Addendum to ICH E6 (R1); Guideline for Good Clinical Practice E6 (R2); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. OHSN-REB is qualified through the CTO REB Qualification Program and is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP).

Study 2

Appendix X. Logic Model for the Ottawa Cancer Foundation



Appendix XI. Ethics Approval from the Ottawa Health Science Network Research Ethics Board for Study 2



June 08, 2022

Dr. Amirrtha Srikanthan

The Ottawa Hospital, General Campus
Department of Medicine
Division of Medical Oncology

Re: OHRI Institutional Approval for Ottawa Health Science Network Research Ethics Board (OHSN-REB) Submission

Protocol ID#: 20220190-01H;

Why am I Still Tired? Adaption, Implementation, and Evaluation of an Intervention for Cancer-Related Fatigue

Dear Dr. Amirrtha Srikanthan,

This letter serves as **Ottawa Hospital Research Institute (OHRI)** Institutional Approval for the above-referenced study. Please maintain this documentation in your investigator study file.

Based on the information you provided about this study through the Clinical Research Registration Form, you have satisfied the requirements for institutional (OHRI) approval. This includes initial research ethics approval by OHSN-REB, appropriate departmental/service area notifications and execution (fully signed versions) of all agreement(s) required to begin the study locally. Please note there may be additional agreement(s) pending execution that are required to send funds, samples, or data to external sites, but are not required for you to begin your study locally.

Changes and/or additions to your study that may require additional agreement(s) or revisions to existing agreement(s) must be communicated to the OHRI Contracts Office. This should be undertaken simultaneously with any related OHSN-REB amendment submission.

Changes and/or additions to your study that affect various hospital/institution departments (e.g., pharmacy, Department of Medical Imaging, EORLA, EEG, etc.) must be communicated to the relevant departments.

As mentioned in the 'Response' tab of the Ethics application, you have 3 months from the date of initial OHSN-REB approval to submit French documents including the translation certificate to OHSN-REB through the Translated Documents section of the ethics application (if applicable).

Should you have any questions, please contact REBadministration@ohri.ca or 613-798-5555 extension 16719.

Appendix XII. University of Ottawa Ethics Approval for Study 2

16/12/2022

Université d'Ottawa

Bureau d'éthique et d'intégrité de la recherche

University of Ottawa

Office of Research Ethics and Integrity

CERTIFICAT D'APPROBATION ÉTHIQUE | CERTIFICATE OF ETHICS APPROVAL

Numéro du dossier / Ethics File Number Titre du projet / Project Title Type de projet / Project Type Statut du projet / Project Status Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy) Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	H-11-21-7124 Why am I Still Tired? Adaption, Implementation, and Evaluation of an Intervention for Cancer-Related Fatigue. Thèse de doctorat / Doctoral thesis Renouvelé / Renewed 09/12/2021 08/12/2023
---	--

Équipe de recherche / Research Team

Chercheur / Researcher	Affiliation	Role
Nicole RUTKOWSKI	École de psychologie / School of Psychology	Chercheur Principal / Principal Investigator
Sophie LEBEL	École de psychologie / School of Psychology	Superviseur / Supervisor
Patricia BARRETT-ROBILLARD	Ottawa Regional Cancer Foundation	Collaborateur / Collaborator

Conditions spéciales ou commentaires / Special conditions or comments

Appendix XIII. Terms of Reference for Patient Advisory Board

Title: Why am I still tired? Adaptation and Implementation of a Cognitive Behavioural Intervention for Cancer-Related Fatigue.

Purpose / Role of the group: The purpose of the advisory group is to collaboratively adapt an existing intervention for cancer-related fatigue (CrF) with healthcare providers, community partners, and cancer survivors. The group is being established by a doctoral student, Nicole Rutkowski and Dr. Sophie Lebel from the University of Ottawa in partial fulfillment of a doctoral thesis. The aim of the group is to meet regularly with partners to adapt and evaluate an intervention that is patient-centered and sustainable. The responsibilities of advisory committee members include meeting regularly with group members, actively engaging in discussions, respecting the opinions of other group members, sharing knowledge and expertise, and providing constructive input.

Advisory Committee: For this project we are collaborating with the Ottawa Regional Cancer Foundation who work with cancer survivors experiencing cancer-related fatigue. A representative from the organization will work closely with the research team to adapt, implement, and evaluate the intervention in the community. Additionally, four cancer survivors will be invited to join the advisory committee from the Ottawa Cancer Foundation or the Patient and Family Advisor Program at the Ottawa Hospital. This group will convene monthly for 4-6 months (Spring/Summer 2021) while adapting the intervention. After this period, members will be asked to periodically review materials and provide input during the piloting process and for the duration of the project. Members will be kept updated as the project progresses. We ask for a commitment of approximately 1 year.

Accountability: This group will work in a two-way responsibility protocol, where the group members will be accountable to the principal investigators, Dr. Sophie Lebel and Nicole Rutkowski, and the lead investigators will be accountable to the group members. Active participation is required from all members. Members will be responsible for attending meetings and reporting back on any assigned activities to the group. Group members will be asked to review and provide feedback on materials (i.e., intervention workbook) in a timely manner. Terms of reference may be reviewed and updated throughout the course of the project. Members are encouraged to bring forth any concerns related to the project at any time.

Working methods: A shared learning approach will be adopted. Members are encouraged to share their knowledge and experience with CrF throughout the process. Our aim is to create an environment for empowered action and acknowledge that members have the capability and capacity to create change in their communities.

Meetings: Nicole Rutkowski, a doctoral student in Clinical Psychology, will organize and chair the meetings. Meetings will be held virtually over Zoom. A tentative agenda will be sent out one week prior to meetings. Members of the group are encouraged to contribute to the agenda if they have a topic they'd like to discuss. Meetings will be held monthly for the first 4-6 months. After this period, the group will convene as necessary to continue to refine and provide feedback on the intervention and

evaluation. Members will be informed of any updates to the project via email to ensure continued collaboration. Meetings will involve group discussion and collaboration, reviewing adapted intervention materials (i.e., workbooks, questionnaires), and refining outcome evaluations (i.e., surveys). Non-members may be invited to group meetings if discussed with group members and agreed upon in advance. For example, if there is someone from your community organization that you believe may provide valuable input on a particular challenge we are encountering.

Sharing of information and resources: A google drive will be accessible to all members of the group in order to aid in information and resource sharing. No confidential materials will be shared or stored in the google drive. Members may upload any materials they believe will be beneficial to the team. Should the need to share confidential materials arise (i.e., data file), all identifying information will be removed and the file will be encrypted.

Definition of Terms:

- **Cancer-Related Fatigue (CRF):** has been defined as a “distressing, persistent, subjective sense of tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning” (Berger et al., 2015, p. 9).
- **Cognitive Behavioural Therapy (CBT):** The Centre for Addiction and Mental Health explains cognitive-behavioural therapy (CBT) as a practical, short-term form of psychotherapy. CBT focuses on the here-and-now—on the problems that come up in day-to-day life. CBT helps people to examine how they make sense of what is happening around them and how these perceptions affect the way they feel.
- **Shared Learning Approach:** Shared learning is the process of working collectively to achieve a common objective in a group.
- **Sustainability:** has been described as “the continued use of program components and activities for the continued achievement of desirable program and population outcomes” (Scheirer, 2013).

Appendix XIV. Timeline and Feedback from Community Partner and Patient Advisory Board

Date	Summary of Meeting (Community Partner)
December 3rd 2021	Meeting with a community partner for the first time. Discussed what the community partner would like in an intervention. Requests: Short program (4-5 sessions), offered virtually in the morning-afternoon, offered 3x per year. Implementation tools requested: Standalone workbook for patients to download/accompany group
April 7th 2021	Discussion creation of patient advisory board and recruiting patients who may be interested. Review of logic model.
Oct 27th 2021	Methods, recruitment, advertisements, webpage, and cost of the intervention discussed. Implementation tools requested: PowerPoint slides to facilitate group.
Date	Summary of Meeting (Patient Advisory Board)
May 20th 2021	Presentation on research done to date (i.e., focus groups), plans for the project, expectations for the advisory board
June 17th 2021	Discussion of the workbook session one & two. Many changes suggested to make it more patient friendly.
July 22nd 2021	Reviewed sessions 3 & 4. Feedback to add learning objectives.
August 26th 2021	Went through the workbook page by page. Discussed formatting changes, such as breaking one page into two to make the font bigger. Moving activities round.
November 15th 2021	Summary of the research and implementation project. Brainstorming for recruitment strategies.
November 18th 2021	Summary of the research and implementation project. Feedback on focus group questions. Brainstorming for recruitment strategies.

