It's Time to Address Fear of Cancer Recurrence in Family Caregivers: Adaptation, Feasibility, and Acceptability Study of an Online Version of the Fear of Recurrence Therapy (FORT)

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Dedications

I dedicate this thesis to my grandfather, Marcel Lamarche, from whom I learned so much about love, compassion and generosity.

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Content of Thesis and Author Contributions

This thesis is manuscript-based, containing a general introduction, three journal articles (two studies and one protocol), and a general discussion. The first study entitled “It’s Time to Address Fear of Cancer Recurrence in Family Caregivers: Usability Study of a Virtual Version of the Family Caregiver -Fear of Recurrence Therapy (FC-FORT)” was published in the journal *Frontiers in Digital Health*. The protocol article entitled "It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Protocol for the Feasibility and Acceptability of a Randomized Pilot Study of the Online Version of the Family Caregiver - Fear Of Recurrence Therapy (FC-FORT)” was published in the journal *Pilot and Feasibility Studies*. The second study entitled “It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Feasibility and Acceptability of a Randomized Pilot Study of the Family Caregiver Version of the Fear of Recurrence Therapy (FC-FORT)” was published in the journal *Psycho-Oncology*.

The thesis author, Jani Lamarche, is the primary author of all journal articles and participated in all components of the two studies. I was responsible for the study design, preparing all study documents (e.g., ethics review board applications, recruitment materials, consent forms, information sheets, questionnaire packages), coordinating and leading the advisory board and the adaptation process, recruitment (including participant screening, eligibility assessment, preparation for group), data collection, entry and analysis, interpretation and dissemination, and writing the manuscripts. I also provided the administrative support for all groups, including preparing and sending the caregiver workbooks by mail, sending email reminders, opening and administrating the videoconference calls, liaising with therapists, providing financial support to therapists and providing gift cards to participants.

My supervisor, Dr. Sophie Lebel, oversaw the project and provided guidance throughout the entire thesis. She offered permission for the adaptation of her clinical intervention (FORT), and

assisted with the study design, ethics review board applications, selection of measures, intervention administration, data collection, analysis, analysis and interpretation, dissemination, and manuscript preparation. Dr. Lebel additionally provided training and weekly supervision to the study therapists.

The core research team of this doctoral thesis also included Drs. Rinat Nissim, Jonathan Avery, Jiahui Wong, Christine Maheu, Sylvie D. Lambert, Andrea M. Laizner, Jennifer Jones, Mary Jane Esplen. Together, they assisted with the study design, provided feedback as part of the advisory board, helped with recruitment efforts, and reviewed manuscripts. Drs. Nissim and Avery also provided support with the ethics review board application at the University Health Network. Dr. Cheryl Harris provided assistance with ethics review board application at The Ottawa Hospital and recruitment efforts.

The FC-FORT Advisory Board assisted with the adaptation process (i.e., reviewed FORT materials, recruitment strategies) and provided feedback on the usability studies.

I also want to recognize the contributions of my honours thesis students Ms. Angélica Cusson and Ms. Ghizlène Sehabi, and Ms. Emma Kearns, the clinical research coordinator of the Psychosocial Oncology Lab. Ms. Cusson provided support with the data analysis, dissemination and manuscript preparation for Study 1. Ms. Sehabi provided support with the data analysis and dissemination of Study 1, and the recruitment efforts for Study 2. Ms. Kearns provided support on the ethics review board application at The Ottawa Hospital, recruitment efforts and data collection for Study 2.

Finally, Ms. Julia Parrott, RP, and Mrs. Melanie Baruch, M.Ed., CCC facilitated the intervention groups and provided weekly feedback as participants in Study 1. Ms. Parrott and Mrs. Patricia Barrett, RN, facilitated the groups in Study 2. Mrs. Nancy Payeur, MSW, RSW, served as a back-up therapist for our studies.

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General Abstract

Fear of cancer recurrence (FCR), defined as the fear, worry, or concern that cancer may come back or progress, is the most common unmet need in cancer survivors. Family caregivers of cancer patients experience equal or greater levels of FCR than survivors themselves. Similarly to cancer survivors, FCR in family caregivers is persistent and associated with negative outcomes. While several interventions have demonstrated their ability to reduce FCR among cancer patients, few interventions have been developed and/or adapted to specifically address family caregiver's FCR. The overarching thesis objectives were: (a) to adapt a standardized and manualized cognitive-existential in-person group therapy intervention aimed at addressing FCR in cancer survivors to family caregivers and to an online format; (b) to conduct a usability study to assess the usefulness, usability, desirability, value, accessibility, credibility, online format and features, and the general readiness of this newly adapted intervention; and (c) to pilot-test the feasibility, acceptability, and clinical significance of the adapted intervention to inform a larger randomized control trial study.

In study 1, an advisory board composed of researchers (n=10), therapists (n=2), and family caregivers (n=4) was created to adapt the original intervention to family caregivers and an online format. The advisory board met on 7 occasions and reviewed the intervention manuals, session content, the questionnaire packages, and recruitment strategies. Major (e.g., virtual format, exercises in self-care and overcoming protective buffering, addition of a 7th session) and minor (e.g., modifying language, adding standalone explanations/examples) adaptations were made to the original intervention. Once adapted, women family caregivers (N=4) and therapists (N=3) were recruited to conduct a usability study. Family caregivers completed the intervention which was comprised of 7 virtual sessions of 90 minutes and included cognitive restructuring exercises, behavioural experiments, relaxation techniques, existential processing of the here-and-now, and finding meaning in life post-diagnosis. All participants completed feedback questionnaires after

each session and took part in an exit interview (30-60 minutes). Overall, family caregivers and therapists expressed good levels of satisfaction with the intervention, but suggestions (e.g., increasing session length to 120 mins; reorganizing flow of sessions and use of breakout rooms) were made to further improve the intervention's content and format. Results were summarized back to the advisory board and a second round of usability testing was deemed necessary. In the second round, new women family caregivers (N=6) and the same therapists completed the adapted intervention. Both family caregivers and therapists expressed high satisfaction with the intervention's usability and the advisory board deemed it ready for pilot testing.

In study 2, the intervention's feasibility, acceptability and clinical significance were further pilot tested using a mixed-method, parallel, two-group (intervention and waitlist control) randomized control trial. Twelve family caregivers (n = 7 intervention; n = 5 control) completed the 7 weekly sessions (120 minutes) of online group therapy and questionnaire packages at pre- (T0) and post (T1), and 3-month follow up (T2). Those in the intervention group also completed exit interviews (30-60 mins). Feasibility and acceptability criteria were partially met. Analyses did not reveal any significant differences on the secondary outcomes between groups or across time. Qualitative analyses revealed high importance, helpfulness, satisfaction, and group cohesion. Suggestions were made to improve the intervention (e.g., grouping caregivers by caregiving experiences, reducing content or increasing number of sessions).

This study is the first to offer an intervention solely dedicated to family caregivers living with FCR. While it demonstrates promising results in addressing FCR in family caregivers, significant issues with the pilot's feasibility (e.g., recruitment, randomization) and acceptability (e.g., dropout, session completion) were discovered. Future research should focus on addressing these issues and efforts should be put into conducting a second pilot study before the intervention's effectiveness can be evaluated in a larger scale randomized control trial.

General Introduction

Overview

In 2024, it is estimated that 247,100 Canadians will receive a cancer diagnosis – an average of 677 diagnoses per day (Brenner et al., 2024). In Canada, cancer represents the leading cause of decease, responsible for approximately 25% of all deaths (Canadian Cancer Society, 2023; Statistics Canada, 2023a), with the following cancers accounting for almost half of all new diagnoses in adults: prostate in men (22%), breast in women (25%), lung in both sexes (12% in men and 14% in women) and colorectal cancer in both sexes (11% in men and 9% in women; Canadian Cancer Society, 2023a). In addition, cancer is responsible for a significant economic burden for Canada (latest estimate suggests $26.2 billion), with patients and their families carrying 34% of those costs (Garaszczuk et al., 2022). Fortunately, in recent years, scientific advancements in prevention, screening, and treatment have allowed for the predicted 5-year survivorship rates of cancer survivors to increase from 25% (1940s), to 55% (1990s), and to 64% (currently for all cancers combined; Canadian Cancer Society, 2023). While annual cancer mortality rates continue to decline, the population of cancer survivors and their families continues to grow (Brenner et al., 2024; Canadian Cancer Society, 2023a). In fact, in 2018 more than 1.5 million Canadians (Statistics Canada, 2022) were living with cancer, or beyond it in what we call survivorship.

Survivorship can be defined as the "experience of living through or beyond an illness" (Canadian Cancer Society, 2024). For some cancer survivors, survivorship may include living with cancer and requiring ongoing treatments; for others it can mean being in complete remission that still requires treatment, or again being in complete remission with a more favorable prognosis (Miller et al., 2008). Additionally, survivorship can be divided in phases, or "seasons" (Mullan et al., 1985), ranging from acute and extending to permanent survivorship. Acute survivorship starts at diagnosis and lasts until the end of the initial cancer treatment (Cancer.Net, 2019). In this phase, cancer

treatment is the main focus. Extended survivorship refers to the period immediately after the end of the initial treatment and lasts for many months afterwards (Cancer.Net, 2019). In this phase, the focus is the side effects of cancer and its treatments. Finally, cancer survivors enter the permanent survivorship phase after many years have passed since their end of treatment (Cancer.Net, 2019). In this phase, long-term side effects of cancer and its treatments are the focus.

For many people, survivorship does not automatically equate a return to a regular lifestyle. In fact, long-term cancer survivors typically experience higher physical symptom burden than the general population, reporting on average 5 physical comorbid conditions (e.g., hypertension, osteoarthritis, polyneuropathy, thyroid disorder; Götze et al., 2018). Moreover, post treatment, most cancer survivors face specific physical (e.g.: fatigue, pain, sexual difficulties), emotional (e.g.: anxiety, body image difficulty), cognitive (e.g., memory, concentration) and practical (e.g.: financial difficulty, returning to work) challenges that significantly impact their quality of life (QOL; Fitch et al., 2020; Schmidt et al., 2022). A recent study by Fitch and colleagues (2020) of 13 534 Canadian survivors found that 54.3% faced at least one major challenge following the end of their cancer treatment and that 45.7% faced more than one. As a result, post treatment, many cancer survivors require additional support. Moreover, given their complex post-treatment needs, cancer survivors' follow up care should include a multitude of health care providers and survivorship care plans (Mutsaers et al., 2023; Sussman et al., 2017). However, lack of appropriate services is a major challenge in survivorship with many cancer survivors expressing concerns with service delivery which encompasses information/communication, follow-up care, hospital/clinic services and health care providers (Fitch et al., 2020). This issue is even greater for family members and/or caretakers accompanying cancer survivors who are often left with little to no support.

Caregiving in Canada

With public healthcare systems being overwhelmed and care being moved towards outpatient settings, family caregivers (FC) have become a crucial extension of the medical system (van Ryn et al., 2011). For the context of this thesis, FC are defined as family members who provide unpaid support and play an integral role in the treatment and care of their loved ones living with or beyond acute or chronic illnesses. In 2018, approximately 7.8 million Canadians (1 in 4) reported providing informal caregiving to a family member or friend (Statistics Canada, 2022); with most identifying as women (ages 45-64) caring for parents (Statistics Canada, 2020). Estimates also suggest that half of Canadians are expected to become FC in their lifetimes (Canadian Centre for Caregiving Excellence, 2023). Informal caregiving has been found to reduce financial burden for families, health care systems and other health related services while simultaneously increasing QOL for patients who are able to remain at home and receive support from loved ones (Statistics Canada, 2022). Namely, it is estimated that FC provide approximately 80% of overall patient care and carry out a large number of tasks such as medication management, physical care, financial management, emotional support, decision making, housework/domestic tasks, and personal care (Fast et al., 2002). Due to the amount of unpaid labour involved, informal caregiving is also estimated to contribute $97.1 billion to Canada's gross domestic product (double the contribution of industries like agriculture, utilities, and hospitality; Eales et al., 2022). Given its significant contribution, "informal unpaid caregiving provided by family and friends has become increasingly recognized as serving an important role in society and in the economy" (Statistics Canada, 2022).

Research is progressively being conducted to better understand the experiences of FC in various populations such as older adults (e.g., Bom et al., 2019; Ringer et al., 2017), individuals with intellectual and developmental disabilities (e.g., Masefield et al., 2020; Papadopoulos et al., 2019; Scherer et al., 2019) or those in palliative care (e.g., Garon et al., 2024; Kavalieratos et al., 2016), as well as in numerous diagnoses such as dementia (e.g., Hellis et al., 2022; McCabe et al., 2016; Queluz et al., 2020), Parkinson's disease (e.g., Geerlings et al., 2023; Perez et al., 2022; Zhao et al.,

2024), multiple sclerosis (e.g., Appleton et al., 2018; McKeown et al., 2003; Rajachandrakumar et al., 2022) and cancer (e.g., Applebaum et al., 2013; Bedaso et al., 2022; Benyo et al., 2023). However, within the health care system, FC are still not formally recognized and support for their unique needs is not readily available. In fact, a survey by the Canadian Centre for Caregiving Excellence found that out of 3099 Canadians, 76% of FC had received no help within the past 12 months – with 53% of FC experiencing significant difficulty finding services and only 10% actually receiving the supports they needed (Canadian Centre for Caregiving Excellence, 2023). While many FC perceive advantages related with their roles (i.e., meaning, purpose, giving back, closeness; Revenson et al., 2015; Statistics Canada, 2022; Stenberg et al., 2010), there are particular challenges associated with providing care to a loved one.

Impacts of Caregiving

According to Statistics Canada (2020), 15% (or 1, 700 000 individuals) of FC in Canada provide between 10-19h of caregiving and 21% (1, 638 000 individuals) of FC provide more than 20h per week of caregiving. Of those providing more than 20h per week, 54% were found to be more likely to describe their caregiving responsibilities as stressful (Statistics Canada, 2022). Moreover, while caring for a loved one can be a full-time job, many FC also have paid work and/or have busy family lives in addition to their caregiving responsibilities which often leads to increased conflict between work and family demands (Petro-Canada CareMakers Foundation, 2024). In fact, in 2022, approximately 1.8 million Canadians identified as “sandwich caregivers” meaning they simultaneously provided care for children and adults with long-term conditions or disabilities (Statistics Canada, 2024). Having multiple caregiving responsibilities has been associated with an increased likelihood of negative impacts on overall well-being (Statistics Canada, 2024). In 2021, Kayaalp and colleagues found that work-family conflicts acted as mediators between caregiver burden and poor mental health outcomes, with increased work-family conflicts leading to worse

caregiver outcomes. In addition, employed caregivers have been identified as experiencing higher caregiver burden compared to others (Hsu et al., 2014). Caregiver burden, a term commonly used within the caregiver community, can be defined as "the level of multifaceted strain perceived by the caregiver from caring for […] a loved one over time" (Liu et al., 2020). Various factors influence caregivers' predisposition to caregiver burden, such as sociodemographic factors, intensity and type of caregiving, patient's physical, psychological and/or existential suffering, lack of choice in caregiving experience, caregivers' personal health and physical functioning, type and levels of support received by caregivers, as well as the physical environment of the care recipient (Shulz et Eden, 2016). Additionally, FC are frequently unaware of what caregiving entails, including the scope of caregiving responsibilities and their impacts on their lives (Given et al., 2012). While many FC are asked to provide complex care, they tend to lack the information, support, or self-confidence required to execute it (Applebaum et al., 2013). In fact, caregiving responsibilities generally pre-suppose that FC have the pre-existing skills (e.g., navigating healthcare systems and insurance, adhering to medical instructions, using medical equipment, pain management, nutrition; Steele et al., 2014) and/or physical capabilities (e.g., lifting, assisting with ambulation) to take care of their loved one (Ferrell et al., 2017). However, this is often not the case and FC are left with little support (i.e., no skills level assessment or training; Ferrell et al., 2017). For this reason, many FC feel ill prepared for their caregiving responsibilities and combined with the increasing demands of caregiving, this often leads individuals to feel burdened and/or distressed.

In addition to caregiver burden, FC often report difficulties associated with providing intense levels of care such as psychological distress (i.e., anxiety disorders, depression, stress related disorders), diminished physical health, difficulties identifying and separating social roles, reduction in overall activities, and difficulties in marital and social relationships (Kent et al., 2016; Kim et al., 2008; Sinha, 2012; Statistics Canada, 2022). Moreover, according to Statistics Canada (2023b), 56% of Canadian FC expressed feeling tired due to caregiving responsibilities, and 44% expressed feeling

worried or anxious throughout the past year. Feelings of loneliness and isolation are also commonly experienced by FC as a result of their caregiving responsibilities (Ysseldyk et al., 2019). Moreover, FC report difficulties navigating the health care system which result in communication difficulties with health care providers, lack of information provided by health care providers, and lack of attention from health care providers surrounding their well-being (Petricone-Westwood et al., 2020). These difficulties have been linked to depression and anxiety in FC (Petricone-Westwood et al., 2020). Research also demonstrates that caregivers tend to experience "lower self-ratings of physical health, elevated levels of stress hormones, higher rates of chronic disease, and impaired health behaviours" because of caregiving (Shulz et Eden, 2016). Likewise, caregiving has been shown to negatively impact exercise, eating and alcohol consumption habits (Ysseldyk et al., 2019).

Finally, caregiving has also been associated with financial burden. Many FC acquire out-of-pocket expenses due to their caregiving responsibilities such as transportation, travelling and accommodation, professional services, and medical supplies (Turcotte, 2013). Additionally, caregiving often impedes on professional obligations which can lead to a reduction in employment income and potential impacts on future career opportunities (Statistics Canada, 2013). Furthermore, FC are often ineligible for income replacement programs and, given that most FC are under the age of 65, are not eligible for pensions (Petro-Canada CareMakers Foundation, 2024). While non-refundable tax credits are a valuable form of financial support for FC, they are often underutilized (e.g., difficult to navigate), inaccessible (e.g., insufficient taxable income) or inadequate (e.g., unable to counter financial consequences of caregiving; Canadian Centre for Elder Law, 2010; National Institute on Aging, 2018; Stall et al., 2019). Therefore, FC are often left with little to no financial support, with only 8% of FC reporting benefiting from federal tax credits (Statistics Canada, 2020).

For these reasons, research consistently demonstrates that FC experience more mental health concerns (Dekel et al., 2005; Duxbury et al., 2011; Zacher et al., 2012) and lower levels of subjective well-being (Pinquart et Sörensen, 2003) than the general population. Overall, it is not surprising that

research consistently indicates that FC are at high risk for psychological and physical distress and should be recognized as patients in their own right, deserving of attention for their unmet need of support (Alfano et al., 2018; Applebaum et al., 2013; Kent et al., 2016; Lambert et al., 2017a; Lambert et al., 2017b). Despite the significant impact of caregiving on FC' lives, few supports and services are available to FC leading to many unmet needs. According to Statistics Canada (2022), the most unmet needs for FC were home care or support (40%), information or advice (39%) and help from medical professionals (36%). Similarly, the Canadian Centre for Caregiving Excellence (2024), reported FC identifying access to free counselling and mental health supports, supportive workplace policies (e.g., days off of work, paid leaves of absence, work-life balance, paid sick leave, higher pay), monthly allowances, respite services (e.g., home care), formal training on care responsibilities, mandatory health care provider assessments, and more generous and accessible tax credits as primary unmet needs. While some aspects and impacts of caregiving are universal, individual sociodemographic characteristics can also influence FC' overall experiences.

Differences in Caregiving Experiences

Given Canada's widely heterogeneous population, diversity considerations in all aspects of healthcare are increasingly important. Amongst FC, diversity factors can lead to a broad range of experiences, outcomes and can add a layer of complexity to the caregiving experience. Gender remains the most explored cultural diversity factor impacting the caregiving experience. Although there continues to be a rise of men in caregiving positions, in Canada, women remain the primary source of informal caregiving across populations (Statistics Canada, 2023b); with 56.5% of FC identifying as women and 43.5% as men (Fast et al., 2011). In the cancer context, gender has been identified as a contributing factor to the overall FC experience (Fast et al., 2011; Lee et Tang, 2015; Swinkels et al., 2019; Schrank et al., 2016; Sharma et al., 2016; Wadhwa et al., 2013). Studies have observed that women FC report higher levels of anxiety (Mystakidou et al., 2013), caregiver burden

(Schrank et al., 2016), and lower QOL (Ovayolu et al., 2014) compared to their male counterparts. Moreover, women FC spend more time providing care (Fast et al., 2011), juggle a higher number of caregiving tasks (Fast et al., 2011), and are less likely to receive help from extended family and friends (Brazil et al., 2009). Women are also more likely to be "sandwich caregivers" and to provide care that is required on a regular basis or set schedule, personal care, healthcare scheduling and coordination, aid with medical treatment and emotional support (Statistics Canada, 2023b). In addition, Kim and colleagues (2007) found that women were more likely to consider their FC experience as being stressful whereas men FC were more likely to consider it as being beneficial. For these many reasons, this thesis focuses specifically on women caregivers. Additionally, the Fear Of Recurrence Therapy intervention (at the centre of this project) has so far only been tested and validated for women cancer patients/survivors (Lebel et al., 2014; Maheu et al., 2016; Maheu et al., 2023; Tomei et al., 2018) limiting the generalizability to men or non-binary FC.

Secondly, studies reveal that racial and ethnic minority caregivers tend to provide more care and experience poorer physical health conditions than their White counterparts (McCann et al., 2000; Pinquart and Sörensen, 2005). Additionally, evidence from meta-analyses reveals that African American caregivers experience lower levels of caregiver burden and depression, and higher levels of fulfillment, while Hispanic and Asian American caregivers experience more depression (Liu et al., 2021; Pinquart et Sörensen, 2005; Pristavec, 2019). Research also demonstrates that racialized caregivers are less likely to access and utilize professional support services (Nápoles et al., 2010; Pinquart and Sörensen, 2005), suggesting that they may experience additional burden and barriers in their caregiving experience (Abe-Kim et al., 2007). In addition, cultural expectations also play a significant role in the caregiving experience. For example, in their qualitative study, Pharr and colleagues (2014) discovered that for many collectivistic cultures, caregiving was an "expected part of life that was passed down from generation to generation". While this was seen as an instrumental, defining and positive experience, it also represented a persistent belief that saying no to caregiving

responsibilities was unacceptable and, as a result, impacted caregivers' levels of stress and general coping (Pharr et al., 2014). Consequently, lack of choice in taking on caregiving responsibilities has been associated with increased levels of caregiver burden and depression (Reinhard et al., 2013; Schulz et al., 2012).

Moreover, place of living has been identified as influencing caregiving outcomes. Namely, individuals living in rural communities have been found to be more likely than their urban counterparts to become FC (Cohen et al., 2022). Furthermore, rural areas are often underserved areas when it comes to health and social services. The lack of health services and fewer resources negatively impact FC experiences (Cohen et al., 2022; Crouch et al., 2017; L'Heureux et al., 2022), leading rural FC to provide more caregiving related to activities of daily living, long term caregiving (Cohen et al., 2022), experience loneliness and isolation (L'Heureux et al., 2022), and more mental and physical health difficulties than their urban counterparts (Cohen et al., 2022; Crouch et al., 2017; L'Heureux et al., 2022). FC in rural areas also tend to underutilize caregiving supports and services, provide more caregiving hours per week (Cohen et al., 2022), and experience employment difficulties due to limited job opportunities and inflexibility (Hussain et al., 2018), as well as loss of wages or increased out-of-pocket expenses (L'Heureux et al., 2022) – ultimately leading to lack of time and financial difficulties.

Additionally, compared to their heterosexual counterparts, caregivers who are part of the LGBTQIA2S+ community are more likely to engage in non-kin related caregiving (Muraco et al., 2011). While this is primarily seen as positive experiences, with most reporting more optimistic outcomes than kin-related caregivers, non-kin related caregiving does include additional challenges (Fredriksen-Goldsen et al., 2013). Namely, caregivers without power of attorney may not have access to medical information and/or are not able to make health care choices for the patient, which may limit their caregiving abilities (Fredriksen-Goldsen et al., 2013). Caregivers also report difficulties

navigating and offering certain caregiving responsibilities due to social norms that view biological families as having the official responsibility for providing care (Nocon et Pearson, 2000).

Furthermore, age may also influence FC' experiences. Older FC tend to report higher levels of psychological challenges, poorer levels of physical health (American Psychological Association, 2005; Schulz et al., 2012; Statistics Canada, 2020) and devote longer hours to caregiving than younger FC (Arriagada, 2020). Alternatively, younger FC may experience life disruptions (e.g., education, career, family; American Psychological Association, 2005) and higher levels of depression and anxiety (compared to their non-FC counterparts; Greene et al., 2017). Moreover, middle-aged caregivers often find themselves "sandwiched" between various responsibilities which can lead to poorer QOL (Statistics Canada, 2024). While there is much research on how caregiving affects FC at different stages of life, evidence is mixed on whether age specifically impacts levels of caregiver burden and distress in FC (Koumoutzis et al., 2021; Koyama et al., 2017; Phetsitong et al., 2022; Spatuzzi et al., 2020;).

Moreover, religion and spirituality has been identified as a positive moderator of caregiver burden – with spiritual/religious individuals experiencing significantly higher QOL than other FC (Colgrove et al., 2007; Taha et al., 2021; Young et al., 2024). In fact, La and colleagues (2024) found that higher levels of spirituality/religiousness tended to buffer the impact of caregiver burden on levels of depression (i.e., FC who were more spirituality experienced less depression).

In addition, personal health and physical functioning has been linked to the caregiving experience. Namely, FC experiencing poor self-rated health, high levels of stress, comorbid medical conditions, sleep difficulties, breathing difficulties, pain, limited mobility, movement or strength were found to be at higher risk of experiencing adverse outcomes (Riffin et al., 2019; Schulz et Eden, 2016). Similarly, FC experiencing mental health difficulties (e.g., depression, anxiety) were found to experience poorer outcomes when it comes to caregiver burden (Pristavec, 2019).

Finally, the type of caregiving relationship (e.g., partner, parent, sibling, children) significantly impacts how FC perceive and experience their caregiving responsibilities (Schulze et al., 2005). For example, FC of spousal caregivers experience lower QOL and more caregiver burden, while adult-children FC report more social strain (Lai et al., 2022). Furthermore, there is evidence to suggest that FC living with their caregiving patient tend to experience increased risks of adverse outcomes such as isolation and poor health (Schulze et Rossier, 2005). Secondary caregivers, while having more balanced caregiving experiences, may also involuntarily contribute to interpersonal tensions or difficulties in care coordination with primary caregivers (Barbosa et al., 2011). Given the significant impact of diversity factors on cancer FC experiences, wherever possible, this thesis explored themes related to diversity and their impact on caregiving.

Caregiving Theories of Stress and Coping

As noted previously, caregiving can have significant consequences on FC well-being, with various factors influencing the caregiving experience. Given the importance of FC in our societies and the widely variable experiences between FC, past caregiving research has focused on developing theoretical frameworks to help us understand the experience of caregiving and predict outcomes for FC.

Transactional Model of Stress and Coping. Most of the caregiving literature draws on Lazarus and Folkman's (1984) stress and coping model which postulates that stress arises not only from objective external events but also from subjective appraisal of said events and available coping mechanisms. Lazarus and Folkman proposed that for each situation, individuals evaluate whether it is threatening, overwhelming, or manageable (primary appraisal). From there, individuals then assess whether their current coping mechanisms are sufficient to manage the demands of that situation (secondary appraisal) and, if necessary, engage in problem (e.g., resolve the situation) or emotion focused coping (e.g., manage emotional response to the situation). Reappraisals of the situation are

continuous to determine whether coping strategies are effective. Within the caregiving context, this model has been particularly helpful given that the impacts of caregiving on FC well-being may be less related to the caregiving tasks themselves (primary appraisal) and more a result of the subjective appraisals of the tasks/caregiving situation (secondary appraisal). This provides a helpful explanation on why FC may respond differently to the same caregiving "stressors".

Appraisal Model of Caregiving. Lawton and colleagues' (1991) appraisal model builds on the stress and coping model by Lazarus and Folkman (1984) while highlighting caregiver specific aspects. Similarly to the stress and coping model, the appraisal model includes primary and secondary appraisal of caregiving situations. However, Lawton and colleagues separate the appraisal into FC specific outcomes, such as appraisal of caregiving satisfaction, caregiving burden, caregiving impact, caregiving mastery (i.e., coping) and caregiving ideology. FC' well-being are influenced by their perceptions of their caregiving responsibilities and personal coping mechanisms, which in turn is reflected in how they perceive their caregiving experience (i.e., satisfaction, burden). This model provides valuable insight on the cognitive processes of FC perceptions and evaluations of their caregiving experience and resources. However, it doesn't take into consideration the larger caregiving context which can limit the understanding of the caregiver experience.

Caregiver Stress Process Model. Alternatively, the caregiver stress process model (Pearlin et al., 1990) highlights the process of interrelated conditions and the broader contextual (i.e., social, psychological, environmental factors) experience of caregiving. Within their model, Pearlin and colleagues identify four conceptual components of caregiver stress: the background/context of the stress process (e.g., sociodemographic characteristics, caregiving history, family and network composition, program availability), the primary (e.g., patient characteristics such as cognitive impairment, problematic behaviour, dependencies for daily life activities) and secondary stressors (e.g., role strains, intrapsychic strains), the mediators of stress (e.g., coping, social support), and the outcomes of manifestations of stress (e.g., depression anxiety, irritability, cognitive disturbances,

physical health, yielding role). In this model, the "objective" features of caregiving (i.e., type of care required, hours of caregiving) are conceptualized as primary stressors leading to stress. The caregiver stress process model provides a broader understanding of caregiving, while also providing a longitudinal perspective on how the caregiving experience can evolve over time. Furthermore, whereas the appraisal model of caregiving evaluates FC' perceptions of coping resources, the caregiver stress process model evaluates the actual availability of resources. It also recognizes the various factors that can contribute to caregiving difficulties, considers individual differences, and acknowledges the use of multiple indicators of adaptation.

Sociocultural Stress and Coping Model. Based on Lazarus and Folkman's model (1984), the sociocultural stress and coping model (Aranda et Knight, 1997; Knight et Sayeg, 2010) expands Lazarus and Folkman's model by highlighting the importance of ethnicity and culture in the stress and coping process. Namely, this model highlights the potential differences in health stressors (i.e., illness-specific demands, disabilities, functional dependencies), FC appraisals of stressors (e.g., caregiving burden) and mediators (e.g., cultural values, acculturation, social support, familism, coping attitudes and behaviours) across different ethnicity, racial and cultural groups. The inclusion of these sociocultural variables is not only essential to our understand of caregiver distress but also highlights the importance of developing culturally relevant interventions.

The Cancer Caregiving Experience Model. Finally, throughout the years, the cancer literature has also begun to develop its own specific conceptual models of the caregiving experience. In 2000, Weitzner, Haley and Chen published the first model of stress and coping for cancer FC. This model is based on Lazarus and Folkman's Transactional Model of Stress and Coping, appraisal model and the stress process model. In 2012, Fletcher and colleagues updated and expanded the model to include cancer specific factors. Briefly, their model includes 3 main components: 1) the stress process, 2) contextual factors, and 3) the cancer trajectory. The stress process, similarly to previously described models, includes primary (e.g., patient illness-related factors, care demands)

and secondary stressors (e.g., roles and relationships, employment and finances, schedule, lifestyle, self-concept, sleep/fatigue), caregiver appraisal (e.g., burden/distress, ability, needs, future outlook, rewards/benefits), cognitive-behavioural responses (e.g., coping, planning ahead, self-care and caregiving behaviours) and FC health and well-being (e.g., mental and physical health, health related quality of life, life satisfaction, meaning, adjustment, personal growth). The second component relates to contextual factors such as personal (e.g., genetics, personality, type and quality of kinship relationship, social support, health status), sociocultural (e.g., gender, age, race, ethnicity, geography), economic (e.g., employment, income, socioeconomic status) and health care (e.g., access to specialized cancer treatment or hospice services, insurance) related factors. Finally, the third component of the model is composed of the cancer trajectory which starts with cancer diagnosis/initial treatment and then branches into either 1) remission, surveillance and cancer-free survivorship or 2) recurrence, second cancer, end-of-life care and bereavement. Specifically, the cancer trajectory is important as caregiving responsibilities and FC appraisal may change drastically depending on the trajectory of illness or the phase in which the patient finds themselves. This appraisal further influences the first component of stress process.

Overall, across the years, the caregiving literature has invested significant efforts in developing theories related to stress and coping to better understand the caregiving experience. While Lazarus and Folkman's Transactional Model of Stress and Coping (1984) is still central, many theories have adapted the model to better fit caregiving realities and, most recently, cancer FC realities.

Family Caregivers of Cancer Patients and Survivors

Understanding FC' experiences and needs is particularly relevant to cancer populations as most of the cancer care is now conducted in outpatient settings requiring FC to work as an extension of the health care team (Northouse and McCorkle, 2015). In fact, both the Canadian Cancer Society

and American Cancer Society consider informal caregiving as essential to patient care (American Cancer Society, 2019; Canadian Cancer Society, 2020). Given the nature of cancer, FC of cancer patients/survivors are more likely to spend significant amounts of time providing caregiving to their loved ones. Namely, advancements in treatment care have resulted in longer survivorship periods and/or patients living with their diseases for increased periods of time and subsequently requiring FC to be active in treatment and care for extended periods of time (Golant et Haskins, 2008). Therefore, as the number of cancer survivors has increased in the past decade, so has the number of FC tending to their loved ones. Within the cancer community, providing informal care requires dealing with survivors' multifaceted needs which includes treatment monitoring, symptom management, providing support (emotion, financial, spiritual, social), as well as providing personal and instrumental care (Kent et al., 2016; Kim et al., 2008; Sinha, 2012). Specifically, FC of cancer survivors are often required to provide more intense care to their loved one, compared to those caring for individuals with other chronic illnesses (Kent et al., 2016; Kim et al., 2008). Moreover, while FC typically have a pre-existing relationship with the cancer patient/survivor, they are often required to shift to their caregiving role suddenly with little to no preparation (van Ryn et al., 2011). Additionally, they are often required to complete technical tasks previously performed by medical staff (Teschendorf et al., 2007). This is an important consideration as the intensity of caregiving responsibilities has consistently been found to be a predictor of negative outcomes in FC (Schulz et Eden, 2016). In addition, cancer caregiving often requires hourly monitoring which can disrupt FC' sleep, increase levels of fatigue, while simultaneously increasing FC mortality (Lee et al., 2015; Saimaldaher et al., 2020; Stenberg et al., 2014). Finally, patients and families bear the majority of indirect costs associated with the cancer care which includes lost earnings due to unemployment, reduced hours of working, transportation, and childcare expenses (Ferrell et al., 2017). Despite being perceived as essential to patient care, caregiver roles and needs are often ignored and/or overlooked by the health care system (Kent et al., 2016; Kim et al., 2008; Sinha, 2012). A systematic review

(Lambert et al., 2012) evaluating unmet needs revealed that cancer FC experienced at least 1 unmet need, with palliative FC reporting higher proportions of unmet needs. Furthermore, they identified the following domains of unmet needs: comprehensive cancer care (e.g., awareness of resources, relationship with healthcare professional, being considered a part of the health team), emotional and psychological (e.g., managing distress, negative feelings, stress), daily life (e.g., impact of caregiving on lifestyle, scheduling, caregiving tasks), relationship (e.g., communication, sexuality, intimacy), information (e.g., regarding illness and treatment, what to expect), and spirituality (e.g., feeling hopeless). In brief, cancer affects the family unit as a whole and FC experience often mirrors that of the cancer survivor. This is the case with fear of cancer recurrence, a common experience for both survivors and FC.

