A Psychoeducational Intervention for People Affected by Pancreatic Cancer

by

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Abstract

The two aims of this thesis were to: (1) develop an interdisciplinary psychoeducational intervention for people affected by pancreatic cancer; and 2) evaluate the feasibility, acceptability, and preliminary efficacy of its implementation. All stages of research were informed by implementation science principles. In Study One, we developed *Living Well with Pancreatic Cancer*—an empirically-based, single session, manualized group intervention focused on supportive care needs in pancreatic cancer. Study Two was a mixed methods study to examine early phase implementation of our intervention in a pancreatic oncology clinic. Content and delivery were acceptable to patients, caregivers, and health care professionals (HCPs). Benefits included improved relationships with HCPs and knowledge of palliative and supportive care. Implementation was feasible, facilitated by stakeholder commitment and research support; however, additional human resourcing is required for sustainability. This research presents an innovative approach to operationalize supportive care and promote uptake of complex interventions into practice.

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Contributions

The completion of this Master's thesis was made possible by many contributors.

This study was designed by me and members of my program advisory committee: Dr. Gary Rodin, Dr. Chris Lo, Dr. Gerald Devins, Dr. Camilla Zimmermann, and Dr. Steven Gallinger. Dr. Gary Rodin served as the Principal Investigator for this study at the University Health Network.

I wrote the Research Ethics Board proposal submitted to the University Health Network, with the support of Dr. Amy Deckert, Anne Rydall, Dr. Chris Lo, Dr. Gary Rodin, and input from Anna Dodd. Dr. Chris Lo and I developed one of the questionnaires used in this study, *Psychoeducation Knowledge Questionnaire*.

The intervention content was developed by myself along with Shari Moura, Kelly Antes, Sarah Buchanan, Ali Henderson, and Louise Lee, with conceptual oversight provided by Dr. Gary Rodin and Dr. Chris Lo. Shari Moura, Kelly Antes, Sarah Buchanan, and other members of the clinical and research team at the Wallace McCain Centre for Pancreatic Cancer introduced the intervention and study to their patients and families. Administrative support was provided by Venissa Kamtapersaud. I recruited the patients, family caregivers, and health care professionals into the study and completed interviews. I conducted all qualitative and quantitative data analyses and wrote the thesis document, with support from Dr. Amy Deckert (second coder) and guidance from Dr. Chris Lo and Dr. Gary Rodin. Additional input was provided by my committee members, Dr. Gerald Devins, Dr. Camilla Zimmermann, and Dr. Steven Gallinger. Amy Chen, an undergraduate student, helped in the data entry and transcription of interview data in this project.

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Table of Contents

List of Abbreviations

CFIR	*Consolidated Framework for Implementation Research*
EOL	*End-of-life*
FAMCARE	*Family Satisfaction with Advanced Cancer Care*
HCP	*Health care professional*
KTA	*Knowledge-to-Action*
MUIS-C	*Mishel Uncertainty in Illness Scale Community Form*
PARiHS	*Promoting Action on Research Implementation in Health Services*
PKQ	*Psychoeducation Knowledge Questionnaire*
PM	*Princess Margaret Cancer Centre*
REB	*Research Ethics Board*
UHN	*University Health Network*
WHO	*World Health Organization*
WMCPC	*Wallace McCain Centre for Pancreatic Cancer*

List of Tables

List of Figures

List of Appendices

Chapter 1: Introduction

There have been great strides in cancer care in broadening the focus from the disease itself to the whole person and the illness experience, including that of the family. In this spirit, there is increased recognition for the need to integrate palliative and supportive care into routine care to support people affected by advanced cancer (Holland, Watson, & Dunn, 2011; Ferrell et al., 2017). Despite calls for such comprehensive cancer care, there is still a pressing need for the development and integration of sustainable and standardized ways to provide supportive care within the disease course. Psychoeducation offers a promising means to address this challenge. There has been interest in leveraging the potential of psychoeducation as a feasible and sustainable way to weave psychosocial care into medical care (Garchinski, DiBiase, Wong, & Sagar, 2014; Schofield & Chambers, 2015; Sagar, 2016). This treatment modality has been used widely in a range of clinical settings, and has been established as an adjunctive treatment for cancer (Lukens & McFarlane, 2004). The psychoeducation model is also amenable to be included within a tiered or stepped model of psychosocial care delivery, by representing the first level of supportive care (Hutchison, Steginga, & Dunn, 2006). To date, however, the application and tailoring of psychoeducational interventions to help support people facing advanced cancer has received limited attention in the literature.