Feedback Summary from Patient Advisory Board on CrF Workbook
- Consistent and larger font size - Accessible colour contrast to maximize readability/different colours (i.e., hues of blues vs orange) - Provide examples for rating scales (i.e., fatigue, sleep, etc) and homework exercises (i.e., SMART goals) - Ensure language is accessible and simple (i.e., between grade 4-8) - More bullet points and less text/Simplify workbook exercises/break up content from 1 page to two - Use a graphic of a person with a visible disability or using mobility aids - Embed videos into the document - Reword sections to include positive wording (i.e., lower fatigue levels reported with higher activity levels vs higher fatigue levels reported with lower activity levels) - Include space for participants to write how fatigue is showing up for them and what may be contributing to their fatigue - Add a land acknowledgement

Appendix XVI. First version of CrF Workbook – Session One

Cognitive Behavioural Therapy for Cancer-Related Fatigue: Workbook

2021

uOttawa

Ottawa Regional Cancer Foundation

Fondation du cancer de la Région d'Ottawa

Table of Contents

1. Welcome to the Workbook for Cancer-Related Fatigue: Workbook

2. What is Cancer-Related Fatigue?

3. What does fatigue mean to you?

4. What is the impact of fatigue on your life?

5. What are the causes of fatigue?

6. What are the symptoms of fatigue?

7. What are the signs of fatigue?

8. What are the effects of fatigue?

9. What are the consequences of fatigue?

10. What are the treatments for fatigue?

11. What are the goals of the workbook?

12. What are the objectives of the workbook?

13. What are the outcomes of the workbook?

14. What are the benefits of the workbook?

15. What are the risks of the workbook?

16. What are the limitations of the workbook?

17. What are the strengths of the workbook?

18. What are the weaknesses of the workbook?

19. What are the opportunities of the workbook?

20. What are the threats of the workbook?

Welcome!

Dear reader, we offer a warm welcome to the workbook. It has been carefully designed to help you understand and manage your cancer-related fatigue. The workbook is divided into two main sections: Session One and Session Two. Session One focuses on understanding fatigue, while Session Two focuses on managing fatigue. The workbook is designed to be used at your own pace, and it is a valuable resource for anyone who is experiencing fatigue. The workbook is designed to be used at your own pace, and it is a valuable resource for anyone who is experiencing fatigue. The workbook is designed to be used at your own pace, and it is a valuable resource for anyone who is experiencing fatigue.

SESSION ONE

What does fatigue mean to you?

What does cancer-related fatigue mean to you?

What does fatigue mean to you?

What does cancer-related fatigue mean to you?

What does fatigue mean to you?

What does cancer-related fatigue mean to you?

What does fatigue mean to you?

What does cancer-related fatigue mean to you?

What does fatigue mean to you?

What does cancer-related fatigue mean to you?

What does fatigue mean to you?

What does cancer-related fatigue mean to you?

What we know about cancer-related fatigue:

What we know about cancer-related fatigue:

What we know about cancer-related fatigue:

What we know about cancer-related fatigue:

What we know about cancer-related fatigue:

What we know about cancer-related fatigue:

Check your knowledge!

When we first discussed fatigue?

When we first discussed fatigue?

When we first discussed fatigue?

When we first discussed fatigue?

When we first discussed fatigue?

When we first discussed fatigue?

Model of Fatigue

Model of Fatigue

Model of Fatigue

Model of Fatigue

Model of Fatigue

Model of Fatigue

Model of Fatigue

Model of Fatigue Exercise

Model of Fatigue Exercise

Model of Fatigue Exercise

Model of Fatigue Exercise

Model of Fatigue Exercise

Model of Fatigue Exercise

Model of Fatigue Exercise

How Do We Break the Cycle of Fatigue?

How Do We Break the Cycle of Fatigue?

How Do We Break the Cycle of Fatigue?

How Do We Break the Cycle of Fatigue?

How Do We Break the Cycle of Fatigue?

How Do We Break the Cycle of Fatigue?

How Do We Break the Cycle of Fatigue?

A Tool for Behavioural Change

A Tool for Behavioural Change

A Tool for Behavioural Change

A Tool for Behavioural Change

A Tool for Behavioural Change

A Tool for Behavioural Change

A Tool for Behavioural Change

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

SESSION ONE COMPLETE!

SESSION ONE COMPLETE!

SESSION ONE COMPLETE!

SESSION ONE COMPLETE!

SESSION ONE COMPLETE!

SESSION ONE COMPLETE!

SESSION ONE COMPLETE!

SESSION TWO

SESSION TWO

SESSION TWO

SESSION TWO

SESSION TWO

SESSION TWO

SESSION TWO

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

A tool to help manage the physical and emotional aspect of fatigue.

The 'Boom and Bust' Cycle

The 'Boom and Bust' Cycle

The 'Boom and Bust' Cycle

The 'Boom and Bust' Cycle

The 'Boom and Bust' Cycle

The 'Boom and Bust' Cycle

The 'Boom and Bust' Cycle

Sleep Hygiene

Sleep Hygiene

Sleep Hygiene

Sleep Hygiene

Sleep Hygiene

Sleep Hygiene

Sleep Hygiene

Check your knowledge!

Check your knowledge!

Check your knowledge!

Check your knowledge!

Check your knowledge!

Check your knowledge!

Check your knowledge!

Relaxation and Physical Activity: Two tools to help manage fatigue

Relaxation and Physical Activity: Two tools to help manage fatigue

Relaxation and Physical Activity: Two tools to help manage fatigue

Relaxation and Physical Activity: Two tools to help manage fatigue

Relaxation and Physical Activity: Two tools to help manage fatigue

Relaxation and Physical Activity: Two tools to help manage fatigue

Relaxation and Physical Activity: Two tools to help manage fatigue

Physical Activity:

Physical Activity:

Physical Activity:

Physical Activity:

Physical Activity:

Physical Activity:

Physical Activity:

Time Management

Time Management

Time Management

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Appendix XVIII. Recruitment Letter for Community Partners and Healthcare Providers

Dear [Community Partner/ Healthcare Provider]

We would like to inform you of a pilot program for cancer-related fatigue being offered at the Ottawa Regional Cancer Foundation in partial fulfillment of a doctoral dissertation. Cancer-related fatigue (CrF) is a common and debilitating symptom that cancer patients experience during and post-treatment. Dr. Sophie Lebel, a professor at the University of Ottawa and myself, Nicole Rutkowski, a PhD Candidate in Clinical Psychology, have adapted an existing intervention from a randomized control trial for individuals experiencing CrF (Fillion et al., 2008).

The program is a 4-week virtual group that incorporates cognitive behaviour therapy and physical activity. We have collaboratively worked with the Ottawa Regional Cancer Foundation and a patient advisory board to adapt this intervention for CrF.

Despite numerous guidelines and studies on CrF, there has been limited implementation of evidence-based services for CrF. We would like to change that with your help! As an organization/individual that works with individuals who may be experiencing CrF, we are interested in speaking to you or your members about this program. We would also appreciate it if you could inform your members about this research study.

If you have any questions or would like us to present to your organization/team, please contact us at _____. We hope that this project will be of interest to you and your members.

Many thanks,

Nicole Rutkowski, BA (Hons)
PhD Candidate, Clinical Psychology
University of Ottawa

Appendix XIX. Informational Sheet for the CrF Program

Information on the Cancer-related Fatigue (CrF) Study.