Fear of Cancer Recurrence in Cancer Survivors

Fear of cancer recurrence (FCR) is defined as the fear, worry, or concern that cancer may come back or progress (Lebel et al., 2016). FCR represents the primary unmet need of cancer survivors post treatment (Baker et al., 2005). Unmet needs can be defined as patient identified needs, services and/or resources that are assessed as being both important and currently unsatisfied (Soothill et al, 2001). If left unaddressed, unmet needs, such as FCR, can lead to lower QOL and increased psychological distress (Hodgkinson et al., 2006). Moreover, FCR is common and manifests itself on a continuum with an estimated 59% of cancer survivors reporting moderate to severe levels of FCR (Luigjes-Huizer et al., 2022), often referred to as clinical FCR (Simard et al., 2015). According to a Delphi study, clinical FCR can be conceptualized by four key characteristics: “(a) high levels of preoccupation; (b) high levels of worry; (c) that are persistent; and (d) hypervigilance to bodily symptoms” (Mutsaers et al., 2020). At the individual level, clinical FCR is associated with impairment in functioning, psychological distress, sleep difficulties, stress response symptoms, and lower QOL (Berrett-Abebe et al., 2015; Hanprasertpong et al., 2017; Kim et al., 2012; Moschopoulou

et al., 2018, Sarkar et al., 2014; Simard et al., 2015; van de Wal et al., 2017). Furthermore, it can also be associated with maladaptive coping strategies such as hypervigilance, excessive body checking, frequent reassurance-seeking (Lebel et al., 2013), difficulties related to uncertainty about and/or planning for the future (Beesley et al., 2008; Lee-Jones et al., 1997), and strains with their social supports (Armes et al., 2009). Combined, these can lead to significant psychological burden. In fact, in cancer survivors, clinical levels of FCR can present themselves as excessive rumination and anxious preoccupation about a potential cancer recurrence, continual efforts to monitor for potential recurrences, and attempts to avoid any reminders of cancer (Lee-Jones, et al., 1997).

Moreover, FCR has been associated with a number of psychological morbidities. Specifically, FCR shares many characteristics with the Diagnostic and Statistical Manual of Mental Disorders (5th ed. Text Revision; DSM-5-TR; American Psychiatric Association, 2022) diagnosis of Generalized Anxiety Disorder (GAD; Roth et al., 2006; Simard et al., 2015; Thewes et al., 2013), which is characterized by "excessive anxiety or worry about a number of events or activities" (i.e.: health, the future, etc.). Intrusive thoughts related to FCR have been deemed to share characteristics with the notion of worrying, a prominent characteristic of GAD, although intrusive thoughts related to FCR often appear more as obsessions (Simard et al., 2015). Mehnert and colleagues (2009) found that intrusive thoughts were present in 37% (n=397) of their sample of breast-cancer survivors. Additionally, they identified significant correlations between fear of cancer progression and intrusive thoughts ($r = 0.63$), suggesting that individuals who have higher levels of intrusive thoughts also have higher levels of fear of cancer progression. In their 2013 study, Thewes and colleagues observed that 36% of early-breast cancer patients met screening criteria for both FCR and GAD. In addition, Roth and colleagues (2006) found that prostate cancer patients scores related to FCR on the Memorial Anxiety Scale for Prostate Cancer (MAX-PC) were significantly correlated with common anxiety/distress measures such the HADS Anxiety Subscale ($r = 0.51$; $p < 0.0001$), the Distress Thermometer ($r = 0.60$; $p < 0.0001$), HADS total scores ($r = 0.44$; $p < 0.0001$), and the FACT

Emotional Well-Being subscale ($r = -0.64$; $p < 0.0001$). Furthermore, cancer patients who met DSM-5 (American Psychiatric Association, 2022) criteria for GAD also had significantly higher mean scores on the MAX-PC compared to those who did not meet GAD criteria [1.08 versus 0.65 (t [362] = 5.27; p = 0001)]. In brief, it seems likely that, although FCR is distinct from GAD, they share several underlying mechanisms (Simard et al., 2015). However, a prominent distinction would be that, unlike GAD patients, FCR patients worries are focused primarily on the possibility of their cancer coming back rather than their overall health, their family, their future, and other aspects of their lives. Additionally, clinical FCR has also been associated with the DSM-5 diagnosis of Panic Disorder (American Psychiatric Association, 2022). Panic Disorder can be characterized as persistent concern or worry about having sudden somatic symptoms arise and the negative consequences associated with them (American Psychiatric Association, 2022). This is unsurprising as higher levels of FCR are more frequent among cancer survivors who report having a higher presence and severity of physical symptoms (Deimling et al., 2006; Liu et al., 2011; Matulonis et al., 2008; Mehnert et al., 2009). Finally, there is some mixed evidence that FCR could be associated with the DSM-5 diagnosis of Illness Anxiety Disorder [formerly referred to as Hypochondriasis in DSM-IV (American Psychiatric Association, 2002)], which can be characterized by a persistent misinterpretation of bodily symptoms which leads to fear of having a serious illness and excessive medical reassurance (American Psychiatric Association, 2022). In their 2013 study, Thewes and colleagues observed that 43% of their sample, who were early-breast cancer patients living with clinical levels of FCR, also met the criteria for a diagnosis of hypochondriasis. However, in their 2015 study, Simard and colleagues found no association between FCR and hypochondriasis. Overall, although FCR shares similarities with other anxiety disorders (Lebel et al., 2020), research suggests that it is "a distinct syndrome specific to the cancer experience" (Simard et al., 2015).

Common risk factors for FCR include younger age, gender (with women being more prone than men), and presence of somatic symptoms (such as pain and fatigue; Simard et al., 2013). Other

factors such as sleep quality and time since diagnosis or treatment have been researched but results remain inconclusive (Simard et al., 2013; Smith et al., 2020). Furthermore, FCR seems to be common and persistent across various types and stages of cancer (Simard et al., 2013). In addition, Mell and colleagues (2022) found that within gynecological cancer survivors, those who reported more distress, hopelessness, anxiety and more post-traumatic growth also experienced higher levels of FCR. Other studies (Stanton et al., 2002; Wade et al., 2005) have suggested that low self-esteem, denial, and avoidance-oriented coping could predict future FCR. Overall, research suggests that FCR is common amongst cancer survivors and can significantly impede well-being. In fact, untreated FCR does not decrease over time and can become a lifelong concern (Koch et al., 2013; Manne et al., 2016; Moschopoulou et al., 2018). For example, Götze and colleagues (2019) observed that 19% of cancer survivors in their study had high levels of FCR 5 years into their survivorship and that 13.4% of cancer survivors still had high levels of FCR 10 years into their survivorship.

At the system level, clinical FCR is associated with increased costs to the medical care system (Champagne et al., 2018; Lebel et al., 2013; Thewes et al., 2012; Williams et al., 2021) due to accrue outpatient visits, emergency department visits, and number of medications used. Cancer survivors living with FCR also tend to delay their discharge from cancer centres, request supplemental follow ups with primary care providers and are more likely to seek re-admission to specialized care centres (Glynne-Jones et al., 1997). In fact, a systematic review (Williams et al., 2021) identified that patients with higher levels of FCR were more likely to have additional primary care calls and appointments and there was some evidence that they utilize counselling services and support groups more. Therefore, when left untreated, FCR can cause significant burden to the overall health care system.

Most importantly, there is evidence from two meta-analyses (Hall et al., 2018; Tauber et al., 2019) of RCT that clinical FCR can be reduced among cancer survivors by either group or individual therapy and evidence of sustained improvements at follow-up (on average 8 months post-therapy).

Additionally, these meta-analyses demonstrated that FCR therapies were also useful in reducing intrusive thoughts, anxiety, depression, and improved QOL (Butow et al., 2017; Merckaert et al., 2017; van de Wal et al., 2017; Wu et al., 2019;). The results from these meta-analyses of controlled trials also suggest that Beck's Cognitive Behavioural Therapy (CBT) and third wave CBT are effective treatments to reduce FCR, with small effects pre-post treatment (Hall et al., 2018; Tauber et al., 2019). CBT is characterized by a structured, short-term approach, that focuses on problem solving and addressing dysfunctional thoughts and behaviours. Third wave CBT interventions include interventions such as mindfulness, acceptance, value-based living, meta-cognition, to name a few (Hayes et Hofmann, 2017). These interventions focus more specifically on the relationship between an individual and their thoughts and emotions – rather than on the content of those thoughts/emotions itself (Hayes and Hofmann, 2017). One of the more notable contributions from third wave approaches is its focus on processes of change through evidence-based procedures (Hayes and Hofmann, 2017). Furthermore, third wave approaches aim to integrate psychosocial, contextual and behavioural processes to gain a more holistic view of psychopathology (Hayes and Hofmann, 2017). While evidence for the efficacy of interventions designed to address FCR in cancer survivors has been demonstrated, to date, there have been no attempts to offer these treatments to FC, despite their unmet needs related to FCR.

Fear of Cancer Recurrence in Family Caregivers

Evaluations of FCR in FC are beginning to emerge and they consistently demonstrate that approximately 50% of FC report equal or greater levels of FCR than cancer survivors themselves (O'Rourke et al., 2021; Smith et al., 2022; Webb et al., 2023). In addition, similarly to cancer survivors, FCR in FC has been demonstrated to be persistent (Boehmer et al., 2016; Moschopoulou et al., 2018), associated with lower QOL (Ochoa et al., 2020), lower functioning (Lin et al., 2016; Longacre et al., 2012; van de Wal et al., 2017), and higher psychological distress (Moschopoulou et

al., 2018; van de Wal et al., 2017). In fact, in their 2023 meta-analysis, Webb and colleagues observed large correlations between FCR and poorer psychosocial outcomes in FC (e.g., depression, anxiety) which were similar to those of observed in survivors. To date, younger FC and patients, women, and treatment types such as chemotherapy and hormonotherapy (O'Rourke et al., 2021; Smith et al., 2022) have been identified as higher risk for FCR in FC. However, further research is still needed to better understand the experience of FC living with FCR.

In couples, research consistently identifies interdependence between patients/survivors' levels of FCR and FC' FCR, whereas FCR increases in one partner leads to increases in the other (Boehmer et al., 2016; Mellon et al., 2007; van de Wal et al., 2017). Furthermore, evidence suggests that the way FC manage their FCR (e.g.: seeking counseling, increased social support) may impact cancer survivors FCR (Boehmer et al., 2016). Protective buffering, or the act of "hiding worries, denying concerns, and yielding to one's partner in an effort to avoid disagreement and reduce one's partner's upset and burden" (Manne et al., 2007), has been deemed as a common coping strategy for cancer patients and FC (Mann et Badr., 2008; Perndorfer et al., 2019). However, protective buffering has been associated with decreased dyadic intimacy (Manne et Badr., 2010; Perndorfer et al., 2018) and diminished emotional and cognitive processing (Cohee et al., 2017; Xu et al., 2019). Additionally, it has been linked to increased FCR in both survivors and FC (Cohee et al., 2015; Manne et al., 2007; Perndorfer et al., 2018; Xu et al., 2019). Thus, addressing protective buffering in FC may lead to reductions in FCR and improved QOL for both FC and survivors.

While most of the scientific literature has been adapted from survivors' experiences, some theoretical models of FCR in FC are beginning to emerge (Mellon et al., 2007; Webb et al., 2022). Using a family-based model, Mellon and colleagues (2007) identified that personal characteristics (i.e., survivor and FC age), stressors (i.e., concurrent family stressors), personal appraisal (i.e., negative meaning of cancer illness) and cancer survivor's levels of FCR were predictors of higher FCR levels in FC. On the other hand, Webb's (2022) model conceptualizes FCR as a pervasive fear

of losing a loved one (i.e., cancer patient/survivor), which is intensified by fear, uncertainty about the future, and a sense of responsibility to protect their loved one from cancer-related stimuli. To cope with these difficult emotions, FC then become hypervigilant which leads to many triggers and protective monitoring. Accordingly, qualitative studies (Banks et al., 2023; Webb et al., 2024) are beginning to explore specificities related to FCR in FC. In their study, Banks and colleagues (2023) identified three FCR themes uniquely related to the experiences of cancer FC. Firstly, FC experience fears of watching their loved one suffer through a recurrence and/or follow-up treatment. This leads to feelings of helplessness (i.e., not being able to alleviate suffering), a persistent and pervasive uncertainty about the future, triggers related to their loved one's health experience and medical appointments, and concerns about quality and longevity of life. Secondly, FC have a need to protect their loved one from a recurrence and/or cancer-related distress, leading to hypervigilance, proactive monitoring of their loved one's health (with the goal of early detection), protective buffering (e.g., shielding loved one from their personal concerns and wellbeing), being seen as strong and in control, and avoiding conversations that could be perceived as upsetting. Finally, FC experience a sense of unpreparedness and uncertainty about the future, including feeling unprepared to be alone and preparing for the worst-case scenario. Banks and colleagues also identified an overarching theme of personal responsibility to maintain their loved one's health and wellbeing, contributing to further hypervigilance and medical mistrust. Similarly, Webb and colleagues' (2024) found themes of intrusive fear, uncertainty (including fear of further treatment, loved one's death, triggers, and hypervigilance of symptoms and proactive monitoring), liminality (i.e., living in a state of limbo, difficulties planning for the future), hopelessness (including doing anything possible to help), and FC' role as protector (e.g., protective behaviours, being positive and hopeful, protective buffering, avoiding conversations or stimuli). Both qualitative studies highlight distinct FCR experiences in FC further justifying the need for individualized conceptualizations of FCR and tailored interventions.

Over the years, many interventions have been developed to address the needs of FC of cancer survivors. A 2010 meta-analysis (Northouse et al., 2010) of 29 RCTs identified that three types of interventions were most offered to cancer FC: psychoeducation, skills training and counseling. Pooled results demonstrated that these interventions had small to medium effect sizes and significantly reduced FC burden, and improved FC coping capabilities, self-efficacy and QOL. However, majority of the interventions (20 out of 29) were delivered jointly to patients and FC and focused primarily on enhancing the care received by the patient. In fact, FC self-care was often a secondary focus. The authors also observed that interventions solely dedicated to FC resulted in FC attributing more meaning and importance to their caregiving role. More recent systematic reviews (Becqué et al., 2023; Sak-Dankosky et al., 2022; Secinti et al., 2023) identified that current FC interventions primarily provide psychoeducation, information, therapy, coping strategies and/or social support. Specifically, interventions typically include components of either patient caregiving (i.e., self-efficiency, specific medical interventions and/or monitoring), FC self-care (i.e., QoL, psychological, physical and social well-being, coping strategies), or family-care (e.g., communicating about cancer, relationship function, dyadic adjustment). In their systematic review, Secinti and colleagues (2023) identified that, while subgroup analyses revealed that therapeutic counselling and skills training demonstrated positive results in reducing caregiver burden, interventions solely concentrating on psychoeducation failed to demonstrate reductions in caregiver burden, highlighting the need for tailored therapeutic interventions rather than general support or education to increase well-being in FC. For the most part, interventions significantly improved FC outcomes (with generally small effect sizes) but considerable heterogeneity exists in the dosage, duration, format (e.g., group, dyadic, individual), content, and delivery (face-to-face, telephone, videoconferencing, self-led) mode of these interventions (Becqué et al., 2023; Sak-Dankosky et al., 2022; Secinti et al., 2023). However, results also demonstrated that improvements were not sustained long term (Sak-Dankosky et al., 2022; Secinti et al., 2023).

In 2017, O'Toole and colleagues' meta-analysis found limited effectiveness of traditional cognitive behavioural therapy (CBT) for FC, with the authors proposing that interventions should move beyond traditional CBT methods. These findings suggest that a blended approach, composed of multiple treatment modalities (such as the Family Caregiver – Fear Of Recurrence Therapy) and different types of exercises, may be a preferrable option for FC.

Finally, Ugalde and colleagues' (2019) systematic review and appraisal of 26 psychosocial interventions for cancer FC focused on the implementation of research into practice. Overall, few studies included evidence related to acceptability (e.g., data collected on stakeholder perspectives, FC included in development of intervention), and feasibility (e.g., screened participants, withdrawal rate, dropouts, participant time commitment for intervention delivery). No study included evidence of adoption (e.g., intention, agreement, or action to employ intervention). There was also mixed evidence for interventions being appropriate (e.g., intervention was a good fit, targeted to high-risk FC). However, there was good evidence of fidelity (e.g., intervention ran as intended, dose delivered, changes to intervention during the study) and costs reported (e.g., staff commitment required for delivery, additional resources, training and expertise). These results suggest that, despite promising evidence, many interventions are not yet widely being implemented in real-world settings. Furthermore, they highlight the discrepancy in the development and evaluation of interventions designed for FC.

In brief, many interventions are currently available to address the daily needs faced by FC of cancer survivors. However, to date, no intervention has been developed to specifically address FCR in FC. In addition, few interventions designed for FC of cancer survivors include outcomes aimed at optimizing research into implementation. Thus, the proposed pilot project is the first attempt to offer clinical psychological services to FC for their FCR needs.

E-Health Interventions

In considering the adaptation of the proposed pilot project, it is important to account for the consistent evidence that FC often cannot access in-person services due to a variety of constraints, such as lack of time and access to transportation, high caregiving burden, social isolation due to caregiving, lack of support for their loved one, financial constraints, mistrust of the scientific community and institutions, stigma, etc. (as cited in Leslie et al., 2019). Previous in-person therapy studies for FC (either in an individual or group format) have also reported difficulty to reach FC and had low attendance and high attrition rates (Applebaum and Breitbart, 2013; Bazzi, 2017; Song et al., 2021). For these reasons, we identified that E-Health interventions would provide a more viable option for this specific population, increasing accessibility and reducing burden associated with the intervention. Simultaneously, in 2019, the novel COVID-19 virus upended most of our lives by spreading rapidly across the world, leading to high mortality rates and significant social and economic impacts (Sohrabi et al., 2020). For many, living through the pandemic also led to a complete change of social habits and a more in-depth comprehension of public health. In their 2022 systematic review, Dellafiore et colleagues, found that FC experienced increased anxiety, depression, and burden as a result of the pandemic. Furthermore, they identified that caregiving responsibilities were intensified and more difficult to perform given that many health care provider appointments were canceled (interrupting communication and care coordination), FC typical formal and informal supports were not accessible, in-home care was virtually impossible to access, and support programs were limited. Moreover, many FC lived with the fear of being infected with COVID-19 either affecting their ability to care for their loved one or transmitting it to their loved (Dellafiore et al., 2022). For FC of cancer patients/survivors, this was particularly pertinent as their loved ones were considered high risk (i.e., due to immunosuppression, potential for serious complications, high contagion and spread; Salha et al., 2021). For many FC, these concerns continue to prevail in the post-COVID era, decreasing the feasibility of traditional in-person interventions (Weinberg, 2020).

For these various reasons, we identified that E-Health interventions represented a more viable option to FC by simultaneously increasing future access to the intervention and considering relevant health implications.

E-Health interventions, or online therapeutic interventions, are rapidly growing as acceptable and sought-after forms of mental health services. E-Health interventions can include therapies conducted by videoconference, telephone, email, or guided (self or professionally) interventions via websites (Hilty et al., 2016). E-Health interventions represent great advantages such as flexibility with sessions and exercises, cost-efficiency, and a wide access to services (Hilty et al., 2016). For cancer FC, E-Health interventions were also found to be accessible, affordable, convenient, and user-friendly (Su et al., 2021). Multiple studies have suggested that E-health interventions could be as efficient as traditional in-person therapy and that participants perceive the same levels of satisfaction and therapeutic alliance (Castro et al., 2020; Chi et al., 2014; Drago et al., 2020; Gentry et al., 2019; Hilty et al., 2016; Nissim et al., 2012; Tang et al., 2014). Online support groups via videoconferencing, in particular, are suggested to be comparable to an in-person intervention as it enables real-time interactive face-to-face exchange, while drawing participants that may otherwise not be able to access support (Banbury et al., 2018) – such as FC of cancer patients/survivors. Furthermore, a very recent systematic review and meta-analysis evaluated the effectiveness of technology-based psychosocial interventions among cancer patients and FC (Low et al., 2024). Their study included interventions dedicated to patients, FC, and patient-FC dyads. Overall, their results revealed that E-Health interventions dedicated to FC individually were efficacious in increasing health related QOL and reducing depression, with small effect sizes (Low et al., 2024). Similar results were found for patient-FC dyads. Of the psychosocial interventions for FC that led to significant results, these included psychotherapy, psychoeducation, and mindfulness or CBT (Low et al., 2024). Furthermore, a pilot study using videoconferencing (Lamarche et al., 2019), a RCT comparing 4 intervention components (3 CBT-based strategies and 1 control) and telecoaching vs no

telecoaching (Wagner et al., 2017; Wagner et al., 2021), a single arm study using web/text (van de Wal et al., 2017), and an RCT using an online self-guided interventions (van den Berg et al., 2015) have suggested that they are effective at lowering FCR among cancer survivors. Given the many time and financial constraints experienced by FC (Sinha, 2012), E-Health interventions represent an attractive alternative and, perhaps, a preferable option to in-person therapies. For this reason, this thesis focuses on adapting a previously validated face-to-face group intervention (FORT; Lebel et al., 2014; Maheu et al., 2016) dedicated to addressing FCR to a virtual group format for FC.

Fear Of Recurrence Therapy

The Fear of Recurrence Therapy, or FORT, is a standardized and manualized therapist led intervention. It consists of 6 consecutive weekly in person group sessions of 90-120 minutes each and weekly assigned homework (Lebel et al., 2014; Maheu et al., 2016; Maheu et al., 2023). It is based on a blended theoretical model of FCR (Lebel et al., 2018) that aims to address key vulnerability factors such as internal and external triggers, exaggerated perceived risk of recurrence, hyper-focus on ambiguous physical sensations, maladaptive coping, uncertainty around cancer and its treatments or care, intolerance of uncertainty, and beliefs the benefits of worrying about one's health (see Appendix A for a summary of the content of the 6 sessions). This model is guided by Leventhal's Common Sense Model (Cameron and Leventhal, 2003; Lee-Jones et al., 1997), Mishel's Uncertainty in Illness Theory (Mishel, 1988), and the cognitive model of worry (Ladouceur et al., 2000). Within Leventhal's Common Sense Model (Cameron and Leventhal, 2003; Lee-Jones et al., 1997), internal and external triggers (i.e.: aches and pains, doctor appointments, date of diagnosis, etc.) can increase perceived risk of cancer recurrence which in turn heightens FCR. Additionally, exaggerated perceived risk leads to hyper-focus on symptoms that would otherwise be deemed as "normal" and to interpretation of said symptoms as evidence of recurrence (Easterling and Leventhal, 1989; Lee-Jones et al., 1997; Simard et al., 2010). Within Mishel's Uncertainty in Illness Theory, when

illnesses, such as cancer, possess characteristics of inconsistency, randomness, complexity, unpredictability, and difficulties accessing information, patients find themselves living with heighten levels of uncertainty (Mishel, 1988). In turn, high levels of uncertainty are associated with increased psychological distress, perceived risk as well as reduced QOL (Mishel, 1988; Mishel, 1981). Related to this, within the cognitive model of worry, uncertainty in illness increases worry in patients which in turn contributes to higher levels of FCR (Ladouceur et al., 2000). In addition, cognitive models of worry suggest that worriers often believe worrying to be beneficial, and that by worrying they can prevent negative outcomes (Ladouceur et al., 2000). This may increase their use of maladaptive coping strategies such as excessive body checking, reassurance seeking, and avoidance (Humphris et al., 2008, Lasry et al., 1992; Skaali et al., 2009; Stanton et al., 2002). Although these coping strategies can reduce distress short term, they tend to increase FCR in the long run (Humphris et al., 2008; Llewellyn et al., 2008; Spiegel et al., 1999).

Key components of FORT include (a) principles of group therapy (e.g. promoting group cohesion by facilitating participants' self-disclosure of their FCR); (b) CBT-based techniques (e.g. cognitive restructuring); and (c) elements of existential therapy (e.g. outlining fears related to death and dying). Furthermore, FORT was developed using principles of Kissane's Cognitive-Existential (CE) approach (Kissane et al., 1997; Kissane et al., 2003) where themes such as death anxiety, living with uncertainty and future goals are put forward. Given the nature of FCR, it was deemed that CBT alone would not be enough to help survivors let go of maladaptive coping strategies (Maheu et al., 2016). Although CBT for health conditions promotes and focuses on the skill development related to monitoring and modifying emotions, thoughts, and behaviours, it does not address the existential issues related to FCR (Maheu et al., 2016) – hence the use of a cognitive-existential approach. Finally, FORT focused on group therapy to allow cancer survivors to identify shared struggles, to connect and support others with similar life experiences, but also to feel understood and supported by others (Maheu et al., 2016).

The key goals of FORT are to: 1) distinguish worrisome symptoms from benign ones; 2) identify FCR triggers and inappropriate coping strategies; 3) facilitate the learning and use of new coping strategies, such as relaxation techniques and cognitive restructuring; 4) increase tolerance for uncertainty; 5) promote emotional expression of specific fears that underlie FCR; and 6) re-examine life priorities and set realistic goals for the future. FORT was also standardized and manualized.

FORT was first pilot tested as a group intervention using a single-arm pre-post study design and 56 breast or ovarian cancer survivors. Results of the pilot study showed reductions of FCR and other secondary outcomes, such as cancer-specific distress, perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, QOL, which resulted in medium effect sizes of pre to post (within group) change that were sustained at a 3-month follow-up (Lebel et al., 2014). A large multisite RCT of FORT was subsequently completed with 136 female cancer survivors who were either randomized to FORT or a structurally equivalent support group. Cancer survivors in the experimental arm experienced FCR reductions 5 times greater than those in the control group (moderate effect size; d = 0.56; Maheu et al., 2023). In addition, compared to the control group, the experimental arm experienced significant decreases in secondary outcomes such as uncertainty in illness (d = 0.66), positive beliefs about worry (d = 0.43), and QOL (d = 0.57). Furthermore, a small-scale RCT pilot study (Tomei et al., 2018) evaluated FORT as an individual therapeutic intervention. Results demonstrated preliminary efficacy of FORT with participants in the treatment group experiencing decreases in FCR [$F_{(1, 15.18)} = 4.57$, $p = .049$, $r^2 = 0.12$], cancer-specific distress [$F_{(1, 14.63)} = 6.05$, $p = .027$, $r^2 = 0.03$], uncertainty in illness [$F_{(1, 13.71)} = 14.91$, $p = .002$, $r^2 = 0.08$] and most improvements being maintained at the 3-month follow-up. Finally, a series of case studies of cancer survivors receiving the individual FORT intervention via videoconference (Lamarche et al., 2019) showed feasibility and satisfaction. Given the theoretically robust framework and demonstrated effectiveness of FORT's in reducing FCR in cancer survivors, exploration of its potential adaptability and application for other populations would be highly relevant.

Current Studies

Rational for Current Studies

Cancer affects the entire family and FC' experiences often mirror those of the cancer survivor. Consistently, research on FC indicates that they are at high risk for psychological and physical distress, and should be recognized as patients in their own right, who deserve attention to their unmet support needs (Alfano et al., 2018; Applebaum et al., 2013; Kent et al., 2016; Kim et al., 2008; Lambert et al., 2012; Lambert et al., 2017a; Lambert et al., 2017b; Van Ryn et al., 2011). Clinically significant FCR, defined as moderate-to-high levels of FCR, affects up to 59% of cancer survivors post-treatment (Luigjes-Huizer et al., 2022). Clinical FCR tends to remain stable over time if unaddressed and is associated with negative outcomes, such as reduced QOL among cancer survivors and increased costs to the medical system (Götze et al., 2019; Koch et al., 2013; Lebel et al., 2013; Simard et al., 2013; Thewes et al., 2012). A systematic review (Smith et al., 2022) found that levels of FCR in FC are equal or greater than levels reported by cancer survivors, and that similarly to cancer survivors, FCR in FC is persistent, and is associated with lower QOL, lower functioning, and higher psychological distress. Moreover, studies of dyads found that FCR experienced by one partner influenced the level of FCR experienced by the other (Boehmer et al., 2016; Kim et al., 2012; Mellon et al., 2007; van de Wal et al., 2017), suggesting that addressing FCR in FC could also be beneficial to cancer survivors. There is now evidence that clinical FCR can be mitigated among cancer survivors by either group or individual interventions (Hall et al., 2018; Tauber et al., 2018). Among efficacious interventions is a brief, 6-week, cognitive existential intervention entitled Fear Of Recurrence Therapy (FORT) (Maheu et al., 2023; Tomei et al., 2018). Unfortunately, few intervention studies have ever been designed or adapted to target FCR in FC. For this reason, our team set out to adapt FORT to bridge this gap.

This thesis has direct implications for the development of clinical services to improve QOL in FC. This project was needed to determine the feasibility of this intervention before it could be further

tested in a larger RCT. Furthermore, this line of research can provide an evidence-based rationale for the promotion of interventions for FCR in FC as a sustainable and routine program that can be implemented across Canada. Currently, FC are systematically unsupported within the health care system processes and practices. Increasing supports for FC contributes to a better experience and outcome for FC, cancer survivors, healthcare providers, and optimizes the use of the health care system.

Overview of the Current Studies

This dissertation consists of two studies. The objectives of the first study were to: 1) adapt and standardize Lebel and Maheu's FORT intervention (Lebel et al., 2014; Maheu et al., 2016; Maheu et al., 2023) to FC and to an online format (adapted name: FC-FORT) using an advisory board; and 2) evaluate the usability of FC-FORT. The objectives of the second study were to: 1) test the feasibility and acceptability of FC-FORT in a pilot mixed-method RCT study using a waitlist control group (WLCG) with a 3-month follow-up; and 2) estimate the clinical significance of FC-FORT on FCR and on secondary outcomes (cancer-specific distress, perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, QOL, group cohesion, and therapeutic alliance).

Approval was obtained from the Institutional Research Ethics Boards of all affiliated investigators: The University of Ottawa, The Ottawa Hospital, and The Princess Margaret Cancer Centre.

Study 1: It's Time to Address Fear of Cancer Recurrence in Family Caregivers: Usability Study of a Virtual Version of the Family Caregiver—Fear Of Recurrence Therapy (FC-FORT)

The purpose of this study was to adapt FORT to FC and to an online format and test its usability in a real-world setting. To ensure that the adaptation was based on FC needs and specific

FCR themes, an advisory board composed of researchers, clinicians, and FC was formed. The Patient Engagement Framework from the Strategy for Patient-Oriented Research (SPOR) developed by the Canadian Institutes of Health Research (2019) was used to guide stakeholder engagement. Furthermore, the adaptation of FC-FORT was guided by the Information Systems Research Framework (Hevner, 2007). Once adapted, FC and therapists were recruited to take part in the usability testing where they completed FC-FORT, feedback questionnaires and semi-structured interviewed. The results from the usability testing were analysed and presented back to the advisory board to determine whether further adaptations and usability testing were needed before moving forward with pilot testing. This study was published as an open access article in the journal *Frontiers in Digital Health* (Lamarche et al., 2023).

Study 2: It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Feasibility and Acceptability of a Randomized Pilot Study of the Family Caregiver Version of the Fear of Recurrence Therapy (FC-FORT)

The purpose of this study was to evaluate the feasibility, acceptability and estimate the clinical significance of the newly adapted FC-FORT. This information was gathered to assess if a larger RCT is warranted depending on the outcomes of this pilot study, and to use these pilot data to estimate effect sizes for the calculation adequate sample size for a larger RCT. To do so, a mixed-method, multicenter, parallel, two-group (intervention vs. waitlist control group; WLCG) RCT design was used. Pre-determined feasibility outcomes were established, namely the 1) ability to recruit 36 FC in 15 months; 2) ability to randomize all 36 FC; 3) questionnaire completion of measures for 90% of participants; 4) ability to deliver FC-FORT as intended as measured by a fidelity rating of above 80% on 75% of reviewed sessions. Similarly, pre-determined acceptability outcomes were based on the 1) ability to deliver FC-FORT to 75% of FC within 15 months

(maximum 25% dropout rate); 2) 80% completion of 5/7 sessions; 3) caregivers' satisfactory ratings ≥ 80% in terms of its content, therapists, and mode of delivery.

Given the feasibility and acceptability of the original FORT intervention, I hypothesized that FC-FORT would be feasible and acceptable for a larger RCT. Additionally, I hypothesized that FC-FORT would demonstrate clinical outcomes that are consistent with previous literature (Lebel et al., 2014; Maheu et al., 2016; Maheu et al., 2023; Tomei et al., 2017). In other words, I expected FC-FORT to result in small effect sizes on the secondary outcomes of FCR (between groups and across time), perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, and protective buffering, group cohesion, and therapeutic alliance.

The protocol of this pilot study was published as an open access article in *Pilot and Feasibility Studies* (Lamarche et al., 2024). The study itself has been revised and resubmitted as an open access article to the journal *Psycho-Oncology* (Lamarche et al., 2025).

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Study 1:
It's time to address fear of cancer recurrence in family caregivers: usability study of a virtual version of the Family Caregiver—Fear Of Recurrence Therapy (FC-FORT)*

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Abstract

Background: Family caregivers of cancer survivors experience equal or greater levels of fear of cancer recurrence (FCR) than survivors themselves. Some interventions have demonstrated their ability to reduce FCR among cancer survivors and dyads (patient and caregivers). However, to date, no validated intervention exists to focus solely on family caregiver's FCR.

Objectives: This study aimed to 1) adapt the evidence-based in-person Fear Of Recurrence Therapy (FORT) for family caregivers (referred here in as FC-FORT) and to a virtual delivery format and 2) test its usability when offered virtually.

Methods: The adaptation of FC-FORT was overseen by an advisory board and guided by the Information Systems Research Framework. Following this adaptation, female family caregivers and therapists were recruited for the usability study. Participants took part in 7 weekly virtual group therapy sessions, a semi-structured exit interview and completed session feedback questionnaires. Therapists were offered a virtual training and weekly supervision. Fidelity of treatment administration was assessed each session. Quantitative data were analyzed using descriptive statistics. Exit interviews were transcribed verbatim using NVivo Transcription and coded using conventional content analysis. Results were presented back to the advisory board to further refine FC-FORT.

Results: The advisory board (n=16) met virtually on 7 occasions to adapt FC-FORT (i.e., patient manuals, virtual format) and discuss recruitment strategies. Minor (e.g., revised text, adapted materials to virtual format) and major adaptations (e.g., added and rearranged sessions) were made to FC-FORT and subsequently approved by the advisory board. Four family caregivers and three therapists took part in the first round of the usability testing. Six family caregivers and the same three therapists took part in the second round. Overall, participants were very satisfied with FC-FORT's usability. Qualitative analysis identified 4 key themes: usability of FC-FORT, satisfaction and engagement with content, group cohesion, and impact of FC-FORT. All participants indicated that they would recommend FC-FORT to others as is.

Conclusions: Using a multidisciplinary advisory board, our team successfully adapted FC-FORT and tested its usability using videoconferencing. Results from this study indicate that the efficacy and acceptability of FC-FORT are now ready to be tested in a larger pilot study.

1. Background

Fear of cancer recurrence (FCR) is defined as the fear, worry, or concern that cancer may come back or progress[1]. FCR is common and manifests itself on a continuum with an estimated 59% of survivors reporting moderate to severe levels of FCR[2] (i.e., clinical FCR). Clinical FCR is associated with impairment in functioning, psychological distress, sleep difficulties, stress response symptoms, and lower QOL[3-9]. Common risk factors for FCR include younger age, gender (with women being more prone than men)[2], and presence of somatic symptoms (such as pain and fatigue)[10]. Furthermore, FCR seems to be common and persistent across various types and stages of cancer[2]. To date, there is evidence from two meta-analyses[11-12] that clinical FCR can be reduced among cancer survivors by either group or individual therapy with small to moderate effect sizes (Hedges's g ranging from 0.28 - 0.33[12] and pooled effect size of g = -0.36[11]) and evidence of sustained improvements at follow-up (on average 8 months post-therapy). While evidence for the efficacy of interventions designed to address FCR in cancer survivors has been demonstrated, to date, there have been few attempts to offer these treatments to family caregivers (FC) despite FC experiencing similar levels of FCR than survivors.

FC are defined as family members who provide unpaid support and play an integral role in the treatment and care of cancer patients and survivors[13-15]. Approximately 50% of FC experience levels of FCR equal or greater than those reported by cancer survivors[16]. Similarly to survivors, FCR in FC is persistent, associated with lower QOL, lower functioning, and higher psychological distress[17]. A recent qualitative exploration[64] of FCR in FC identified three key themes including fear that the patient will suffer, protecting the patient from a potential recurrence and/or cancer-related distress, and sense of unpreparedness or uncertainty (in relation to losing the patient). Results also demonstrated that FC felt an important sense of personal responsibility for the life of the patient and that this was a driving factor for both FC and patient FCR. Furthermore, studies suggest that, in

couples, levels of FCR experienced by one partner influences FCR levels experienced by the other partner[17-19]. Thus, it appears that treating FCR in FC could impact FCR in both FC and survivors.