Pancreatic cancer, regardless of stage, has one of the worst prognoses of all cancers, with a 5 year survival rate of just 8% (Canadian Cancer Society, 2017). The majority of patients present with advanced and unresectable disease at diagnosis. The clinical management of patients affected by pancreatic cancer is complex, given the high symptom and disease burden. The informational and supportive care needs for people are high (Beesley et al., 2016a), and efforts to address these early in the disease course can help reduce uncertainty and promote preparedness. The rapidity of disease onset and deterioration, coupled with the complex physical and psychosocial needs, firmly establish the need to prioritize palliative and supportive care in this population (Ducreux et al., 2015; Sohal et al., 2016). This is critical to improve quality of life and quality of care, relieve suffering, and help in planning for the future. Indeed, there have been calls for innovative ways to provide psychosocial support for people affected by pancreatic cancer (Beesley et al., 2016a).

Taken together, further research is necessary to develop standardized, evidence-based, tailored, and feasible supportive care models, to help further operationalize supportive care in oncology. Research to contribute to such efforts may be best initiated in a population with relatively homogeneous survival rates, such as that of pancreatic cancer. This will require a collaborative approach to appropriately tailor interventions to pancreatic cancer, and should include comprehensive evaluations of feasibility, acceptability, and efficacy. A focus on implementation strategies is also imperative, given the current emphasis in health care towards optimizing intervention uptake and sustainability in clinical practice.

Chapter 2: Literature Review

2.1 Pancreatic Cancer

With a mortality rate that is the highest of all major cancers and that is closely paralleled with its incidence, pancreatic cancer is a highly fatal disease. It is the 4th leading cause of cancer-related death in North America and has a median survival of 4.6 months, with less than 10% of patients surviving past 5 years (Canadian Cancer Society, 2017; Carrato et al., 2015). These figures have remained static over the last 30 years. In the near future, pancreatic cancer is projected to become the second leading cause of cancer-related death in the United States (Rahib et al., 2014), third in Canada (Canadian Cancer Society, 2017), with overall mortality rates rising globally (International Agency for Research on Cancer, 2008). Although partly due to our aging population, the increase in pancreatic cancer mortality differs from almost any other solid tumour malignancy, which has plateaued or declined over the years.

In 2017, there were an estimated 5,500 new cases of pancreatic cancer diagnosed and 4,800 deaths in Canada (Canadian Cancer Society, 2017). The incidence and mortality rates are similar in men and women, with 2,800 new cases and 2,400 deaths in men, and 2,700 new cases and 2,400 deaths in women annually. Thus far, efforts at primary disease prevention or early detection have had limited success. There are a few known risk factors associated with pancreatic cancer, including age (≥60), family history or familial risks (*e.g., BRCA2*, *CDKN2A* or *P16*), cigarette smoking, excess body weight and obesity, heavy alcohol consumption, and history of medical condition (*e.g.,* diabetes and pancreatitis) (Kamisawa, Wood, Itoi, & Takaori, 2016). However, the proportion of cases caused by these risk factors is relatively small and the modifiable risk factors are not well understood, thereby limiting the advancement of prevention efforts.