Principle Investigators: Nicole Rutkowski & Dr. Sophie Lebel
Community partner: Patricia Barrett-Robillard, RN, Ottawa
Regional Cancer Foundation



uOttawa

Ottawa Regional
Cancer
FoundationFondation
du cancer
de la région d'Ottawa

Cancer-related fatigue has been defined as a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and that significantly interferes with usual functioning (Berger et al., 2015, p.9)

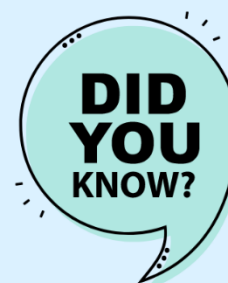
Physical activity and cognitive behavioural therapy have been found to improve CrF and are currently recommended in Canadian best practice guidelines. Despite many research interventions showing positive outcomes on CrF, few programs have been implemented into our communities. This program is attempting to change that. We'd like to be here for the long-term!

60-99%

of cancer patients will experience CrF during active cancer treatment.

30%

of cancer survivors will continue to experience CrF long-term.



What does the CrF intervention look like?

Participants will be randomized to an intervention group or a wait-list group and asked to complete surveys at 3 time points. The intervention group will meet for four consecutive weeks online for 90 minutes in groups of 10-15. Groups will be led by a cancer coach. The wait-list group will be offered the intervention after 3 months. Groups will be offered in the winter, spring, and fall of 2022.

Session One

1. Risk factors, causes, and types of CrF.
2. The model of CrF and how many different factors may be contributing to CrF.
3. Self-monitoring and progressive muscle relaxation.



Session Two

1. Activity pacing and how to schedule activities.
2. Sleep, relaxation, and self-compassion.
3. Physical activity and goal setting.



Session Three

1. Emotions and CrF. Strategies to manage difficult emotions and stress.
2. Link between emotions and thoughts.
3. ABC model of emotions and how to decrease negative emotions.



Session Four

1. Negative patterns of thinking and how to distance from unhelpful thoughts.
2. Types of social support and how to ask for help.
3. Reflection and setting personal goals.



****If you are interested or would like to refer someone, please have them contact us directly at CRFstudy@uottawa.ca. As there is a limited amount of spots, participants will be chosen on a first come, first served basis.****

Appendix XX. Consent form for CrF Intervention

Title of the study: Why am I Still Tired? Adaption, Implementation, and Evaluation of an Intervention for Cancer-Related Fatigue.

Project Team:

Nicole Rutkowski, BA (Hons)
School of Psychology,
Department of Social Sciences
University of Ottawa

Patricia Barrett-Robillard, RN,
BScN, MNRS, NBH-WHC
Cancer Coach and Health Impact
Supervisor
Coach en matière de cancer

Sophie Lebel, PhD
School of Psychology,
Department of Social Sciences
University of Ottawa

Invitation to participate:

You are being invited to participate in the abovementioned research study conducted by Nicole Rutkowski in partial fulfillment of a doctoral thesis, supervised by Dr. Sophie Lebel and in collaboration with the Ottawa Regional Cancer Foundation. This consent form provides you with information to help you make an informed choice. Please read this document and ask any questions you may have.

Taking part in this research initiative is **voluntary**. You have the option to not participate at all or you may choose to leave the research project at any time. Whatever you choose, it will not affect the services you receive at the Ottawa Regional Cancer Foundation now or in the future.

Purpose of the study:

The purpose of this study is to determine whether a four-week community-based program reduces cancer-related fatigue. We will also be determining whether your sleep, physical activity and mood improve which have all been found to contribute to cancer-related fatigue. You are being asked to take part in this study because you meet the following eligibility criteria: a) you are over 18 years old, b) you have received a cancer diagnosis, c) you have completed your cancer treatment, d) you report experiencing cancer-related fatigue, e) you are not experiencing any unmanaged/undermanaged mental health disorder judged to be clinically contra-indicated and/or affecting the group work, based on your own disclosure or clinically identified by the group facilitator during the first group session, and f) you speak, read, and write in English.

Study procedures

In this study, you will be “randomized” into one of two groups described below. “Randomized” means that you are put into a group by chance, like flipping a coin. You will be randomized either to the 4-week intervention group or a wait-list group. Each participant will have a 1:1 chance to be placed in the intervention. If you are placed in the wait-list group, you will receive the intervention 2 months after the intervention group. During the 3 months you will be asked to complete questionnaires while you wait. This is very important as it will tell us whether any improvements are related to intervention or if fatigue improves on its own over time.

Participation:

If you decide to participate, and are chosen to receive the intervention immediately, your participation will consist of attending 90-minute virtual groups for 4 consecutive weeks on cancer-related fatigue. During the 4 weeks, you will be asked to participate in activities, participate in group discussions, and complete homework. You will also be asked to complete a questionnaire package before the start of the intervention, one week after the intervention is completed, and at 2-months post intervention. The questionnaires will ask about your cancer-related fatigue, physical activity, your mood, sleep, and your confidence in managing

your fatigue. After the completion of the intervention, you will also be asked to fill out a satisfaction survey where you can provide feedback on your experience of the intervention. All surveys should take approximately 30 minutes. There will also be an option to participate in a focus group after completion of the intervention to provide your feedback and offer suggestions to improve the intervention.

If you are chosen to be in the waitlist control group, your participation will consist of completing a 30-minute questionnaire package at the start of the study, after 5 weeks and at a 2-month follow-up. The questionnaires will assess your cancer-related fatigue, physical activity, your mood, sleep, and your confidence in managing your fatigue. You may skip any questions that make you uncomfortable or that you do not wish to answer. After three months, you will be offered the chance to receive the intervention for cancer-related fatigue. You will only be asked to complete the satisfaction survey where you can provide feedback on your experience of the intervention and have the option to participate in the focus group should you wish too. However, you will not be asked to re-complete the questionnaire packages you completed during your wait time.

Video Recording:

The intervention group will be recorded for the sole purpose of quality assurance (i.e., to make sure the therapy is given to you as intended) and to provide feedback to the facilitator. The video recordings will not be associated with any identifying information. Only members of the research team will have access to the video recordings. As this is a research study, video recording is a necessary aspect of this intervention. Therefore, you will not be able to participate in the study should you choose to opt out of the recordings. All videos will be permanently deleted once they have been reviewed for quality assurance.

Risks:

Your participation in this study will entail that you volunteer personal information, engage in physical activity, and discuss your experiences with cancer and/or fatigue, and this may cause you to feel minor physical discomfort from increased physical activity and emotional distress from sharing experiencing or hearing others share their experiences with cancer. We have made efforts to minimize these risks. For example, resources will be provided in the group workbook in case you need additional emotional support. Additionally, you are not obligated to participate in group discussions if you feel uncomfortable. For physical exercise, we recommend beginning slowly and increasing your activity at your own pace.

One of the questionnaires asks about suicidality, which may be distressing to you. If you endorse suicidality, the research assistant will contact you to make sure you are safe and conduct a risk assessment. If you are deemed low risk, you will be provided with a resource list and offered a consultation with Dr. Sophie Lebel who can refer you for additional services. If you are deemed moderate risk for suicidality, you will be advised to contact your family doctor, Dr. Lebel will follow-up to see if you would like to be referred to a local psychosocial oncology service and offer to meet virtually with you. Dr. Lebel would also discuss whether the fatigue group would be appropriate at this time for you. If you are deemed high risk, you will be directed to the nearest emergency room. Dr. Lebel will follow up with you and offer to meet virtually and refer you to appropriate services. Dr. Lebel would also discuss whether the fatigue group would be appropriate at this time for you.

Benefits:

Your participation in this study may reduce your experience of cancer-related fatigue, increase your physical activity and your mood and improve your sleep. Currently, there are no widely available interventions for cancer-related fatigue, by participating in this study you are contributing to the advancement of knowledge and helping establish a sustainable intervention for cancer-related fatigue in Ottawa, from which other cancer survivors may also benefit.

Costs:

There are not costs associated with participating in this study other than your time.

Confidentiality and Privacy:

If you decide to participate in this study, the research team will only collect the information they need for this study. The information you will share will remain strictly confidential. The contents will be used only for the purposes of determining whether this intervention is effective and improving implementation and your identity will be protected.