Many interventions have been developed to address the needs of FC of cancer survivors[20-22]. Generally, these include psychoeducation, skills training and counselling in individual, group, and paired settings. Results from two meta-analyses[20-21] suggest that interventions dedicated to FC generally have small to medium effect sizes in reducing FC burden, alleviating psychological symptoms, and improving FC coping capabilities, self-efficacy and QOL overall. In addition, to date, three dyadic (for survivors and FC) interventions[16] have been developed to address FCR in FC. Whereas results from one study[23] suggested a significant reduction of FCR in survivors' post-intervention (compared to the control group), no significant decline was demonstrated in FC's FCR. Thus, this is the first attempt to develop and evaluate an intervention to individually address FCR in FC. In considering the adaptation of the proposed pilot project, it is important to account for the consistent evidence that FC often cannot access in-person services due to a variety of constraints. Previous in-person therapy studies for FC have reported difficulty to reach FC and had low attendance and high attrition rates[24]. Furthermore, traditional in-person interventions may also not be feasible in the current COVID-19 era[25]. Therefore, e-health interventions could provide a more viable option for this specific population.

Multiple studies have suggested that therapist guided e-health interventions could be as efficient as traditional in-person therapy and that participants perceive the same levels of satisfaction and therapeutic alliance[26-32]. Virtual support groups via videoconferencing are suggested to be comparable to in-person interventions as it enables real-time interactive face-to-face exchange, while drawing participants that may otherwise not be able to access support[33]. Indeed, a systematic review[34] found e-Health interventions to be feasible, usable, and acceptable for FC of cancer survivors. Another systematic review[35] identified that, compared to care as usual, therapist led e-Health interventions effectively reduced symptoms of depression and improved quality of life of FC of

cancer survivors. Given the many constraints experienced by FC[13], including accessibility and financial, e-Health interventions represent a great alternative and, perhaps, a preferable option to in-person therapies.

Given the limited evidence-based interventions developed for FC to manage their FCR, our team set out to adapt and pilot an intervention to better inform a larger randomized control trial. The aim of the present study was to adapt the Fear Of Recurrence Therapy (FORT)[36-38] to FC and to a virtual format and test its usability. FORT is a standardized and manualized therapist led in person intervention. It consists of 6 consecutive weekly group or individual sessions of 90-120 minutes each and weekly assigned homework[36-37] (See Table 1 for a detailed description of each session). Sessions 1 to 4 aim to build skills and coping strategies in preparation for session 5 where participants are asked to identify and expose themselves to their worst fears related to FCR. Session 6 serves a wrap up and last chance to ask clarifying questions. The key goals of FORT include helping women: 1) distinguish worrisome symptoms from benign ones; 2) identify FCR triggers and inappropriate coping strategies; 3) facilitate the learning and use of new coping strategies, such as relaxation techniques and cognitive restructuring; 4) increase tolerance for uncertainty; 5) promote emotional expression of specific fears that underlie FCR; and 6) re-examine life priorities and set realistic goals for the future. FORT is based on a blended theoretical model of FCR[39] that aims to address key vulnerability factors such as internal and external triggers, exaggerated perceived risk of recurrence, hyper-focus on ambiguous physical sensations, maladaptive coping, uncertainty around cancer and its treatments or care, intolerance of uncertainty, and beliefs about the benefits of worrying about one's health. Key components include: 1) principles of group therapy (e.g., promoting group cohesion by facilitating participants' self-disclosure of their FCR), 2) Cognitive Behavioural Therapy-based techniques (e.g., cognitive restructuring), and 3) elements of existential therapy (e.g., identifying and addressing fears related to death and dying). FORT[36;38] has previously demonstrated its effectiveness at reducing FCR (moderate effect size; d = -0.53) and secondary outcomes [triggers,

(d= -0.415), coping (d = -0.244), cognitive avoidance (d = -0.424), QOL mental health (d = 0.165)] in women cancer survivors[38] with sustained improvements at a 3-month follow up. Additionally, a series of case studies of cancer survivors receiving the individual FORT intervention via videoconference[40] suggested acceptability and usability. Given that FORT has so far only demonstrated its effectiveness with female cancer patients/survivors and that nothing is known about its potential impact on FCR in men or non-binary individuals, the present study focuses specifically on women FC. Furthermore, research consistently indicates that women carry a heavier caregiver burden than men[46].

2. Methods

2.1. Adaptation Framework

The adaptation of the Family Caregiver - FORT (FC-FORT) was guided by the *Information Systems Research Framework*[41]. This framework consists of three components that simultaneously influence each other: the Rigor Cycle, the Design Cycle, and the Relevance Cycle.

In the Rigor Cycle, the advisory board used its expertise and the existing FC literature to define and inform the content needing adaptation to FC concepts (e.g.: protective buffering, self-care, communication with cancer patients/survivors) and to a virtual format. Findings from the Rigor Cycle then informed the Design Cycle where the adapted FC-FORT program was developed (adaptation of the patient and therapist manuals, modifications to deliver the intervention virtually). This first version of FC-FORT was then put into the Relevance Cycle in the real-world environment where it was field tested by FC and therapists (See below Round 1). The results gathered in the first round were presented back to the advisory board who assessed that a second Design Cycle was needed. Further adaptations (see Table 3) were then made to FC-FORT, and the second version of FC-FORT was put into the Relevance Cycle for a second round of usability testing (See below Round 2). The results gathered were then presented back to the advisory board who deemed to have a

satisfactory version of FC-FORT. In a future part of this project, FC-FORT will be further evaluated in a pilot study and results will become incorporated in the Rigor Cycle as an addition to the knowledge base.

2.2 Adaptation of the Family Caregiver – Fear Of Recurrence Therapy (FC-FORT)

A multidisciplinary advisory board (16 members) comprised of 8 health researchers with expertise in psychosocial oncology and caregiving, 2 clinical psychologists, two therapists with experience in virtual support group formats and psychosocial oncology, and 4 female FC (having taken or currently taking care of partners) was created. FC were recruited through The Ottawa Hospital's Patient Engagement Office, Cancer Chat Canada and Twitter. Interested FC met with the study's research coordinator and lead psychologist to discuss their eligibility, advisory board expectations and their involvement. The *Patient Engagement Framework* from the *Strategy for Patient-Oriented Research* (SPOR) developed by the Canadian Institutes of Health Research[42] was used to guide patient engagement. SPOR is guided by four principles: inclusiveness, support, mutual respect, and co-building. Core areas of engagement include: 1) Patient Engagement in Governance and Decision-Making, 2) Capacity Building for Patient Engagement, and 3) Tools and Resources. See Table 1 below for examples of how this study included these core areas.

Table 1: Inclusion of SPOR Core Areas

Patient Engagement in Governance and Decision-Making	Capacity Building for Patient Engagement	Tools and Resources
• Detailed terms of references when onboarding • Clear roles and expectations within advisory board • Inclusion in decisive parts of the process (i.e., adaptation, review of results, recruitment strategies, approval of final intervention)	• Obtained funding for the project and offered stipends to FC • Flexible schedule (i.e., dates/times/videoconferencing) to ensure FC could be present • Authorships on presentations and papers	• Training and orientation for advisory board and review process • Provided education on FCR and FORT • Video capsules

This advisory board met on Zoom on seven separate occasions, from November 2020 to April 2021, to oversee the adaptation of the FORT patient manual and provide feedback on recruitment strategies and the study's questionnaire package. The initial meeting focused on the study objectives, overall timeline, and roles and responsibilities. Following the initial meeting, members of the advisory board were asked to review two sessions each week to determine appropriateness of FCR content for caregivers and online format. Brief video capsules (10-15 minutes), created by study's lead psychologist, explaining each of the FORT sessions were provided to facilitate their understanding and review. Feedback was received either by email or live during the meetings. Each meeting was recorded and reviewed by the research coordinator to confirm the feedback received. All aspects of sessions (i.e., exercises, text, images, graphics, examples) were reviewed with the entire advisory board and group discussions were held regarding their relevance to FC experiencing FCR, readability, understanding and acceptability. Discussions surrounding themes from the existing literature on FC's fears (i.e., fear of loved one suffering or dying, protectiveness, responsibility for patient's wellbeing), needs and unique challenges related to FCR were also conducted and considered when informing the adaptation to FC. The advisory board was consulted after each round of the usability study (described below) to discuss next steps (i.e., readiness for testing in a randomized controlled trial or need for an additional round of usability study). See Chart 1 for a Flow Diagram of the present study.

2.3 Adaptations of FORT to FC-FORT

The general structure, principles, key goals and components of FC-FORT remained very similar to FORT. Nonetheless, as expected, input from our advisory board led to some minor and major adaptations. Major adaptations included offering the intervention virtually (rather than in person), incorporating exercises aimed at addressing FC's self-care, overcoming protective buffering (i.e., the tendency to withhold sharing painful feelings to not burden others)[43-44] by having difficult

conversations with loved ones regarding FCR, and discussing (i.e., identifying knowledge gaps about family member's cancer experience, additional information needed and problem solving how to obtain it) and optimizing use of loved ones' health care teams (i.e., identifying lack of knowledge on FCR, identifying key members of the health care team, navigating meetings with health care providers while being a caregiver). Minor adaptations included softening the language of the patient workbook to represent caregivers' realities, additional examples and stand-alone explanations specifically related to FC fears and experiences, addition of YouTube videos, making the workbook more visually pleasing, and virtual breakout rooms before each session (to encourage FC to mingle amongst each other) and in session 5 (allow group facilitators to check-in with participants). The inclusion of this supplementary content also led to the addition of a 7th session. Please see Table 3 for a list of all suggestions and adaptations.

2.3 Usability Study

2.3.1 Design

Participants took part in the FC-FORT intervention facilitated by two therapists (and 1 back up therapist). FC and therapists completed session feedback questionnaires, administered via Qualtrics, which collected data about specific aspects of each of the FC-FORT sessions. Post-intervention, semi-structured exit interviews, partially informed by the feedback questionnaires, were conducted with therapists and FC virtually using Zoom. These interviews provided a more general understanding of FC's experiences and general impact of FC-FORT, where difficulties arose, and how well FC-FORT met FC expectations and objectives. An initial round of the usability study was conducted, and results were presented to the advisory board. Following this, adaptations were made to FC-FORT, and a second round of usability testing was deemed necessary.

2.3.2 Participants

Canadian adult female FC were eligible to participate if they : 1) cared for an adult survivor of any cancer type (stages I-III) who had completed their treatments and not experienced a recurrence, 2) had a score of 13 or greater on the Caregiver version of the Fear of Cancer Recurrence Inventory-Short Form[62], 3) spoke English, 4) had access to a computer and stable internet connection, 5) were not participating in another therapist-led psychosocial support group or a peer-led support group related to FCR, and 6) were not experiencing unmanaged/undermanaged mental health disorder judged to be clinically contra-indicated and/or likely to affect the group work. Canadian therapists, recruited to administer FC-FORT, were deemed eligible if they: 1) were registered professionals in counselling or psychotherapy, 2) had at least 5 years of experience in psychosocial oncology, and 3) had led at least one support group. Participants were recruited through Cancer Chat (a virtual support group program of de Souza Institute in Canada), the Princess Margaret Cancer Centre in Toronto, Canadian cancer societies, social media, and community support partners across Canada. The same recruitment procedures were used for both rounds of the usability study.

2.3.3 Procedure

The University of Ottawa's Office of Research Ethics and Integrity provided approval for this study (reference number H-05-20-5584). Interested FC contacted the research coordinator to be screened for eligibility, and, if appropriate, completed the consent form and prepared for the group work (i.e., reviewed expectations, assessed appropriateness of group)[36-37]. In addition, each FC was asked to provide further information regarding specific fears related to cancer recurrence and their caregiver experiences. Pre-intervention, FC received a standardized electronic or paper manual describing each session's activities and assignments, were asked to complete a sociodemographic questionnaire and provided their emergency contact information. Therapists were provided with a standardized FC-FORT facilitator's manual and received a 2h virtual training on FC-FORT by one of the study psychologists. FC and therapists then completed the 7-week FC-FORT intervention. Two

days prior to each session, the research coordinator sent FC a reminder, the necessary materials if needed (e.g., audio files for the relaxation exercises) and the Zoom link via email. Participants were asked to inform the research coordinator via email if they needed to miss a session. On the days of the session, the research coordinator opened the Zoom meeting 30 minutes prior to the start of each session and was responsible for letting participants into separate break out rooms for FC (offer a chance to get to know each other) and therapists (brief session prep or check-in). Therefore, outside of the 2h sessions, FC and therapists had no direct contact with each other. The research coordinator also managed the Zoom during the sessions (i.e., breakout rooms, recording the sessions, sharing permissions). During each session, participants were strongly encouraged to keep their cameras and microphones on, to use the chat feature for group messaging and private messaging between participants was discouraged (as it could not be monitored). Therapists began each session with a weekly check-in (i.e., how participants were doing), reviewed the weekly homework, and then moved through each of the workbook exercises. Participants were invited to jump in when pertinent, but therapists also made sure to engage participants that spoke less (i.e., round tables, asking FC directly). In addition, therapists separated the content of each session equally and shared their screens for relevant exercises (i.e., to show graphs or YouTube videos) or to ensure that participants were all at the same place in the workbook. While one therapist guided the content of the group, the other monitored the Zoom chat and participants wellbeing. Participants were offered a short break (5-10 mins) midway through each session. Therapists finished each session with a grounding and check-out (i.e., how participants were feeling) exercises. After each session, therapists and FC were asked to complete a feedback questionnaire[51] via Qualtrics. These questionnaires consisted of closed and open-ended questions aimed at assessing the usefulness (i.e., sessions provide information and tools that help understand and manage FCR), usability (i.e., user-friendly, easily understandable, can be followed-along with ease), desirability (i.e., visually appealing, organization of the information is clear, information is presented as a positive addition to the user experience), value (i.e., sessions

provide a deeper understanding of FCR and valuable tools to manage FCR), accessibility (i.e., easy to follow along and navigate, information is relevant and easy to absorb), the virtual delivery format (i.e., breakout rooms) and features (i.e., exercises that were helpful and could be referred to at a later time), overall satisfaction, the general readiness of each session and potential additions, deletions or changes. The questionnaire is based on the user experience honeycomb developed by Morville & Sullenger in 2010[52] and was adapted from Tan-MacNeill & colleagues'[53] usability study. Close-ended questions were rated on a 5-point Likert scale ("Strongly Agree" to "Strongly Disagree"; "Extremely Ready" to "Not At All Ready"; "Extremely Satisfied" to "Not At All Satisfied"). Open-ended questions allowed participants to provide further information on each aspect of the session in text boxes with no word or character limit.

To enhance therapist administration adherence of FC-FORT, the group facilitators were provided with a weekly 30-minute supervision with the study's lead psychologist. In addition, all sessions were recorded and reviewed by the research coordinator using an updated version of the fidelity checklist used to evaluate adherence during the previous FORT studies[36-38,54]. If adherence was less than 80% on any session, the research team provided additional feedback and supervision to the group facilitators.

Post-intervention, FC and therapists were invited to take part in a brief semi-structured exit interview (30-60 minutes) with the research coordinator. To maximize participation, FC were compensated 20$ for their interview time. Interviews were recorded via Zoom and then transcribed verbatim by the second author and/or using NVivo Transcription. The content of these interviews and questionnaires were analyzed, summarized, and presented back to the advisory board to further refine the FC-FORT content and format.

2.3.4 Data analysis

Quantitative data were summarized using descriptive statistics. Qualitative data were analyzed using conventional content analysis[55]. Once transcribed, transcripts were read repeatedly by the first author and the second author to obtain an overall sense of the data. Exact words/sentences were then highlighted to capture key concepts discussed by participants. Transcripts were systematically coded into anticipated (i.e., motivations to participate, benefits of participation, expectations) and emergent codes by the first author, in collaboration with the second author. This was an iterative process whereby an initial set of themes were coded, applied to new transcripts, and revised to adjust for new information, until no new codes emerge. These codes were then sorted into subcategories and then into a smaller number of categories by the first two authors, with disagreements being resolved through discussion.

3. Results

3.1 Round 1

In total, 6 female FC demonstrated interest in participating in the study, were interviewed, deemed eligible, and provided consent. Of those 6, 1 FC withdrew her consent before the start of the group and 1 FC was unable to participate at the time of the group but demonstrated interest in participating later on. Ultimately, 4 female FC (66% of initially recruited participants) and 3 therapists (2 facilitators and 1 back up) participated in the first round of FC-FORT (January 28th, 2022, to March 11th, 2022). The mean age of FC was 51 years old (SD = 11.67; range = 32-63). Most (n=3) were taking care of partners, whereas 1 FC was taking care of a parent. Survivors were diagnosed with prostate (n=2), melanoma (n=1), or pancreatic (n=1) cancer. Their mean score on the caregiver version of the FCRI-SF was 25.8 (SD = 25.8; range = 21-32). FC described fears related to losing their loved one and the impact of their deaths on other family members, repercussions of additional cancer treatments on loved one's health and quality of life (i.e., pain), and increased caregiver burden. FC were mainly White (n=3), in a marriage/common law relationship (n=3),

employed full-time (n=3), and had higher education (n=3). FC rated their loved one's perceived risk for cancer recurrence as equal to (n=2), more likely (n=1) or much more likely (n=1) than other persons. Motivations to participate included gaining information and skills to manage their FCR, giving back to research, and helping their loved one manage their FCR. Average FC participation rate was 86% (5 sessions had 100% attendance, 1 session had 75%, and 1 session had 50%). Average therapist administration fidelity rating was 84.5%. All sessions had a fidelity rating of 80% and above, except for session 4 (65% rating) due to the health care professional's visit taking longer than planned. Similarly, the primary issues with the administration fidelity were time related (i.e., therapists had to skip certain exercises). Average response rates for all (n=7) session feedback questionnaires combined were 68% for FC and 71% for therapists. All participants took part in the exit interviews.

3.1.1 Feedback questionnaires

Overall, FC and therapists agreed to strongly agreed that FC-FORT sessions were useful, usable, desirable, accessible, and valuable (See Tables 4 & 5). They agreed that the FC-FORT virtual format and the activities at each session were helpful to better understand and manage their FCR. They also agreed that sessions included a satisfactory amount of information (i.e., felt neither over or underwhelming). FC and therapists reported being very satisfied and rated FC-FORT sessions as very ready for end users. Therapists also reported a need for this program (i.e., few interventions offered to FC experiencing FCR despite their distress). Overall, the most acceptable sessions were 1, 2, 6, and 7. The least acceptable were sessions 3, 4, and 5 as they were rated by participants with only moderate satisfaction due to lack of perceived value, accessibility, and readiness. Qualitative data from the feedback questionnaires identified that organization/flow of session (session 3), the healthcare professional's visit (presentation by a registered nurse, with longstanding experience in

psychosocial oncology, about symptoms of recurrence in various cancer types; session 4) and the emotional difficulty of exercises and break out room (session 5) impacted their overall scores.

3.1.2 Exit interviews

Qualitative analysis identified 4 key results: participant's experience with the format, satisfaction and engagement with the content, group cohesion, and perceived impact of FC-FORT according to participants.

3.1.2.1 Participant's experience with the format

Overall, FC and therapists expressed that the length of FC-FORT was appropriate. Whereas some FC indicated that they might have appreciated more sessions, they also agreed that seven weeks allowed for enough time to cover the content, get to know the group, and explore their FCR. No participants indicated that it should be shortened.

"*I think it was appropriate. I think there's room if you wanted to go up to 8 weeks, but at the same time, the way that the sessions are organized and laid out, because you follow the structure, you're not really pushing things along in a subsequent week and I think that 7 sessions is appropriate. I think it's much better than if it was going to be 6 weeks. I think 6 weeks would be a bit challenging."* [Therapist 2 (T2)]

Both FC and therapists agreed that 90-minutes were not enough to comfortably cover the content of each session. In some cases, FC reported that they did not feel as though they had a chance to completely engage with an exercise. In other cases, some exercises were skipped completely.

"*We always ran out of time and I don't think anyone was sitting there "I wish this would end", we were all engaged from the beginning to the end, but again, that might've been sufficient if we didn't go through the homework or each checking in as to whether or not we went through the homework but there were some things in the booklet that we didn't go through because we didn't have time and it wasn't picked up in the next session*" (P2).

In terms of timing, FC indicated that Friday sessions were convenient as it provided a chance to debrief over the weekend. However, having sessions during a workday created some barriers for FC who worked fulltime.

"*If it was in the evening yeah, no worries. But I work full time, so […] I'm only available in the evenings and weekends so it was a struggle for me to do every session because I only have a break for an hour and the sessions were 1:30 so I had to extend my day or take time off to do the sessions.*" (P2)

Finally, FC and therapists agreed that the virtual format increased the accessibility to FC-FORT as it was practical and convenient. In addition, a few FC mentioned that having the group virtually provided an additional sense of safety which increased their emotional vulnerability and allowed them to further explore and challenge their FCR.

"It was actually good, doing it online it gives me a sense of distance and safety. I am present and I can see people […] That's really important when you're sharing anything that personal. Being online, I'm in the safety of my own home, I can step away at the end of it and I don't have to drive home if I'm emotionally rot, I didn't have to set aside an hour to get downtown to get to the meeting and then an hour after." (P5)

3.1.2.2 Satisfaction and engagement with the content

FC and therapists reported feeling very satisfied with FC-FORT (i.e., workbook, content, coping strategies). Preferences varied in terms of which exercises FC found most helpful; however, relaxation/mindfulness exercises (e.g., mindful eating, guided imagery) seemed to have been preferred to cognitive ones (e.g., thought log). Some FC mentioned that it was the combination of all the tools that promoted change.

"There were certainly some exercises in there that were useful but none of them on their own would have given me the "ha-ha" moments that I've had." (P5)

Of note, while session 5 was the least highly rated according to the feedback questionnaires, all FC mentioned that it stood out as being the most valuable to address their FCR as it allowed them to concretely identify/name their fears (often for the first time), rate them in terms of intensity, and openly share and discuss them with the rest of the group and facilitators. This suggests this session, while helpful, was particularly challenging for FC.

"There was one [session] where we were kind of rating our fears and concerns and after I did that, I looked at it and I didn't realize that [those fears were] going on. It really jumped out at me when I was dealing with it because I hadn't really thought about it in an organized way." (P5)

FC also noted that group support mechanisms (e.g., conversations and exchanges) had significantly contributed to a better understanding of their FCR, normalized their caregiving experiences, and increased their sense of coping (i.e., validating their difficulties, learned new coping strategies).

"*I think even listening to the other women and their fears and coping techniques and what they do to recharge their battery, it brings the tone that we're worthy and "oh I never thought of doing that to recharge my battery, that's quicker" and "oh I think I'll try that". Kind of made an impact."* (P6)

FC and therapists did identify some issues with the FC-FORT content. Primarily, the health care professional's visit (session 4) was deemed unhelpful by almost all participants due to diversity in types of cancer and participant's locations (i.e., each province has its separate guidelines and procedures), and the information provided (i.e., too generic).

"You have people from across the country […] So, unless you have a representative for each of the provinces of the people who are participating in the group who can speak to the local services, it's not really helpful. Because the information about the actual cancers, there's a multitude of information from the cancer agencies, Cancer Canada, everything, I hadn't come across the

symptoms of when it reoccurs because most of it talks about the cancer when it's happening, but the actual having a healthcare provider, I didn't really find that valuable." (P2)

In addition, the organization of certain sessions and the use of the breakout room were seen as reducing the usability of FC-FORT and participants' overall experience. For example, in some sessions (e.g., session 3), some participants found that the exercises did not flow well together and led to confusion. P6 described this session as "very up and down". FC also expressed that they would have preferred to remain as a group for session 5 and that they found the breakout room to be out of place or isolating.

"There's one thing that I definitely think needs to be changed. When we went through our worst feelings or the worst fears that we had we were given breakout rooms to write that down and the breakout rooms were alone and […] I think that that particular exercise is too emotionally intense to leave people on their own." (P2)

Finally, FC experiences with the homework and logs (both for the cognitive and mindfulness exercises) were mixed. While some participants appreciated the logs as it gave them an opportunity to reflect upon and articulate their feelings, some found that they were not helpful for the management of their FCR or were not easy to complete (i.e., confusing, language use was not patient friendly). In addition, most participants reported that they often forgot or were too busy to complete the homework throughout the week.

"[…] The thought log was not for me. I think part of that was the way it was written. The "how I felt before 0-100%, how I felt after" it kind of didn't make sense to me. […] it was more frustrating than anything so that's why I gave it up pretty much right away." (P5)

3.1.2.3 Group cohesion

Overall, FC and therapists indicated that they experienced trust, acceptance, sharing, understanding, connection within the group. For example, P6 stated: *"I really didn't think it would click quite the way that it did being online and not in person. I didn't quite think that it would be*

unity feeling.". Furthermore, T2 felt that *"the cohesion was there, I think they were genuinely happy to see one another and to hear one another's update and they cared what everybody else was doing, they were okay to share so, when I think of the mark of did, we reach to kind of measure cohesion."*.

In addition, FC described feeling supported, validated, and included by both therapists throughout FC-FORT. Most FC also indicated that the therapists' skills (i.e., time and group management, knowledge) facilitated overall group cohesion. On their end, therapists reported feeling that the weekly check-ins contributed to enhancing group cohesion.

"I think [the therapists] worked well together […] and they both were so good at making you feel comfortable about whether you were snot crying […] or having a moment or the epiphany moment, they were so good at working through all of that with you, both of them. It was great. (P6)

While FC indicated that they appreciated the smaller group size, as it allowed for deeper personal connections and made it more comfortable to share personal information, some FC noted that the somewhat limited diversity within the group (i.e., caregiving role & experience, age, cancer types, coping strategies) occasionally made it difficult for them to connect with others.

"I was pleasantly surprised by the size of the group; I thought it was going to be a lot more people and that would've been more difficult for me. In some sense it would've been more difficult, in others it would've felt less difficult in that there's a bit of opportunity to not have to share and interact. I would always do that, I think also having more individuals, you get a broader perspective. […]. I was going to say, because it's such a small group, there wasn't a whole lot of experiences that matched mine, they were sort of on one side and I was on the other." (P2)

Finally, all participants indicated that the virtual format of the group did not affect their sense of connection or group cohesion.

"I was honestly surprised, I was expecting to feel a little less of a group and more single people doing this but just doing it at the same time rather than a group, but it worked, we became that group and it worked as a group. I can't say that being online made it any different." (P6)

"I didn't feel like I lost any of the personal connection. I think it's a brilliant way to do any groups in the future." (P5)

3.1.2.4 Perceived Impact of FC-FORT on participants

All FC reported that FC-FORT has had a positive impact on their lives. Most noted that they now had a better understanding of their FCR, that they had gained tools (i.e., understand and recognize triggers, recognize their biggest fears, relaxation, and mindfulness exercises) to better manage their FCR and that FC-FORT had had an impact on their stress/anxiety (i.e., felt calmer about their fears) personal relationships, the stress they experience at work, and their quality of life.

"I feel like I'm much better able to understand why that fear is so hard for me and what's really at the root of it and once I know what my triggers are then I know how to deal with them so that was the most important gain from this group." (P2)

When asked how important the group had been for them [(on a continuum from 0 (Not important) to 10 (Extremely important)], FC rated, on average, the importance of FC-FORT in their lives as 9. In addition, all FC indicated that they would recommend FC-FORT to others.

"I would highly recommend this to somebody coming into it because right away let's get the coping techniques for you into practice and get you that and make sure that you're in a good spot." (P6)

Finally, FC indicated that they planned to continue using coping strategies learned through FC-FORT or review the workbook as needed. FC identified consistency as their primary obstacle to implementing these changes long term.

"There's a lot of reflective questions that are in the workbook and I try to take the weekends to focus in more on this type of reflective work and it helps to ground and center me." (P4)

"I know that there will be a challenge when it's going well not to do the relaxation and the mindfulness and then, all of a sudden, you're in a panic situation and then you have to come back to it and relearn it and re-practice it." (P6)

3.1.3 Adaptations and changes

Results from this initial usability round were presented back to our advisory board in April 2022. Based on results and expert feedback, a second round was deemed necessary. To address participants primary concerns, key adaptations were made to FC-FORT including increasing length of sessions from 90 to 120 minutes, removing and reorganizing exercises (e.g., removing the health care professional's visit, changing order of exercises within sessions), modifying some of the virtual features (e.g., instead of separating participants into individual break out rooms that therapists then entered, all participants stayed in the main Zoom as a group and an individual break out room was created for a therapist. FC were sent one at a time to see the therapist, while the rest of the group stay in the main Zoom) and changing some of the workbook's written content (e.g., softening language, adding examples, modifying questions to increase standalone comprehension). Please see Table 2 to see an exhaustive list of suggestions and modifications.

3.2 Round 2

In total, 8 female FC demonstrated interest in participating in the study, were interviewed, deemed eligible and 6 provided their consent. Of the initial 8, 1 FC declined to participate due to scheduling conflicts and 1 FC was unable to participate at the time of the group but demonstrated interest in participating later on. Ultimately, 6 female FC (75% of initially recruited participants) and the same 3 therapists (2 facilitators and 1 back up) from round 1 participated in the second round of FC-FORT from May 19th, 2022, to June 29th, 2022. The mean age of FC was 52 years old (SD = 10.46; range = 21-68). Most (n=4) were taking care of partners, whereas 2 FC was taking care of adult children. Patient cancer types included leukemia (n=3), lymphoma (n=1), prostate (n=1) or sarcoma (n=1). FC were mainly White (n=5), in a marriage/common law relationship (n=5) and had higher education (n=5). Their mean score on the caregiver version of the FCRI-SF was 24 (SD = 3.48; range = 21-29.5). FC described fears related to losing their loved one, repercussions of

additional cancer treatments on loved one's health, quality of life (i.e., pain) and future, and increased caregiver burden and impact on FC future plans. FC rated their loved one's perceived risk for cancer recurrence as equal to (n=2), more likely (n=1) or much more likely (n=2) than other persons. Motivations to participate included gaining information and skills to manage their FCR and giving back to research. Average FC participation rate was 81% (4 sessions had 100% attendance, 2 sessions had 66.7%, and 1 session had 33.3%). Therapist average administration fidelity rating was 89%. All sessions had a fidelity rating of 80% and above. Average response rates for all (n =7) session feedback questionnaires combined were 76% for FC and 85.7% for therapists. All participants took part in the exit interviews.

3.2.1 Feedback Questionnaires

Results obtained from this second round resembled those of the first (See Table 6 & 7). Overall, FC and therapists reported being very satisfied with FC-FORT. FC rated FC-FORT sessions as very ready for end users, while therapists rated them as extremely ready. Of note, session 5 received the lowest rating from FC (Table 6) with readiness and satisfaction being rated as moderate. In addition, FC indicated "Neither agreeing nor disagreeing" with the value of session 5. Qualitative data from the feedback questionnaires identified that the readiness of participants to face these fears and the difficulty of the exercises themselves impacted the overall rating.

3.2.2 Exit Interviews

Similar results as Round 1 emerged: participant's experience with the format, satisfaction and engagement with the content, group cohesion, and impact of FC-FORT on participants. However, only themes relevant to the modifications made after Round 1 will be highlighted below.

3.2.2.1 Participant's experience with the format

FC and therapists stated that they appreciated the format of FC-FORT. FC and therapists still expressed that the overall length of FC-FORT was appropriate and agreed that 120-minutes was enough to comfortably cover the content of each session and have in-depth discussions. In addition, this allowed for a break midway through the sessions – which was appreciated by FC.

"First, I thought it was going to be pretty long […] but the time flew by. […] it was never like, "Oh, when is this going to be over?" It was like, "Oh boy, are we ready for a break already?" […] And it was really good having the bathroom breaks partway through." (P7)

FC and therapists agreed that the virtual format increased their accessibility to FC-FORT in terms of practicality, flexibility, and convenience. In addition, most FC expressed having appreciated the opportunity to connect with other FC across Canada.

"[…] For me, the online format works absolutely beautifully. What I also like is being able to have opinions from people in different provinces […] having that cross-Canada [perspective] is kind of interesting as well so I love the online format." (P10)

3.2.2.2 Satisfaction and engagement with content

FC and therapists reported feeling very satisfied with FC-FORT (i.e., workbook, content, coping strategies). Once again, preferences varied in terms of which exercises FC found most helpful, with relaxation/mindfulness exercises being slightly more preferred than cognitive ones. Of note, most FC mentioned that session 5 (i.e., writing down worst fear) stood out as being the most valuable to address their FCR.

"Writing out that worst case scenario really stands out.[…] I was actually able to get it down on paper so that I could read over what was floating around in my brain, in my thoughts […] as if I was just an observer […]. Somehow seeing it written down […] it helped me to pre deal with emotions and to see a different perspective of it." (P8)

However, some FC had trouble engaging in session 5, specifically the writing of the worst-case scenario, due to the challenging nature of the exercise and their individual situations.

"I found this session very upsetting actually. I know it was meant to be in many ways, however I was not emotionally ready to take part in some of the exercises." (P11)

"The tools and conversation were useful but the writing out our biggest fears was hard and I'm not sure if it would be a great exercise for everyone." (P4)

All FC indicated that group conversations had contributed to normalizing their fears and increasing their sense of coping

"I gained so much comfort from having a space where people talked about this freely because really in my day-to-day life, everyone around me is aware of what's going on, but I would never just like openly or comfortably talk about […] how scary it is and expect them to understand. Versus this space, everyone really did understand and was dealing with it in their own way. […] But it was it was nice to get people's advice and have people properly understand you." (P4)

"I think just the solidarity of hearing other people's experiences was great because I've been very kind of isolated […]." (P10)

Consistently completing homework continued to be the primary challenge for FC. However, most stated that the weekly homework debriefs provided another chance to engage in the homework as it led to group discussions regarding various topics and learn about others' experiences - regardless of if they had completed the homework themselves. FC indicated that being able to refer to the homework assignments in the future or at a more convenient time was an additional bonus.

"The fact that they were available and then that the discussion that followed was never dependent on whether the group did [the homework; …]. Going over, say what the homework was, because I can think of at least once where I hadn't even looked at it and it didn't matter because it was brought into the conversation in such a with such good explanation. And then the conversation,

the session just flowed from there. So, it's there, I think it's really good that it's there in the workbook, but you know, doing it after the fact isn't going to take away from its effectiveness." (P8)

Finally, two FC expressed that the use of the one-on-one breakout room with one of the group therapists negatively affected their overall experience in Session 5. In fact, FC mentioned that the short time allotted to each participant made them feel rushed and unheard.

"I found the breakout sessions confusing and a bit abrupt. Not sure if I fully understood what they were for. […] Either more clarity on use of breakout sessions, or more time." (P8)

"[…] The only session that I came out feeling not so good was when there was one session where we broke out into individual groups like one on one if we wanted to talk to [the therapists]. But it was so timed and short lived that it actually triggered me about being cut off, about wanting to talk about it. And I think if you're going to go one on one, you have to be able to allow a little more time." (P9)

3.2.2.3 Group cohesion

Overall, FC and therapists indicated that they experienced good group cohesion. In fact, P8 expressed that they appreciated the "*level of connectedness*" that was established as early as the first session. In addition, T2 expressed "*when I think back to this specific group, I actually think we had a really […] cohesive group, a very rich group, there was the support for one another that was really there"*. FC indicated that participant's openness and vulnerability contributed to the group cohesion.

"I felt like people connected. I felt […] there was meaningful conversation. I think it definitely exceeded what I expected in those ways. It felt like everybody participated, no one monopolized all the conversation or some of the things you get sometimes in groups." (P11)

Both FC and therapists found the group size allowed participants opportune time for expression and supported the creation of a safe and mutually supportive environment to engage in each exercise according to their needs/comfort levels and increased diversity within the group.

"This group of ladies from across Canada with different cancers, different parts of the cancer journey and different cancers period and different stages of life that we're all at. And I thought, who'd have thought that there'd be this group and it didn't take long to really feel "I'm not the only one with these thoughts", and that was actually it was really comforting." (P8)

"If some people don't come, I feel like the size of the group is still good. And also sometimes I didn't want to talk if there's a question that I just didn't resonate with and [...] so a six people like you kind of have the freedom of doing that [...]." (P4)

Finally, participants indicated that, overall, the virtual format of FC-FORT did not affect their sense of connection or group cohesion (i.e., allowed for exchanges, unstructured conversations, shared experiences). FC indicated that therapists' time management abilities, capacity to include all members in conversation, and weekly check-ins contributed to the success of the virtual platform.

"I found [the therapists] directed it really well and made sure everybody got a chance to speak. Even if they asked them if they wanted to share anything and they didn't want to, they were okay with that too, but everybody usually said something when given the opportunity." (P9)

"Professionally guided discussions and safe environment for us all to share and it really created [...] a very cohesive group." (P8)

Challenges with cohesion were primarily related to participant attendance (i.e., missing sessions or joining from different settings) and participation during the group (i.e., natural tendencies to talk more or less than others, willingness to engage in exercises).