Low survival rates are also largely attributed to the diagnosis of pancreatic cancers at a late and advanced stage. As the pancreas lies deep within the abdomen, cancers of its origin can grow and develop without causing any symptoms. Pancreatic cancer is therefore often not detected until the development of symptoms associated with tumour growth. Pancreatic cancer also disseminates to distant sites early in its natural history. The majority of people (80-85%) present with inoperable disease (locally advanced or metastatic) upon diagnosis. For these individuals, systemic combination chemotherapy, including FOLFIRNOX or Gemcitabine/nab-Paclitaxel, is the mainstay of treatment, resulting in a median survival of approximately 8-12 months (Von Hoff DD et al., 2013; Jo et al., 2014). However, there are currently no targeted therapies or immunotherapeutic strategies available to significantly improve survival. Only 15-20% of people are suitable for initial surgical resection, which remains the only curative option for pancreatic cancer. Even after a potentially curative surgery and followed by adjuvant chemotherapy, most patients eventually have recurrence and median survival is still poor at an estimated 23 months (Neoptolemos et al., 2010).

2.2 Physical Symptoms and Treatment Effects

People with pancreatic cancer often present with vague and nonspecific symptoms, such as upper abdominal, epigastric and/or back pain, painless jaundice, weight loss, anorexia, and changes in bowel patterns (Kanji & Gallinger, 2013). As disease progresses, further symptoms and systemic manifestations reflect the pathophysiology of pancreatic cancer, including loss of pancreatic function or obstruction of nearby structures. Pain affects around 80% of patients and its etiology is multifactorial (Kanji & Gallinger, 2013). It may be experienced as antecedent abdominal, back, or shoulder pain; neuropathic pain, especially with infiltration of the peri-pancreatic nerves and celiac plexus; related to comorbid depression; and as a debilitating symptom that continues as disease progresses. Significant, unintended weight loss in pancreatic cancer is often due to cancer anorexia-cachexia syndrome, pancreatic exocrine insufficiency, and side effects from treatment such as loss of appetite, and nausea and vomiting. Stabilization of weight loss is important in the management of pancreatic cancer as it can improve quality of life and prolong survival (Davidson, Ash, Capra, Bauer, & Cancer Cachexia Study Group, 2004; Bachmann et al., 2008).

Other common symptoms include nausea and vomiting, loss of appetite, fatigue, changes in bowel habits, diarrhea and constipation, hyperglycemia, and steatorrhea (Labori, Hjermstad, Wester, Buanes, & Loge, 2006; Kanji & Gallinger, 2013; Keane, Horsfall, Rait, & Pereira, 2014; Tang, Von Ah, & Fulton, 2018). Loss of appetite has been reported to be one of the most distressing symptoms, yet is also one that is often minimized by health care professionals (HCPs) (Tang et al., 2018). The management and experience of appetite loss is particularly complicated in this population due to its association with treatment effects, cachexia, pancreatic exocrine insufficiency, and depression. For people who received chemotherapy, fatigue, cognitive changes, and neuropathy were among the most commonly reported symptoms (Frick et al., 2017). Common side effects following radiotherapy for pancreatic cancer include hematologic toxicities, vomiting, and liver dysfunction (Cohen et al., 2005).

2.3 Psychosocial Effects and Informational Needs

2.3.1 Patients

The psychosocial sequelae of pancreatic cancer are significant for both patients and caregivers affected. It is well established that patients with pancreatic cancer suffer from elevated psychological distress compared to patients with other types of cancer (Fras, Litin, & Pearson, 1967; Holland et al., 1986; Shakin & Holland, 1988; Zabora, BrintzenhofeSzoc, Curbow, Hooker, & Piantadosi, 2001; Jia et al., 2010; Clark, Loscalzo, Trask, Zabora, & Philip, 2010). Some studies have reported that men with pancreatic cancer have depression and distress ratings equal to or higher than women with pancreatic cancer (Holland et al., 1986; Clark et al., 2010). There has been longstanding speculation about the association between pancreatic cancer and psychological symptoms and the potential for shared pathophysiological factors (Yaskin, 1931; Green & Austin, 1993; Passik & Breitbart, 1996; Passik & Roth, 1999; Boyd & Riba, 2007). Informed speculations arise from clinical presentation of psychiatric symptoms prior to diagnosis and reports of comorbidity between pancreatic cancer and psychiatric symptoms, yet specific associations and confirmatory data have not been established. The diagnosis and management of an advanced and progressive disease such as pancreatic cancer also pose challenges to one's self identity, and the re-negotiation of self identity can be an ongoing adaptive process in relation to previous roles and relationships (Gibson et al., 2016). Moreover, the onset of a serious illness such as pancreatic cancer introduces threat and uncertainty, and high uncertainty in the illness experience can considerably affect one's ability to process information and adapt to the realities of disease (Berylne, 1977; Mishel, 1990). Further in-depth explorations of psychological symptoms and distress remain underexplored in this population.