There are limits to confidentiality when participating in a group activity. While the researchers will respect the confidentiality of participant data, we cannot guarantee that other members of the group will preserve the confidentiality of the information you will share. Group members will be asked, however, to respect other group members confidentiality. In order to minimize the risk of security breaches and to help ensure your confidentiality, it is recommended that you use standard safety measures, such as signing out of your account and closing your browser when you have completed the surveys.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be analyzed and will be published/presented to the scientific community at meetings and in journals.

Conservation of Data:

Records identifying you, such as the consent form, will be kept confidential and will not be disclosed or made publicly available, except as described in this consent document. Only the Project leads will have access to the data. All study documents related to you will bear only our assigned code. Audio/video recordings will be deleted immediately after transcription and the quality assurance process. The data collected both hard copy and electronic data; including survey datasets, researchers' notes, and consent forms will be kept in a secure manner and stored on an encrypted USB that is locked in a cabinet in Dr. Sophie Lebel's locked laboratory at the University of Ottawa. Only the members of the research team will have access to this data. This data will be retained for a period of 10 years after study completion, after which time the data will be safely disposed of by either shredding any paper documents or by permanently deleting the data from the encrypted USB.

Voluntary participation:

I am under no obligation to participate and if I choose to participate, I can withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences or affecting the services I could receive in the future at the Ottawa Regional Cancer Foundation. If I choose to withdraw, all data gathered until the time of withdrawal will be removed from the dataset and not used in the study, unless otherwise indicated. If I have any questions about the study, I may contact the researcher or their supervisor. If I have any questions regarding the ethical conduct of this study, I may contact the Office of Research Ethics and Integrity via email (ethics@uottawa.ca) or telephone (613-562-5387).

It is recommended that I keep a copy of this consent form for my records.

Signatures:

I have read this consent form. I have had the opportunity to discuss this research study with a member of the research team. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statement or implied statements. Any relationship (such

as employee, student or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this clinical trial is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Acceptance: By selecting the consent statement below, **I agree to participate in the Why am I still tired? Cancer-related fatigue research study.**

☐ Yes, I want to participate.

(Name/Code): _____

Email/Telephone number: _____

Emergency Contact Information:

Name: _____ Relationship: _____ Telephone number: _____

☐ No, I do not want to participate.

I agree to being contacted and receive more information about participating in the focus groups after my completion of the intervention:

Yes ☐ No ☐

Participant signature _____ Date _____ (day/month/year)

Participant printed name: _____

Investigator or Delegate Statement I have carefully explained the study to the study participant. To the best of my knowledge, the participant understands the nature, demands, risks and benefits involved in taking part in this study.

Investigator/Delegate's Printed Name Investigator/Delegate's Signature Date

Appendix XXI. Consent Form for Focus Group after CrF Intervention

Focus Group Consent Form

Purpose

You have been invited to participate in a focus group being conducted by the University of Ottawa in collaboration with the Ottawa Regional Cancer Foundation. The purpose of this focus group is discussing your experiences completing the cancer-related fatigue group, such as your satisfaction with the content of the program and workbook, the strengths and weakness of the program, and barriers and supports to accessing the program. The discussion will be conducted by Nicole Rutkowski, graduate student in the Clinical Psychology Doctoral Program and Dr. Sophie Lebel Professor at the University of Ottawa. The information learned in this focus group will be used to improve and adapt the cancer-related fatigue group to ensure it is meeting the needs of cancer survivors. Your feedback is very important to creating an accessible, sustainable, and relevant intervention for individuals experiencing cancer-related fatigue.

Voluntary Participation

Your participation in the focus group is **voluntary** and will not affect the services you receive at the Ottawa Regional Cancer Foundation now or in the future. You have the right to withdraw from the focus group at any time should you wish too. However, given the nature of focus groups and data being highly dependent on the overall group discussion, your individual data cannot be withdrawn from the focus group data.

Procedure

As part of this study, you will be placed in a group of 6 – 12 individuals with whom you completed the intervention. The focus will last for approximately 60-90 minutes. A moderator will ask you several questions while facilitating the discussion. This focus group will be audio-recorded, and a note-taker will be present. However, your responses will remain confidential, and no names will be included in the final report. If you choose to participate in the focus group, you do not have to answer any questions that make you uncomfortable or that you do not want to answer.

You can choose whether or not to participate in the focus group, and you may stop at any time during the course of the study.

Please note that there are no right or wrong answers to focus group questions. Our research team wants to hear many varying viewpoints and would like everyone to contribute their thoughts. Out of respect, please refrain from interrupting others. However, feel free to be honest even when your responses counter those of other group members.

Benefits and Risks

Your participation can contribute to the improvement of the cancer-related fatigue intervention. Cancer-related fatigue is a very common experience and participating gives you the opportunity to shape a service that may benefit the survivorship community in Ottawa. No risks are anticipated beyond those experienced during an average conversation.

Confidentiality

Should you choose to participate, you will be asked to respect the privacy of other focus group members by not disclosing any content discussed during the study. The research team from the School of Psychology at the University of Ottawa will analyze the data, but—as stated above—your responses will remain confidential, and no names will be included in any reports. However, while the research team will keep data confidential, full confidentiality cannot be guaranteed given the presence of other participants in the focus group.

Conservation of Data:

The data collected both hard copy and electronic data; including transcripts, researchers' notes, and consent forms will be kept in a secure manner and stored on an encrypted USB that is locked in a cabinet. Audio recordings will be deleted immediately after transcription. Only the members of the research team will have access to this data. This data will be retained for a period of 10 years after study completion.

Contact

If I have any questions about the study, I may contact the researcher, Ms. Rutkowski via email or their supervisor, Dr. Sophie Lebel. If I have any questions regarding the ethical conduct of this study, I may contact the Office of Research Ethics and Integrity via email (ethics@uottawa.ca) or telephone (613-562-5387).

It is recommended that I keep a copy of this consent form for my records.

I understand this information and agree to participate fully under the conditions stated above.

Acceptance: By signing the consent statement below, I agree:

- I have reviewed the information sheet and have had any questions about the study answered to my satisfaction.
- I agree to have the focus group audio-recorded.
- I agree to maintain confidentiality of information shared in this focus group.
- I have received a copy of this information letter.
- I agree to participate in this focus group for research purposes.

Participant signature _____

Participant printed name: _____ Date _____
(day/month/year)

Appendix XXII. Sociodemographic and Implementation questionnaire

What is your age?

Gender What is your gender?

Marital Status: What is your marital status?

- ☐ Married (1)
- ☐ Widowed (2)
- ☐ Divorced (3)
- ☐ Separated (4)
- ☐ Single (5)
- ☐ Common law (6)

Education What is your highest education level?

- ☐ No schooling (1)
- ☐ Primary (2)
- ☐ Secondary (3)
- ☐ Technical/College (4)
- ☐ University (5)
- ☐ Masters (6)
- ☐ Doctorate (7)

Work: Which describes your work the best?

- ☐ Physical labour (1)
- ☐ Clerical/technical (2)
- ☐ High professional (3)
- ☐ Civil service (4)
- ☐ Other, please specify: (5) _____

Ethnicity What is your ethnicity?

- ☐ White (1)
- ☐ Black or African American (2)
- ☐ First Nations, Inuit, and Métis (3)
- ☐ Asian/ Pacific Islander (4)
- ☐ Other, please specify: (5) _____

Cancer What type of cancer were you diagnosed with?

- ☐ Breast (1)
- ☐ Prostate (2)
- ☐ Colorectal (3)

- ☐ Lung (4)
- ☐ Urogenital (5)
- ☐ Other, please specify (6) _____

Cancer stage What stage of cancer were you diagnosed with?

- ☐ Stage I (1)
- ☐ Stage II (2)
- ☐ Stage III (3)
- ☐ Stage IV (4)

YR diagnosis: What year did you receive your diagnosis?

Treatment How long has it been since your treatment ended?

- ☐ <6 months (1)
- ☐ <1 year (2)
- ☐ 1 year (3)
- ☐ 2 years (4)
- ☐ 3 years (5)
- ☐ 4 years (6)
- ☐ 5 years (7)
- ☐ 6 years (8)
- ☐ 7+ years (9)

Prior dx Have you received a prior diagnosis of cancer?