"I don't know of anything that hindered it. It's hard if people missed some weeks, but that can't always be helped. I felt more connected to the ones that were there more often [...]." (P7)

"I do think attendance was difficult. And I do think having sometimes folks either just be on the phone and not be on video or being in the car. I think those things kind of stopped group cohesion. I think it's still happened. I think it's still existed." (T1)

4. Discussion

This study aimed to 1) adapt the FORT intervention for FC living with FCR (FC-FORT) and to a virtual format and 2) test its usability. A multidisciplinary advisory board composed of the research team, community therapists and FC was recruited and oversaw the adaptation of FORT and its patient and therapist manuals. Based on their expertise and feedback, many minor and major adaptations were made. Notably, additional exercises aimed at addressing FC's self-care, overcoming protective buffering by having difficult conversations with loved ones regarding FCR, and discussing and optimizing the use of their loved ones' health care teams were added. As a result, a seventh session was included to accommodate this added content. FC-FORT remains, like FORT, a standardized and manualized therapist-led group intervention aimed at addressing FCR in FC through mindfulness exercises, cognitive-existential therapy, and principles of group therapy. However, a major recommendation was for FC-FORT to be offered as a synchronous, online, virtual group via the platform Zoom, instead of a face-to-face group.

Following these adaptations, two rounds of usability testing ensued. Based on participant feedback, further modifications were made to FC-FORT. Namely, the session length was increased from 90 to 120 minutes, exercises were removed or reorganized, and some of the patient manual's written content and virtual features were modified. Overall, results from both rounds demonstrated that FC and therapists found FC-FORT to be useful, usable, desirable, accessible, and valuable. In addition, they reported high levels of satisfaction with both the content and the virtual format of FC-FORT, felt that FC-FORT was ready for use and indicated that they would recommend it to others. Given these results, FC-FORT is deemed for pilot testing. A key contributor to the successful adaptation of FORT to FC-FORT is the contribution of valuable FC insight in both the adaptation and usability testing of the intervention. In fact, including FC in research could be considered a best practice as it leads to meaningful additions to the scientific literature as well as improved health outcomes[42]. However, a 2019 systematic review[56] found that a large number of studies dedicated to

cancer FC interventions did not in fact include FC input in the development and evaluation of their interventions. It would seem that this study therefore distinguishes itself from previous interventions studies dedicated to FC.

One of the most notable findings from this study is FC and therapists' appreciation for the virtual aspect of FC-FORT's adaptation. Overall, participants mentioned that the virtual format increased their accessibility as it was practical, flexible, and convenient. Some even mentioned that the virtual format provided them with an increased sense of safety. In addition, they expressed still being able to experience trust, acceptance, sharing, understanding, and connection with other group members (i.e., group cohesion) and therapists (i.e., therapeutic alliance). Alternatively, the primary issue reported by FC related to the virtual format was the use of the breakout room feature in Session 5. Altogether, our results suggest that while the fundamental components of group interventions are present when using a virtual format (i.e., group cohesion, therapeutic alliance, developing coping strategies to manage FCR), it seems that the "technical" aspects of the interventions (e.g.: breakout rooms, participants keeping their cameras closed) may be less appreciated by participants/more difficult to adapt to a virtual setting (e.g.: one on one time between therapists and participants). Therefore, while the virtual format provides many advantages for FC and was generally well received by participants, further reflection is needed on how to better adapt some specific aspects of face-to-face interventions to virtual settings.

Moreover, FC recruitment and attendance proved to be challenging. While our initial recruitment efforts were limited to the provinces of Ontario and Quebec, these yielded limited interest from the caregiver community. Given the well-documented difficulties[57] in recruiting this specific community (i.e., high levels of burden or accessibility issues) as well as limited capacity to recruit in traditional hospital settings due to the COVID-19 pandemic (i.e., caregivers no longer allowed in the hospital with patients) our team decided to expand our recruitment efforts across Canada. The virtual format of FC-FORT combined with the pandemic context (i.e., lockdowns, no

accessible in person services, remote work) provided an ideal scenario for this change in recruitment and an opportunity to increase the intervention's accessibility. Interestingly, almost all FC expressed that had FC-FORT not been virtual they would not have been able to participate or would have been limited in their full participation. Moreover, many also expressed having appreciated the opportunity to connect with other FC from across Canada with whom they most likely would not have connected with otherwise. These results echo the previously established literature demonstrating that e-health interventions may effectively be more acceptable and feasible for FC[34-35; 58.] Additionally, the lessons learned throughout this study and the adaptations made to our recruitment strategy will also allow us to modify our recruitment efforts for the next phase of the project (i.e., the pilot study). Namely, we will continue to expand our recruitment nationally and will aim to further recruit through social medias and community support partners across Canada given that this is how most of our FC were recruited.

Finally, some studies[59-60] have previously focused on the adaptation process of in-person interventions for FC to a virtual format. For example, Zulman and colleagues adapted an in-person intervention, aimed at improving communication between partners, to a virtual format. Similarly to the current study, their results demonstrated that many elements of in-person interventions can be successfully adapted to a virtual format and perceived as acceptable by dyads (patients and partners). A multidisciplinary team, including FC, was also used in the adaptation process further demonstrating the necessity of FC insight in research. Additionally, Northouse & colleagues evaluated the feasibility of adapting a previously in-person intervention for dyads and found that it was feasible (i.e., good retention rates, accessibility, and satisfaction) to offer this intervention using a virtual delivery format. However, less is known about the adaptation of validated interventions previously dedicated to cancer survivors to FC. Therefore, the results of this adaption of FORT to FC-FORT demonstrate the pertinence of adapting previously validated interventions dedicated to cancer survivors with specific FC related content. Overall, participants indicated that they

appreciated the content of the manuals and found them to be pertinent to them/their experience. However, results from this study suggest that while FC reacted well overall to the intervention exercises (with some preferences for the mindfulness/relaxation exercises), what FC most appreciated from FC-FORT was the ability to go through the intervention material in a group format. More specifically, according to participants, FC-FORT provided an opportunity to speak openly about FCR with other FC and a chance to connect with others who are experiencing similar difficulties (in both FCR and caregiving). Noteworthily, while specific content was added to better reflect FC common difficulties, the elements of FC-FORT that were both most and least appreciated resembled what was reported in the original FORT validation study[61]. For example, in the original FORT study, Session 5 was also reported as the most difficult session by cancer survivors but generally deemed the most useful. Moreover, unstructured conversations and exchanges amongst participants were also some of the most appreciated aspects of FORT. Similarly to FORT, primary challenges throughout both rounds included homework completion. This project is a first step in establishing the pertinence of adapting pre-existing FCR interventions dedicated to patients for FC with few modifications made.

5. Study limitations

Limitations of the current study include small group size (4 instead of intended 6-8) for the first round of usability testing. Moreover, not all FC used FC-FORT exactly as intended with most missing one or two sessions. In addition, as is common in psycho-oncology research with FC, most participants were White women taking care of male partners. Canadian representation was also limited with participants only coming from either British Columbia or Ontario. Future adaptations of this study should include diverse populations and formats (i.e., combined women and men, in person, hybrid). Given the current adaptation of FORT to a new population (i.e., caregivers) and to a virtual format, our team chose to limit the amount of adaptations in order to more accurately represent the

usability, and eventual feasibility and acceptability, of FC-FORT. However, FORT is currently being adapted to Mexican breast cancer survivors[63]. Similar adaptations of FC-FORT could be made to represent for men FC and other cultural adaptations. Based on the lessons our team learned throughout the study, future adaptations should include an advisory board of caregivers, researchers and health care professionals in order to appropriately adapt FC-FORT. This study, as well as upcoming pilot study, are the first steps in developing further adaptations for diverse populations.

6. Conclusions

This study demonstrated the usability of the adapted FC-FORT with family caregivers and in a virtual format. Themes from the usability testing emphasized the importance of including FC in research and developing/adapting targeted and accessible therapist-led group interventions for Canadian FC living with FCR. Results indicate that FC-FORT's feasibility and acceptability is ready to be pilot tested in a mixed-method randomize-control trial.

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Table 2: Overview of FORT Sessions

Session 1: Introduction to the group, learning new skills to deal with FCR (60-90 minutes)	• Introduction by each participant with a focus on their experience with FCR. • Introduce ABC model of cognitive behavioural therapy. • Introduce FCR model. • Introduce notion of cognitive restructuring and identify triggers. • Teach progressive muscular relaxation. • **Homework:** Practice progressive muscular relaxation daily; complete thought record and challenge maladaptive thinking about fear of cancer recurrence.
Session 2: Providing information, increasing tolerance for uncertainty (60-90 minutes)	• Prepare questions for visit from health care professional who will be providing education about signs of recurrence in session 3. • Help participants deal with the fact that uncertainty can never be completely eliminated. • Discuss ways of regaining a sense of control. • Teach the use of calming self-talk. Provide participants with relaxation files and instruct them to use calming self-talk phrases when appropriate. • **Homework**: Listen to relaxation files every day; practice calming self-talk; complete thought record and challenge maladaptive thinking about fear of cancer recurrence and prepare questions for the nurse visit.
Session 3: Building your coping skills (60-90 minutes)	• Visit from health care professional. • Increase tolerance for uncertainty by discussing acceptable level of worry. • Challenge faulty beliefs about benefits of worry. • Decrease maladaptive coping strategies. • Teach guided imagery. • **Homework**: Practice guided imagery daily; continue challenging faulty beliefs about benefits of worry; complete thought record adding a column for behaviors to monitor the kinds of coping strategies participants are adopting.
Session 4: Getting deeper into underlying fears (60-90 minutes)	• Provide psychoeducation about worry and the need for exposure to worse fears. • Promote emotion expression and confront specific fears that underlie FOR. • Write down worse fear scenario. • Teach mindfulness exercise. • **Homework:** Read worst case scenario every day and then do a self-care activity. Practice mindfulness exercise daily.
Session 5: Moving beyond specific fears (60-90 minutes)	• Review exposure to worst case scenario exercise. • Discuss ways of coping with some of the feared outcomes. • Promote expression of feelings of demoralization.

	• Encourage participants to become re-engaged with important life goals, people or activities they may have given up. • Discuss what meaning the future and planning now have for them. • Teach mindfulness exercise. • **Homework:** Write down goals and priorities for the future.
Session 6: Review and conclusion (60-90 minutes)	• Review all content covered. • Discuss future goals. • Setting new priorities. • Promote the expression of saying good-bye to the group and provide closure.

Table 3: Suggestions and Adaptations Made to FC-FORT

Categories of Proposed Changes	Advisory Board	Family Caregivers/Therapists (Round 1)
Content	Separate the amounts of psychoeducation content and theories from Session 1 into two sessions Reduce jargon, soften language, and make models more accessible Add quotes, images, graphs, colours to help with understanding and differentiation Add YouTube videos to review during the group Add therapist dialogue on myths about worrying and helpful vs unhelp worries Add example of "fear of dogs" to demonstrate avoidance and exposure frameworks Add example scenario to Session 5 to guide participants Reduce expectations for homework and attendance (compared to FORT) Modify mindful eating exercise (ask participants to bring a small bite size snack). Send email reminder about bringing the food. Send a reminder prior to Session 5 to prepare participants to the difficulty of the session	Soften language and reduce expectations (especially homework) Review and reorganize the content of sessions 2, 3, 4 Remove health care provider's visit
Additional sections	Add a section on communication with loved one with cancer to address protective buffering Add a section on self-care to address FC needs (i.e., sleep, happiness) and/or difficulties taking time for themselves (i.e., guilt) Add a section about FC objective knowledge on FCR within their family member's cancer experience, identifying knowledge gaps, difficulties in obtaining additional information, problem solving how to properly obtain the information, navigating and/or utilizing the patient's health care team, how to ask questions or discuss with health care providers	

	• Adding an FAQ in the workbook Add a 7th session to accommodate the content Addition of a follow up check-in (1 month later) or a booster session*	
Additional information	Overall, increase examples and explanations so the workbook can stand alone and be referred to later on Given the diversity of cancers within the group, make the healthcare provider's visit more general and focused on FC Ask the healthcare provider to leave their contact information in the event that FC have additional questions*	Increase examples and explanations so the workbook can stand alone and be referred to later on
Technical features	Use a virtual group format Use max session length of 90 minutes Add a breakout room 30 minutes before the start of each session to create a space where FC can connect Add a breakout room to session 5 so therapists can connect with FC individually Biweekly sessions* Record each session in order to send to participants who may have missed a session and would like to review* Ask participants to send their weekly homework to therapists to increase completion* Grouping caregivers by cancer types*	Remove the individual breakout room in Session 5 Establish more rigid group norms regarding the use of the chat function Ensure that participants use their camera every session Increase session length to 120 minutes
Accessories	While the intervention should use a virtual format, participants should receive a paper version of workbook that they can write in and keep Send audio files via email each week so participants can use them for their homework As much as possible, therapists should share their screens with participants	Group all audio files in one place (e.g.: google Drive) and send them at the beginning
Peer support	Participants should be encouraged to share the contact information at the end of the intervention	
Additional resources	Add resources at the back of the workbook	

Table 4: Overview of FC-FORT Sessions

Session 1: Introduction to the group, learning new skills to deal with FCR (120 minutes)	• Introduction by each participant with a focus on their experience with fear of cancer recurrence (FCR). • Introduce ABC model of therapy, FCR model, cognitive restructuring and identify FCR triggers. • Psychoeducation on the importance of self-care, ways to engage in self-care and potential obstacles. • Teach cognitive restructuring to challenge FCR related thoughts. • **Homework:** Complete thought log and practice self-care.
Session 2: Identifying knowledge gaps on FCR (120 minutes)	• Discuss uncertainty in FCR and caring for a loved one with cancer. • Discussing FC's knowledge regarding FCR, identifying gaps in knowledge and navigating the patient's health care team to obtain knowledge on FCR. • Teach progressive muscle relaxation (PMR). • **Homework:** Complete thought log and practice daily PMR.
Session 3: Increasing tolerance for uncertainty (120 minutes)	• Discuss acceptable level of worry. • Challenge faulty beliefs about benefits of worry (in relation to FCR). • Discuss uncertainty and ways of regaining a sense of control. • Teach the use of calming self-talk & introduce FC to relaxation files. • **Homework**: Challenge faulty beliefs about benefits of worry. Practice calming self-talk & PMR daily.
Session 4: Building your coping skills (120 minutes)	• Provide psychoeducation about worry and the need for exposure to worse fears. • Discuss maladaptive coping strategies used when experiencing FCR (focusing on avoidance). Group discussion and sharing of different coping strategies to address FCR. • Address communication difficulties with loved ones relating to FCR • Teach guided imagery. • **Homework**: Have a conversation about FCR. Practice guided imagery daily; challenge faulty beliefs about benefits of worry; complete thought record with behaviour.
Session 5: Getting deeper into underlying fears (120 minutes)	• Pink elephant exercise (i.e., demonstration on the impact of avoidance). • Promote emotion expression and confront specific fears that underlie FCR by writing down worse fear scenario. • Teach body scan exercise. • **Homework:** Read worst case scenario daily. Practice self-care & body scan exercise daily.
Session 6: Moving beyond specific fears (120 minutes)	• Review exposure to worst case scenario exercise. • Discuss ways of coping with some of the feared outcomes. • Encourage participants to become re-engaged with important life goals, people or activities despite FCR. • Discuss what meaning the future and planning now have for them.

	• Teach mindful eating. • **Homework:** Write down goals and priorities for the future, practice mindfulness daily.

Table 5: Sample characteristics (N=10)

Variable		Values
Age (years), mean (SD)		51.6 (10.46)
Ethnicity, n (%)		
	White	9 (90%)
	Asian	1 (10%)
Province, n (%)		
	Ontario	5 (50%)
	British Columbia	5 (50%)
Marital Status, n (%)		
	Single/Never married	2 (20%)
	Married/Common-law	8 (80%)
Level of Education, n (%)		
	Part of university/college	2 (20%)
	University/college	4 (40%)
	Graduate school	3 (30%)
Occupational Status, n (%)		
	Unemployed	1 (10%)
	Unemployed due to illness	1 (10%)
	Employed part-time by choice	1 (10%)
	Employed part-time due to illness	1 (10%)
	Employed full-time	3 (40%)
	Student	1 (10%)
	Retired	2 (20%)
Annual Income Level, n (%)		
	$00,000-$20,000	1 (10%)
	$41,000-60,000	2 (20%)
	$61,000-80,000	2 (20%)
	Greater than $100,000	4 (40%)
Cancer Type, n (%)		
	Prostate	3 (30%)
	Pancreatic	1 (10%)
	Melanoma	1 (10%)
	Acute myeloid leukemia	3 (30%)
	Hodgkins Lymphoma	1 (10%)
	Sarcoma	1 (10%)
Stage, n (%)		
	Gleason score of 9	1 (10%)
	Gleason score of 7	1 (10%)
	III	1 (10%)
	IIA	1 (10%)
	Unknown	6 (60%)

Treatment Received, n (%)		
	Surgery	3 (30%)
	Chemotherapy	3 (30%)
	Chemotherapy & radiation	1 (10%)
	Surgery, chemotherapy	1 (10%)
	Surgery, radiation, adjuvant chemotherapy	1 (10%)
Relationship with Patient/Survivors, n (%)		
	Spouse/partner	7 (70%)
	Parent	2 (20%)
	Child	1 (10%)
Receiving other psychological support, n (%)		
	Yes	2 (20%)
	No	7 (70%)
Living with a chronic medical condition		
	Yes	4 (40%)
	No	5 (50%)

Table 6: Perceived risk of their loved one's recurrence

Question:	**Compared to persons of their age, how do you rate your family member's perceived risk of cancer recurrence?**				
	Much less likely	Less likely	Equal to	More likely	Much more likely
	0	0	4 (40%)	2 (20%)	3 (30%)

Table 7: Round 1 & 2 - Family Caregivers' Session Feedback Questionnaires (Mean Scores)

	Session 1		Session 2		Session 3		Session 4		Session 5		Session 6		Session 7		Overall	
	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2
Useful	4.125	3.75	4.25	3.88	4.25	4.5	3.75	4.13	4	3.3	4	4.08	4.5	4.25	4.125	3.983
Usable	4.625	4.83	4.875	4.38	4.5	4.7	4	5	4.5	4	4	4.67	4.5	5	4.429	4.654
Desirable	4.25	4.17	4.75	4.25	4	4.2	3.5	4.75	4	3.8	4	4.33	4	4.5	4.071	4.286
Accessible	4.375	4.42	4.625	4	3.5	4.2	3.75	4.75	4	3.8	4	4.25	4.25	4.25	4.071	4.238
Features	4.917	4.08	4.75	4.25	3.833	4.07	3.833	4.17	3.833	3.53	4	4.17	4	4	4.167	4.040
Satisfactory amount of information and tools	2.875	2.834	2.875	2.75	2.5	2.7	2.5	2.5	2.75	2.2	3	2.833	3	3	2.786	2.668
Valuable	4.125	3.83	4.625	3.75	3.5	4.1	3.375	4.25	3.75	3.4	4	4.17	4.75	4.25	4.018	3.964
Readiness	4	3.67	4	3.75	3	3.8	3	3.75	3.5	2.6	4	4.17	4	4.5	3.643	3.748
Overall satisfaction	4.25	4.33	4.25	3.75	3	4.5	3.25	4.5	4	3	4	4.17	4	4	3.821	3.964
Addition/removal of content*	1.08	1.333	1.33	2.25	1.667	2	1.833	2	1	1.8	1	1.167	1.667	1.5	1.368	1.607

All scores are out of a 5 point Likert Scale ("Strongly Agree" to "Strongly Disagree"; "Extremely Ready" to "Not At All Ready"; "Extremely Satisfied" to "Not At All Satisfied").

*Scores are out of a 3 point Likert Scale ("No", "Maybe", "Yes")

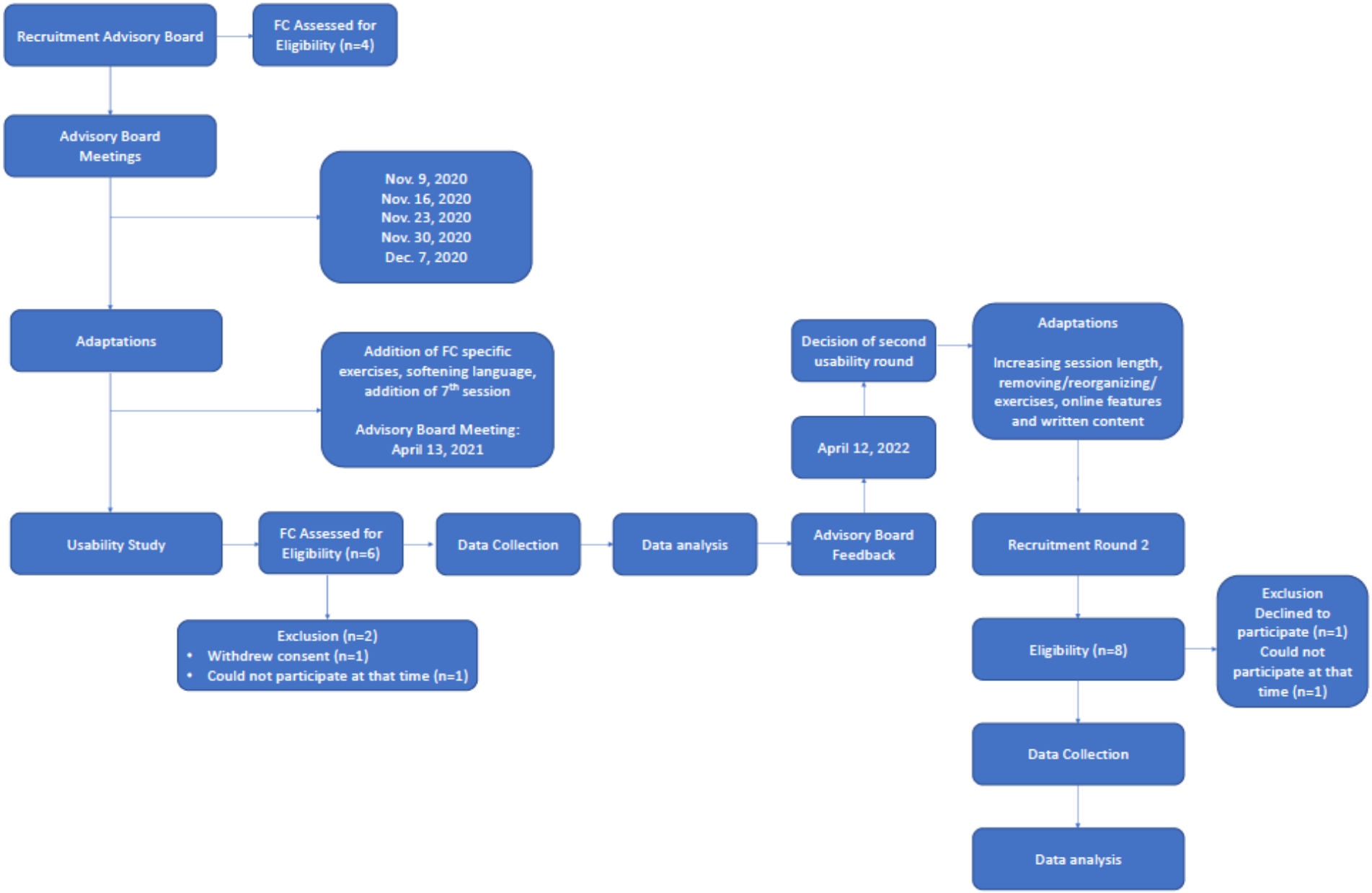
Table 8: Round 1 & 2 - Therapists' Session Feedback Questionnaires (Mean Scores)

	Session 1		Session 2		Session 3		Session 4		Session 5		Session 6		Session 7		Overall	
	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2	R1	R2
Useful	4.25	5	4.5	5	5	5	4.5	5	5	5	5	4	5	4.5	4.75	4.79
Usable	4.25	5	5	4.75	5	5	3	5	4	5	5	4	5	4.5	4.46	4.75
Desirable	4	5	5	5	5	5	3.5	5	4	5	5	4	4	4.5	4.357	4.79
Accessible	3.75	5	5	5	4.5	5	3	4.75	3.5	4.5	5	4	5	4.5	4.25	4.68
Features	4	4.5	4	4.5	5	4.83	3.667	4.83	4	3.5	4.333	3.67	3.333	4.5	4.048	4.33
Satisfactory amount of information and tools	2.5	3	3	3	3	3	3	3	3	3	3	3	3	3	2.929	3
Valuable	4.833	5	4	5	4.667	5	3.833	5	4.667	5	5	4	4.833	4.5	4.548	4.79
Readiness	3.5	5	4	5	5	4.5	2.5	4.5	4	5	5	4	3.5	4.5	3.929	4.64
Overall satisfaction	3.5	5	4	5	5	4.5	3.5	4.5	4	4	5	4	4.5	4.5	4.214	4.5
Addition/removal of content*	1.833	1	1.667	1.1675	1.333	1.5	1.667	1.167	1	1.33	1	1	1.333	1	1.405	1.167

All scores are out of a 5 point Likert Scale ("Strongly Agree" to "Strongly Disagree"; "Extremely Ready" to "Not At All Ready"; "Extremely Satisfied" to "Not At All Satisfied").

*Scores are out of a 3 point Likert Scale ("No", "Maybe", "Yes")

Chart 1: Flow Diagram



Protocol Article: It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Protocol for the Feasibility and Acceptability of a Randomized Pilot Study of the Online Version of the Family Caregiver - Fear Of Recurrence Therapy (FC-FORT)*

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* Please note that this article is an exact replica of the published version. See reference below.

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Abstract

Background: Fear of cancer recurrence (FCR) is common, persistent, and is associated with lower quality of life, impaired functioning, and psychological distress in cancer patients. Studies suggest that family caregivers of cancer patients experience equal or greater levels of FCR than patients themselves. In the past five years, several interventions have demonstrated their ability to reduce FCR among cancer patients and patient-caregiver dyads. However, to date, no intervention exists to individually target family caregiver's FCR. The aims of the proposed pilot study are to 1) assess the feasibility and acceptability of the newly adapted Family Caregiver – Fear Of Recurrence Therapy (FC-FORT) intervention to inform a larger randomized control trial study, and 2) estimate the clinical significance of FC-FORT. Initial evaluation of FC-FORT revealed high user satisfaction and usability.

Methods: A parallel, two-group, pilot randomized controlled trial comparing FC-FORT to a waitlist control (care as usual) will be conducted. Participant inclusion criteria are a) women family caregivers taking care of adult cancer patients (no recurrence), b) experiencing clinical levels of FCR, c) access to a computer/internet connection, and d) living in Canada. Participants (n=36) will be recruited at Ottawa and Toronto hospitals, previous study participant pools, through social media and community partners across Canada. Participants in the intervention group will complete the FC-FORT intervention (7 consecutive weeks of virtual group therapy and homework). Participants in the control group will be offered the intervention after their participation in the study. All participants will be asked to complete questionnaire packages at baseline (T0), immediately post-intervention (7 weeks; T1) and at 3-months post-intervention (T2) to assess primary (FCR) and secondary outcomes (i.e., illness uncertainty, quality of life). Participants in the intervention group will be asked to complete measures of group cohesion and therapeutic alliance after sessions one and four and will be asked to take part in a semi-structured exit interview exploring their overall experience with the intervention.

Discussion: This project will evaluate the acceptability and feasibility of the newly adapted FC-FORT to inform a larger trial

1. Background

Fear of cancer recurrence (FCR), or the fear, worry, or concern that cancer may come back or progress[1], manifests itself on a continuum with 59% of cancer survivors experiencing moderate to severe levels of FCR (also known as clinical FCR)[2]. At the individual level, clinical FCR is associated with impairment in functioning, psychological distress, sleep difficulties, stress response symptoms, and lower QOL[3-9]. Younger age, gender (with women being more susceptible than men), and the existence of somatic symptoms like pain and fatigue are all common risk factors for FCR[10]. Moreover, FCR appears to be prevalent and persistent across various cancer types and stages[10]. According to two meta-analyses published to date[11-12], clinical FCR can be decreased in cancer survivors by either group or individual therapy with small to moderate effect sizes and evidence of sustained improvements at follow-up (on average 8 months post-therapy). Although there is evidence that interventions created to address FCR in cancer survivors are effective, to date, there have been few attempts to provide these treatments to family caregivers despite their unmet FCR needs.

Family caregivers (herein referred to as caregivers), also defined as family members who provide unpaid support, play an integral role in the treatment and care of cancer survivors[13-15]. According to a recent systematic review[16], approximately 50% of caregivers experience levels of FCR equal or greater than those reported by cancer survivors. FCR in caregivers, similarly to cancer survivors, is persistent, associated with lower QOL, lower functioning, and higher psychological distress[16]. In addition, FCR has been found to be one of the primary unmet need most frequently associated with caregivers reporting depressive symptoms[17]. Furthermore, in couples, FCR experienced by one partner can influence the other partner's FCR[9, 18-19]. Therefore, treating FCR in caregivers could improve QOL for both caregivers and cancer survivors.

Many interventions have been developed to address the needs of caregivers[20-21]. Generally, interventions for caregivers include psychoeducation, skills training and counselling

in individual, group, and paired settings. Results from two meta-analyses[20-21] suggest that interventions dedicated to caregivers generally had small to medium effect sizes in reducing caregiver burden, alleviating psychological symptoms, and improving caregivers coping capabilities, self-efficacy and QOL. To date, three studies (two qualitative and one randomized control trial [RCT])[16] have been developed to address FCR in caregivers. However, while the results from the two-site, parallel-group RCT (1:1 randomization)[22] suggested a significant reduction of FCR in survivors' post-intervention [compared to the control group; $F(1, 71) = 8.6$, $p = 0.005$], no significant decline was demonstrated in the FCR of caregivers. In addition, all of them focused specifically on FCR within dyads (survivors and caregivers). Thus, this is the first attempt to develop and evaluate an intervention to individually address FCR in caregivers. In considering the adaptation of the proposed pilot RCT, it is important to account for the consistent evidence that caregivers often cannot access services due to a variety of constraints (e.g., time, finances, travel, patient-focused view, lack of resources, negative perceptions of mental health professionals and services, stigma avoidance)[23-25]. Previous in-person therapy studies for caregivers have reported difficulty in reaching caregivers and had low attendance and high attrition rates[26]. Furthermore, traditional in-person interventions may also not be feasible in the current COVID-19 era[27]. Therefore, an online format may provide a more viable option for this specific population.

When it comes to cancer care, e-Health, or web-based interventions, are becoming increasingly popular as they provide several benefits over traditional in-person interventions such as unrestricted space, accessibility, flexibility, cost-effectiveness, time-efficiency, convenience, and stigma reduction[28-29]. A systematic review[30] found evidence of small to large effect sizes for web-based dyadic interventions on physical health ($d = 0.17$-0.75), psychological health ($d = 0.04$-0.08), overall quality of life ($d = 0.20$-0.68), and dyadic relationships ($d = 0.30$-

0.95). More specifically, online support groups via videoconferencing are suggested to be comparable to in-person interventions as they enable real-time interactive face-to-face exchange, while drawing participants that may otherwise not be able to access support. Banbury & colleagues[31] conducted a systematic review of telehealth interventions delivering support groups through videoconferencing and found that online support groups were effective (pre- and post-intervention similar to face-to-face groups, usual care and significantly better than text-based forums, high levels of cohesion and perceived social support between participants, and increase accessibility), feasible (i.e., participants were provided with the appropriate tools, usability was high, the majority of studies reported few technical issues), and had high acceptability (high levels of participant satisfaction, high attendance with few dropouts, convenience was highly valued and privacy was not a concern). Additionally, their implementations were comparable to face-to-face interventions (strong reliability and validity). Moreover, a recent systematic review[32] identified that, compared to care as usual, e-Health interventions effectively reduced symptoms of depression and improved quality of life of caregivers of cancer survivors. Another systematic review[33] found e-Health interventions to be feasible, usable, and acceptable for caregivers of cancer survivors. Finally, there is also evidence from a range of interventions that e-Health interventions can be effective at lowering FCR among cancer survivors. These interventions include a pilot study using videoconferencing[34], web/text based randomized control trial[35] and pilot study using a single pre-post design[9], and an RCT using an online self-guided format[36]. Given the many constraints experienced by caregivers[13], including access and financial, e-Health interventions represent a suitable alternative and, perhaps, a preferable option to in-person therapies.

2. Aims of the Current Study

The primary aim of this pilot RCT is to examine the feasibility (defined by the rates of recruitment, retention, and questionnaire completion) and the acceptability (including satisfaction, adherence, perceived usefulness, and attrition) of FC-FORT.

The secondary aim is to estimate the potential clinical significance (i.e., whether changes can be observed) of FC-FORT on FCR, cancer-specific distress, perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, group cohesion, therapeutic alliance, and QOL as established by comparing improvements between and within groups (FC-FORT, WLCG).

3. Methods

3.1 Design

The proposed project is a pilot, mixed-method, multicenter, parallel, two-group, unblinded RCT where caregivers are randomized to receive either 1) FC-FORT or 2) care as usual (WLCG). The study design was guided by the adapted CONSORT checklist for pilot trials[37-38]. The reporting of this protocol is in line with the SPIRIT guidelines[39].

3.2 Eligibility

Inclusion criteria include: 1) women adult caregivers caring for an adult cancer survivor of any type of cancer, stages I-III, who has completed treatments and has not had a recurrence of their cancer; 2) a score of 13 or greater on the Caregiver Version of the Fear of Cancer Recurrence Inventory - Short Form (range 0-36), suggesting clinical levels of FCR[5,40] ; 3) access to a computer and stable internet connection; and 4) living in Canada. Exclusion criteria include 1) caregivers who do not identify as women; 2) caregivers of a pediatric cancer survivor; 3) non-English speaking; 4) caregivers currently participating in another therapist-led psychosocial support group or a peer-led support group; and 5) caregivers with unmanaged/undermanaged

mental health disorder judged to be clinically contra-indicated and/or likely to affect the group work. This study will focus on women caregivers specifically as research consistently indicates that women carry a heavier caregiver burden than men[41]. Additionally, the FORT intervention has only been tested with women so far and studies on FCR in caregivers include mostly/only women caregivers[4,9,42].

3.3 Sample Size Justification

Sample size for the present pilot study was calculated based on the estimated sample size needed in a future RCT with a two-arm design (intervention vs. waitlist control) and three measurement occasions (pre-, post-, and 3-month follow-up). Sensitivity power analyses were performed with G*Power 3.1 using a two-sided, type 1 error rate of 0.05 and 95% power, of an independent sample size of fifty-seven participants per arm, and with a three-time assessment. Under these conditions, an effect size of 0.40 (Cohen's d) would detect a difference between FC-FORT and a WLCG. Based on FORT's observed dropout rate and loss to follow-up[43-44], an additional 20% participants per treatment group would be needed, thus requiring sixty-eight participants per arm for a total of 136 study participants. This would mean conducting sixteen groups of nine caregivers (eight interventions and eight WLCG who would get the intervention after 3 months). Assuming a four-year recruitment rate for the RCT, we need to be able to recruit four groups (i.e., thirty-six caregivers) in a period of 15 months during the present study to demonstrate feasibility of this future RCT.

3.4 Recruitment

Thirty-six women caregivers will be recruited to participate in the study. Participants will be recruited using advertisement at the Princess Margaret Survivorship Clinic and the Princess Margaret Caregiver Clinic, The Ottawa Hospital, previous study participant pools, with cancer

societies (e.g., Prostate Cancer Canada and Ovarian Cancer Canada), through social media, and with community support partners across Canada. Interested caregivers will contact the research coordinator via email to be screened for eligibility and to complete the consent form.

3.5 Allocation, Randomization and Concealment

Eligible participants will attend a one-on-one pre-therapy meeting with the research coordinator or assistant to prepare them for the group work (i.e.: review expectations and assess whether group work is appropriate for the participant)[45]. For most participants this will be done during their initial eligibility meeting. These pre-therapy meetings will occur prior to randomization to reduce potential bias.

Before randomization, all eligible participants will complete a) the consent form, b) the sociodemographic questionnaire, and c) the baseline measures. A list of four group allocations with equal numbers of intervention (I) and WLCG groups (e.g., I-I-WLCG-WLCG; I-WLCG-WLCG-I, etc.) will be randomly generated by the research coordinator. To limit bias, we will have each of the four allocations in separate sealed envelopes that will be opened one by one by an independent research assistant not associated with the project each time nine participants are deemed eligible (minimizing attrition). Overall, four groups (two intervention and two WLCG) of nine participants each will be created. Study therapists will be blinded to participant allocation as well as feasibility and acceptability outcomes. All participants will be assigned a participation ID at the onset of the study (prior to randomization) which will be used to complete questionnaire packages and data analysis.