In recent years, there has been increasing attention to the informational and supportive care needs of people affected by pancreatic cancer. In a population-based case control study conducted in Australia, people diagnosed with pancreatic cancer rated their need for support across five domains: psychological wellbeing, physical functioning and daily living, information, clinical care, and sexual health (Beesley et al., 2016a). The overall levels of supportive care needs were high, spanned across multiple domains, and were mostly the same for people with and without non-resectable disease. Physical function, activities of daily living, and relief from fatigue and pain were rated as requiring the greatest need for support. Almost all participants reported psychosocial needs that were currently unmet by services, including concerns and worry for loved ones, feeling uncertainty about the future and a lack of control. High levels of unmet needs for information about disease and symptom management, assistance for family members, and practical concerns, were also reported. Further, high unmet needs persisted over time at 2- and 4-month follow-ups, and pain and anxiety were identified as risk factors for unmet needs (Beesley et al., 2016b). These results suggest that pain and psychological distress may be inadequately addressed and/or highlight their association with rapid disease progression. Insufficient information about the disease and its management and perceived difficulties in communicating with HCPs can further exacerbate the distress and uncertainty of diagnosis (Rodin et al., 2009; Gooden, Tiller, Mumford, & White, 2016; Beesley et al., 2016a).

In a needs assessment study of patients who were awaiting surgery or had undergone surgery for hepato-pancreato-biliary cancers, including pancreatic cancer, the desire for medical or physical information was deemed to be most important (Gillespie, Kacikanis, Nyhof-Young, Gallinger, & Ruthig, 2017). Examples included information about how to manage pain and other symptoms, possible side effects, and interpretation of medical test results. Face-to-face discussions with HCPs was the preferred education modality in studies of people affected by gastrointestinal cancer and advanced cancer (Wong et al., 2002; Papadakos et al., 2014).

One unmet supportive care need that has been shown to be a source of considerable distress for people affected by pancreatic cancer is management of complex dietary issues (Gooden & White, 2013). Using a qualitative inquiry framework, Gooden and White (2013) examined in detail individuals' difficulties with managing complex gastrointestinal symptoms and its marked impact on quality of life. These difficulties were perceived to be related to a lack of information and access to dietary HCPs. These findings highlight the need for an increased focus on symptom management of dietary and gastrointestinal symptom distress within pancreatic cancer care. Consistent with these findings, a survey study conducted with people treated for resectable pancreatic adenocarcinoma reported that most patients were interested in exercise and diet intervention programming, with an emphasis on improving quality of life and physical function (Arthur et al., 2016).

2.3.2 Family Caregivers

The experience of cancer inflicts significant emotional burden on caregivers and family members affected by pancreatic cancer, who exhibit similar or even greater levels of distress than their patient counterparts (Janda et al., 2017). The role of family caregivers has often been overlooked, although they assume much responsibility for supporting their loved ones, symptom management, communicating with the healthcare team, and routine household tasks (Engebretson, Matrisian, & Thompson, 2015). In surveys and in-depth interviews, caregivers have described feelings of crisis, heartbreak, and shock upon diagnosis, high burden of caregiving demands, unmet needs for information and support from HCPs, and difficulties in providing supportive care, including food preparation and adequate nutrition (Petrin, Bowen, Alfano, & Bennett, 2009; Locher et al., 2010; Sherman, McGuire, Free, & Cheon, 2014; Engebretson et al., 2015). Caregivers of patients with pancreatic cancer have also described feeling unable to manage the demands of caregiving, particularly during the accelerated period of health decline.