- ☐ No (1)
- ☐ Yes (2)

Display This Question:

If Have you received a prior diagnosis of cancer? = Yes

Prior dx type: What past cancer diagnosis did you receive?

Display This Question:

If Have you received a prior diagnosis of cancer? = Yes

In what year did you receive your previous cancer diagnosis?

Medication Are you currently taking any medication?

- ☐ No (1)

- Yes (2)

Display This Question:

If Are you currently taking any medication? = Yes

Dose: Please list the medications and dose you are currently taking:

Chronic illness Do you have any other chronic illnesses?

- No (1)
- Yes (2)

Display This Question:

If Do you have any other chronic illnesses? = Yes

Other illness: Please list the other chronic illnesses you experience:

Hx insomnia Do you have a history of insomnia?

- No (1)
- Yes (2)

Hrs of sleep How many hours of sleep do you get every night?

Hx of depression Do you have a history of depression?

- No (1)
- Yes (2)

Smoking Do you smoke cigarettes?

- No (1)
- Yes (2)

HCP discuss Has any healthcare provider discussed cancer-related fatigue with you?

- Yes (1)
- No (2)

Display This Question:

If Has any healthcare provider discussed cancer-related fatigue with you? = Yes

Which HCP Which healthcare provider discussed cancer-related fatigue with you? Please select all that apply.

- Family doctor (1)
- Oncologist (2)
- Nurse at the hospital (3)
- Nurse in the community (4)
- Cancer coach (5)
- Other, please specify (6) _____

Initiate Discussion: Have you ever initiated a conversation about fatigue with your healthcare provider?

- No (1)
- Yes (2)

Display This Question:

If Have you ever initiated a conversation about fatigue with your healthcare provider? = No

Reason for no: Was there a reason you did not disclose experiencing fatigue to your healthcare provider?

Display This Question:

If Have you ever initiated a conversation about fatigue with your healthcare provider? = Yes

Recommendations What recommendations or help did you receive to help address your fatigue?

Location Where are you located?

- Ottawa (1)
- Gatineau (2)
- Rural Community outside of Ottawa (3)
- Other, please specify (4) _____

Service impact Has your income impacted your ability to access services after your cancer treatment?

- Yes (1)
- Somewhat (2)
- No (3)

Display This Question:

If Has your income impacted your ability to access services after your cancer treatment? = Yes

Or Has your income impacted your ability to access services after your cancer treatment? = Somewhat

How service impact Please explain how income has impacted your ability to access services:

Payment If you had to pay to attend this group, would it affect your decision to participate?

- ☐ Yes (1)
- ☐ Maybe (2)
- ☐ No (3)

Income: What is your household income? Why do we ask? We know financial concerns can be a barrier to accessing services. We are interested if our program is accessible to everyone and not determined by household income level.

- ☐ <20k (1)
- ☐ \$20-39k (2)
- ☐ \$40-59K (3)
- ☐ \$60-69k (4)
- ☐ \$80-99k (5)
- ☐ \$100-149k (6)
- ☐ \$150k + (7)
- ☐ Prefer not to answer (8)

Tech: Do you feel comfortable with technology?

- ☐ No (1)
- ☐ Somewhat (2)
- ☐ Yes (3)

Barriers: Did you experience any barriers in accessing this program?

- ☐ Yes (1)
- ☐ Somewhat (2)
- ☐ No (3)

Barriers explained: If yes or somewhat, please list any barriers you experienced:

Appendix XXIII. Functional Assessment of Chronic Illness- Fatigue (FACIT-F)

Below is a list of statements that other people with your illness have said are important. **Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

		Not at all	A little bit	Some -what	Quite a bit	Very much
HI7	I feel fatigued	0	1	2	3	4
HI12	I feel weak all over	0	1	2	3	4
An1	I feel listless ("washed out")	0	1	2	3	4
An2	I feel tired	0	1	2	3	4
An3	I have trouble <u>starting</u> things because I am tired	0	1	2	3	4
An4	I have trouble <u>finishing</u> things because I am tired	0	1	2	3	4
An5	R-I have energy	0	1	2	3	4
An7	R-I am able to do my usual activities	0	1	2	3	4
An8	I need to sleep during the day	0	1	2	3	4
An12	I am too tired to eat	0	1	2	3	4

An14	I need help doing my usual activities	0	1	2	3	4
An15	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
An16	I have to limit my social activity because I am tired	0	1	2	3	4

SOCIAL/FAMILY WELL-BEING

		Not at all	A little bit	Some -what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4

Q1	Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box and go to the next section.				
GS7	I am satisfied with my sex life	0	1	2	3 4

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Appendix XXIV. Multidimensional Fatigue Inventory (MFI)

MFI® MULTIDIMENSIONAL FATIGUE INVENTORY

© E. Smets, B. Garssen, B. Bonke.

Instructions:

By means of the following statements we would like to get an idea of how you have been feeling **lately**.
There is, for example, the statement:

"I FEEL RELAXED"

If you think that this is **entirely true**, that indeed you have been feeling relaxed lately, please, place an **X** in the extreme left box; like this:

yes, that is true ☒1 ☐2 ☐3 ☐4 ☐5 no, that is not true

The more you **disagree** with the statement, the more you can place an **X** in the direction of "no, that is not true". Please do not miss out a statement and place only one **X** in a box for each statement.

1	I feel fit.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
2	Physically, I feel only able to do a little.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
3	I feel very active.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
4	I feel like doing all sorts of nice things.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
5	I feel tired.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
6	I think I do a lot in a day.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
7	When I am doing something, I can keep my thoughts on it.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
8	Physically I can take on a lot.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
9	I dread having to do things.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
10	I think I do very little in a day.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
11	I can concentrate well.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
12	I am rested.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
13	It takes a lot of effort to concentrate on things.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
14	Physically I feel I am in a bad condition.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
15	I have a lot of plans.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
16	I tire easily.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
17	I get little done.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
18	I don't feel like doing anything.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
19	My thoughts easily wander.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true
20	Physically I feel I am in an excellent condition.	yes, that is true	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	no, that is not true

Appendix XXV. Insomnia Severity Index (ISI)

Insomnia Severity Index (ISI)

1. Please rate the current (i.e., last week) **SEVERITY** of your insomnia problem(s).

90-120	>120	<30 min		30-45	45-90
		None	Mild	Moderate	Severe
<u>Very</u>					
Difficulty falling asleep:	0		1	2	3
4					
Difficulty staying asleep:	0		1	2	3
4					
Problem waking up too early:	0		1	2	3
4					

2. How **SATISFIED**/dissatisfied are you with your current sleep pattern?

<u>Very Satisfied</u>			<u>Very Dissatisfied</u>	
0	1	2	3	4

3. To what extent do you consider your sleep problem to **INTERFERE** with your daily functioning (e.g. daytime fatigue, ability to function at work/daily chores, concentration, memory, mood, etc.).

Not at all	A Little	Somewhat	Much	Very Much
Interfering				Interfering
0	1	2	3	4

How **NOTICEABLE** to others do you think your sleeping problem is in terms of impairing the quality of your life?

Not at all	Barely	Somewhat	Much	Very Much	
Noticeable				Noticeable	
0	1	2	3	4	

5. How **WORRIED**/distressed are you about your current sleep problem?

Not at all	A Little	Somewhat	Much	Very Much	
0	1	2	3	4	

© Morin, C.M. (1993). Insomnia: Psychological Assessment and Management. New York: Guilford Press.