3.6 Fear Of Recurrence Therapy (FORT) Intervention

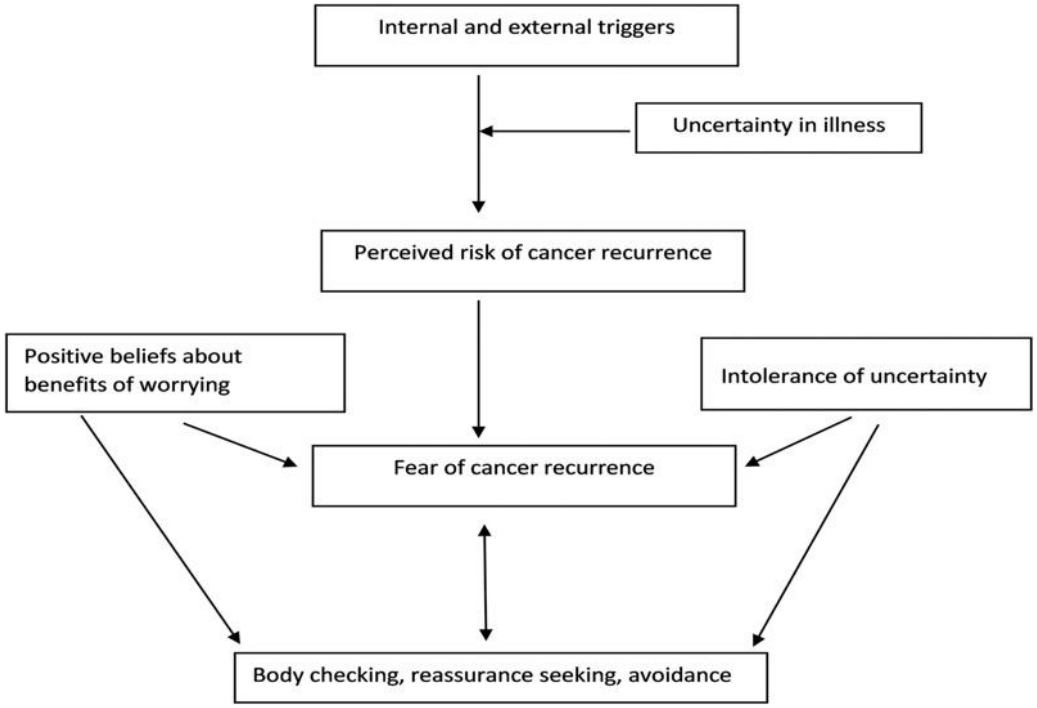
The Fear Of Recurrence Therapy (FORT) is a standardized and manualized intervention that consists of six consecutive weekly sessions[43-45]. It was first pilot tested as a group

intervention using a single-arm pre-post study design and 56 breast or ovarian cancer survivors. Results of the pilot study showed reductions of FCR and other secondary outcomes, such as cancer-specific distress, perceived risk of cancer recurrence, illness uncertainty, intolerance of uncertainty, positive beliefs about worrying, coping, QOL, which resulted in medium effect sizes of pre to post (within group) change that were sustained at a 3-months follow-up[43]. A large multisite RCT of FORT was subsequently completed with 136 women cancer survivors who were either randomized to FORT or a structurally equivalent support group. Cancer survivors in the experimental arm experienced FCR reductions five times greater than those in the control group (moderate effect size; d = -0.53)[44]. In addition, compared to the control group, the experimental arm experienced significant decreases in secondary outcomes [triggers, (d= -0.415), coping (d = -0.244), cognitive avoidance (d = -0.424), QOL mental health (d = 0.165)], with sustained improvements at a 3-months follow up. Moreover, FORT was also adapted to an individual format in a pilot study RCT[46]. Results also demonstrated that survivors in the experimental arm experienced significant decreases, over time, in both FCR [primary outcome; $F(2, 27.87) = 15.82$, $p < 0.001$*] and secondary outcomes such as cancer-specific distress [$F(2, 28.68) = 10.58$, $p < 0.001$*], uncertainty in illness [$F(2, 30.24) = 21.46$, $p < 0.001$*], reassurance seeking [$F(2, 29.63) = 3.92$, $p = .031$*], cognitive avoidance [$F(2, 29.01) = 6.22$, $p = .006$*], and intolerance of uncertainty [$F(2,24.71) = 5.43$, $p = .011$*] with sustained improvements at the 3-month follow up[46]. Finally, a series of case studies of cancer survivors receiving the individual FORT intervention via videoconference[34] suggested acceptability and usability.

FORT is based on a blended theoretical model of FCR (Figure 1)[47] that aims to address key vulnerability factors such as internal and external triggers, exaggerated perceived risk of recurrence, hyper-focus on ambiguous physical sensations, maladaptive coping, uncertainty

around cancer and its treatments or care, intolerance of uncertainty, and beliefs about the benefits of worrying about one's health. This model is guided by Leventhal's Common Sense Model[48-49], Mishel's Uncertainty in Illness Theory[50] and the cognitive model of worry[51].

Figure 1: Model of Fear of Cancer Recurrence (Lebel & al., 2018; adapted from Lee-Jones & al., 1997).



It was developed using principles of Kissane's Cognitive-Existential (CE) approach[52-53] where themes such as death anxiety, living with uncertainty, and future goals are put forward. FORT integrates principles of group therapy to facilitate cancer survivors/caregivers to identify and express shared struggles, to connect and support others with similar life experiences, but also to feel understood and supported by others[45].

The key goals of FORT include helping women: 1) distinguish worrisome symptoms from benign ones; 2) identify FCR triggers and inappropriate coping strategies; 3) facilitate the

learning and use of new coping strategies, such as self-care, relaxation techniques and cognitive restructuring; 4) increase tolerance for uncertainty; 5) promote emotional expression of specific fears that underlie FCR; and 6) re-examine life priorities and set realistic goals for the future. Key components of this intervention include a) principles of group therapy (e.g., promoting group cohesion by facilitating participants' self-disclosure of their FCR); b) Cognitive Behavioural Therapy-based techniques (e.g., cognitive restructuring); and c) elements of existential therapy (e.g., outlining fears related to death and dying).

To adapt FORT to FC-FORT a multidisciplinary advisory board, comprised of the research team, two therapists with experience in online support group formats and psychosocial oncology, and four women caregivers, was created. This advisory board met online to oversee the adaptation of the FORT patient manual and provide feedback on recruitment strategies and the study's questionnaire package. The following modifications were made to the original FORT intervention to better represent caregivers' experiences: a) additional exercises aimed at addressing caregivers' self-care, overcoming protective buffering (i.e., the tendency to withhold sharing painful feelings to not burden others); b) additional suggestions that support difficult conversations with loved ones regarding FCR, with the focus more on facilitating discussions that support optimizing use of loved ones' health care teams; c) softening the overall language of the workbooks to represent caregivers' realities; and d) the addition of a seventh session to incorporate the additional content. A usability study of FC-FORT then ensued[54]. Overall, ten caregivers and three therapists, recruited through social media, community support partners across Canada, and the Princess Margaret Cancer Centre, took part in the usability study. Therapists and participants were asked to complete a short session feedback questionnaire[55] to assess the usefulness, usability, desirability, value, accessibility, and credibility of each session,

as well as provide impressions of the online format and features and the general readiness of the session for end users. Brief videoconference or telephone exit interviews post-intervention were conducted with both the participating caregivers and therapists. Combined FC session participation rate was 85%. Response rates for the session feedback questionnaire were 72% for FC and 78% for therapist. Average fidelity rating for therapist administration of FC-FORT was 87%. All participants (n=10) and the two group facilitators took part in the exit interviews. In addition, all participants and therapists found FC-FORT to be acceptable (i.e., useful, usable, desirable, valuable, etc.). The mean satisfaction rating for participants and therapists combined was “Very Satisfied”. FC-FORT was rated as “Very Ready” by participants and “Extremely Ready” by therapists. Generally, exercises were well received by participants. Following the initial round of the usability study, key changes made to FC-FORT include increasing length of sessions to two hours, removing and reorganizing exercises (i.e., removing the health care professional’s visit, changing order of exercises within sessions), and modifying some of the online features (i.e., break out rooms, chat; see details in Lamarche & al., 2023[54]). In addition, all participants indicated that they had appreciated FC-FORT’s virtual format (i.e., appreciated the convenience, felt safer/more comfortable in their own spaces, ability to meet other women from across Canada, could not meet in person due to personal or loved one’s health conditions). All participants expressed good group cohesion with other group members & therapists. However, one participant indicated that the virtual format had occasionally impacted their connection to others.

3.6 The Adapted Family Caregiver – Fear Of Recurrence Therapy (FC-FORT) Intervention

Like the original FORT, FC-FORT is a standardized and manualized therapist led intervention. It consists of seven consecutive weekly group sessions of 120 minutes each, offered via videoconference, and weekly assigned homework. It is built upon FORT's original blended theoretical model of FCR (Figure 1)[47] with some adaptations made to represent caregivers' realities. It also includes principles of Kissane's Cognitive-Existential therapy[52-53], principles of group therapy, and Cognitive Behavioural Therapy-based techniques.

3.7 Intervention Groups

Participants in the intervention group will complete the seven-week FC-FORT intervention (see Table 1). Membership will be closed once groups are formed and the sessions have started to enhance group cohesiveness and consistency[56]. Before starting the intervention, participants will receive a standardized electronic or paper manual describing each session's activities and assignments. Participants will be asked to complete questionnaire packages and measures as per the data collection schedule detailed below.

3.8 Waitlist Control Groups

Participants in the WLCG will not receive any interventions initially. They will be asked to complete questionnaire packages as per the data collection schedule detailed below. Once the 3-month questionnaire returned, caregivers in the WLCG will be offered FC-FORT.

3.9 Therapist Recruitment, Training and Supervision

Three therapists (two co-facilitators and one back up therapist) will be recruited to conduct the FC-FORT videoconference therapy sessions. Therapist competency to administer FC-FORT will be determined by the following criteria: 1) registered allied health professionals

with experience in counselling/psychotherapy and psychosocial oncology, 2) ability to offer virtual services across Canada, 3) at least five years of experience in psychosocial oncology, and 4) having led at least one support group.

To enhance therapist adherence to treatment, therapists recruited for the study will be provided with a standardized FC-FORT manual and will be trained by the team of research psycho-oncologist specialists through an online training. The study psychologists will provide weekly 30-minute supervision to the study therapists. Furthermore, the study will use an updated version of the fidelity checklist that was used to evaluate adherence during the previous FORT studies[45-46]. Some examples of items on the fidelity checklist include: "The therapists refer back to the theoretical framework", "The therapists initiated problem-solving skills". The research coordinator and assistant will check the videos of all sessions from every group. If adherence is less than 80% on any session, the research team will provide additional feedback and supervision to the therapists running the group. This approach to monitoring treatment integrity and fidelity has been successful in previous FORT studies[45-46].

3.10 Minimizing Dropouts and Attrition

Based on prior research on FORT[43,45], to maximise attendance, participants will be told during informed consent procedures about the importance of attending all seven sessions to ensure that they benefit from the intervention. Participants will receive an email reminder about each upcoming session along with the videoconference invitation information, as well as reminders to complete session measures. They will be asked to inform group therapists if they are to be absent. Participants who miss more than two sessions will be asked to stop the intervention and restart with the next available group. This approach was successfully tested in previous FORT studies[43,46]. To maximize the completion of the questionnaire package,

participants in the intervention and WLCG will be compensated 20$ for each of the three packages they will complete (pre-intervention, immediately after the intervention and 3-months post-intervention). To minimize differential attrition from the WLCG participants, we will email them monthly with an update about the wait time. All WLCG participants will be offered FC-FORT after study completion regardless of their questionnaire completion.

3.11 Data Collection

Participants will be asked to complete questionnaire packages (approximately 20 minutes each) pre and immediately post-intervention (seven weeks), and at 3-month post-intervention. All measures and questionnaires will be administered online via Qualtrics. Participants in the intervention groups will also be asked to complete measures after sessions one and four and take part in a semi-structure exit interview. Additionally, data will be logged throughout the recruitment (all steps until consent) and course of the study (follow-up of enrolled and randomized caregivers).

3.11.1 Questionnaire Package

The questionnaire package will be available in English and includes the following self-administered measures to evaluate this project's primary and secondary outcomes. Measure selection is based on the original FORT intervention (REF), theoretically guided by Leventhal's Common Sense Model[49], Mishel's Uncertainty in Illness Theory[50], and cognitive model of worry[51]. FORT's pilot[43] and RCT[44,46] studies demonstrated good questionnaire completion rates. Some modifications to the original measure selection to reflect caregiver realities and themes (i.e., protective buffering). All measures evaluate a distinct part of the FCR experience or of the content/processes of the intervention. Whenever possible, the short form of instruments was used to reduce respondent burden.

Caregiver Version of the Fear of Cancer Recurrence Inventory – Short Form (FCRI-SF)[5,40]. The primary outcome of the study, FCR, will be measured using the FCRI-SF. The FCRI-SF has been validated with both cancer survivors and caregivers[40]. A score of 13 or greater on this 9-item instrument (range 0-36) indicates clinical level of FCR[5]. The original FCRI-SF has been shown to have adequate reliability and validity (construct validity; $r = 0.68$ to 0.77; and reliability scores; $\alpha = 0.95$)[5]. The caregiver version of the FCRI has also demonstrated good internal consistency ($\alpha = 0.95$)[40] and test-retest reliability ($\alpha = 0.88$)[40].

Perceived Risk of Cancer Recurrence[57]. Perceived risk of cancer recurrence will be assessed using a one-item question rated on a 5-point Likert scale from "Much less likely" to "Much more likely"[57]: "Compared to persons of their age, how do you rate your family member's perceived risk of cancer recurrence?".

Intolerance of Uncertainty Scale – Short Form (IUS-12)[58]. Intolerance of uncertainty will be measured with the IUS-12 which measures reactions to uncertainty, ambiguous situations and the future and is comprised of two factors, prospective anxiety (seven items) and inhibitory anxiety (five items). Both factors have good internal consistencies ($\alpha = 0.85$)[58].

Mishel Uncertainty in Illness Scale Short-Form (MUIS-SF)[59]. Uncertainty in illness will be measured by the MUIS-SF. It consists of five items rated on a 5-point Likert scale. The MUIS-SF has adequate internal consistency ($\alpha = 0.70$)[59].

Why People Worry About Health Questionnaire[60]. Positive beliefs about worrying will be measured using the Why People Worry About Health Questionnaire. It has excellent internal consistency ($\alpha = 0.90$), and satisfactory temporal stability ($r = 0.71$)[60].

Cognitive Avoidance Questionnaire (CAQ)[61]. Coping will be measured with the CAQ that contains twenty-five items that measure avoidance coping. The CAQ has excellent internal consistency ($\alpha = 0.95$), and good test-retest reliability ($r = 0.85$)[61].

Protective Buffering Scale[62]. Protective buffering will be measured with the Protective Buffering Scale. This scale consists of ten items rated on a 5-point Likert scale. Internal reliability for this scale is good in both partners and cancer survivors ($\alpha = 0.80\text{-}0.89$)[62].

Satisfaction. Participant opinions regarding satisfaction with FC-FORT will be assessed using a one-item question rated a 5-point Likert scale from "Very satisfied" to "Very unsatisfied": "How satisfied are you with the Family Caregiver – Fear of Recurrence Therapy?".

Sociodemographic information. Variables such as age, gender, ethnicity, marital status, family member role (e.g., spouse, partner, child, sibling), education level, medical history of their loved one, and more, will be collected through a demographic questionnaire pre-intervention.

3.11.2 After session measures (sessions 1, 4 and 7)

Group Cohesiveness Scale (CGS)[63]. Group cohesion will be measured using the CGS which consists of seven items rated on a 5- point Likert scale. The GCS has good internal consistency ($\alpha = 0.87$)[63].

Working Alliance Inventory – Revised Short Form (WAI-SR)[64]. Therapeutic alliance will be measured using the WAI-SR. It is composed of twelve items (compared to its original thirty-six) rated on a 7-point Likert scale. The WAI-SR has corresponding versions for therapist and clients. The WAI-SR has good internal consistency ($\alpha = 0.91\text{-}0.92$)[64].

3.11.3 Participant Exit Interviews

To gain further insights about the feasibility, acceptability, and potential clinical significance of the FC-FORT, participants in the intervention groups will be asked to participate in a one-on-one semi structured interview with the research coordinator (who is not involved in the clinical administration of FC-FORT) after completing the intervention. These interviews will enable a holistic understanding of their experience of FC-FORT, elucidate key intervention processes, and identify additional secondary outcomes. The interview guide contains questions regarding participant expectations, general impact of FC-FORT, helpful/unhelpful segments, group cohesion & therapeutic alliance, timing and length, homework practice, usability of learned material and participant suggestions. These interviews will be conducted via videoconferencing, are anticipated to last between 30-60 minutes, will be recorded and transcribed verbatim. Lastly, the research coordinator will attempt to interview participants who dropped out of the intervention to understand any hindering factors. They will do so by emailing participants once to invite them to take part in the exit interview process.

3.11.4 Study Log

The research coordinator will collect the number of individuals approached, number of individuals self-referred to the study, the number of individuals eligible and ineligible, the number of participants consented and randomized, the number of participants who declined, withdrew, and dropped out (and why).

3.12 Data Analysis

SPSS version 28 and NVivo version 12 software will be used for data analysis.

3.12.1 Quantitative Analysis

Descriptive statistics with 95% confidence intervals will be used to report on the primary outcomes.

Feasibility Data. Recruitment and refusal rates will be reported descriptively. Rates for completed measures, questionnaire packages and missing data will be calculated using similar methods. Therapist adherence to FC-FORT will be calculated based on fidelity rating of each session (aiming for above 80% on 75% of sessions).

Acceptability Data. Dropout rates will be calculated. Participant adherence to FC-FORT will be calculated based on the number of sessions missed (aiming for 80% completion). FC-FORT will be considered satisfactory based on a score of ≥ 4 for 80% of participants on the satisfaction measure.

Clinical Significance. Descriptive statistics will be used to report on FCR outcomes. Variability of the main and interaction effects will be examined for secondary outcomes using separate mixed ANOVA models, with Bonferroni corrections applied. Partial eta squared (η_p^2) and associated confidence intervals will be calculated as an estimate of the effect size both over time (within groups) and between groups. Missingness will be evaluated on a case-by-case basis such that drop-outs will be excluded. Data will be analyzed when all recruitment and data collection has been performed.

3.12.2 Qualitative Analysis

A conventional content analysis method in which codes are directly derived from the data rather than starting with a theory or research findings as an initial guide will be used[66]. Interviews will be audiotaped, transcribed verbatim, and managed using the qualitative software program NVivo. Members of the research team will undergo multiple readings of a single text to

systematically identify units of meaning and will assign codes, words, or short phrases, to these units[67]. They will then come to consensus on the grouping of related codes into categories and/or subcategories that will be inserted in the coding framework to facilitate their description and interpretation to uncover trends and patterns in the data. Transcripts will be systematically coded into anticipated (e.g., motivations to participate, benefits of participation) and emergent themes using thematic analysis. This is an iterative process whereby an initial set of themes are coded, applied to new transcripts, and revised to adjust for new information, until no new codes emerge. Data analysis will consist of three phases: 1) data disassembling into codes, 2) congregation of codes that are related or share some common characteristics into categories, and 3) identify patterns and relationships between the codes and categories[68]. Further along the analytic process, categories can often be further analyzed to develop themes. Themes are recurring concepts that emerge from analysis that typically represent underlying meaning between categories in content analysis and require a higher level of abstraction[67, 69]. Coding will be conducted by a trained research assistant under the close supervision of the research team. To facilitate trustworthiness, each transcript will be read by the qualitative team and 20% will be coded independently by the study coordinator. The qualitative team will meet on a weekly basis to discuss the coding structure in the coding framework and assess for agreement and consensus. Trustworthiness in the validity of our findings will be addressed by 1) weekly debriefing sessions with the research team members to reduce the risk of biased decisions; 2) the use of appropriate quotations; and 3) keeping an audit trail of self-reflexivity[66,70]. Throughout the analysis, categories will be examined with an explicit gender and intersectionality lens[71] to allow us to understand how identity factors (e.g., gender, sexual orientation, minority, rural vs. urban context, or socioeconomic status) simultaneously shape our participants' experiences with FC-FORT.

3.13 Pilot Outcomes Justifying a Larger Trial

The protocol of this pilot project will be deemed feasible based on the 1) ability to recruit thirty-six caregivers in 15 months; 2) ability to randomize these thirty-six caregivers; 3) complete questionnaire packages and measures for 90% of participants; 4) ability to deliver FC-FORT as intended as measured by a fidelity rating of above 80% on 75% of reviewed sessions.

FC-FORT will be deemed acceptable based on 1) ability to deliver FC-FORT to twenty-seven caregivers in 15 months (25% dropout rate); 2) 80% completion of five out of the seven sessions; 3) caregivers' satisfactory ratings > than 80% in terms of its content, therapists, and mode of delivery.

The clinical significance of the FC-FORT pilot study will be measured with effect sizes (CONSORT guidelines for pilot studies)[37] with 95% confidence intervals. Based on a systematic review of caregiver interventions[20], an ES $\geq$ 0.3 for the intervention group will be considered a clinically meaningful finding for the primary and secondary outcomes at 3-months post-intervention compared to those in the waitlist control group (WLCG).

4. Discussion

Caregivers experience similar or greater levels of FCR than cancer patients. In addition, FCR in caregivers is persistent and associated with negative outcomes (i.e., quality of life, psychological distress, etc.). Although some interventions exist to address FCR in dyads (caregivers and cancer patients), this is the first study to offer an intervention to caregivers individually. Studies also suggest that levels of FCR in caregivers significantly impact levels of FCR in cancer patients themselves. Therefore, by addressing FCR in caregivers, this study could potentially contribute to reducing overall levels of FCR in cancer patients.

The present study primarily aims to test the feasibility and acceptability of the newly adapted FC-FORT intervention among caregivers living with clinical levels of FCR. Given the

efficacy and acceptability of FORT (the original intervention) with cancer patients, the similarities between FCR in caregivers and cancer patients, as well as the rigorous approach to adaptations made to FORT prior to the RCT, we posit that FC-FORT could have significant impact on potential clinical outcomes. In fact, if this pilot study's protocol is deemed feasible and acceptable, we will proceed towards the development of a larger multi-site RCT designated to evaluate FC-FORT.

Finally, this study will contribute to the literature on caregivers' unmet needs and further underscore the importance of well-designed, standardized psychological interventions targeting the emotional well-being of caregivers. Further, by supporting caregivers needs, they will be better equipped to carry out the challenging caregiving role in supporting their loved one in their cancer journey. Thus, overall, increasing supports for caregivers contributes to a better experience and outcomes for caregivers, cancer survivors, healthcare providers, and optimizes the use of the health care system.

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Table 1: Session Details

Session 1: Introduction to the group, learning new skills to deal with FCR (120 minutes)	• Introduction by each participant with a focus on their experience with fear of cancer recurrence (FCR). • Introduce ABC model of therapy, FCR model, cognitive restructuring and identify triggers. • Teach cognitive restructuring and self-care. • **Homework:** Complete thought record and practice self-care.
Session 2: Identifying knowledge gaps on FCR (120 minutes)	• Discuss uncertainty and ways of regaining a sense of control. • Discuss the patient's health care team. • Teach progressive muscle relaxation. • **Homework:** Complete thought log and practice daily progressive muscle relaxation.
Session 3: Increasing tolerance for uncertainty (120 minutes)	• Discuss acceptable level of worry. • Challenge faulty beliefs about benefits of worry. • Discuss uncertainty and ways of regaining a sense of control. • Teach the use of calming self-talk & listening to relaxation files. • **Homework**: Challenge faulty beliefs about benefits of worry. Practice calming self-talk and progressive muscle relaxation daily.
Session 4: Building your coping skills (120 minutes)	• Discuss maladaptive coping strategies. • Address communication difficulties and teach new coping skills to address your fear of cancer recurrence. • Teach guided imagery. • **Homework**: Having a conversation about FCR. Practice guided imagery daily; challenge faulty beliefs about benefits of worry; complete thought record with behaviour.
Session 5: Getting deeper into underlying fears (120 minutes)	• Provide psychoeducation about worry and the need for exposure to worse fears. • Promote emotion expression and confront specific fears that underlie FCR by writing down worse fear scenario. • Teach mindfulness exercise. • **Homework:** Read worst case scenario daily. Practice self-care & mindfulness exercise daily.
Session 6: Moving beyond specific fears (120 minutes)	• Review exposure to worst case scenario exercise. • Discuss ways of coping with some of the feared outcomes. • Encourage participants to become re-engaged with important life goals, people, or activities. • Discuss what meaning the future and planning now have for them. • Teach mindfulness exercise. • **Homework:** Write down goals and priorities for the future, practice mindfulness exercise.
Session 7: Review and conclusion (120 minutes)	• Review all content covered. • Discuss future goals and setting new priorities. • Promote the expression of saying good-bye to the group and provide closure.

Study 2:
It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Feasibility and Acceptability of a Randomized Pilot Study of the Family Caregiver Version of the Fear of Recurrence Therapy (FC-FORT)*

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Abstract

Objective: Fear of cancer recurrence (FCR) is common, persistent, and associated with lower quality of life, impaired functioning, and psychological distress in family caregivers (FC) of individuals with a cancer diagnosis. Interventions are needed to specifically target FCR in FC. This study aimed to pilot test the adapted Family Caregiver – Fear Of Recurrence Therapy (FC-FORT) to establish its feasibility, acceptability, and clinical significance.

Methods: This pilot study used a mixed-method, parallel, two-group randomized control trial (FC-FORT vs waitlist control group) design. Women FC were recruited through Canadian hospitals, community partners, and social media. FC in the intervention group completed 7 weekly sessions of virtual group therapy (FC-FORT) and an exit interview. All participants completed questionnaires at baseline, post-intervention, and 3-month follow-up. Feasibility (e.g., recruitment, allocation, fidelity), acceptability (e.g., dropout, completion, satisfaction) and clinical significance of secondary outcomes were evaluated. Descriptive statistics, mixed ANOVAs, and conventional content analyses were used.

Results: Regarding feasibility, 22 FC were recruited, 18 were randomized and therapist fidelity was 87%. As to acceptability, 67% of participants completed ≥ 5 sessions (33% dropout). Questionnaire completion rate was 92%. FC satisfaction was 80%. Analyses did not reveal any significant differences on the secondary outcomes between groups. Qualitative analyses revealed high importance, helpfulness, satisfaction, and group cohesion. Suggestions were made by FC for improvements.

Conclusions: This is one of the first interventions to address FCR in FC. While acceptability of FC-FORT was good, important feasibility issues need to be addressed before moving forward with a larger randomized control trial.

1. Background

Fear of cancer recurrence (FCR) can be defined as the "fear, worry or concern that cancer may come back or progress"[1]. Whereas FCR has been well documented in cancer survivors[2], less is known about family caregivers' (FC) experience of FCR. FC, defined as family members who provide unpaid and informal support, play an integral role in the treatment and care of individuals with a cancer diagnosis[3]. Recent systematic reviews[4-6] indicate that approximately 50% of FC experience levels of FCR equal or greater than those reported by cancer survivors. Similarly to survivors, FCR in FC is persistent, associated with lower quality of life (QoL), lower functioning, and higher psychological distress (i.e., depression, anxiety, loneliness)[4-6]. Furthermore, consistent positive associations have been found between levels of FCR in FC and survivors[4-5]. Therefore, treating FCR in FC could improve QoL for both FC and cancer survivors. Qualitative differences[7-8] and conceptual models[9] are emerging distinguishing the experience of FCR in FC from that of survivors. While shared themes like fear, uncertainty, hopelessness, and liminality exist, unique FC themes related to FCR include concerns about losing a loved one or witnessing their suffering, the caregiver's protective role, and feeling unprepared[7-8].

Although there is evidence that interventions created to address FCR in cancer survivors are effective[6], to date, there have been few attempts[7-8] to provide these treatments to FC despite their unmet FCR needs. The goal of the present study was to pilot test an adapted version of the validated in-person group intervention for cancer survivors entitled the Fear Of Recurrence Therapy (FORT)[9-11]. In the project's initial phase, FORT (i.e., manuals, content, administration) was adapted to FC (adapted name: Family Caregiver – Fear Of Recurrence Therapy) with input from an advisory board, and its usability was evaluated[12]. Our adaptation accounted for the consistent evidence that FC often face barriers to accessing services (e.g., time, finances,

negative perceptions of mental health services)[13-14]. In addition, previous in-person therapy studies show low attendance and high attrition rates[15] among FC. In combination with the impacts of COVID-19, our adaptation aimed to mitigate these limitations by also adapting FORT to an online format.

The primary aims of this pilot randomized controlled trial (RCT) were to examine the feasibility, acceptability, and clinical significance of FC-FORT. The results of this pilot study informed the relevance of a larger RCT.

2. Methods

2.1 Study Design

This study is a pilot, mixed-method, parallel, two-group randomized control trial where FC were randomized to receive either 1) FC-FORT or 2) waitlist control group (WLCG). The primary outcomes were feasibility (e.g., recruitment, allocation, fidelity) and acceptability (e.g., dropout, completion, satisfaction). The secondary outcome investigated the potential clinical significance of FC-FORT on various aspects (e.g., FCR, intolerance of uncertainty). See CONSORT diagram (Figure 1).

Ethics approval was obtained from the University of Ottawa (H-05-20-5584), The Ottawa Hospital (20230147-01H), and the Princess Margaret Cancer Centre (21-5060.3). The study was registered at Clinical Trials. Gov (NCT05441384). For additional information, please refer to the study protocol[17].

2.2 Participants

Canadian women caring for an adult cancer survivor (any cancer type, stages I-III, completed treatments, no recurrence), fluent in English, experiencing clinical FCR (score of ≥13 on the Caregiver Version of the Fear of Cancer Recurrence Inventory-Short Form[18-19]), with a

computer and internet access were recruited. We focused on women as research consistently demonstrates that they are at higher risk for caregiver burden[20] and FCR[2,5]. Furthermore, FORT[9-11] has so far only been validated with women limiting the generalizability to men or nonbinary individuals. Recruitment occurred from September 2022 to December 2023. Flyers were shared widely across cancer and caregiving networks throughout Canada, with printed copies posted in key traffic areas of the Princess Margaret Cancer Centre and over 600 letters mailed to cancer survivors of The Ottawa Hospital inviting their FC to participate. Interested participants emailed the research coordinator and met with them or a research assistant via videoconference to assess their eligibility, obtain consent, and prepare them for group work. All participants provided informed consent before being randomized, completing the baseline measures and sociodemographic questionnaire.

2.3 Randomization and Procedures

We aimed to recruit 36 FC (four groups of nine participants; see sample size justification below). To minimize attrition associated with waiting to enroll participants, we used block randomization. Specifically, four sealed envelopes (two intervention and two WLCG) were created by the research coordinator and kept by a blinded independent research assistant. Once nine participants provided informed consent, they were randomized to a study group by the research assistant and completed their baseline assessment (T0). Post-intervention assessment (T1) was conducted immediately after completion of FC-FORT or 7 weeks post-randomization (WLCG). Follow up assessment (T2) was conducted 3 months post-intervention (FC-FORT) or 3 months after T1 (WLCG). Participants in the intervention group were also asked to complete additional measures at sessions 1, 4 and 7, and a semi-structured exit interview. WLCG

participants were offered FC-FORT after completing the T2 assessment.

2.4 Therapist Recruitment, Training and Supervision

Three therapists were recruited to facilitate FC-FORT. Therapist competency was determined by the following criteria: 1) registered allied health professionals with expertise in counselling/psychotherapy and psychosocial oncology, 2) ability to offer virtual services across Canada, 3) at least 5 years of experience in psychosocial oncology, and 4) led at least one support group.

To enhance adherence to treatment, therapists were provided with a standardized FC-FORT manual, a virtual training session (2h) with the research team, and weekly 30-minute supervision offered by one of the study psychologists (SL). The research coordinator and assistant reviewed the videos of all sessions using a fidelity checklist to assess treatment adherence. If adherence was less than 80% on any session, the study psychologist (SL) provided additional feedback and supervision to the therapists.

2.5 Study Intervention

Like the original FORT[9-11], FC-FORT is a standardized and manualized therapist-led intervention (see Table 1). FC-FORT consists of 7 consecutive weekly group sessions of 120 minutes each, offered via videoconference, and between session assignments. It builds upon FORT's original blended theoretical model of FCR[21] with some adaptations made to represent caregivers' realities[12] (e.g., protective buffering). Main components include Kissane's Cognitive-Existential therapy[22-23], principles of group therapy, and Cognitive Behavioural Therapy-based techniques. Key goals of FC-FORT include: 1) distinguishing worrisome symptoms from benign ones; 2) identifying FCR triggers and inappropriate coping strategies; 3) facilitating the learning

and use of new coping strategies, such as self-care, relaxation techniques and cognitive restructuring; 4) increasing tolerance for uncertainty; 5) promoting emotional expression of specific fears that underlie FCR and reducing protective buffering; and 6) re-examining life priorities and setting realistic goals for the future. For additional information on FC-FORT, please refer to our adaptation[12] and protocol articles[17].

Groups consisted of a "closed" format to enhance cohesiveness and consistency. Participants who missed more than two sessions were asked to stop the intervention and restart with the next available group to ensure they received FC-FORT as intended. For analysis purposes, they were counted as dropouts. Before starting the intervention, participants received a standardized electronic and paper manual describing each session's activities and assignments.

2.6 Primary Outcomes: A Priori Benchmark for Success[17]

Feasibility in this pilot study was based on the 1) ability to recruit 36 FC in 15 months; 2) ability to randomize all 36 FC; 3) questionnaire completion of measures for 90% of participants; 4) ability to deliver FC-FORT as intended as measured by a fidelity rating of above 80% on 75% of reviewed sessions.

Acceptability was based on the 1) ability to deliver FC-FORT to 75% of FC within 15 months (maximum 25% dropout rate); 2) 80% completion of 5/7 sessions; 3) caregivers' satisfactory ratings $\geq$ 80% in terms of its content, therapists, and mode of delivery.

2.7 Secondary Outcomes

Clinical significance, or the potential practical importance of FC-FORT on secondary outcomes, was determined using effect sizes with 95% confidence intervals. A systematic review of FC interventions[7] considered a small Cohen's d ($\geq$ 0.3) clinically meaningful at 3-months

post-intervention. For the purposes of this pilot study, partial eta squared (η_p^2) will be reported and effect sizes of ≥ 0.01 will be considered clinically meaningful.

2.7.1 Measuring Secondary Outcomes

All measures were administered in English and online through Qualtrics.

FCR was measured using the Caregiver Version of the Fear of Cancer Recurrence Inventory – Short Form (FCRI-SF)[24-25]. The FCRI-SF has been validated with both cancer survivors and caregivers[24]. A score of 13 or greater on this 9-item instrument (range 0-36) indicates clinical level of FCR[24]. The caregiver version of the FCRI has demonstrated good internal consistency ($\alpha = 0.95$)[25] and test-retest reliability ($\alpha = 0.88$)[25].

Perceived risk of cancer recurrence was assessed using a one-item question rated on a 5-point Likert scale from "Much less likely" to "Much more likely": "Compared to persons of their age, how do you rate your family member's perceived risk of cancer recurrence?".

Intolerance of uncertainty was measured with the Intolerance of Uncertainty Scale – Short Form (IUS-12)[26] which measures reactions to uncertainty, ambiguous situations and the future and has good internal consistency ($\alpha = 0.85$)[26].

Uncertainty in illness was measured by the Mishel Uncertainty in Illness Scale Short-Form (MUIS-SF)[27]. It consists of 5 items rated on a 5-point Likert scale. The MUIS-SF has adequate internal consistency ($\alpha = 0.70$)[27].

Positive beliefs about worrying were measured using the Why People Worry About Health Questionnaire[28]. It has excellent internal consistency ($\alpha = 0.90$), and satisfactory temporal stability ($r = 0.71$)[28].

Coping was measured with the Cognitive Avoidance Questionnaire (CAQ)[29] that contains 25 items that measure avoidance coping. The CAQ has excellent internal consistency ($\alpha = 0.95$), and good test-retest reliability ($r = 0.85$)[29].

Protective buffering was measured with the Protective Buffering Scale[30]. This scale consists of 10 items rated on a 5-point Likert scale. Internal reliability for this scale is good in both partners and cancer survivors ($\alpha = 0.80\text{-}0.89$)[30].

Satisfaction with FC-FORT was assessed using a one-item question with a 5-point Likert answer scale from "Very satisfied" to "Very unsatisfied": "How satisfied are you with the Family Caregiver – Fear of Recurrence Therapy?".