The greater prevalence of distress in caregivers compared to patients affected by pancreatic cancer, as demonstrated by Janda and colleagues (2017), is compatible with other studies of caregivers of patients with mixed advanced cancers (Braun, Mikulincer, Rydall, Walsh, & Rodin, 2007). Unmet supportive care needs of family caregivers of individuals with advanced cancer have been related to high levels of caregiver burden and poor caregiver health (Sharpe, Butow, Smith, McConnell, & Clarke, 2005). As patients continue to deteriorate and lose autonomy, family caregivers experience increasing levels of psychological distress (Dumont et al., 2006). It has been further demonstrated that the distress of patients and caregivers affected by advanced cancer is interrelated, and the experience of caregiving burden is related to disease severity and social relatedness (Lo et al., 2013).

2.4 Quality of Life

A systematic review was recently conducted to characterize studies of the quality of life of patients and family caregivers affected by pancreatic cancer (Bauer et al., 2018). The synthesis of a small number of studies available suggests that quality of life across all domains (*i.e.*, physical, psychological, social, sexual, spiritual, general) is significantly impaired for people with pancreatic cancer relative to the general population or patients with other cancer types, particularly with regard to psychological wellbeing and functioning. Of note, physical symptom burden including pain and fatigue negatively impacts quality of life. Caregivers also face similar substantial challenges to their own quality of life across all domains. Taken altogether, this review highlights the compromised quality of life experienced by all those affected by pancreatic cancer. Attending to disease burden and supportive care needs is critical to improve quality of life, achieve optimal care, relieve suffering, and promote opportunities for people to engage in personally meaningful activities.

2.5 Interdisciplinary Approach to Care

An interdisciplinary approach to the management of people affected by pancreatic cancer is needed in view of their multiple and complex symptoms and problems. These care teams often comprise clinicians from a range of disciplines, including palliative care, surgery, medical and radiation oncology, gastroenterology, nursing, dietetics, rehabilitation, psychiatry, and social work (Muircroft, 2016). There is increasing evidence that an interdisciplinary approach to care can improve clinical outcomes for people with pancreatic cancer (Pawlik et al., 2008; Schiffman et al., 2016). The overall essence of interdisciplinary care in pancreatic cancer is to help patients remain well for as long as possible and achieve best quality of life.

2.6 Palliative and Supportive Care

In recognizing the shortened survival time and multidimensional impact of diagnosis and disease, early detection of distress and integration of palliative and supportive care is imperative in this population (Sohal et al., 2016). The primary goals of palliative care are to manage pain and symptoms, provide psychosocial, emotional, spiritual, and informational support, and to improve quality of life. Comprehensive supportive care broadly aims to manage pain and symptoms; provide psychosocial, spiritual, and informational support; support self-management and effective communication with the health care team; to ultimately support best possible quality of life. It is well established in research and is now embedded in clinical practice guidelines that early integration of palliative and psychosocial care, concurrent with standard oncology care, is essential to the management of pancreatic cancer and other advanced cancers (Ducreux et al., 2015; Sohal et al., 2016; Ferrell et al., 2017; Knaul et al., 2017).

Despite mounting evidence for high levels of unmet supportive care needs, palliative and supportive care services remain under-utilized and are not established in the routine care of people affected by pancreatic cancer (Muircroft, 2016). In the study conducted by Beesley and colleagues (2016a), only 15% of patients with pancreatic cancer reported accessing psychosocial support (*i.e.*, psychologist, psychiatrist, social worker, or telephone counsellor), 28% consulted a dietitian, and 45% of patients accessed palliative care services. In fact, the majority of patients with advanced cancer with clinically significant distress are not referred or are referred too late to palliative or psychosocial care, or do not receive adequate treatment (Ahmed et al., 2004; Ellis et al., 2009; Wentlandt et al., 2012). This may be partly due to the limited availability or accessibility of services (Bruera & Hui, 2010; Hui et al., 2010) and to the perceived stigma attached to palliative care, and its association with death (Zimmermann et al., 2016). Although the field of palliative care was indeed initially focused on treating patients at the very end of life, early palliative care is now internationally recognized to be “applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life” (WHO, 2002). Early involvement of specialized palliative care services has been shown to improve quality of life, satisfaction with care, and reduce distress for patients with advanced cancer (Bakitas et al., 2009; Temel et al., 2010; Zimmermann et al., 2014). Moreover, patients with pancreatic cancer experience a number of unique and complex pathophysiological symptoms, and require early recognition and management from palliative care to achieve the best possible outcomes (Muircroft & Currow, 2016). Palliative care consultation and intensive follow-up has been associated with less aggressive care near death in patients with advanced pancreatic cancer (Jang, Krzyzanowska, Zimmermann, Taback, & Alibhai, 2015). Overall, the understanding and acceptance of palliative care is a critical step towards providing optimal care and promoting best quality of life for people affected by pancreatic cancer (Gooden et al., 2016).