Appendix XXVI. Generalized Anxiety Disorder-7 (GAD-7)

Over the Last 2 weeks, how often have you been bothered by any of the following problems?	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS	NEARLY EVERY DAY
1. Feeling nervous, anxious or on edge	☐ 0	☐ 1	☐ 2	☐ 3
2. Not being able to stop or control worrying	☐ 0	☐ 1	☐ 2	☐ 3
3. Worrying too much about different things	☐ 0	☐ 1	☐ 2	☐ 3
4. Trouble relaxing	☐ 0	☐ 1	☐ 2	☐ 3
5. Being so restless that it is hard to sit still	☐ 0	☐ 1	☐ 2	☐ 3
6. Becoming easily annoyed or irritable	☐ 0	☐ 1	☐ 2	☐ 3
7. Feeling afraid as if something awful might happen	☐ 0	☐ 1	☐ 2	☐ 3

1. If you checked off any problems on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐ 0	☐ 1	☐ 2	☐ 3

Appendix XXVII. Patient Health Questionnaire (PHQ-9)

Over the last 2 weeks , how often have you been bothered by any of the following problems?	NOT AT ALL	SEVERAL DAYS	MORE THAN HALF THE DAYS	NEARLY EVERY DAY
1. Little interest or pleasure in doing things	☐ 0	☐ 1	☐ 2	☐ 3
2. Feeling down, depressed, or hopeless	☐ 0	☐ 1	☐ 2	☐ 3
3. Trouble falling or staying asleep, or sleeping too much	☐ 0	☐ 1	☐ 2	☐ 3
4. Feeling tired or having little energy	☐ 0	☐ 1	☐ 2	☐ 3
5. Poor appetite or overeating	☐ 0	☐ 1	☐ 2	☐ 3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	☐ 0	☐ 1	☐ 2	☐ 3
7. Trouble concentrating on things, such as reading the newspaper or watching television	☐ 0	☐ 1	☐ 2	☐ 3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	☐ 0	☐ 1	☐ 2	☐ 3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	☐ 0	☐ 1	☐ 2	☐ 3

10. If you checked off any problems on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?			
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
☐ 0	☐ 1	☐ 2	☐ 3

Appendix XXVIII. Godin Leisure-Time Exercise Questionnaire

Godin Leisure-Time Exercise Questionnaire

During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

Times Per

Week

STRENUOUS EXERCISE**(HEART BEATS RAPIDLY)** _____

(e.g., running, jogging, hockey, football, soccer,
squash, basketball, cross country skiing, judo,
roller skating, vigorous swimming,
vigorous long distance bicycling)

MODERATE EXERCISE**(NOT EXHAUSTING)** _____

(e.g., fast walking, baseball, tennis, easy bicycling,
volleyball, badminton, easy swimming, alpine skiing,
popular and folk dancing)

MILD EXERCISE**(MINIMAL EFFORT)** _____

(e.g., yoga, archery, fishing from river bank, bowling,
horseshoes, golf, snow-mobiling, easy walking)

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN SOMETIMES NEVER/RARELY

1. ☐2. ☐3. ☐

Godin, G. (2011). The Godin-Shephard leisure-time physical activity questionnaire. *Health & Fitness Journal of Canada*, 4(1), 18-22.

Appendix XXII. PROMIS Self-Efficacy for Managing Chronic Conditions

Please respond to each question or statement by marking one box per row. Please answer the following questions with fatigue as your symptom.

Self-Efficacy for Managing Chronic Conditions - Managing Symptoms – Short Form 8a

Please respond to each question or statement by marking one box per row.

CURRENT level of confidence...		I am not at all confident	I am a little confident	I am somewhat confident	I am quite confident	I am very confident
SEMSX010	I can manage my symptoms during my daily activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX014	I can keep my symptoms from interfering with relationships with friends and family.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX009	I can manage my symptoms in a public place	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX011	I can work with my doctor to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX017	I can keep my symptoms from interfering with my personal care	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX008	I can manage my symptoms when I am at home	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX015	I can keep my symptoms from interfering with the work I need to do.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SEMSX027	I can find the information I need to manage my symptoms	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Appendix XXIX. Adapted Evaluation Measure from the Ottawa Cancer Foundation

Hello!

We are writing to you today because we would like to know more about your experience while participating in our Programs. As part of the team's ongoing desire to ensure a high-quality experience for our clients, we would like to know whether the Cancer-related fatigue group was helpful and how satisfied you were with that experience. The survey will take approximately 10 minutes to complete. Your responses to these questions along with your suggestions and comments will help us continually improve the program. Please know that your responses are anonymous, no individual responses will be shared and no information that allows us to identify you is being collected.

Consent to participate:

I agree to participate in this survey. The survey is designed to gather information about my experience in the cancer-related fatigue group. The data collected, along with suggestions and comments will be used (without attribution) as part of a research study that is evaluating the Why am I still Tired? Cancer-related fatigue group, with the purpose of improving the group to meet the needs of people post cancer. Aggregated (i.e., no identifying information will be used) results may be published. I also understand that my responses are anonymous and that no individual responses will be shared. Finally, I understand that my participation in this survey is voluntary and that I am free to decline to participate, without consequence.

Consent: Do you agree to participate?

☐ Yes (1)

☐ No (2)

Skip To: End of Survey If Do you agree to participate? = No

End of Block: Default Question Block

Start of Block: Block 1

What were your objectives in accessing this program?

How effective was the program at helping you meet your objectives?

- ☐ Not effective at all (1)
- ☐ Slightly effective (2)
- ☐ Moderately effective (3)
- ☐ Very effective (4)
- ☐ Extremely effective (5)

Display This Question:

If How effective was the program at helping you meet your objectives? = Not effective at all
Or How effective was the program at helping you meet your objectives? = Slightly effective

Please, explain why the program was not completely effective at helping you meet your objectives.

Timing When would have it been most ideal for you to take this program?

- ☐ When I was diagnosed, before starting my cancer treatment (1)
- ☐ During my cancer treatment (2)
- ☐ After completing my cancer treatment (3)

End of Block: Block 1

Start of Block: Accessibility

Was it easy to access the program?

- ☐ Yes, completely (1)
- ☐ Yes, somewhat (2)
- ☐ No (3)

What made it easy or difficult to access the program?

Payment If you had to pay for the program, would you have still attended the program?

- ☐ Yes (1)
- ☐ Maybe (2)
- ☐ No (3)

Cost How much would you be willing to pay for the program?

- ☐ Under \$50 (1)
- ☐ \$50-75 (2)
- ☐ \$75-100 (3)
- ☐ \$100-150 (4)
- ☐ I would not be willing to pay. (5)

End of Block: Accessibility

	Strongly Disagree (1)	Disagree (2)	Neither agree nor disagree (3)	Agree (4)	Strongly agree (5)
The start and end times of this program were convenient for me (i.e., 10-11:30AM). (1)	☐	☐	☐	☐	☐
The length of each weekly session was appropriate for the program (i.e., 90 minutes). (2)	☐	☐	☐	☐	☐
The program was an appropriate length of time (i.e., 4 weeks). (3)	☐	☐	☐	☐	☐
The coach was welcoming, treated members of the group with respect, without judgement, and with sensitivity. (4)	☐	☐	☐	☐	☐
The coach answered questions and presented information clearly. (5)	☐	☐	☐	☐	☐
I prefer that this program was offered virtually. (6)	☐	☐	☐	☐	☐

I would prefer
to have
completed this
program in
person. (7)

☐☐☐☐☐

End of Block: Block 5

Start of Block: Satisfaction

What was your satisfaction with the information covered in the program?

- ☐ Very satisfied (1)
- ☐ Satisfied (2)
- ☐ Neither satisfied nor dissatisfied (3)
- ☐ Dissatisfied (4)
- ☐ Very dissatisfied (5)
-

What was your satisfaction with the cancer-related fatigue workbook?

- ☐ Very satisfied (1)
- ☐ Satisfied (2)
- ☐ Neither satisfied nor dissatisfied (3)
- ☐ Dissatisfied (4)
- ☐ Very dissatisfied (5)
-

Overall what was your satisfaction with this program?

- ☐ Very satisfied (1)
- ☐ Satisfied (2)
- ☐ Neither satisfied nor dissatisfied (3)
- ☐ Dissatisfied (4)
- ☐ Very dissatisfied (5)
-

Would you recommend this program to other cancer survivors experiencing fatigue?

- ☐ Yes (1)
- ☐ No (2)
-

Display This Question:

If Would you recommend this program to other cancer survivors experiencing fatigue? = No

Please explain why you would be unlikely to recommend this program:

End of Block: Satisfaction

Start of Block: Block 7

Improvement What would you change or improve about the program or workbook?

Is there anything else you would like to share with us at this time?