Variables such as age, gender, ethnicity, marital status, family member role (e.g., spouse, partner, child, sibling), education level, medical histories for FC and survivors were collected using a sociodemographic questionnaire.

2.7.2 Additional Outcomes

Group cohesion was measured using the Group Cohesiveness Scale (CGS)[31] which consists of 7 items rated on a 5- point Likert scale. The GCS has good internal consistency ($\alpha = 0.87$)[31].

Therapeutic alliance was measured using the Working Alliance Inventory – Revised Short Form (WAI-SR)[32]. It is composed of 12 items rated on a 7-point Likert scale. The WAI-SR has corresponding versions for therapist and clients. The WAI-SR has good internal consistency ($\alpha = 0.91\text{-}0.92$)[32].

2.8 Exit Interviews

To gain further insights about the acceptability of FC-FORT, participants in the intervention group were asked to take part in a one-on-one semi structured interview (30-60 minutes) via videoconferencing post-intervention. Interviews were conducted by the research coordinator or assistant, and focused on participant expectations, general impact of FC-FORT, helpful/unhelpful segments, group cohesion & therapeutic alliance, timing and length, homework practice, and usability of learned material.

2.9 Sample Size Calculation

Sample size for the present pilot study was calculated based on the estimated sample size needed in a future RCT. For the RCT, a priori sensitivity power analyses were performed with G*Power 3.1 using a two-sided (intervention vs waitlist control group; WLCG), type 1 error rate of 0.05 and 95% power, independent sample size of 57 participants per arm, and with a three-time assessment (pre-, post-, and a 3-month follow up). Under these conditions, an effect size of 0.40 (Cohen's d; based on average effect size of FCR interventions for patients) would detect a difference between FC-FORT and a WLCG. Based on FORT's observed dropout rate and loss to follow-up[9-11], an additional 20% participants per treatment group would be needed, thus requiring 68 participants per arm for a total of 136 study participants. This would mean conducting 16 groups of 9 FC (8 interventions and 8 WLCG). Assuming a 4-year recruitment rate for the RCT, we needed to be able to recruit 4 groups (36 FC) in a period of 15 months during the present study to demonstrate feasibility of this future RCT.

2.10 Statistical Analyses

SPSS version 28 was used for the quantitative data and NVivo version 12 software for the qualitative data management and analysis. Descriptive statistics were used to report on the

primary outcomes. Secondary outcomes were analysed using mixed ANOVA models, with Bonferroni corrections applied. Effect sizes and associated confidence intervals were calculated as an estimate of the effect size both over time (within group) and between groups. Interviews were recorded, transcribed verbatim, and double coded inductively by the research coordinator and assistant. Given the limited theoretical and conceptual information available regarding interventions addressing FCR in FC, conventional content analysis[33] was used.

3. Results

3.1 Sample Characteristics (Table 2)

The mean age of participants was 50.2 years. Participants were White (53.3%), South Asian (26.7%), Chinese (13.3%) and Black (6.7%). Most were married (73.3%), college graduates (86.7%), employed full-time (46.7%), and earned ≥$80,000 annually (60%). Participants were providing care to their adult children (40%), spouses/partners (20%), parents (27%), and other family members (13.3%). Participants had no relation to one another. The most prevalent types of cancer diagnoses were breast (20%) and lymphoma (20%), with a mean time since diagnosis of 6.1 years (SD = 7.1). Average (SD) score on the CV-FCRI-SF at baseline (T0) was 27.1 (7.2) for the intervention group and 26.1 (3.1) for the WLCG.

3.2 Primary Outcomes

3.2.1 Feasibility. Over 15-months, 22 participants were interested and eligible, and 20 participants provided informed consent. Of these, 18 were randomized to the intervention group (n = 9) and the WLCG (n = 9), while 2 were not randomized due to the end of recruitment. Baseline assessment was completed by 15 participants (intervention = 7; WLCG = 8). The intervention group lost one participant post-intervention (T1) and one at T2. No participants were lost in the WLCG. One WLCG participant did not complete their T1 assessment due to

unforeseen circumstances but completed their T2 and T3; they were included in the final analyses. Overall questionnaire completion was 91.7% (SD = 6.6, Range = 86-100%). At the baseline (T0), post-intervention (T1), and follow up assessments (T2), response rates were respectively 89%, 89%, and 100% for the WLCG and 100%, 86% and 86% for the intervention group. Therapists' adherence to treatment delivery was high with fidelity ratings of ≥ 80% (M= 86.7%, SD = 3.46, Range = 81-91) on 100% of sessions. Feasibility benchmarks were partially met. Namely, questionnaire completion and therapist fidelity benchmarks were achieved, whereas recruitment and randomization benchmarks were not.

3.2.2 Acceptability. FC-FORT was delivered to 12 FC (33% dropout rate). 6 FC dropped out post-randomization, with more having dropped out from the WLCG [n = 4 (44.4%)] than the intervention group [n = 2 (22.2%)]. In total, 8 FC (66.7%) completed ≥ 5 sessions, with higher completion in the intervention group [n = 6 (85.7%)] than the WLCG [n = 2 (40%)]. Moreover, 4 FC dropped out after beginning group therapy, with more having dropped out from the WLCG [n = 3 (60%)] than the intervention group [n = 1 (14.3%)]. Reasons for dropout included being removed by the research team due to missing more than 2 sessions, scheduling issues, emotional readiness, and family member's cancer recurrence. FC satisfaction ratings with content, therapists, and mode of delivery was 80% (T1 = 86.6%; T2 = 73.4%). Acceptability benchmarks were partially met. Namely, FC satisfaction benchmark was achieved, whereas dropout and session completion benchmarks were not.

3.3 Secondary Outcomes

Effect sizes of ≥ 0.01 were found between group x time for FCR ($F_{(2,24)} = 0.671$, $p = 0.520$, $\eta_p^2 = 0.053$, 95% CI [0, 0.231]) and perceived risk of recurrence ($F_{(2,24)} = 0.204$, $p =$

0.817, $\eta_p^2 = 0.017$, 95% CI [0, 0.141]). They were also found across time for FCR, perceived risk of recurrence, intolerance of uncertainty, uncertainty in illness, positive beliefs about worrying and cognitive avoidance. See Table 3 for additional details. Moderately strong therapeutic alliance (Session 1: M=39.80; Session 4: M=44.83; Session 7: M=43.17) and strong group cohesion (Session 1: M=29.2; Session 4: M=31.33; Session 7: M=32.17) were observed throughout the intervention.

3.4 Qualitative Results (Table 4)

3.4.1 Expectations of FC-FORT. Prior to beginning the group, participants expressed hoping to gain knowledge/coping strategies to manage their FCR. Furthermore, shared experiences with other women FC were a salient expectation and reason to join the group. A few participants expressed that they expected the group would be more advisory style, rather than an active intervention. All participants understood that the group would be comprised of women FC, but some were under the impression that it would be homogenous in experiences (i.e., only parents).

3.4.2 Participants' Experiences with FC-FORT. Overall, participants reported appreciating FC-FORT's content and delivery, especially the variety of exercises, sharing and relating to other FC, therapists' facilitation, and the additional resources provided (e.g., workbook). Participants regularly completed the between session assignments. Primary barriers included time and types of exercises (i.e., individual preferences, emotionally challenging). All participants enjoyed the virtual format of the group. Specifically, being able to log off immediately, the lack of commute, the opportunity to be in a "safe" environment while discussing difficult topics, and a degree of separation from other participants, with most expressing that they would not have joined otherwise. Participants reported strong group

cohesion (i.e., sense of connection, support, shared understanding), which was positively influenced by the all-women nature of the group, shared experiences, and videoconferencing format (i.e., ability to see each other). Participants' level of engagement (i.e., open camera, regular presence and active participation) significantly impacted FC' sense of connection to one-another with more engagement leading to increased cohesion. However, for some FC, the diversity of caregiving experiences sometimes made it harder to relate. Participants felt that the session length (2h) and group duration (7 sessions) were appropriate, though some felt certain sessions were rushed or lacked time for everyone to share.

3.4.3 Perceived Impact of FC-FORT. Participants found FC-FORT helpful in reducing their FCR and improving their emotional regulation. All participants rated the importance of the group ≥ 8/10. Most participants expressed that they would recommend the group to others, with 1 FC saying that it would depend on the person. Many participants identified the group as being a safe/understanding space to connect with others facing similar challenges, addressing the lack of understanding from others in their personal lives. The ability to connect with women "in the same boat" was very impactful. All participants continued using the tools and materials provided in the group to manage their FCR and other aspects of their lives (e.g., sleep).

3.4.4 Suggestions for Improvements. Participants suggested adding examples, definitions, clarifying wording, incorporating theory to some exercises, and providing resources on legal issues related to caregiving. Some recommended extending or adding sessions for better content pacing, a few expressed a personal desire for long term support, and one suggested incorporating a booster session. Some participants suggested smaller groups or grouping participants by similar caregiving experiences (e.g., spouses, parents). Finally, some recommended that open cameras should be mandatory throughout sessions and allowing outside

contact with group members at the onset of the intervention.

4. Discussion

This study aimed to evaluate the feasibility, acceptability, and clinical significance of the newly adapted FC-FORT intervention using a pilot, mixed-method, parallel, two-group (intervention vs WLCG) RCT.

Regarding primary outcomes, feasibility and acceptability criteria were partially satisfied. Reaching FC proved to be difficult, with most participants recruited through social media. Our efforts recruiting in hospitals yielded minimal results, likely due to COVID-19 restrictions and/or indirect recruitment strategies (i.e., reaching FC through patients, posted flyers). Alternative recruitment approaches include direct hospital recruitment (e.g., identifying FC in clinics, calling FC directly) in more Canadian provinces and modifying our recruitment language (use of "caregiver"). For many, "caregiver" does not accurately describe their role with their loved one and can hold negative connotations (e.g., dependency, burden)[34]. Interestingly, this study included a higher proportion of FC caring for adult children and, similarly to our usability study[16], a younger population than typical in cancer caregiving research. These findings suggest that FC-FORT may be more acceptable to some caregiver groups than others. While not mentioned by our participants, recruitment challenges may also have been influenced by the group format, intervention duration, and/or virtual delivery.

Furthermore, FC-FORT was delivered to fewer participants than intended (dropout rate 8% higher than the expected 25% seen in FORT). Research consistently demonstrates that caregivers are a hard population to recruit and retain[15,35]. A potential reason for this is that cancer FC typically carry high levels of caregiving burden and tend to prioritize their loved one resulting in limited time available for themselves[13-14]. Slow recruitment rates impacted

participants' ability to participate at the time of randomization (i.e., scheduling conflict, loss of interest), with significant effects on the control group suggesting that a waitlist approach may be impractical for FC. Potential improvements include establishing smaller group sizes to expedite randomization, homogenous group composition based on FC roles (e.g., parent, spouse) or patient cancer type, and a review randomization procedure with our advisory board.

Alternatively, rates for the completion of questionnaire packages and therapist adherence were high, highlighting the feasibility of data collection and administration of FC-FORT. FC satisfaction of FC-FORT's content, therapists, and mode of delivery was also strong. Exit interviews further corroborated that FC found FC-FORT helpful in addressing their FCR and normalizing their caregiving experiences and valued its online format. These results reflect the significant efforts invested in the adaptation and usability testing of FC-FORT. Furthermore, they support the growing evidence that online, professionally facilitated psychological interventions improve health related quality of life, coping, and mental health outcomes in FC[36] . Participant suggestions for improvements will be reviewed with our advisory board for potential further adaptations.

Regarding secondary outcomes, both therapeutic alliance and group cohesion were rated highly and maintained over time, consistent with the qualitative data obtained from the exit interviews and previous iterations of FORT[9-12]. Although not statistically significant, effect sizes of ≥ 0.01 were found for FCR, perceived risk of recurrence, intolerance of uncertainty, uncertainty in illness, positive beliefs about worrying and cognitive avoidance further suggesting the potential clinical relevancy of FC-FORT.

At this time, FC-FORT does not meet the necessary feasibility and acceptability criteria indicated to move forward with a larger RCT. However, results demonstrate that participants

found FC-FORT to be very likeable and findings suggest its potential effectiveness. It is recommended that our study protocol be thoroughly reviewed (specifically recruitment and randomization strategies) by our advisory board and that a second pilot study be conducted to gather additional data.

4.1 Study Limitations

The small sample size, high attrition, and sociodemographic characteristics challenge the generalizability of this pilot study. Future studies should include diverse populations, various delivery formats, and cultural adaptations. Volunteer bias may also have influenced results as participants were likely to be motivated and interested in the topic. Lastly, statistical findings should be interpreted cautiously due to the pilot's limited statistical power.

4.2 Clinical Implications

While FCR remains a common unmet need for FC, few interventions have been developed to address their needs[4-5]. Our team was one of the first to adapt a validated patient group FCR intervention[9-11] to FC and to an online format[12]. Our findings indicate that FC-FORT is satisfactory and is deemed helpful by FC in managing FCR. This represents a key step in providing evidence-based, tailored interventions to FC experiencing FCR. Furthermore, results suggest that FC role (i.e., parent, spouse) may impact FCR experiences and that groups with similar caregiving experiences may be preferrable. Study findings also highlight the promising nature of adapting existing patient-focused interventions for FC support.

5. Conclusions

While FC-FORT was deemed helpful by FC and received a high satisfaction rating, there were significant issues with the pilot's feasibility (e.g., recruitment, randomization) and

acceptability (e.g., dropout, session completion). These need to be addressed before FC-FORT is deemed ready for a larger RCT to evaluate its effectiveness.

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Figure 1: CONSORT Diagram

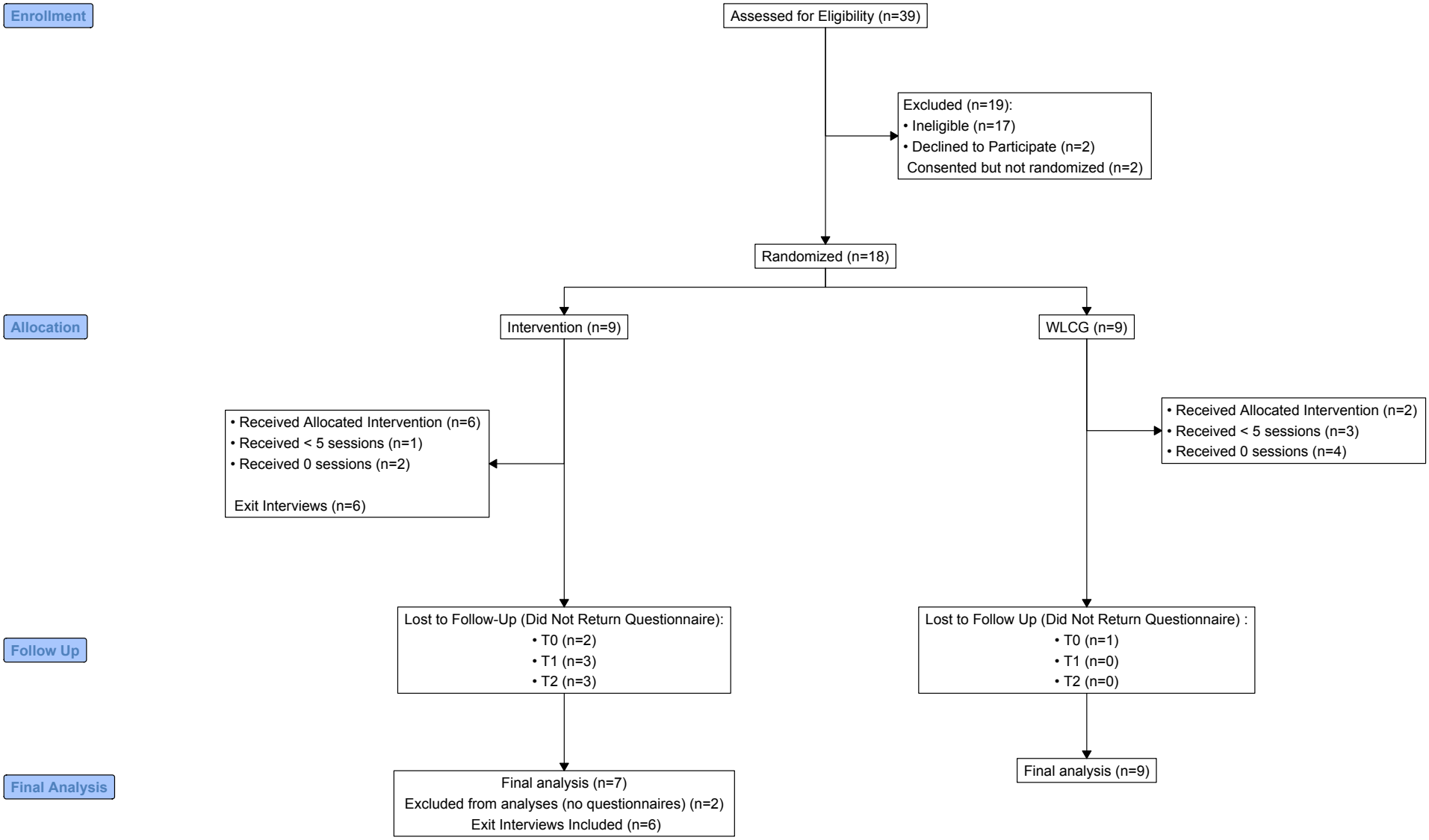

Table 1: Overview of FC-FORT Sessions

Session 1: Introduction to the group, learning new skills to deal with FCR (120 minutes)	• Introduction by each participant with a focus on their experience with fear of cancer recurrence (FCR). • Introduce ABC model of therapy, FCR model, cognitive restructuring and identify triggers. • Teach cognitive restructuring and self-care. • **Homework:** Complete thought record and practice self-care.
Session 2: Identifying knowledge gaps on FCR (120 minutes)	• Discuss uncertainty and ways of regaining a sense of control. • Discuss the patient's health care team. • Teach progressive muscle relaxation. • **Homework:** Complete thought log and practice daily progressive muscle relaxation.
Session 3: Increasing tolerance for uncertainty (120 minutes)	• Discuss acceptable level of worry. • Challenge faulty beliefs about benefits of worry. • Discuss uncertainty and ways of regaining a sense of control. • Teach the use of calming self-talk & listening to relaxation files. • **Homework**: Challenge faulty beliefs about benefits of worry. Practice calming self-talk and progressive muscle relaxation daily.
Session 4: Building your coping skills (120 minutes)	• Discuss maladaptive coping strategies. • Address communication difficulties and teach new coping skills to address your fear of cancer recurrence. • Teach guided imagery. • **Homework**: Having a conversation about FCR. Practice guided imagery daily; challenge faulty beliefs about benefits of worry; complete thought record with behaviour.
Session 5: Getting deeper into underlying fears (120 minutes)	• Provide psychoeducation about worry and the need for exposure to worse fears. • Promote emotion expression and confront specific fears that underlie FCR by writing down worse fear scenario. • Teach mindfulness exercise. • **Homework:** Read worst case scenario daily. Practice self-care & mindfulness exercise daily.
Session 6: Moving beyond specific fears (120 minutes)	• Review exposure to worst case scenario exercise. • Discuss ways of coping with some of the feared outcomes.

	• Encourage participants to become re-engaged with important life goals, people, or activities. • Discuss what meaning the future and planning now have for them. • Teach mindfulness exercise. • **Homework:** Write down goals and priorities for the future, practice mindfulness exercise.
Session 7: Review and conclusion (120 minutes)	• Review all content covered. • Discuss future goals and setting new priorities. • Promote the expression of saying good-bye to the group and provide closure.

Table 2: Sample Characteristics at Baseline (T0, *n* = 15)

	Total	FC-FORT (n = 7)	WLCG (n = 8)
Age, M (SD) [Range]	50.2 (15.58) [27-74]	55.86 (13.93) [29-74]	45.25 (16.09) [27-72]
Race (%)			
White	8 (53.3%)	5 (71.4%)	3 (37.5%)
South Asian	4 (26.7%)	2 (28.6%)	2 (25%)
Chinese	1 (13.3%)		2 (25%)
Black	1 (6.7%)		1 (12.5%)
Marital Status (%)			
Single, Never Married	3 (20%)		3 (37.5%)
Married/Common-Law	11 (73.3%)	6 (85.7%	5 (62.5%)
Separated, Divorced	1 (6.7%)	1 (14.3%)	
Education (%)			
Part of University/College	2 (13.3%)	2 (28.6%)	
University/College	9 (60%)	4 (57.1%)	5 (62.5%)
Graduate School	4 (26.7%)	1 (14.3%)	3 (37.5%)
Occupational Status (%)			
Employed Full-Time	7 (46.7%)	4 (57.1%)	3 (37.5%)
Employed Part-Time by Choice	3 (20%)		3 (37.5%)
Unemployed Due to Illness	2 (13.3%)	1 (14.3%)	1 (12.5%)
Retired	3 (20%)	2 (28.6%)	1 (12.5%)
Annual Income (%)			
$21,000-40,000	1 (6.7%)		1 (12.5%)
$41,000-60,000	3 (20%)	2 (28.6%)	1 (12.5%)
$61,000-80,000	1 (6.7%)	1 (14.3%)	
$81,000-100,000	4 (26.7%)	2 (28.6%)	2 (25%)
Greater than $100,000	5 (33.3%)	1 (14.3%)	4 (50%)
Province (%)			
Ontario	12 (80%)	5	7
Alberta	2 (13.3%)	1	1
Nova Scotia	1 (6.7%)	1	
Recruitment Method (%)			

Hospital recruitment	3	2	1
Community partners and/or social media	12	5	7
Family Member's Cancer Type (%)			
Breast	3 (20%)	2 (28.6%)	1 (12.5%)
Hodgkin's Lymphoma	3 (20%)	1 (14.3%)	2 (25%)
Bladder	2 (13.3%)		2 (25%)
Ovarian	2 (13.3%)	1 (14.3%)	1 (12.5%)
Kidney	1 (6.67%)	1 (14.3%)	
Leukaemia	1 (6.67%)		1 (12.5%)
Prostate	1 (6.67%)	1 (14.3%)	
Oral	1 (6.67%)		1 (12.5%)
Glioblastoma Multiforme	1 (6.67%)	1 (14.3%)	
Family Member's Cancer Stage (%)			
I	1 (6.67%)		1 (12.5%)
II	3 (20%)	1 (14.3%)	2 (25%)
III	3 (20%)	2 (28.6%)	1 (12.5%)
IV	2 (13.3%)	2 (28.6%)	
Unknown/Other	6 (40%)	2 (28.6%)	4 (50%)
Time Since Diagnosis, M (SD) [Range]	6.91 (7.09) [1-23]	5.2 (6.72) [1-17]	7 (6.86) [2-21]
Relationship with Family Member (%)			
Spouse/Partner	3 (20%)	2 (28.6%)	1 (12.5%)
Sibling	1 (6.7%)		1 (12.5%)
Parent	7 (46.7%)	2 (28.6%)	5 (62.5%)
Child	3 (20%)	3 (24.9%)	
Other (e.g., Aunt)	1 (6.7%)		1 (12.5%)
Receiving Psychological Services (%)			
Yes	5 (33.3%)	3 (42.9%)	2 (25%)
No	10 (66.7%)	4 (57.1%)	6 (75%)
Perceived Risk of Cancer Recurrence (%)			
Equal To	4 (26.7%)	2 (28.6%)	2 (25%)
More Likely	5 (33.3%)	1 (14.3%)	4 (50%)
Much More Likely	6 (40%)	4 (57.1%	2 (25%)

Table 3: Mixed ANOVA Analyses Examining Secondary Outcomes

Secondary Outcomes	Baseline (T0)		Post-Intervention (T1)		Follow-Up (T2)		Time x Group	Main Effect of Time
	Intervention Group (n = 7)	WLCG (n = 8)	Intervention Group (n = 6)	WLCG (n = 8)	Intervention Group (n = 6)	WLCG (n = 9)	F values, p values, and η_p^2 [95% CI]	F values, p values, and η_p^2 [95% CI]
	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)		
CV-FCRI-SF (Range: 0-36)	27.14 (7.22)	26.13 (3.09)	21.5 (8.34)	26.5 (4.31)	24.17 (5.15)	25.67 (5.32)	$F_{(2,24)}$ = 0.671, 0.520, 0.053 [0, 0.231]	$F_{(2,24)}$ = 0.504, 0.611, 0.040 [0, 0.207]
Perceived Risk (Range: 1-5)	4.29 (0.951)	4 (0.756)	4.17 (1.169)	3.75 (0.886)	3.50 (1.76)	3.56 (1.01)	$F_{(2,24)}$ = 0.204, 0.817, 0.017 [0, 0.141]	$F_{(2,24)}$ = 0.821, 0.452, 0.064 [0, 0.250]
IUS-12 (Range: 12-60)	37.29 (10.01)	37.13 (8.59)	32.33 (12.53)	34.75 (10.07)	32.5 (11.57)	34 (9.10)	$F_{(2,24)}$ = 0.039, 0.962, 0.003 [0, 0.031]	$F_{(2,24)}$ = 0.523, 0.599, 0.042 [0, 0.210]
MUIS-SF (Range: 5-25)	14.14 (3.29)	14.25 (3.11)	13.33 (2.73)	14.13 (4.79)	14.33 (3.33)	13.78 (3.77)	$F_{(2,24)}$ = 0.101, 0.904, 0.008 [0, 0.095]	$F_{(2,24)}$ = 0.120, 0.888, 0.010 [0, 0.106]
WHQ (Range: 13-65)	23.29 (6.58)	28.5 (12.49)	23.5 (8.85)	30.38 (11.17)	27.17 (13.50)	30.63 (13.70)	$F_{(2,24)}$ = 0.076, 0.927, 0.006 [0, 0.076]	$F_{(2,24)}$ = 0.286, 0.754, 0.023 [0, 0.164]
CAQ (Range: 25-125)	64.29 (24.08)	64.75 (13.19)	54.17 (21.86)	62.38 (23.34)	56.33 (20.46)	64.88 (15.85)	$F_{(2,24)}$ = 0.037, 0.963, 0.003 [0, 0.027]	$F_{(2,24)}$ = 0.152, 0.860, 0.012 [0, 0.122]
PBS (Range: 1-50)	35.43 (10.55)	40.5 (4.84)	29.83 (9.50)	38.88 (6.24)	32 (11.56)	39.88 (8.20)	$F_{(2,24)}$ = 0.039, 0.962, 0.003 [0, 0.041]	$F_{(2,24)}$ = 0.045, 0.956, 0.004 [0, 0.163]

CV-FCRI-SF=Caregiver Version – Fear Cancer Recurrence Inventory – Short Form; IUS-12=Intolerance of Uncertainty Scale – Short Form; MUIS-SF=Mishel Uncertainty in Illness Scale Short-Form; WHQ=Why People Worry About Health Questionnaire; CAQ=Cognitive Avoidance Questionnaire; PBS=Protective Buffering Scale.

Table 4: Qualitative Results – Themes and Quotes from Exit Interviews (*n* = 6)

Overarching Themes	Codes	Quotes
Expectations of FC-FORT	Hoping to Benefit from FC-FORT	I was down and out, and it seems like nobody understands my situation. I mean, I have friends and family, but not in this situation. I thought it would be a good idea to be able to participate with people that are in the same boat as I am. (P22) I had high hopes that I would walk away with something. I didn't have a particular name or category or anything for it. But I was hoping that I would walk away with something that would make this easier. (P25) I wanted to be with a like-minded group and, you know, to think about it differently. What are their coping strategies? How do they cope with it? (P26)
	Expectations About Format	I first thought it was just like a study of what was needed kind of to help other caregivers in the future. Like, not so much me, other people that might need it. Because maybe this will help bring about more resources for caregivers or at least get the word out that there are resources, because there are, apparently, but you don't get told about them, right? (P28) My expectations were that I was going to be in a group with people like me, who are the parents of adult children, going through the caregiving experience of cancer. (P25) Well, [the research coordinator] had said that it was just going to be a small group, all women, caregivers. So that's what I expected. (P22)
Participants' Experiences with FC-FORT	Virtual Format	I was happy about it [being an online group], because it gave me a degree of anonymity. It gave me a degree of control. It gave me a degree of safety and security for myself that I needed. (P25) I think that […] Zoom was the best format because of… there are two reasons for it. You don't have to commute, and […] we can see face to face. We can see the expressions of the people. (P26) In some ways I think we were able to be more open because we were still with the person, but not physically. So, you can, I think, be more open in a way, because you can just say "bye" and hit a button. […] You can see the person and talk to them, but it's still a little different than being in a

		room. […] I think with the group you can share more, maybe because you're not physically there, it's almost like talking to a bartender, right? You know what I mean? You talk to them, you leave, right? They never see you again. (P28) I'm going to say it may sound a bit out there, but it's almost like the universe sometimes puts a group together. You don't… although you don't know why, there's some little spider webs that weave things together. There's some common ground […]. So, in this one, yes, obviously there's the cancer, but also just the misfits of the different relationships that everybody was in the caretaking, but yet that common ground. So, I think being on Zoom or teams like that, it allows for that to just come to manifestation of its own accord. (P29)
	Content	[The exercises were] easy and easy to tap into. I don't have to find different space. I don't have to do anything. I could just… I could be anywhere, at any time. And so, those techniques I can just take a second and use the techniques. And so that's one thing that I don't I don't need to get a mat to lie down on. You know, I don't need a quiet space like this by myself. So that's what's really beneficial. (P25) I think exposure to multiple different modalities of like the mindfulness techniques and just realizing that when you experiment with different things, that maybe you wouldn't have naturally attempted or went to on your own, just that forced exposure, you find new ways that may be more successful than your old ways. (P29) No, just some sessions made me upset. But it's just, we were going deep, but it wasn't, it wasn't not helpful. (P22) Session five is really tough and [the facilitators] wanted to sit with me, but leaning into that stuff was really tough. (P30)
	Therapist Facilitation	The way [the facilitators] have put the questions forward […] they were so much open-ended questions. So, you cannot just say yes or no to it. You have to say that, okay, you know, this is how I feel. This is how I think I should be dealing with it. (P26) It felt like [the facilitators] cared about the group, and they listened. (P28) [The facilitators] were lovely. And they accepted. I felt that we were accepting and sort of hugged by them from the get-go. (P30)

	Timing/Length	Time went by fast. By the time you looked at the clock, an hour had gone by. It was break time. And then it yeah, it really went by fast. So, it was really interesting. It kept me interested in the topics and everything. (P22) I know it's a long commitment to somebody to do longer than that. It couldn't have been any shorter. (P25) I think if you go too long, people will, you know, like anything, their train of thought and their interest waned, unfortunately, in our society already. So, I think seven is probably a good number. (P28)
	Homework	Like every week, I probably work a couple of days on the homework. Like a couple of days here, a day here and a day there. (P22) I mean, there was one [homework assignment] that was harder. So, [I did] all of them, except the worst-case scenario one. […] That was very difficult. (P25) […] so it's a time commitment. And I think I didn't realize that how important homework will be. (P26) Well, it depends… the written type of homework, I did pretty much every time. And then some of the other stuff depending on my week. (P28)
	Group Cohesion	Just like everybody is in the same boat. Everybody. Everybody has the same story as mine. So, I mean, I felt connected to the group because we all have the same story. Being care givers of people we love that have cancer. (P22) I mean, I think the more in depth we got, the greater [we connected] because there was a greater understanding, there was a greater trust and there is a greater exchange of information from all parties. So, from the first one, everybody, there's a bit of in trepidation and things like that. But then, you know, by week three, everybody kind of knows everybody. You kind of have the backs, like a bit of a of a thought in your mind about their story, right? They connect when they start to talk. You can relate to how it's impacting them or their loved ones and those kinds of things. (P29)

		A helpful thing was that engagement. […] So, I guess being present, you know, and then also, you know, participating, right? Not just sitting back and letting everybody else participate and just listen. (P26) You don't want to say it to somebody who's going to judge you for those feelings. So having that open exchange and dialogue and feeling that the circle was, you know, that closed group and there was a sense of trust that the information that was exchanged in there was going to be kept safe. And so that allowed for that freedom of exchange. And in addressing the elephant in the room. (P29) I did feel I thought we had a really strong sense of cohesiveness with the group. […] we were all very open and trusting and disclosing with each other of really raw things. And it was it was really great. People would use different language to describe their experience and, you know, I came to a point of just understanding my powerlessness. And then someone else described that as helplessness. And, you know, it was really great. (P30) […] A great group of women, great and good facilitators. I love that, you know, that it was all women. (P29) I think, you know the opening circle… like opening, you know, check-in and the check-out is always helpful because it's that opening the group it's a pattern, right? And then the closure the saying goodbye. I think it's important, even on a weekly basis. (P29) Um, differences in experience [hindered my sense of connection]. Yeah, 100% like that. I mean, […] it's not my spouse, right? It's not my mom. […] It's my child. (P25) Not relating, feeling like an outlier, feeling outside of a shared experience. Their experiences were very shared. (P30) The fact that some people didn't show up was a problem. The fact that some people didn't have their camera on was a problem because we didn’t know if they were there or not. (P30)
Perceived Impact of FC-FOR…T	Helpfulness in Reducing FCR	I get to get up and get moving and I get to do stuff instead of sitting on the couch and thinking all day. I get to get up and start moving, walking, doing things for myself. Because if I don't take care of myself, I won't be able to take care of my [loved one]. (P22)

		It's empowered me to embrace the fear and ask the questions and make some decisions cognitively, like in my head in relationship to it. And so, I have that space now. I have that room now when I'm having those intrusive thoughts, when I'm, you know, when I am triggered, I have space now to step back and get into my head and look at it objectively before I fall off the deep end. […] I feel like I have more tools now to manage what happens. And I also feel like I will have forgiveness for myself with whatever I feel or do, with what happens. (P25) You know, […] I [can] take a backseat. I think I can concentrate more on myself and my health and say that, okay, this is the time that I have to take care of myself. I have taken care of others a lot. And now it's me. (P28) I feel like I'm in a better headspace. Even though there's things that are annoyed, I'm annoyed about, I feel like I have a better grounded sense about myself and I'm less reactive and less emotional than I would have been at the onset of the group So it has definitely had positive impacts and it's, you know, recognizable to other individuals that are close to me in my life that they can also see that. (P29)
	Importance of Group	I would say the group made me see a lot of stuff, so I would say probably a nine. (P22) Very much depends. […] I hesitate to put someone into a situation that was at times as raw as it was in that group. Do I think the information presented was great? Yes. Do I think how it was presented was great? Yes. Do I think it was beneficial? Yes. Would I recommend it? Eesh. (P25) Yeah, absolutely [I would recommend]. Yeah. Like, I might tell them, you might go deep. You may discover things you didn't anticipate. But the skills are fabulous. (P30)
	Continued use of Tools	My mind keeps coming back to [my loved one] and [their] diagnosis and it's a struggle to keep my mind focused on what I'm doing. […] So, the more I do [the exercises], it seems like the more that I can keep going, that I can do it without his situation popping up. So, I guess it's just practice and practice. (P22) I think, you know, just being more mindful of using those mindful techniques in my life and recognizing that the more you do it, the less of an effort is required. It becomes more like… It's like making memories. Creating that new habit. And then recognizing that it doesn't take much devotion to do it. Once you start doing it a few times, it's really easy. (P29)

		I can actually say it was extremely helpful because I now use these skills every day. You know, it might be a breathing thing, or it might be a thought log it might be, you're going down the rabbit hole. Just stop. Park it. You know, I am using the skills a lot. And like I said, they weren't new to me. But the penny dropped with them, and I could see the applications for them. (P30)
	Normalization & Reduction in loneliness of experience	[…] everybody was saying how they felt and what how the fear recurrence impacts them. And I could relate to that. (P22) Because it is it is helpful to talk to other people - it doesn't sound like it would be, but it is – that are going through the same situation because my friends and family don't, I mean, they don't understand it, right? Like, I mean, they do, they try to, but they really don't. But until you're with someone that actually does, right, it actually is helpful to kind of understand that other people are in the same situation. And we can all kind of hopefully, not even help each other, but just kind of be there. (P28)
Suggestions for Improvements	Content	Maybe the manual could, maybe, provide more explanation about some of the theory, maybe? (P30) I think, there could have been something, maybe, about things like the legal aspects when somebody is getting to that stage, whether it's now or not. I recognize that some people just don't really necessarily do their due diligence about like knowing about having wills done. There are legal matters, making sure that everybody has.. they're both on all of […] their banking information […]. But it might have been a good opportunity to touch on it because sometimes if people are overloaded with stuff, it may be something that's overlooked, but the consequences of it could be grave. (P29)
	Similar group composition	But I think that that would be helpful even if the group is smaller, to have everybody in the same boat. I mean, I know everybody is in the same boat and I know I keep saying that, but it's just different when it's your child. It's just different. (P25) I think a similar cohort would have helped me a lot. There's pros and cons of diversity versus, you know, homogeneity. But for me, I really would have liked to been with spousal caregivers. Okay, so that's a big recommendation. (P30)
	Timing/Length	I also think that for some of the sessions that we did, there was too much for the 2 hours and at the same time allow for the type of sharing that was encouraged in the sessions. So, I think I think some of them had too many exercises in them, if that makes sense. So, by either extending it longer or condensing it would have been beneficial. (P25)

		I think I would have instead of these seven sessions like it would if it was a 1.5 hour and it spread out to 8 or 9 sessions, it will be good enough. (P26)
	Intervention Administration	I think I'd make it a requirement that the camera should be on. Yeah, but I don't know if that's ethical or not. I'm trying to give people a choice, but that was a hindrance for me. (P30) One of the things I would say about […] my previous group, we were allowed […] that continuity with those of us who wanted to continue. But I think the difference with that group and this group is that that conversation (about exchanging contact information) was had at the beginning, so that we already were having outside contact as group members throughout. (P29)

General Discussion

Summary of Research

This dissertation sought to investigate the adaptation and pilot testing of a standardized and manualized cognitive-existential virtual group therapy intervention (Family Caregiver - Fear Of Recurrence Therapy; FC-FORT) aimed at addressing fear of cancer recurrence (FCR) in family caregivers (FC). In Canada, FC are considered an extension of the health care system and provide crucial support to patients and survivors throughout their cancer journey. However, FC have often been underrepresented in cancer research and continue to be underserved in hospital and community settings. Many FC experience high levels of caregiver burden and other psychological distress (e.g., anxiety, depression) related to their caregiving experiences. Furthermore, approximately 50% of FC experience equal or greater levels of FCR than cancer patients themselves. However, to our knowledge, no interventions have been developed to (a) individually (i.e., outside of dyadic settings) or (b) specifically target their FCR. When left untreated, FCR can lead to reductions in quality of life, impaired functioning and increased psychological distress. For this reason, we set out to bridge the gap in bringing evidence-based care to FC living with FCR.