2.6.1 Discussions about End of Life

Central to palliative care is the need for clear and realistic communication between patients, family caregivers, and HCPs. Difficulty with communication may contribute to distress for patients and family caregivers affected by pancreatic cancer (Gooden et al., 2016). Effective communication about end of life is therefore pivotal in facilitating adjustment to serious illness and maintaining quality of life throughout the disease trajectory. These include discussions about the illness, goals of care, realistic options for treatment, code or resuscitation (DNR) status, palliative and hospice care, and the optimal venue for dying. In the context of advanced cancer, end-of-life (EOL) discussions have been associated with higher quality of life for patients and cascading to better quality of life for bereaved caregivers, more preference-concordant care, and earlier palliative care use and hospice referrals (Wright et al., 2008; Mack et al., 2010). This underscores the need to initiate EOL discussions early in the disease course, during periods of relative stability rather than waiting until active deterioration, as reflected in clinical practice guidelines (Clayton, Hancock, Butow, Tattersall, & Currow, 2007a; Murray, Kendall, Boyd, & Sheikh, 2005). This can afford more time for patients to understand their prognosis and make informed decisions about treatment and EOL care preferences, ultimately improving quality of life at the end of life. Indeed, early initiation of EOL discussions is associated with less aggressive care, greater hospice use, and better quality of life (Mack et al., 2012; Ahluwalia et al., 2015; Zakhour et al., 2015).

Open communication about prognosis often does not occur until the very end of life, often within the last month of life, or not at all in patients with terminal cancer (Bradley et al., 2001; Keating et al., 2010). Even when conducted, such discussions may be done poorly (Desharnais, Carter, Hennessy, Kurent, & Carter, 2007). This failure is presumably related to the challenging nature of these discussions for physicians, who may have personal discomfort, feelings of unpreparedness, or received little training in this area (Daugherty & Hlubocky, 2008; Granek, Krzyzanowska, Tozer, & Mazzotta, 2013). Uncertainties about the right timing and about balancing medical evidence, patients' wishes, and physician's own emotional involvement create further barriers to timely and frank communication (Pfeil, Laryionava, Reiter-Theil, Hiddemann, & WInkler, 2015). Fear of distressing patients and eliminating hope has also been documented as reasons for physician's reluctance to provide prognostic information and to prepare their patients for dying and death (Fallowfield, Jenkins, & Beveridge, 2002). Of note, physician reluctance to communicate openly and their use of euphemisms do not facilitate patient hope (Hagerty et al., 2005), whereas realistic discussion about prognosis and EOL issues do not increase patient anxiety or decrease satisfaction with care (Clayton et al., 2007b). Necessary in the care of people affected by pancreatic cancer is therefore effective communication and early initiation of EOL discussions, to minimize distress, support patients and their families, and optimize quality of life.

2.7 Supportive Care Interventions

Despite the growing recognition of the importance of addressing supportive care needs and the calls for increased support for patients with pancreatic cancer, there have been few studies and no randomized controlled trials published on supportive care interventions tailored to the unique needs of people affected by pancreatic cancer.