Appendix XXX. Table of Outcomes for the Evaluation Measure Designed by the Ottawa Cancer Foundation

	N=25 (%)
How effective was the program at helping you meet your objectives?	
Not effective at all	0
Slightly effective	2 (8)
Moderately effective	9 (36)
Very effective	10 (16)
Extremely effective	4 (16)
When would have it been most ideal for you to take this program?	
Upon diagnosis	5 (20)
During treatment	2 (8)
After treatment	17 (68)
Was it easy to access the program?	
Yes, completely	21 (84)
Yes, somewhat	4 (16)
If you had to pay to attend this group, would it affect your decision to participate?	
Yes	9 (18.2)
Maybe	12 (48)
No	4 (16)
How much would you be willing to pay for the program?	
<\$50	10 (40)
\$50-75	7 (28)
\$75-100	3 (12)
\$100-150	2 (8)
Unwilling to pay	3 (12)
The program provided a supportive environment for me to connect with others who share similar experiences.	
Strongly Disagree	1 (4)
Disagree	1 (4)
Neither agree nor disagree	2 (8)
Agree	8 (32)
Strongly agree	13 (52)
This program provided me with knowledge and the opportunity to develop new skills I can incorporate into my day-to-day living.	
Disagree	2 (8)
Agree	11 (44)
Strongly Agree	12 (48)
This program helped me identify ways to improve my health and wellbeing.	
Disagree	2 (8)
Agree	9 (36)
Strongly agree	14 (56)
This program helped me develop strategies/skills so that I am better able to cope with my fatigue.	
Disagree	2 (8)
Neither agree nor disagree	1 (4)
Agree	13 (52)
Strongly agree	9 (36)
My quality of life has improved.	
Disagree	2 (8)
Neither agree nor disagree	4 (16)
Agree	15 (60)
Strongly agree	4 (16)
The start and end times of this program were convenient for me (i.e., 10-11:30 AM).	

Strongly disagree	1 (4)
Disagree	1 (4)
Neither agree nor disagree	1 (4)
Agree	15 (60)
Strongly agree	7 (28)
The length of weekly session was appropriate for the program (i.e., 90 minutes).	
Disagree	5 (20)
Neither agree nor disagree	3 (12)
Agree	15 (60)
Strongly agree	2 (8)
The program was an appropriate length (i.e., 4 weeks).	
Disagree	8 (32)
Neither agree nor disagree	7 (28)
Agree/Strongly Agree	10 (40)
The coach was welcoming, treated members of the group with respect, without judgement, and with sensitivity.	
Strongly disagree	1 (4)
Neither agree nor disagree	1 (4)
Agree	4 (16)
Strongly agree	19 (76)
The coach answered questions and presented information clearly.	
Disagree	2 (8)
Agree	6 (24)
Strongly agree	17 (68)
I prefer the program to be offered virtually.	
Neither agree nor disagree	6 (24)
Agree	5 (20)
Strongly agree	14 (56)
I would have completed this program in person.	
Strongly disagree	6 (24)
Disagree	7 (28)
Neither agree nor disagree	9 (36)
Agree	2 (8)
Strongly agree	1 (4)
What was your satisfaction with the information covered in the program?	
Very satisfied	16 (64)
Satisfied	7 (28)
Neither satisfied nor dissatisfied	1 (4)
Dissatisfied	1 (4)
What was your satisfaction with the cancer-related fatigue workbook?	
Very satisfied	9 (36)
Satisfied	10 (40)
Neither satisfied nor dissatisfied	3 (12)
Dissatisfied	3 (12)
Overall what was your satisfaction with the program?	
Very satisfied	14 (56)
Satisfied	8 (32)
Neither satisfied nor dissatisfied	1 (4)
Dissatisfied	2 (8)
Would you recommend this program to other cancer survivors?	
Yes	22 (88)
No	3 (12)

Appendix XXXI. Optional Focus Group Interview with CrF Program Participants

Focus Group Guide Cancer-Related Fatigue Intervention

Preamble

- Introduction of the person running the focus group (name, designation, study name).
- I would like to take this opportunity to thank you once again for taking the time to share your experiences about the cancer related fatigue intervention you completed.
- We are conducting this focus group to learn about your experience and on how we may improve the intervention.
- Your input as a participant of the intervention is critical to understanding the strengths and weakness of the intervention and workbook you received, as well as any obstacles you may have in accessing the intervention. We hope that this interview will help evaluate the efficacy of the intervention and assist us in improving the service.

Interview Format

- The focus should take approximately 60 minutes and primarily involves open-ended questions regarding your experiences as a participant in the intervention.

Permission/Consent to Record Interview

- All information exchanged in this focus group will remain confidential, reported only at aggregate levels, as indicated on the informed consent form that you have previously signed. Only the research team will have access to the collected data. You will not be named in any reports or publications that may be generated from this study.
- To improve the accuracy of my notes and to facilitate the follow-up work, analysis, and overall value of this work, I would like to record this focus group if this is acceptable to you. Any identifiers such as your name will be removed from the typed versions of the focus group. We will also keep all tapes in a password protected file on a desktop computer situated in locked area at the University of Ottawa until data analysis is complete. Once data is analyzed we will destroy the tapes.

Cancer-Related Fatigue Intervention

1. How was your general experience in the program?
2. Were you satisfied with the content of the intervention?
 - a. Was there any other content you wish was included?

- a. Did you find the intervention helpful or unhelpful to better manage your fatigue?
 - i. In what ways was it helpful? Or unhelpful?
- b. How did you find completing the intervention online?
- c. How did you find the length of the sessions?
 - ii. Did you feel overloaded with information at any point?
- 3. What are your thoughts on the participant workbook?
 - i. Lay-out? Length? Readability? Ease of use?
 - ii. Do you have any suggestions for improvement of the workbook?
- 4. What do you think could be changed or improved about the intervention?
- 5. What do you think are the strengths of the intervention? How about the weaknesses?
- 6. Did you face any obstacles to participating in the intervention?
- 7. Would the cost of the intervention be a barrier for you?
- 8. Do you believe the intervention is easily accessible?
If no, how could we improve the accessibility of this intervention?

This wraps up the questions I wanted to ask you today. Do you have any additional comments or questions?

Thank you very much for participating in this focus group. If you have any further questions, you can contact me directly, or contact Dr. Sophie Lebel, the principal investigator on the project.

Appendix XXXII. Fidelity Checklist for Sessions 1-4

Date:**Group Leader:****Rater:**

SESSION ONE – WINTER 2022 Group			
	Skill/Activity	Completed? Yes (1) or No (0)	Comments
1.	Group Leader (GL) introduces herself		
2.	GL reviews group etiquette expectations for group		
3.	Each group member (GM) introduces themselves briefly		
4.	GL reviews agenda for the sessions content		
5.	GL initiates group discussion on what fatigue means to the group		
6.	GL reviews the definition of cancer related fatigue		
7.	GL provides education on risk factors for CRF		
8.	GL provides education four possible causes of fatigue		
9.	GL provides education 3 types of fatigue		
10.	GL provides education on long-term CRF and proinflammatory cytokine hypothesis		
11.	GL explains Model of fatigue		
12.	GL presents self-monitoring tool		
13.	GL presents progressive muscle relaxation		
14.	GL provides education on the benefits of PMR		
15.	GL plays Dr. Russ Harris video on two nervous systems		
16.	GL provides education on how relaxation can help with sleep		
17.	GL leads PMR exercise for a minimum of 5 minutes		
18.	GL reviewed homework for next session		
19.	GL had adequate time management (i.e. spent enough time on each exercise and finished on time)		
	TOTAL		