Study 1

This thesis began with the adaption of the validated in-person Fear Of Recurrence Therapy (FORT) group intervention to the FC population and the evaluation of its usability when offered virtually. An advisory board was created to review the intervention manuals, session content, questionnaire packages, and recruitment strategies. Through advisory board feedback, several adaptations were made to the original FORT intervention, such as the development of the virtual format, exercises in self-care and overcoming protective buffering, the addition of a 7th session, and modifications to the language and examples. Once FC-FORT was adapted, two rounds of usability

testing ensued to evaluate its usefulness, usability, desirability, accessibility, features, information, value, readiness, as well as participants' satisfaction. Canadian women FC and psychosocial oncology therapists were asked to take part in 7 weeks of online group therapy, complete session feedback questionnaires, and participate in an exit interview. Overall, FC and therapists expressed high levels of satisfaction with the intervention and its components (i.e., found FC-FORT to be desirable, accessible, useful, etc.). Based on the comments received in the session feedback questionnaires and exit interviews, adaptations, such as increasing session length to 120 mins, removing the healthcare professional's visit, reorganizing the flow of sessions and reviewing the use of the breakout rooms, were made to further improve the intervention's content and format. Results from the exit interviews demonstrated that participants appreciated the virtual format, found FC-FORT's content to be helpful at reducing their FCR, and experienced good group cohesion. The data from both rounds of usability testing were presented to the advisory board who approved all adaptations and ultimately deemed FC-FORT ready for pilot testing.

Study 2

Using a mixed-method, parallel, two-group (FC-FORT vs waitlist control group) randomized control trial, FC-FORT was pilot tested to evaluate its feasibility (e.g., recruitment, allocation, fidelity), acceptability (e.g., dropout, completion, satisfaction), and potential clinical significance on various aspects (e.g., FCR, intolerance of uncertainty). Canadian women FC were asked to take part in 7 weeks of online group therapy, complete questionnaire packages (pre/post intervention, 3 month follow up) and measures of group cohesion and therapeutic alliance (sessions 1, 4, 7), as well as take part in an exit interview. Results from this study revealed that feasibility and acceptability criteria for FC-FORT were partially met. In terms of feasibility, questionnaire completion and therapist fidelity benchmarks were achieved, whereas recruitment and randomization benchmarks were not.

In terms of acceptability, participant satisfaction benchmark was achieved, whereas dropout and session completion benchmarks were not. Primary concerns regarding feasibility and acceptability included difficulties recruiting this population, as well as attrition at the time of randomization. Clinically relevant effect sizes ($\eta_p^2 \geq 0.01$) were found between group and time for FCR and perceived risk of recurrence, suggesting potential effectiveness of FC-FORT on FCR. Qualitative analyses revealed that participants found FC-FORT to have high importance in their lives, be helpful in reducing their FCR, appreciated the virtual format, were very satisfied with the intervention itself, and experienced good group cohesion. In fact, quantitative results highlighted moderately strong therapeutic alliance and strong group cohesion throughout the intervention. While the content, format, and administration of FC-FORT were very well received by FC and therapists, significant issues with the feasibility and acceptability of its methods were noted throughout this pilot study. Given these results, FC-FORT is not currently ready to be tested for effectiveness in a larger RCT. Next steps include discussions with the FC-FORT advisory board regarding recruitment strategies and allocation, and a second round of pilot testing to evaluate modifications.

Contributions of Thesis Research

The adaptation, usability and pilot testing of the Family Caregiver – Fear Of Recurrence Therapy (FC-FORT) represents a crucial step in addressing the often-overlooked issue of FCR among FC of cancer survivors. Taken together, this thesis advances our understanding of (a) the experience of FC living with FCR, (b) the development of targeted, evidence-based FCR interventions for FC, and (c) methodological contributions to research.

Living with FCR: The FC Experience

Our findings align with prior systematic reviews (O'Rourke et al., 2021; Smith et al., 2022; Webb et al., 2023) indicating that FC' experiences of FCR are comparable to those of patients. Specifically, we found that FC experienced high levels of fears and worries about the possibility of cancer recurrence (Lamarche et al., 2024). Furthermore, they described their FCR as persistent and overwhelming, often linked to feelings of uncertainty and a perceived lack of control (Lamarche et al., 2024). They also reported being triggered by various factors, frequently related to symptomatology, leading to hypervigilance and challenges in future planning (Lamarche et al., 2024). These observations correspond with validated models of FCR for patients (Lebel et al., 2018; Mutsaers et al., 2020) and echo previous literature (Banks et al., 2023; Webb et al., 2024) on FC' experience of FCR. In fact, our findings insert themselves well in those of currently emerging models of FCR in FC (Mellon et al., 2007; Webb et al., 2022). Specifically, Webb's model contextualizes FCR as an overarching fear of losing a loved one which is compounded by fear, uncertainty, and a perceived responsibility to protect their loved ones "from both external cancer-related stimuli and their own worries and concerns", which leads to triggers and protective monitoring (Webb et al., 2022). However, our results also suggest that the experiences of FCR among FC differ in some respects. In their qualitative studies, Webb (2024) and Banks (2023) found distinct FC themes related to FCR such as concerns about losing their loved one, witnessing their suffering, the caregiver's role as protector, as well as feeling unprepared. While our studies yielded similar results, other aspects such as the isolating experience of FCR, difficulties in communication related to FCR, and differences in FCR based on caregiving role were identified (Lamarche et al., 2024).

Addressing FCR Needs: Targeted, Evidence-Based FCR Interventions for FC

Interventions addressing FCR needs in FC require a targeted, evidence-based approach to address their unique needs. This section explores three key components highlighted by the results of this thesis. Namely, the use of supportive interventions that provide personalized care, a group format that foster peer support and normalization, and an online format that addresses accessibility while simultaneous leading to better outcomes for FC.

Supportive Interventions. This thesis expands our limited understanding of the supportive FCR needs of FC, highlighting their need for access to various tools for managing FCR, self-care and developing skills to navigate difficult conversations with loved ones. During the adaptation process, our advisory board stressed the inclusion of self-care within FC-FORT. While FC play a vital role in reducing healthcare costs and improving care outcomes for cancer patients and survivors (Statistics Canada, 2022), many lack the skills needed for effective caregiving (Given et al., 2012), which can lead to negative consequences on their well-being. In fact, caregiving often leads to less rest (Carter, 2002), fewer self-care behaviours (i.e., physical activity, healthy eating, socializing), and delayed medical care (Burton et al., 1997) which ultimately affects their well-being. Research on self-care practices in FC indicate that FC tend to engage in fewer health-promoting or self-care behaviours than non-caregivers (Acton, 2002). Conceptually, increased caregiver stress leads to lowered perceptions of health, increases in presence of physical and psychological symptoms, increases in depressed mood, and declines in physical function (Liu and Wylke, 2007). However, the literature also suggests that FC with higher caregiver burden tend to utilize self-care behaviours more (Liu and Wykle, 2007; Scharlach et al., 1997). Namely, the greater the number of symptoms (i.e., stress, physical/psychological symptoms) experienced by FC led them to devote more time into managing their own health related issues by engaging in self-care (Liu and Wykle, 2007). Liu and colleagues (2007) posit that this may be an effort to maintain

personal well-being in order to continue providing for their loved one, a heightened awareness of their own vulnerability as a result from prolonged exposure to a loved one with an illness, or simply a greater demand of self-care posed by higher symptom load. In addition, Pope and colleagues (2017) found that personal self-care in FC was generally associated with emotional well-being, pain, perceived stress and general health. In their 2016 study, Dionne-Odom and colleagues also found that lower engagement in self-care behaviours was significantly associated with increase symptoms of anxiety, depression and health related quality of life. Given the significant burden faced by cancer FC (Kent et al., 2016; Kim et al., 2008), integrating self-care practices into their daily routines is crucial for both FC well-being and patient care. Existing systematic reviews (Becqué et al., 2023; Northouse et al., 2010; Sak-Dankosky et al., 2022) also support the inclusion of self-care in FC interventions. Additionally, our advisory board strongly recommended incorporating an exercise on effective communication into FC-FORT. A central focus of this exercise is addressing protective buffering, a coping strategy many cancer patients and caregivers use to withhold distressing emotions to shield loved ones from worry (Manne and Badr, 2008). While often well-intentioned, protective buffering creates emotional distance, hinders open communication and increases FCR in both survivors and FC (Manne and Badr, 2010; Perndorfer et al., 2019; Xu et al., 2019). FC-FORT aimed to reduce protective buffering by helping FC develop the skills needed to overcome avoidance of difficult conversations, promote honest conversations and strengthen connections, ultimately fostering better support for patients and FC. Furthermore, both our quantitative and qualitative data indicated that FC found FC-FORT beneficial in reducing their FCR and improving their overall coping. Participants valued the effectiveness and variety of the intervention's exercises, which included psychoeducational content, cognitive and relaxation/mindfulness techniques, group support activities (such as sharing experiences and providing mutual support), and additional resources (like workbooks and audio relaxation files) in alleviating FCR. In addition, they

appreciated the transferability of exercises to other aspects of their lives (e.g., sleep, stress, anxiety). Our results suggest that interventions that include multiple components may be more effective than single component interventions. Previous systematic reviews have also reflected the combination of various exercises in most FC interventions, promoting better outcomes (Becqué et al., 2023; Northouse et al., 2010; Sak-Dankosky et al., 2022). In adapting FC-FORT, few components of the original intervention were deemed unnecessary or unhelpful. Most changes involved additions or modifications that better reflected the realities faced by FC. Notably, the visit from a healthcare professional (included in the original FORT intervention; Lebel et al., 2014; Maheu et al., 2016; Maheu et al., 2023) was the only element not included in FC-FORT. This could suggest that the need for connection and shared experiences may be more important for FC in managing their FCR than seeking information. Alternatively, it could also reflect the difficulty of providing enough relevant information in such heterogeneous group of FC (i.e., different cancer types, stages, and caregiving roles). However, this finding contrasts with previous research on interventions for FC (Becqué et al., 2023; Northouse et al., 2010; Sak-Dankosky et al., 2022) and does not align with the current knowledge on addressing FCR in patients and survivors (Lebel et al., 2016; Lebel et al., 2018; Maheu et al., 2023). A recent qualitative study (Breuning et al., 2024), which examined the burdens and support preferences of cancer FC, found that FC expressed a desire to share or receive support on several topics, including preparing for what lies ahead, coping with their own emotions and needs, end-of-life, managing the emotional stress of patients, impacts on relationships and family communication, coping with treatment side effects and complications, and fostering an encouraging environment—not solely focused on sorrow and suffering. Encouragingly, many components of FC-FORT, while tailored to FCR, are well suited to address these issues. Moreover, our studies suggest that many mechanisms of change (e.g., decreasing experiential avoidance, valued living; Lebel et al., 2022; Maheu et al., 2023) and supportive needs (e.g., social and

emotional support, receiving help to manage FCR, connectedness to other women; Lebel et al., 2022; Maheu et al., 2023) identified in previous FORT studies also apply to FC-FORT.

Group Format. Of importance, this thesis contributes to the growing body of evidence suggesting that group interventions are an acceptable, and perhaps preferrable, format for FC. Specifically, our findings emphasize the relevance of group work in combating loneliness among FC, fostering peer validation and connection, and normalizing experiences through sharing. Previous research supports these conclusions; for instance, Northouse and colleagues (2010) found that groups significantly improved FC coping and Becqué and colleagues (2023) reported that group interventions led to meaningful improvements in FC outcomes and daily functioning. However, much of the literature on cancer FC continues to emphasize the importance and efficacy of dyadic interventions (Badr et al., 2019; Chen et al., 2023; Low et al., 2024; Luo et al., 2020; Wang et al., 2025). One explanation for this is the fact that dyadic interventions highlight the interdependence of FC and patient well-being and have the potential of addressing cancer related concerns in two important populations. While this approach does demonstrate positive outcomes, there is evidence that suggests that interventions that focus solely on FC needs can lead to more favourable appraisal of caregiving benefits (Northouse et al., 2010). Furthermore, in their systematic review, Becqué and colleagues (2023) identified that individual interventions for FC were associated with improved outcomes on caregiver burden and anxiety. Although each intervention format has its distinct advantages and limitations, additional research is needed to directly compare the effectiveness of group, dyadic, and individual interventions for FC. Moreover, cancer FC often experience moderate to high levels of loneliness (Gray et al., 2020), which can have negative physical and psychological effects (Ross et al., 2020). The high caregiver burden frequently experienced by cancer FC (Kent et al., 2016; Kim et al., 2008) has also been linked to higher levels of loneliness (Ross et al., 2020). Our results also suggest that external sources of support, such as professionals and peer settings,

may complement FC supportive needs better than relying on family members or their own social networks. Findings from our pilot study highlighted the desire of FC to connect and share with others in similar caregiving roles. This echoes previous qualitative work by Breuning and colleagues (2024) who investigated the needs of female and male parents, adult children and partners taking care of loved ones with a variety of types of cancers. In their study, they identified FC' needs for peer-to-peer exchanges to decrease loneliness, share emotions, and help to prepare for what was to come next. However, similarly to our participants, FC identified wanting to "find someone similar to themselves in order to have the most benefit from sharing their experiences" (Breuning et al., 2024). The most important characteristic for a 'match' was being in a similar caregiving relationship, something also echoed by participants in our pilot study, followed by comparable prognosis and severity of the disease. Thus, it appears that homogeneous groups may be more suitable for FC than heterogenous groups.

Online Format. Additionally, this thesis significantly contributes to the growing literature on the appropriateness of technology-based psychosocial interventions (Low et al., 2024) for FC. In our studies, FC reported appreciating the virtual format, described experiencing positive group cohesion and therapeutic alliance (supported by our quantitative data), and described an increased sense of safety and accessibility in participation because of the virtual format. Low and colleagues' (2024) systematic review and meta-analysis identified that technology-based psychosocial interventions significantly improved health related QoL, alleviate depressive symptoms, and increase self-efficacy. Given FC' high caregiver burden, their often-isolating experience, and difficulties with accessibility, this thesis further highlights their on-going needs for virtual care services. Additionally, some studies have previously explored the adaptation of in-person interventions for FC to a virtual format. For instance, Zulman and colleagues (2012) successfully transitioned an in-person intervention aimed at improving communication between partners to a

virtual setting. Like the current study, their findings indicated that many components of in-person interventions can be effectively adapted for virtual delivery and are well-received by dyads (patients and partners). Their adaptation process also involved a multidisciplinary team, including FC, highlighting the importance of incorporating FC insights in research, as the present thesis did. Additionally, Northouse and colleagues (2010) assessed the feasibility of adapting a previously in-person intervention for dyads and found it to be feasible, noting good retention rates, accessibility, and satisfaction with the virtual format.

Contributions to Methodology

The adaptation of FORT to FC-FORT underscores the importance of modifying established interventions for cancer survivors to include content specifically relevant to FC. Adapting existing interventions can represent an efficient, cost-effective and timely solution for underserved populations (Moore et al., 2021). Given the range of evidence-based FCR interventions for cancer patients, the urgent need of FCR interventions for FC, and the available literature on the similarities between patient and FC experience of FCR, an adaptational rather than a developmental approach was chosen for this project. Achieving an optimal match between the intervention and context requires thoughtful and systematic adaptation. Furthermore, replications (rather than adaptations) of existing interventions with new populations or contexts are less likely to achieve positive outcomes (Moore et al., 2021). For this reason, adaptation frameworks are essential to ensure the most effective results. This thesis inserts itself well within the ADAPT framework (Moore et al., 2021), which was developed to adapt existing health-related interventions to new contexts. ADAPT consists of four distinct steps: 1) Assessment of rationale for intervention and consideration of intervention-context fit of existing interventions; 2) Planning for and undertaking adaptations; 3) Planning for and undertaking piloting and evaluation; and 4) Implementing and maintaining adapted

interventions at scale. ADAPT is also set within a context of the inclusion of diverse stakeholders and the inclusion of patient-partners in research. This thesis focused specifically on steps one trough three with the creation of a multidisciplinary advisory board, clear rational, consideration and suitability of adapting FORT for FC, an in-depth adaptation process of FC-FORT, as well as a pilot study to determine FC-FORT's feasibility and acceptability. More specifically, we used the *Information Systems Research Framework* (Hevner, 2007) to guide its adaptation and evaluation. This framework provided a systematic approach to the design, development and evaluation of FC-FORT, allowed for integration of multiple perspectives and implementation of theory into practice, and emphasized relevance, rigor and continuous evaluation. Although adaptation frameworks are available and commonly used, the reporting of adaptations and modifications within scientific articles is still not widely done (Wiltsey Stirman et al., 2019). Consistent reporting of modifications can enhance intervention outcomes (i.e., engagement, acceptability, clinical outcomes, fit for population) and maximize their implementation (Wiltsey Stirman et al., 2019). The *Framework for Reporting Adaptations and Modifications-Expanded* (FRAME; Wiltsey Stirman et al., 2019) was developed to "to facilitate a more nuanced consideration of modifications and to work toward identifying forms of modifications that may enhance interventions vs. those that may reduce effectiveness". It includes various aspects such as identifying when, how and who made the modifications, if they were planned or not, what was modified and why, the level and nature of modification, and whether modifications were fidelity consistent. While our adaptation process was not as refined as FRAME, many of its principles were used in our adaptation and usability studies. For example, study 1 includes a list of suggestions made by our advisory board during the adaptation process and feedback received following our first usability study (See Table 2 in Lamarche et al., 2023) and whether adaptations were implemented. However, many criteria highlighted by FRAME were not included which could cause issue should aspects of FC-FORT be

deemed ineffective. For example, our studies did not include the level of delivery (i.e., for whom or what the modifications were made), context (e.g., format, setting, personnel), or relationship fidelity of the adaptations made to FC-FORT. As such, future adaptation studies of FC-FORT should concretely implement FRAME. Our results highlight the importance and benefits of using adaptation frameworks. Furthermore, adaptations, while less time consuming than complete intervention development, are still resource demanding. Using an adaptation framework can serve as guide while promoting efficiency, ultimately reducing potential use of resources. Furthermore, frameworks lead to more rigorous and transparent research.

Moreover, including FC in research is increasingly recognized as a best practice, contributing significantly to the scientific literature and enhancing health outcomes (Canadian Institutes of Health Research, 2019). Namely, FC have firsthand experience of health, illness, and navigating the health care system, making them valuable allies in health research. However, a systematic review focusing on the implementation of FC interventions (Ulgade et al., 2019) revealed that many studies failed to incorporate FC input during the development and evaluation of their interventions. The current thesis therefore sets itself apart from earlier intervention development and implementation research. Using the Strategy for Patient-Oriented Research (SPOR) recommendations developed by the Canadian Institutes of Health Research (2019), our team formalized the integration of our caregiver-partners in the adaptation and evaluation of FC-FORT to ensure capacity for meaningful engagement. Furthermore, our study fostered the concept of coproduction (Hawkins et al., 2017) to achieve the best fit between the exist FORT intervention and the new contexts of FC and online formats. This ultimately led to caregiver-identified priorities and outcomes and significant participation (e.g., commitment, active contributions, offering of ideas) from our advisory board. Through their valuable feedback, as well as the collected data from both of our studies, we have developed an intervention that is specifically tailored to the supportive needs of

FC related to FCR. Again, to our knowledge, this is the first intervention to address FCR in this population, thus contributing to bridging the gap in offering evidenced-based and tailored interventions to FC. However, to our knowledge, there is currently no available data regarding the adaptation of validated interventions designed for cancer survivors specifically for FC.

In brief, this thesis contributes to a better understanding of (a) the experience of FC living with FCR, (b) the development of targeted, evidence-based FCR interventions for FC, and (c) methodological contributions to research. We now turn to the strengths, limitations and clinical implications of the thesis.

Thesis Strengths

This thesis has several strengths. Firstly, this project enhances our understanding of FCR in FC and highlighted valuable information regarding their supportive needs. It contributes to the emerging literature on these subjects and could further contribute to the development of validated models and measures of FCR in FC. Additionally, the adaptation of this virtual FCR group intervention poses an original contribution to the research as this project is one of the first interventions to address FCR in FC. This project does not only address the existing gap in the literature on psychological interventions aimed at addressing FCR in FC, but also actively provided support to FC who experienced clinical levels of FCR. Moreover, this thesis highlighted the relevance and acceptability of online interventions for FC and provides further insight on the possibilities related to adapting previously validated interventions designed for patients to FC. Given the multitude of available knowledge surrounding psychological interventions addressing FCR in patients, the ability to transfer existing knowledge and successfully adapt it to FC represents a cost and time efficient approach. Furthermore, FC-FORT includes a strong theoretical foundation, which emphasizes specific, practical tools and strategies to managing FCR in FC. Given its cognitive-

behavioral and existential components, and its structured and standardized format, FC-FORT can serve as a valuable resource for clinicians treating FC with FCR as it is adaptable to different cancer types and stages and could also be applied various other health conditions. Finally, a significant strength of this thesis is its rigorous scientific method which included both quantitative and qualitative work, the use of an advisory board which included both research, clinical, and real-life experiences, many rounds of evaluation, and was based in specific guidelines (i.e., CONSORT) and frameworks (i.e., ADAPT, the Information Systems Research Framework). These research methods allowed us to obtain exhaustive data and highlight key issues with FC-FORT's protocol. While the sample size was small, it did include a wide range of cancer types, caregiving experiences, and stages. Furthermore, although we experienced difficulties with recruitment and attrition, we obtained good questionnaire completion rates and participation in exit interviews. Overall, the methods used in this project allowed for a rich and holistic understanding of FC' experiences with FC-FORT, FCR, and caregiving.

Thesis Limitations

While this thesis included various strengths, it is also important to note its limitations. First, both Study 1 and Study 2 experienced significant difficulties with recruitment which resulted in small sample sizes (n = 10 and n = 20, respectively). While previous research (Song et al., 2021; Leslie et al., 2019) has highlighted that FC are generally a difficult population to recruit, exhaustive recruitment efforts were made throughout both studies. Despite opening our recruitment nationwide and recruiting through major oncology centres, FC participation and interest was limited. It is possible that our more "passive" recruitment efforts (i.e., sending letters to patients inviting their FC to participate, posters) may have contributed to this. In addition, although we aimed to make the study as feasible as possible (i.e., virtual format, limited number of sessions, use of short form

measures), it is possible that FC facing burnout or fatigue from their caregiving responsibilities may have been less motivated to take part in the study. Furthermore, the emotional and time investment needed to engage in a 7-week group therapy (2h weekly sessions), may have impacted FC' ability or willingness to participate. Moreover, as is often the case in psycho-oncology research, most participants were White married women, with high levels of education and socioeconomic statuses. In addition, FC taking care of a loved one with stage IV cancer were not eligible to participate in the study. This is an important note as FC taking care of people living with more advanced cancers or those in the palliative stage typically experience higher levels of caregiver burden as well as fear of cancer progression – an extension of FCR (Bergerot et al., 2022). Further research should include this population to ensure that their needs are met. Canadian representation was also somewhat limited with most participants coming from either British Columbia or Ontario. Furthermore, given that FORT has so far only been validated with women and that women typically carry higher caregiver burden and experience higher levels of FCR, we chose to exclude men from this thesis, while acknowledging that research demonstrates that men FC do experience FCR and caregiver burden. Moreover, both studies included a small number of therapists (n = 3) who delivered the intervention, which may have positively impacted therapist fidelity but limits the ability to detect therapist effects. Finally, volunteer bias may also have influenced the collected data as participants might have been particularly motivated and interested in the topic. Overall, these issues limit the generalizability of the studies' findings and their application to a broader population. Therefore, results should be interpreted with caution.

Additionally, we experienced difficulties with participant attrition as well as dropouts in Study 2. When designing the study, we decided to use block randomization whereas a group would be allocated every time 9 FC had been recruited and provided consent. This technique had been successfully used in the original FORT study to minimize attrition. However, given our difficulties

with recruitment, it often took months to recruit enough participants to be able to allocate a group. Therefore, we lost many FC once groups had been allocated due to scheduling difficulties or loss of interest. Furthermore, in the WLCG, many participants completed the questionnaire packages all 3 time points, but then were no longer available to receive FC-FORT once their participation in the study was completed – which led to high levels of dropouts. These results suggest that WLCG may not be feasible for this population. Finally, participant attrition as well as dropouts resulted in reductions in session completion rates – with many participants not receiving FC-FORT as intended (i.e. 5 out of 7 sessions). Our recruitment efforts may also have been impacted by the length of the group (i.e. 2 hours) and/or the duration of the intervention. As mentioned previously, FC carry significant caregiver burden, which may have deterred them from joining a 7-week long group where the importance of weekly attendance was highly reinforced. However, according to systematic reviews, most cancer FC interventions have a mean length of between 5.2 to 20 sessions (Becqué et al., 2023; Low et al., 2024; Northouse et al., 2010; Sak-Dankosky et al., 2022), with a wide variety in terms of length and delivery format. Northouse and colleagues' (2010) meta-analysis revealed mixed results where interventions with more sessions were found to be positively and significantly correlated with better coping outcomes, but negatively related to burden, depression, and marital-family relationship outcomes. Evidently, FC-FORT's recruitment strategies need to be reviewed, modified, and further investigated. Recommendations include recruiting through hospitals in additional provinces across Canada, directly engaging with FC in hospital environments (such as having physicians identify eligible caregivers in clinics and reaching out to them via letters or phone calls), and adjusting the language used on the recruitment poster (for instance, incorporating the term 'caregiver'). There is evidence suggesting that the term "caregiver" may not accurately describe FC' role with their loved one and often held negative connotations (e.g., dependency, burden; Petro-

Canada CareMakers Foundation, 2024). Other terms, such as care partner, carer, or simply using relational terms (i.e., spouse, parent, children) may be more appropriate or relatable to FC.

Clinical Implications

This thesis represents one of the first intervention to directly address FCR in FC. The findings from these studies highlight the significance of providing tailored group intervention services for FC experiencing FCR. Additionally, the online format of this group intervention provided increased flexibility for FC (many would not have been able to participate otherwise), a sense of emotional safety while discussing difficult topics, and the ability to meet other women from across Canada with shared experiences. Furthermore, as discussed, for FC the group format is an important part of addressing their FCR (i.e., normalization, reduction of stigma) and decreasing caregiver burden by increasing social support.

Despite the evidence that FC experience equal or greater levels of FCR compared to patients, there are still no individual or group interventions designed to address FCR in FC. Furthermore, in clinical contexts FC are not receiving any support for their FCR. This group intervention addresses the increasing clinical demand for FC to be considered as patients themselves and have access to psychological services that can not only enhance their QoL and well-being, but also those of patients' and survivors'. While further research is needed to establish FCR guidelines and screening tools that are specific to FC and evaluate the effectiveness of other FCR interventions for FC, this project represents a first step in bridging an important gap in bringing evidence-based care to FC. It is hoped that the results of this project will bring initial insight to healthcare professionals and clinicians in understanding the importance of addressing FCR with FC, FC needs related to FCR, as well as concrete strategies on how to do so in a clinical setting. We hope that this research will serve as proof of the importance of providing access to psychological services for FC accompanying a

loved one through a cancer experience. Currently, Canadian FC receive little to no support for their FCR within the health care system. At the individual level, potential suggestions to address this includes providing psychoeducational information to FC about FCR at time of their loved one's diagnosis as well as where they can access support to manage these fears. At the systems levels, potential suggestions include the development of more caregiver centered programs in psychosocial oncology, development of FCR interventions designed for FC, and healthcare provider training in the detection and management of FCR in FC. Early access to psychological services can help patients address their emotional concerns related to their diagnosis, potentially reducing the likelihood of developing clinically significant FCR (Lebel et al., 2024). Finally, as mentioned previously, levels of FCR in FC impact those experienced by patients (Boehmer et al., 2016; Mellon et al., 2007; van de Wal et al., 2017). Therefore, addressing FCR in FC can also lead to decreases in FCR experienced by patients which could lead to reductions in healthcare use, as well as increases in QoL and overall well-being. Providing services for their unmet FCR needs would not only benefit FC' themselves, but also patients and the overall Canadian health care system.

Future Directions

Despite the significant distress and caregiving burden experienced by FC of cancer survivors, very few services are currently available to support them. Although the literature on FCR is expanding, much of our understanding remains centered in the experiences of cancer patients and survivors. Evidence consistently shows that FC have unique supportive needs regarding FCR that differ from those of patients. Therefore, immediate future directions should prioritize the validation of FCR models specifically for FC. Currently, there are limited frameworks addressing FCR in this population, and further research is essential to establish a scientific consensus on clinical levels of FCR among FC. Validated models are crucial for identifying and addressing the complex emotional

challenges caregivers face, ultimately leading to improved outcomes for both caregivers and cancer patients. A validated model of FCR in FC would facilitate the development and validation of measures specifically designed to identify FC needing additional support related to their FCR. Future research should also focus on the development of evidenced-based interventions aimed at addressing FCR and their implementation within the Canadian public healthcare system. To our knowledge, FC-FORT is one of very few interventions currently developed to address FCR in FC. While our results suggest that FC-FORT is highly appreciated by FC and deemed useful in addressing FCR, issues with feasibility and acceptability still need to be addressed. Therefore, future directions include addressing these concerns to move forward with a larger randomized control trial. Demonstrating the effectiveness of FC-FORT could pave the way for its integration into psychosocial care within the public health system. Finally, this thesis highlights the importance of developing FC-specific measures to assess FCR. While emerging tools such as the caregiver version of the Fear of Cancer Recurrence Inventory (Lin et al., 2018) and the Caregiver Fear of Cancer Recurrence/Progression Measure (Webb et al., 2024) are beginning to appear, additional research is needed to establish a consensus on a FCR model for FC and further validate these tools for clinical application.

Future iterations of this study should encompass diverse populations and delivery formats (i.e., in person, hybrid). Our results, along with emerging evidence (Breuning et al., 2024), suggest that FC may benefit from group interventions tailored to similar caregiving experiences (e.g., spouses or parents). Consequently, it may be appropriate to adapt FC-FORT to consider specific caregiving contexts and cancer types to enhance its relevance and effectiveness. Moreover, this project has primarily focused on FC of cancer survivors with cancer stages I-III. Future studies should include FC of more advanced cancer patients, incorporating a focus on fear of cancer progression, as their concerns and supportive needs may differ. Finally, adaptations of FC-FORT

should consider cultural needs specific to various populations. These adaptations could mimic the work currently being done by the original FORT team in Mexico (Rivera-Olvera et al., 2022), Spain (Estapé et al., 2023), and with the adolescents and young adult population (Panjwani et al., 2024) and with parents (Lebel et al., 2024). Based on the lessons our team learned throughout the study, future adaptations should continue to include an advisory board of caregivers, researchers, and health care professionals to ensure that FC-FORT is appropriately tailor to meet the needs of this diverse population.

In conclusion, this thesis was one of the first to offer an evidence-based intervention to FC living with FCR. Advancing research on FCR models and interventions tailored specifically for FC is crucial to addressing their unique needs, improving their well-being, and enhancing support for both FC and cancer patients.

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APPENDIX A: TERMS OF REFERENCE – ADVISORY BOARD

Name of group: Cancer Caregiver Advisory Board

Title: It's time to address fear of cancer recurrence in the family caregiver: Adaptation, feasibility, and acceptability study of an online version of the Fear Of Recurrence Therapy (FORT) for family caregivers. (March 2020)

Purpose / role of the group: The purpose of the group is to oversee the adaptation of an online Fear of Recurrence Therapy (FORT), as well as to provide feedback regarding recruitment strategies and a proposed questionnaire package. Members will be asked to review the contents of the existing therapy manual and provide feedback regarding its applicability to caregivers. Additionally, members will be asked to review and provide feedback on the online format of the existing therapy manual and activities. Further, the advisory board will discuss themes from the existing literature on family caregivers' needs and unique challenges, and consider how they inform the FORT adaptation to family caregivers.

Membership: The membership of the group is open to 4-6 female family caregivers from different age groups and types of family relationship (i.e. spouse, daughter, etc.), who care for adult patients with different types of cancer. The advisory board will also consist of the research team and two experienced therapists from Cancer Chat. The membership period is one year with the possibility of extension.

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 Dr. Rinat Nissim, 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 for reporting back on any assigned activities to the group. Group members will be asked to review and provide feedback on materials (i.e. intervention booklets) in accordance with deadlines collaboratively decided upon as a group. Members are encouraged to bring forth any concerns related to the project at any time.

Review: Terms of reference will be reviewed at the end of the one-year membership period, if need be. The group may review the relevance and value of its work at each online or in person meeting.

Working methods / ways of working: A shared learning approach will be used for this group. Both the research team and the advisory board will work together to reach a common objective: addressing fear of cancer recurrence in family caregivers. Each member's knowledge and experience will be used to achieve overall better results. No subgroups will be convened.

Meetings

This advisory board will meet regularly online to oversee the adaptation of FORT. Members will be compensated for their travels. The meetings will be organised by the research team's research

coordinator and will be chaired by the principal investigators, Dr. Sophie Lebel and Dr. Rinat Nissim. The meetings will include all advisory board members as well as the complete research team. Agenda topics will be generated based on the project timeline and research team's needs. Additional topics can be added at any point upon request. Meeting agendas in PDF formats will be sent by email to all members two days before each meeting. The format of each meeting will be based on the provided meeting agenda. Generally, the principal investigators will discuss each topic one by one and welcome feedback or responses from members. Questions and/or concerns can be raised at any point. The research coordinator for this project will be in charge of taking meeting minutes and sharing them with all members by email. Non-members will not be invited to group meetings.

Sharing of information and resources (including confidential materials)

All necessary information and resources will be provided to each group member by email. A shared Google drive with restricted access, facilitated by the research coordinator, will also be created for the group members. 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

- **Family caregiver:** Defined as family members who provide unpaid support.
- **Fear of Cancer Recurrence:** Defined as the fear, worry, or concern that cancer may come back or progress.
- **Fear Of Recurrence Therapy (FORT):** FORT is a cognitive-existential intervention previously validated with cancer survivors. It consists of 6 weekly face-to-face sessions offered in a closed group format

Cancer Chat: A division of the de Souza Institute, a National Knowledge Translation Centre in Oncology. Cancer Chat offers a broad range of therapist-led online support groups, including general support groups for family care

APPENDIX B: PARTICIPANT INFORMED CONSENT FORM (USABILITY STUDY)

Title of the study:	**It's time to address fear of cancer recurrence in the family caregiver: adaptation, feasibility, and acceptability study of an online version of the Fear Of Recurrence Therapy (FORT) for family caregivers.**
Co-Principal Investigators:	Dr. Sophie Lebel, School of Psychology, Faculty of Social Sciences, University of Ottawa (Ottawa). Dr. Rinat Nissim, Cancer Clinical Research Unit (CCRU), Princess Margaret Cancer Centre, University Health Network (Toronto).
Research Coordinator:	Jani Lamarche, School of Psychology, Faculty of Social Sciences, University of Ottawa (Ottawa).
Funding source:	University of Ottawa

Invitation to Participate: I am invited to participate in the abovementioned research study conducted by Dr. Sophie Lebel and Dr. Rinat Nissim.

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like.

Purpose of this study: The purpose of the study is to adapt the Fear of Recurrence Therapy (FORT), previously validated with cancer survivors, for family caregivers using an online format, to test its feasibility and acceptability and to estimate the clinical significance of this adaptation on fear of cancer recurrence and other outcomes. This study is the first to target fear of cancer recurrence in family caregivers.

To make our intervention feasible for family caregivers, we will offer the intervention via an online videoconferencing format, in partnership with Cancer Chat of the de Souza Institute, a national provider of online therapist-led support groups for cancer survivors and FC.

Participation: Your participation will consist essentially of attending an online pre-therapy meeting with one of the study therapists, a weekly online group therapy session of 90-120 minutes each for 7 weeks, during which you will be asked to participate in activities, participate in group discussions, and complete homework. After each of the 7 sessions, you will also be asked to complete a short session feedback questionnaire to provide us with your impressions of the content of the session and the online format and features and the general readiness of the session for end users. You will also be asked to complete a sociodemographic questionnaire. You may skip any questions that make you uncomfortable or that you do not wish to answer. You will also be asked to participate in a brief recorded videoconference or telephone exit interview with the research coordinator (30 mins to 1 hour).

All intervention sessions will be video-recorded and reviewed by members of the research team to make sure the therapy is given to you as intended. 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.

Length of involvement in the study: The entire study will last approximately 3 years. Your participation in the study will last approximately 2 months.

Risks: Your participation in this study will entail that you volunteer very personal information, and this may cause you to experience a heightened anxiety during your participation in the group session. You have the assurance of the researcher that every effort will be made to minimize these risks. If you experience any discomfort, please discuss this in session or with the facilitators. The Co-PIs and group leaders will be responsible for facilitating referrals for individual counselling within the psychosocial oncology programs of the recruiting sites.

Benefits: Your participation in this study may result in a decrease of your fear of cancer recurrence, and an increase in your quality of life and your coping. Furthermore, your participation in this study will help bridge an important gap in bringing evidence-based care to family caregiver who have never been offered help before for their fear of cancer recurrence.

Confidentiality and anonymity: The information you will share will remain strictly confidential. In order to minimize the risk of security breaches and to help ensure your confidentiality we recommend that you use standard safety measures such as signing out of your account, closing your browser and locking your screen or device when you are no longer using them / when you finish a session.

How is my personal information being protected?

- All information collected during your participation in this study will be identified with a unique study number, and will not contain information that identifies you, such as your name, address, etc.
- The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave Dr. Sophie Lebel's laboratory at the University of Ottawa.
- Anything said between any two or more group members at any time is part of the group and is confidential. Everything said in this group is confidential and is not to be shared with anyone outside of the group.
- Members of the group agree to keep confidential the names of other members of the group and what is said in the group. As a member of this group, you agree to not disclose to anyone outside the group any information that may identify another group member. This includes, but is not limited to, names, physical descriptions, biological information, and specifics to the content of interactions with other group members.
- Under the professional and ethical norms of conduct of the Ontario College of Psychologists, confidentiality may be broken in very specific situations, such as:

1. Disclosures of imminent danger to yourself or others
2. Disclosures of information about a child in need of protection
3. Disclosures of sexual abuse by a health professional
4. inappropriate or incompetent treatment or care of a resident in a long-term care facility that caused pre-injury or risk of harm to the resident
5. Summons of documents as provided for in court order.

- Any documents or samples leaving The University of Ottawa or the University Health Network will contain only your unique study number. This includes publications or presentations resulting from this study.
- Session history (in text format) will be saved in the University Health Network system and detached from individual information. For more information, please visit https://www.uhn.ca/PatientsFamilies/Patient_Safety_Advocacy/Privacy/Pages/privacy_policy.aspx
- For audit purposes only, your original study records may be reviewed by the University of Ottawa Ethics Board.

Conservation of data: The data collected (questionnaire package, database, consent form, recorded exit-interviews, transcripts and relevant notes*)* will be kept in a secure manner. As such, the electronic data will be stored on a password protected computer in Dr. Sophie Lebel's locked laboratory at the University of Ottawa. The session histories (in text format) will be saved in the University Health Network firewall protected system where only the Cancer Chat team, the session facilitators and Co-Principal Investigators will have access. Recorded video sessions will be recorded through Zoom on Dr. Sophie Lebel's work computer and moved to the University of Ottawa's secure OneDrive virtual cloud. Video sessions will be deleted immediately after the transfer has been made to the OneDrive virtual cloud. Only Dr. Sophie Lebel and her research coordinator will have access to this OneDrive account. When possible, files will be password protected in the University of Ottawa's OneDrive virtual cloud. Additionally, all paper documents will be stored in a locked file cabinet inside the locked laboratory. Only the research team and the research coordinator will have access to this data. The data will be kept in Dr. Sophie Lebel's laboratory and on the University Health Network system for a retention period of 10 years. After the 10 years, the data will be safely disposed of by either shredding the paper documents or by permanently deleting the data from the laboratory's computer and the University Health Network system.

Compensation: You will be compensated ($20) for your participation in the exit interview. If you choose to withdraw from the study, you will not receive compensation.

Voluntary Participation: You are under no obligation to participate and if you choose to participate, you can withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you withdraw your consent, the study team will no longer collect your identifying information for research purposes. All questionnaires are assigned by participant number in order to increase anonymity. Only the members of the research team will have access to this information. If you choose to withdraw, all data gathered until the time of withdrawal will be destroyed in the manner described above.

Will I be informed about any new information that might affect my decision to continue participating?

You will be told in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

It's time to address fear of cancer recurrence in the family caregiver: adaptation, feasibility, and acceptability study of an online version of the Fear Of Recurrence Therapy (FORT) for family caregivers.

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about fear of cancer recurrence.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

If you have any questions about this study, please contact the co-principal investigators, Dr. Sophie Lebel or Dr. Rinat Nissim.

If you have any questions regarding the ethical conduct of this study, you may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5

Tel.: (613) 562-5387

Email: ethics@uottawa.ca

There are two copies of the consent form, one of which is mine to keep.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

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 C: SESSION FEEDBACK QUESTIONNAIRES

Session Feedback Questionnaire for Caregivers

Well done on making it through FC-FORT session # X!
The following questions will ask you about your experience with the session. Please answer the questions as openly and honestly as possible. Your feedback will help with modifications and updates to the final version of the online program.
This questionnaire will take you about X minutes to complete.

1) Useful

- This session provided information that helped me better understand my fear of cancer recurrence.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- This session provided tools that helped me better manage my fear of cancer recurrence.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **usefulness** of this session. Include any suggestions you may have to improve **usefulness:**

2) Usable

- This session was user-friendly.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- I was able to follow-along and understand this session with ease.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **usability/findability** of this session. Include any suggestions you may have to improve **usability/findability**:

3) Desirable

- This session was visually appealing and the organization of information on the screen was clear. The *way* the information was presented was a positive addition to the user experience.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **desirability** of this session. Include any suggestions you may have to improve **desirability**:

4) **Accessible**

- It was easy to follow-along and absorb all the necessary information in this session.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- If this session was included with the rest of the FC-FORT online program, I believe it would be easy to navigate this session and find all the relevant information.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **accessibility** of this session. Include any suggestions you may have to improve **accessibility**:

5) Features (e.g., Workbook, Relaxation Audio Files, and Supplemental Materials)

- The relaxation audio files in this session are helpful, and I would refer to them at a later time.
    - Strongly agree
    - Agree

  - Neither agree or disagree
  - Disagree
  - Strongly disagree

- The activities (e.g. thought record) in this session are helpful, and I would refer to them at a later time.
  - Strongly agree
  - Agree
  - Neither agree or disagree

- The workbook section of this session is helpful, and I would refer to it at a later time.
  - Strongly agree
  - Agree
  - Neither agree or disagree

Please provide comments that support your rating about the **features** of this session. Include any suggestions you may to improve the **features** included in the session:

6) Valuable

- Overall, the information provided in this session is valuable to me.
  - Strongly agree
  - Agree
  - Neither agree or disagree
  - Disagree
  - Strongly disagree

- Overall, this session provided a deeper understanding of what fear of cancer recurrence is.
  - Strongly agree
  - Agree
  - Neither agree or disagree
  - Disagree
  - Strongly disagree

- I found the tools to manage fear of cancer recurrence to be valuable.
  - Strongly agree
  - Agree
  - Neither agree or disagree
  - Disagree
  - Strongly disagree

Please provide comments that support your rating about the **value** of this intervention. Include any suggestions you may have to improve the **value** of the session:

7) Readiness

- How ready is this session for use with caregivers of cancer patients who experience fear of cancer recurrence?
    - Extremely ready
    - Very ready
    - Moderately ready
    - Slightly ready
    - Not at all ready

- Do you think there is a satisfactory amount of information about fear of cancer recurrence in this session?
    - Yes
    - Maybe
    - No

- Do you think there is a satisfactory amount of tools to manage FCR in this session?
    - Yes
    - Maybe
    - No

Please provide comments that support your ratings about the **readiness** of this intervention, Include any suggestions you may have that would help make the information appear more **ready** for other caregivers:

8) Overall Satisfaction:

- How satisfied are you with this session?
    - Extremely satisfied
    - Very satisfied
    - Moderately satisfied
    - Slightly satisfied
    - Not at all satisfied

Please provide any additional feedback you have about your **overall satisfaction** with the session. Include any suggestions you may have to improve your **overall satisfaction** of the session:

9) General Comments:

- Do you think anything should be *added* to this session for it to better meet your needs?
    - Yes
    - Maybe
    - No

Please provide comments about what can potentially be **added** to better meet your needs:

- Do you think anything should be *deleted* from this session for it to better meet your needs?
    - Yes
    - Maybe
    - No

Please provide comments about what can potentially be **deleted** to better meet your needs:

- Do you think anything in this session should be *changed or reordered* for it to better meet your needs?
    - Yes
    - Maybe
    - No

Please provide comments about what can potentially be **changed or reordered** to better meet your needs:

Please provide any additional feedback you have about the session. If you do not believe it is **ready for use**, in what ways must it be modified to be ready?:

Session Feedback Questionnaire for Therapists

Thank you for reviewing the FC-FORT session #X!
The following questions will ask you about your experience with the session. Your feedback will help with modifications and updates to the final version of the online program.
This questionnaire will take you about X minutes to complete.

1) Useful

- I believe this session provided information that would help caregivers better understand their fear of cancer recurrence.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- I believe this session provided tools for caregivers to better manage their fear of cancer recurrence.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **usefulness** of this session. Include any suggestions you may have to improve **usefulness:**

2) Usable

- Caregivers would find this session to be user-friendly.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- Caregivers would be able to follow-along and understand this session with ease.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **usability/findability** of this session. Include any suggestions you may have to improve **usability/findability**:

3) Desirable

- Caregivers will think this session is visually appealing and the organization of information on the screen is clear. Caregivers would feel that the *way* the information was presented was a positive addition to the user experience.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **desirability** of this session. Include any suggestions you may have to improve **desirability**:

4) **Accessible**

- Caregivers will think that this session is easy to follow, and they will be able to absorb all the necessary information in this session.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- If this session was included with the rest of the FC-FORT online program, caregivers would be able to easily navigate this session and find all the relevant information.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

Please provide comments that support your rating about the **accessibility** of this session. Include any suggestions you may have to improve **accessibility**:

5) Features (e.g., Worksheets, Videos, and Supplemental Materials)

- Caregivers will find the relaxation audio files in this session helpful and will likely refer to them at a later time.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- Caregivers will find the activities (e.g. thought record) in this session helpful and will likely refer to them at a later time.
    - Strongly agree
    - Agree
    - Neither agree or disagree

- Caregivers will find the workbook section of this session helpful and will likely refer to it at a later time.
    - Strongly agree
    - Agree
    - Neither agree or disagree

Please provide comments that support your rating about the **features** of this session. Include any suggestions you may to improve the **features** included in the session:

6) Valuable

- Overall, the information provided in this session would be valuable to caregivers.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- Overall, this session will provide caregivers with a deeper understanding of what fear of cancer recurrence is.
    - Strongly agree
    - Agree
    - Neither agree or disagree
    - Disagree
    - Strongly disagree

- Caregivers will find the tools to manage fear of cancer recurrence to be valuable.
    - Strongly agree
    - Agree
    - Neither agree or disagree

- Disagree
- Strongly disagree

Please provide comments that support your rating about the **value** of this intervention. Include any suggestions you may have to improve the **value** of the session:

7) Readiness

- How ready is this session for use with caregivers of cancer patients who experience fear of cancer recurrence?
  - Extremely ready
  - Very ready
  - Moderately ready
  - Slightly ready
  - Not at all ready

- Do you think there is a satisfactory amount of information about fear of cancer recurrence in this session?
  - Yes
  - Maybe
  - No

- Do you think there is a satisfactory amount of tools to manage fear of cancer recurrence in this session?
  - Yes
  - Maybe
  - No

Please provide comments that support your ratings about the **readiness** of this intervention. Include any suggestions you may have that would help make the information appear more **ready** for caregivers:

8) Overall Satisfaction

- How satisfied are you with this session?
  - Extremely satisfied
  - Very satisfied
  - Moderately satisfied
  - Slightly satisfied
  - Not at all satisfied

Please provide any additional feedback you have about your **overall satisfaction** with the session. Include any suggestions you may have to improve your **overall satisfaction** of the session:

9) General Comments:

- Do you think anything should be *added* to this session for it to better meet caregivers' needs?
    - Yes
    - Maybe
    - No

Please provide comments about what can potentially be **added** to better meet caregivers' needs:

- Do you think anything should be *deleted* from this session for it to better meet caregivers' needs?
    - Yes
    - Maybe
    - No

Please provide comments about what can potentially be **deleted** to better meet caregivers' needs:

- Do you think anything in this session should be *changed or reordered* for it to better meet caregivers' needs?
    - Yes
    - Maybe
    - No

Please provide comments about what can potentially be **changed or reordered** to better meet caregivers' needs:

- Do you think there is a need for this type of program (e.g., are there caregivers looking for this type of intervention)?
    - Yes
    - Maybe

- No

Please provide comments about the need for this type of program (e.g., are there caregivers looking for this type of intervention):

Please provide any additional feedback you have about the session. If you do not believe it is **ready for use**, in what ways must it be modified to be ready?:

APPENDIX D: INTERVIEW GUIDE (USABILITY AND PILOT STUDIES)

This interview is being conducted as part of a study to evaluate the FC-FORT. My goal is to understand as deeply as I can your own experience as a participant in this group program. Please don't feel rushed and take your time to answer my questions. We can always reschedule the interview if you feel unable to fully participate today. Please know that you may stop the interview, or discontinue your participation in the study at any time.

EXPECTATIONS: How did you hear about this group? Can you tell me why did you decide to participate in this group? Before you started the group, what were your expectations? How did you hope to benefit from this group? Did you have any hesitations or concerns about the group before it began? How did you feel about the fact that this is an online group? Was the group what you expected? In what way?

GENERAL IMPACT: How did the group impact your fear of recurrence or your experience as a caregiver in general, if at all? Do you see an impact on other aspects of your life? How so? How important has the group been for you (on a scale from 1-10)? Please explain. Would you recommend it to others? (why and why not). How do you think the online format impacted your experience in this group, if at all?

HELPFUL SEGMENTS: Overall, how helpful do you think the group was for you? Which parts of the group did you find most helpful and what made them so? What was it about the group sessions/skills that made them helpful? Is there a session/skill that you remember as particularly helpful? What made it helpful?

UNHELPFUL SEGMENTS: Was there anything about the group that was not helpful? If so, which parts and what made them unhelpful? Is there a session or a skill that you remember as particularly unhelpful? What made it unhelpful? What were the main challenges for you?

GROUP COHESTION: Did you feel connected to the therapists and/or the other group members? What do you think helped or hindered your sense of connection? How do you think the online format impacted your sense of connection, if at all?

TIMING AND LENGTH: What about the timing in which the group was offered to you – e.g., do you think the group could have benefited you more if offered at a different time? Was the length of the sessions appropriate? How about the length of the whole group?

HOMEWORK PRACTICE: During the group did you manage to do the homework practice? How often? Were there some practices and exercises easier to do than others? Is there anything that might have made a practice easier to do?

USING WHAT YOU LEARNED: Have you continued to practice what you have learned? If so, which practices do you continue to use? How often? What are the challenges in doing so? What makes it possible?

SUGGESTIONS: Is there anything about this group that can be improved? Is there anything else that can be added to our group that would benefit you? Would you have preferred to have this group offered in-person? (why or why not).

OTHER SUPPORT: Were you seeking or participating in other similar groups before or while participating in this group? (if yes, ask for details). If so, what was different about this group? (for better or worse)

APPENDIX E: PARTICIPANT INFORMED CONSENT FORM (PILOT STUDY) – UNIVERSITY OF OTTAWA

Title of the study:	**It's time to address fear of cancer recurrence in the family caregiver: adaptation, feasibility, and acceptability study of an online version of the Fear Of Recurrence Therapy (FORT) for family caregivers.**
Co-Principal Investigators:	Dr. Sophie Lebel, School of Psychology, Faculty of Social Sciences, University of Ottawa (Ottawa). Dr. Rinat Nissim, Cancer Clinical Research Unit (CCRU), Princess Margaret Cancer Centre, University Health Network (Toronto).
Research Coordinator:	Jani Lamarche, School of Psychology, Faculty of Social Sciences, University of Ottawa (Ottawa).
Funding source:	University of Ottawa

Invitation to Participate: I am invited to participate in the abovementioned research study conducted by Dr. Sophie Lebel and Dr. Rinat Nissim.

Participation in this study is voluntary. Please read this Participant Informed Consent Form carefully before you decide if you would like to participate. Ask the study team as many questions as you like.

Purpose of this study: The purpose of the study is to adapt the Fear of Recurrence Therapy (FORT), previously validated with cancer survivors, for family caregivers using an online format, to test its feasibility and acceptability and to estimate the clinical significance of this adaptation on fear of cancer recurrence and other outcomes. This study is the first to target fear of cancer recurrence in family caregivers.

To make our intervention feasible for family caregivers, we will offer the intervention via an online videoconferencing format, in partnership with Cancer Chat of the de Souza Institute, a national provider of online therapist-led support groups for cancer survivors and FC.

Study design: The proposed study is a multicentre randomized controlled trial, designed to compare an online psychotherapy group intervention (FORT) to a waitlist control group of female family caregivers who care for their loved ones with cancer and are suffering from fear of cancer recurrence. Upon determining that you are eligible to participate, you will be randomly assigned by chance to

receive the psychotherapy group intervention immediately or at a later date (after three months). Each participant will have an equal chance of being selected for either group (50:50).

Participation: If you are chosen to receive the intervention immediately, your participation will consist essentially of attending an online pre-therapy meeting with one of the study therapists, a weekly online group therapy session of 120 minutes each for 7 weeks, during which you will be asked to participate in activities, participate in group discussions, and complete homework. You will also be asked to complete a 20-minute questionnaire package before starting the therapy, immediately after the last session, and 3 months later. The questionnaires assess your fear of cancer recurrence, the psychological impact of cancer, uncertainty, coping, and quality of life. You will also be asked to complete measures after the first session and fourth sessions. These measures assess group cohesion and your relationship with the group facilitators. You may skip any questions that make you uncomfortable or that you do not wish to answer. You will also be asked to participate in a brief audio recorded telephone exit interview with the research coordinator (30 mins to 1 hour).

If you are chosen to be in the waitlist control group, your participation will consist essentially of attending an online pre-therapy meeting with one of the study therapists and completing a 20-minute questionnaire package at the start of the study, after 7 weeks and at a 3-month follow-up. The questionnaires will assess your fear of cancer recurrence, the psychological impact of cancer, uncertainty, coping, and quality of life. 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 online psychotherapy group intervention (FORT). At that point, you will not be asked to complete additional questionnaires nor an exit interview.

All intervention sessions will be video-recorded and reviewed by members of the research team to make sure the therapy is given to you as intended. 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.

Length of involvement in the study: The entire study will last approximately 3 years. Your participation in the study will last approximately 6 months.

Risks: Your participation in this study will entail that you volunteer very personal information, and this may cause you to experience a heightened anxiety during your participation in the group session. You have the assurance of the researcher that every effort will be made to minimize these risks. If you experience any discomfort, please discuss this in session or with the facilitators. The Co-PIs and group leaders will be responsible for facilitating referrals for individual counselling within the psychosocial oncology programs of the recruiting sites.

To ensure your physical and psychological safety throughout the study, we require that you please provide the following emergency contact information:

Telephone Number (best number to reach you): _____
Address (from which you'll be joining the group sessions): _____

Emergency contact

Full Name: _____
Relation: _____
Telephone Number (best number to reach them): _____

Benefits: Your participation in this study may result in a decrease of your fear of cancer recurrence, and an increase in your quality of life and your coping. Furthermore, your participation in this study will help bridge an important gap in bringing evidence-based care to family caregiver who have never been offered help before for their fear of cancer recurrence.

Confidentiality and anonymity: The information you will share will remain strictly confidential. In order to minimize the risk of security breaches and to help ensure your confidentiality we recommend that you use standard safety measures such as signing out of your account, closing your browser and locking your screen or device when you are no longer using them / when you finish a session.

How is my personal information being protected?

- All information collected during your participation in this study will be identified with a unique study number, and will not contain information that identifies you, such as your name, address, etc.
- The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave Dr. Sophie Lebel's laboratory at the University of Ottawa.
- Anything said between any two or more group members at any time is part of the group and is confidential. Everything said in this group is confidential and is not to be shared with anyone outside of the group.
- Members of the group agree to keep confidential the names of other members of the group and what is said in the group. As a member of this group, you agree to not disclose to anyone outside the group any information that may identify another group member. This includes, but is not limited to, names, physical descriptions, biological information, and specifics to the content of interactions with other group members.
- Under the professional and ethical norms of conduct of the Ontario College of Psychologists, confidentiality may be broken in very specific situations, such as:
    1. Disclosures of imminent danger to yourself or others
    2. Disclosures of information about a child in need of protection
    3. Disclosures of sexual abuse by a health professional
    4. Disclosures of inappropriate or incompetent treatment or care of a resident in a long-term care facility that caused pre-injury or risk of harm to the resident
    5. Summons of documents as provided for in court order.
- Any documents or samples leaving The University of Ottawa or the University Health Network will contain only your unique study number. This includes publications or presentations resulting from this study.
- Session history (in text format) will be saved in the University Health Network system and detached from individual information. For more information, please visit

https://www.uhn.ca/PatientsFamilies/Patient_Safety_Advocacy/Privacy/Pages/privacy_policy.aspx

- For audit purposes only, your original study records may be reviewed by the University of Ottawa Ethics Board.

Conservation of data: The data collected (questionnaire package, database, consent form, recorded exit-interviews, transcripts and relevant notes*)* will be kept in a secure manner. As such, the electronic data will be stored on a password protected computer in Dr. Sophie Lebel's locked laboratory at the University of Ottawa. The session histories (in text format) will be saved in the University Health Network firewall protected system where only the Cancer Chat team, the session facilitators and Co-Principal Investigators will have access. Recorded video sessions will be recorded through Zoom on Dr. Sophie Lebel's work computer and moved to the University of Ottawa's secure OneDrive virtual cloud. Video sessions will be deleted immediately after the transfer has been made to the OneDrive virtual cloud. Only Dr. Sophie Lebel and her research coordinator will have access to this OneDrive account. When possible, files will be password protected in the University of Ottawa's OneDrive virtual cloud. Additionally, all paper documents will be stored in a locked file cabinet inside the locked laboratory. Only the research team and the research coordinator will have access to this data. The data will be kept in Dr. Sophie Lebel's laboratory and on the University Health Network system for a retention period of 10 years. After the 10 years, the data will be safely disposed of by either shredding the paper documents or by permanently deleting the data from the laboratory's computer and the University Health Network system.

Compensation: You will be compensated ($20) every time you complete this study's questionnaire package (total of three times). If you choose to withdraw from the study, you will only receive compensation for the number of times you completed the questionnaire package.

Voluntary Participation: You are under no obligation to participate and if you choose to participate, you can withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you withdraw your consent, the study team will no longer collect your identifying information for research purposes. All questionnaires are assigned by participant number in order to increase anonymity. Only the members of the research team will have access to this information. If you choose to withdraw, all data gathered until the time of withdrawal will be destroyed in the manner described above.

Will I be informed about any new information that might affect my decision to continue participating?

You will be told in a timely fashion of any new findings during the study that could affect your willingness to continue in the study. You may be asked to sign a new consent form.

Consent to Participate in Research

- I understand that I am being asked to participate in a research study about fear of cancer recurrence.
- This study was explained to me by _____.
- I have read, or have had it read to me, each page of this Participant Informed Consent Form.
- All of my questions have been answered to my satisfaction.
- If I decide later that I would like to withdraw my participation and/or consent from the study, I can do so at any time.
- I voluntarily agree to participate in this study.
- I will be given a copy of this signed Participant Informed Consent Form.

If you have any questions about this study, please contact the co-principal investigators, Dr. Sophie Lebel or Dr. Rinat Nissim.

If you have any questions regarding the ethical conduct of this study, you may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5

Tel.: (613) 562-5387

Email: ethics@uottawa.ca

There are two copies of the consent form, one of which is mine to keep.

_____	_____	_____
Participant's Printed Name	Participant's Signature	Date

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 F: PARTICIPANT INFORMED VERBAL CONSENT FORM (PILOT STUDY) – THE OTTAWA HOSPITAL

Verbal Consent Script

Study Title: It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Feasibility and Acceptability Study of an Online Version of the Fear of Recurrence Therapy (FORT)
Principal Investigator: Dr Cheryl Harris
OHSN-REB Number: 20230147-01H
University of Ottawa REB Number: H-05-20-5584

Participant name:	**Person calling:**
Date Called:	**Time Called:**

Hello, may I please speak with [name of the potential participant].

***If respondent asks who the caller is:**
If speaking to someone other than the potential participant or SDM, limited information about the study should be provided as information about the study could reveal personal health information.
My name is [name of caller] and I am calling from [The Ottawa Hospital and/or The University of Ottawa (choose most appropriate answer depending on participant)] about a research study.

***If potential participant is unavailable:**
Do not leave a message regarding call back information as this may reveal personal health information.
Is there a better time to call back? Date/time:

***If potential participant indicates they are not interested:**
Thank you for your time. Goodbye.

***If potential participant is respondent:**
Continue with script below

This is [name of caller] calling from [The Ottawa Hospital and/or The University of Ottawa (choose most appropriate answer depending on participant)].

Is this an ok time to talk?

☐ No ***If no** → Is there a better time? Date/time:
☐ Yes ***If yes** → *Continue with script below*

The study is being conducted by Dr. Cheryl Harris at The Ottawa Hospital, Dr. Sophie Lebel at The University of Ottawa and Dr. Rinat Nissim at the University Health Network.

You are a candidate for this research because you are a caregiver of an adult cancer survivor, who has finished their treatment and has not had a recurrence in their cancer.

The goal of the research study is to evaluate the feasibility and acceptability of a newly adapted virtual intervention aimed at addressing fear of cancer recurrence in family caregivers (Family Caregiver - Fear Of Recurrence Therapy [FC-FORT]).

Are you willing to hear more about the study?

☐ No ***If no →** Thank you for your time. Goodbye
☐ Yes ***If yes →** *Continue with script below*

I am now going to read some important information about our study. Please feel free to stop me to ask questions at any time.

Conflicts of Interest:
There are no conflicts of interest to declare related to this study.

Design of the Research Study:
Our study is a two-group, randomized, controlled-trial with blind assignment to group. This means that you are put into a group by chance (like flipping a coin). Neither you, nor the research team can choose the group you will be in. You will have an equal (50:50) chance of being assigned to either of the programs (the intervention program or control program). The purpose of randomization is to ensure that those receiving the study intervention and those who are not are identical in every other respect. That way, we can be sure that any differences we observe between the two group are due to the study intervention and nothing else. If you were randomized to the control program, at the end of your 6-month participation, you will be asked if you wish to complete the intervention program.

Research Activities:
If you are randomized in the intervention group, your participation in the study would involve:

- Attending weekly online group therapy session of 120 minutes each for 7 weeks. During these sessions, you will be asked to participate in activities, group discussions, and complete homework.

- Completion of 1 exit interview. During the interview, you will meet with a member of the research team. Each interview will be about 30-60 minutes in length and will take place virtually. You will be asked to speak about your overall experiences with the Family Caregiver – Fear Of Recurrence Therapy intervention and group therapy.

- Completion of 3 questionnaire packages before starting the therapy, immediately after the last session, and 3 months later. The purpose of the survey/questionnaire is to assess your fear of cancer recurrence, the psychological impact of cancer, uncertainty, coping, and quality of life. Each survey/questionnaire will take about 20 minutes to complete. In addition, you will be asked to complete measures (approximately 10 minutes) after the first, fourth

and seventh sessions. These measures assess group cohesion and your relationship with the group facilitators.

The questionnaire packages and measures are administered online via a link that will be sent to your email address.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

If you are randomized in the control group, your participation in the study would involve:

- Completion of 3 questionnaire packages at the start of the study, after 7 weeks, and 3 months later. The purpose of the survey/questionnaire is to assess your fear of cancer recurrence, the psychological impact of cancer, uncertainty, coping, and quality of life. Each survey/questionnaire will take about 20 minutes to complete.
  The questionnaire packages and measures are administered online via a link that will be sent to your email address.

  The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

- After three months, you will be offered the chance to receive the online psychotherapy group intervention (FORT). At that point, you will not be asked to complete additional questionnaires nor an exit interview.

You will be audio and video recorded throughout all of the sessions and exit interview for research purposes.

Do you have questions about the activities this study involves?

☐ No ***If no →** *Continue with script below*

☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Voluntary Participation and Withdrawal:

Taking part in this study is voluntary.

You have the option to not participate at all, or you may choose to leave the study at any time (this is called withdrawal), without having to provide a reason.

Do you have questions about the voluntary nature and ability to withdraw from of this study?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Potential Risks, Harms, Discomforts:

Taking part in this study may make you feel uncomfortable. You may become uncomfortable while discussing your experiences. You may choose not to answer questions or leave the group or exit interview at any time if you experience any discomfort.

You have the assurance of the research team that every effort will be made to minimize these risks. If you experience any discomfort, please discuss this in session or with the facilitators. The study investigators and group leaders will be responsible for facilitating referrals for individual counselling within the psychosocial oncology programs of the recruiting sites.

While the study team will take precautions to protect your confidentiality, we cannot guarantee that other members of the focus group will respect your privacy or keep the discussions of the group confidential. For this reason, you should avoid using names of other people when describing scenarios or experiences.

Do you have questions about the potential risks this study involves?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Potential Benefits:

If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you. Your participation in this study may result in a decrease of your fear of cancer recurrence, and an increase in your quality of life and your coping. Furthermore, your participation in this study will help bridge an important gap in bringing evidence-based care to family caregiver who have never been offered help before for their fear of cancer recurrence.

We hope the information learned from this study will help other people living with fear of cancer recurrence in the future.

Do you have questions about the potential benefits this study involves?

☐ No ***If no →** *Continue with script below*

☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Privacy/Confidentiality:

If you decide to participate in this study, we will only collect the information needed for this study.

Records identifying you at this center will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) research records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The University of Ottawa, the Sponsor of this study; and to oversee the conduct of research at this location
- The University of Ottawa Health Sciences and Science REB who oversees the ethical conduct of this study
- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
- Ottawa Hospital Research Institute to oversee the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your unique study number (participant code).

This research study is collecting information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond. Providing information on your race or ethnic origin is voluntary.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

During the discussions, you will be encouraged to refrain from using names. If names or other identifying information is shared during the discussion, it will not be included in the written records.

The audio/video recordings will be stored in a secure location at the University of Ottawa and listened to/viewed only by members of the research team. The recordings will be kept until they have been transcribed (turned into written records), and then they will be destroyed.

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 used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Do you have questions about the how your privacy will be protected?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Cost to participation:

Participation in this study will not involve any additional costs to you.

Payment or Reimbursement:

If you decide to participate in this study, you will receive a virtual $20 gift card of your choosing (from either coffee shops, grocery & retail stores, or Amazon) every time you complete one of the study's questionnaire packages (three packages for a total of $60). If you choose to withdraw from the study, you will only receive compensation for the number of times you completed the questionnaire package. The gift card will be sent to you by email after completion of all the questionnaire packages.

Do you have questions about the costs of participation or payment/reimbursement?

☐ No ***If no →** *Continue with script below*
☐ Yes ***If yes →** *Answer questions and document all questions and answers before continuing with script below*

Questions: _____

Answers: _____

Other Comments: _____

Participant Rights:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Questions:

In case you have any questions, here are some contact numbers that are good to have. Do you have a pen and paper ready?

For questions about your rights as a research participant or about ethical issues related to the study, you can contact The Ottawa Health Science Network Research Ethics Board at 613-798-5555, extension 16719, and speak to someone who isn't involved in the study at all.

If you have any questions regarding the ethical conduct of this study, you may contact the Protocol Officer for Ethics in Research at:
University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5
Tel.: (613) 562-5387
Email: ethics@uottawa.ca

I can answer any questions that you may have about the research study right now, but if you think of additional questions later on, you can contact the Principal Investigator, Dr Cheryl Harris.

Have all of your questions been answered?

☐ No ***If no →** *Answer questions and document all questions and answers*

before continuing with script below

Questions: _____

Answers: _____

Other Comments: _____

☐ Yes ***If yes →** *Continue with script below*

If I decide later that I would like to withdraw my participation and/or consent from the study, I know that I can do so at any time.
☐ _Yes ☐ _No

Consent:

Based on the description of the study, would you like to participate? Or would you like some time to think about it?

☐ No ☐ Yes ☐ More time to think about it

***If they do not want to participate:** Thank you for your time. Goodbye.

***If they do want to participate:** *Continue with script below*

***If they would like more time:** *Continue with script below*

For your records and/or to help in making your decision, I can send you the Information Sheet via MyChart, mail or email. What is your preference?

☐ MyChart

☐ Mail

***If Mail**: Record and confirm address: _____

☐ Email (as a link [Microsoft 365 SharePoint/OneDrive, TOH Methods Centre Electronic Data Capture System, DocuSign, etc.] or password protected attachment)

***If Email:** Before I can initiate email contact with you, I'm required to inform you of the risks associated with use of email. I'm going to read a series of statements to you. Please stop me at any time if you have questions.

Read the 'Research Participant Consent to Communicate by Email'

Discussed on: _____/____/____ Time: _____ hours

Consenting Process completed by: _____ Date: _____/____/____

Record and confirm email address: _____

***If they wanted more time:** When would be a good time for me to call you back to answer any further questions you may have and obtain your decision? Date/time:

For the purposes of the group, we will be using email to communicate with you to send you the group materials, reminders, and the links for the virtual group meetings. Do we have your permission to contact you via email?

No – No problem! Unfortunately, that will limit your participation in the study (i.e., may not receive all the materials). Are there any specific concerns that I can address? (Research assistant records participant's choice and, if appropriate, addresses participants' concerns).

If participant does not want to share email address:
Do we have your permission to contact you via phone?

Yes – Perfect! (Research assistant records participant's choice and takes down contact information).

Wrap up with a reminder of the next steps and end the call.

Documentation of Verbal Consent

Study Title: It is Time to Address Fear of Cancer Recurrence in Family Caregivers: Feasibility and Acceptability Study of an Online Version of the Fear of Recurrence Therapy (FORT)

OHSN-REB Number: 20230147-01H
University of Ottawa REB Number: H-05-20-5584

Name of Participant: _____

Date of Discussion: _____

Duration of Discussion: _____

SIGNATURES

- The participant's questions have been answered,
- The participant understands the information within this Verbal Consent Script,
- Each page of the Verbal Consent Script has been read to the participant.
- The participant agrees to take part in this study.

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.

Consent was obtained prior to any study-specific procedures ____.

_____	_____	_____
Signature of Person Conducting Consent Discussion	Printed Name and Role	Date