SESSION TWO – WINTER 2022 Group			
	Skill/Activity	Completed? Yes (1) or No (0)	Comments
1.	GL reviews agenda for the sessions content		
2.	GL reviewed last session homework and provided opportunity for GM to share		
3.	GL provided education on behaviour that may result in sleep troubles		
4.	GL provided education on behaviour that may improve sleep		
5.	GL asks GM what sleep habits they do and/or which sleep habits they would like to implement		
6.	GL defines self-compassion		
7.	GL provides education on the benefits of self-compassion		
8.	Self-compassion exercise: GL asks GMs to provide a self-critical and self-compassionate response example		
9.	GL provides education on the benefits of physical activity		
10.	GL plays video of Dr. Jones on CRF and Exercise		
11.	GL provides education on cancer and deconditioning		
12.	GL provides education on physical activity guidelines		
13.	GL provides education on how to increase motivation for physical activity		
14.	GL asks GMs about examples of physical activity they may enjoy or currently engage in.		
15.	GL presents examples of physical activity		
16.	GL discusses the cost/benefit of increasing physical activity and allows for some group discussion		
17.	GL presents SMART goals		
18.	GL provides education on the boom and bust cycle		
19.	GL provides education on activity pacing		
20.	GL reviewed homework for next session		
21.	GL had adequate time management (i.e. spent enough time on each exercise and finished on time)		
	TOTAL		

SESSION THREE – WINTER 2022 Group			
	Skill/Activity	Completed? Yes (1) or No (0)	Comments
1.	GL reviews agenda for the sessions content		
2.	GL reviewed last session homework and provided opportunity for GM to share		
3.	GL provides education on emotions and fatigue (i.e., chronic stress and how it impacts nervous system)		
4.	GL provides education on strategies that are helpful for emotional regulation		
5.	GL provides education on strategies that are less helpful for emotional regulation		
6.	GL presents and discusses the CBT model of emotions		
7.	GL leads exercise “you see a good friend on your walk” and asks GM to identify thoughts		
8.	GL presents several potential thoughts and asks GM what emotions may result from each thought		
9.	GL leads example “washing dishes” exercise and allows opportunity for GM to identify emotion		
10.	GL leads example exercise “HCP comment” and allows opportunity for GM to identify emotion		
11.	GL summarizes how emotions are linked to thoughts		
12.	GL provides education on behaviour that increases risk of emotionality		
13.	GL provides education on the purpose of emotions		
14.	GL plays video on the ABC of emotion		
15.	GL presents example of Jane		
16.	GL open discussion on the activating event, belief and consequence concerning Jane		
17.	GL provides summary oh how the ABC model can help manage fatigue		
18.	GL provides education on strategies to challenge unhelpful thoughts.		
19.	GL reviewed homework for next session		
20.	GL had adequate time management (i.e. spent enough time on each exercise and finished on time)		
	TOTAL		

SESSION FOUR – WINTER 2022 Group			
	Skill/Activity	Completed? Yes (1) or No (0)	Comments
1.	GL reviews agenda for the sessions content		
2.	GL reviewed last session homework and provided opportunity for GM to share		
3.	GL provides education on the definition of thinking traps and when we become at risk to being more vulnerable		
4.	GL plays video on thinking traps		
5.	GL provides education on 10 common thinking traps		
6.	GL presents “washing dishes” example and offers GMs opportunity to identify thinking trap		
7.	GL presents “HCP comment” example and offers GMs opportunity to identify thinking trap		
8.	GL leads white polar bear exercise		
9.	GL provides education on cognitive fusion/defusion		
10.	GL plays sushi train video on cognitive defusion		
11.	GL presents examples of ways to distance from unhelpful thoughts (i.e., leaves on a stream, etc)		
12.	GL provides education on the importance of social support and its impact on health		
13.	GL provides education on the four types of social support		
14.	GL provides summary of skills learned in the group		
15.	GL provides summary of knowledge gained in the group		
16.	GL leads reflection on take aways from the group and allow GM to contribute		
17.	GL asks GMs about goals and allows opportunity for sharing		
18.	GL reviewed final homework for the group		
19.	GL had adequate time management (i.e. spent enough time on each exercise and finished on time)		
	TOTAL		

Appendix XXXIII. Maintenance: Ottawa Cancer Foundation CrF Program Satisfaction Survey – April 2024

Q2 How effectively did the content of this program meet your expectations?

Answered: 7 Skipped: 1

5.0★
average rating



	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
☆	0.00% 0	0.00% 0	0.00% 0	0.00% 0	100.00% 7	7	5.00

#	COMMENT	DATE
1	This was an excellent program and covered so much great information !	4/26/2024 10:36 AM
2	Very good information and helpful techniques	4/24/2024 8:35 PM
3	Good, didn't. Miss any sessions because of choice in person or online when I was not well.	4/24/2024 9:47 AM
4	It was very useful and it met my expectations. Sharing patient's experiences also helped a lot.	4/23/2024 9:07 PM
5	Exactly has described	4/23/2024 7:11 PM
6	Excellent	4/23/2024 6:35 PM

Q3 How effectively did this program help reduce your stress or anxiety in general?

Answered: 7 Skipped: 1

4.6★
average rating



	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
☆	0.00% 0	0.00% 0	14.29% 1	14.29% 1	71.43% 5	7	4.57

#	COMMENT	DATE
1	Effective techniques were covered re stress and all were helpful.	4/26/2024 10:36 AM
2	still working on it	4/24/2024 8:35 PM
3	Good, being with others experiencing same emotions helpful.	4/24/2024 9:47 AM
4	I can't give a percentage but the methods given to deal with stress, negative emotions and the muscle relaxation techniques helped. Also, tips on how to improve sleep were valuable.	4/23/2024 9:07 PM
5	Still a work in progress	4/23/2024 7:11 PM
6	I attended the program every time.I free it is better for me to understand the teacher.	4/23/2024 6:35 PM

Q4 How effectively did this program help you feel less isolated or more connected to others going through similar experiences?

Answered: 7 Skipped: 1

4.6★
average rating

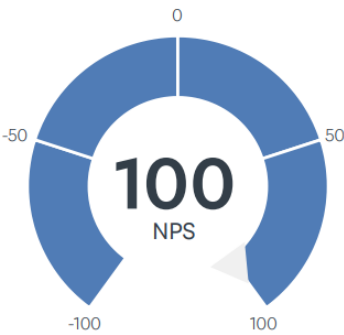


	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
☆	0.00%	0.00%	14.29%	14.29%	71.43%		
	0	0	1	1	5	7	4.57

#	COMMENT	DATE
1	it is good not to feel like i am the only one	4/24/2024 8:35 PM
2	Good, but must learn to make new friends as In am loosing friends and family due to cancer.	4/24/2024 9:47 AM
3	Meeting face to face with other patients was very useful although unfortunately I had to attend one session virtually.	4/23/2024 9:07 PM
4	When I was in the room,I tried hard to understand the teacher and other people in the room,I felt less isolated and more active .	4/23/2024 6:35 PM

Q6 How likely is it that you would recommend this program to someone else who might need it?

Answered: 8 Skipped: 0



DETRACTORS (0-6)	PASSIVES (7-8)	PROMOTERS (9-10)	NET PROMOTER® SCORE
0	0	100%	100
0	0	8	

Q8 What did you like about the program?

Answered: 7 Skipped: 1

#	RESPONSES	DATE
1	The program affirmed that we cancer patients can have a bit of control in how we deal with cancer-related fatigue.	4/27/2024 9:45 PM
2	We had a very good group and everyone seemed very comfortable discussing problems and goals plus the coordinators were well informed and were able to give very helpful answers,	4/26/2024 10:36 AM
3	It was good to have the option to attend online since I became ill and could not attend in person	4/24/2024 8:35 PM
4	Choice of Online or in person sessions. Helped me balance out my day activities,	4/24/2024 9:47 AM
5	The timing was good (10-12pm) - the length of the session was right. Longer session would lose the attention span of the attendees.	4/23/2024 9:07 PM
6	Liked the face to face interaction	4/23/2024 7:11 PM
7	I should say thank you very much for your preparation especially for the materials helped me to understand a little easily because I could prepared before class.	4/23/2024 6:35 PM

Q9 Did you dislike anything about the program?

Answered: 4 Skipped: 4

#	RESPONSES	DATE
1	No	4/26/2024 10:36 AM
2	Not really.	4/23/2024 9:07 PM
3	No	4/23/2024 7:11 PM
4	No. I like the pictures and the explanations. Since I had attended the classes, I have made my plan to do exercises 45 minutes on bed in the morning and 40 minutes running on the running machine in the evening. Because I know how to overcome the fatigue	4/23/2024 6:35 PM