In one of the 5 research articles identified (see Table 1), Sun and colleagues (2016) assessed the feasibility of an interdisciplinary supportive care planning intervention for patients with pancreatic cancer aimed to address quality of life needs. The first phase of the intervention was comprised of a comprehensive quality of life assessment, which was presented at interdisciplinary rounds and informed care coordination plans and recommendations. The second phase of the intervention involved two nurse-administered patient education sessions covering topics across quality of life domains: (1) first session - physical and emotional wellbeing (*e.g.,* pain, constipation/diarrhea, nausea/vomiting, anxiety/depression); (2) second session - social and spiritual wellbeing (*e.g.,* communication, social support, advanced healthcare planning, meaning of illness). The authors found the intervention to be feasible to implement in an ambulatory care setting and acceptable to patients with pancreatic cancer, and aim to test the efficacy of the intervention to improve quality of life in a future larger scale multisite randomized trial.

A few studies of online supportive care interventions for people affected by pancreatic cancer have been reported. To address the unique set of challenges in survivorship in this population, Frick et al. (2017) developed an Internet-based resource to create individualized survivorship care plans. As the tool is publicly accessible, it can be searched for independently by patients and families or they can be made aware of the resource from HCPs. Upon inputting data regarding demographics diagnosis, and treatment course, the resource provides individualized, comprehensive health care recommendations for future care for patients, family members, or HCPs. The majority of respondents (83%) indicated they would share their survivorship care plan summary with their health care team. This kind of tool has the valuable potential to improve communication between patients and physicians about treatment-related effects, coordination across multidisciplinary health care teams, and prognostic discussions.

A public website hosted by the Johns Hopkins Pancreatic Cancer Research Center, launched in February 1995, provides detailed information about pancreatic cancer, treatment options, and includes interactive components (*e.g.*, physician blogs, unmonitored discussion board for patient and family users to interact). In a first study, the investigators aimed to examine the effect of adding a Frequently Asked Questions module on postings in the chat room of the website (Coleman et al., 2005). Findings revealed the need for more information about pain management, prognosis, and EOL care, particularly for family caregivers. In a second study, spirituality was identified as another aspect that required support for people affected by pancreatic cancer, mostly family caregivers (Nolan et al., 2006). To address these previous findings, the Johns Hopkins Pancreatic Cancer Research Center added an interactive webpage for users to interact and access a palliative care nurse practitioner and sought to examine the extent to which people would utilize this service and their experiences (Grant & Wiegand, 2011). In this study, patients and caregivers affected by pancreatic cancer were interested and benefitted from the interactive palliative care nursing resource. The participants were predominantly female caregivers, and they mostly posed questions related to physical concerns of pancreatic cancer. The positioning of a palliative care nursing resource on a pancreatic cancer website, rather than on a dedicated palliative care or hospice site, can offer specific palliative care information and support to patients and caregivers affected by pancreatic cancer.

Table 1. Summary of reviewed studies on supportive care interventions in pancreatic cancer (n=5)

Author	Setting	Sample	Objective	Methods	Results
Coleman et al., 2005	USA	n=600 postings on a pancreatic cancer website (patients and family members)	To examine the changes in chat room conversations pre- and postaddition of an FAQ module to the pancreatic cancer Web site	Descriptive-comparative mixed method	• 3 themes: information seeking, giving, or both; support seeking, giving, or both; reporting status or death
Nolan et al., 2006	USA	n=600 postings on a pancreatic cancer website (patients and family members)	To describe the spiritual issues addressed in the chat room of a pancreatic cancer Web site	Qualitative	• 4 themes: spiritual convergence, reframing suffering, hope, and acceptance of the power of God and eternal life
Grant & Wiegand, 2011	USA	individuals who accessed the webpage over an eight-week study period; convenience sampling	To evaluate (1) the number and geographic location of those visiting; (2) number and type of questions posted and whether those posting were patients or caregivers; (3) the experience with a webpage with an interactive palliative care nursing resource	Descriptive	• 707 website visits; 395 unique computer visitors • 85% of questions related to physical issues of pancreatic cancer and its treatment • 20 participants completed online survey; found the resource to be helpful, easy to use, and recommended it as an ongoing resource
Sun et al., 2016	USA	n=10 patients with pancreatic cancer	To determine the feasibility of an interdisciplinary supportive care planning intervention in patients with pancreatic cancer during disease-focused treatments	Quantitative	• 58% accrual • changes in QOL outcomes, although not statistically significant • participants were highly satisfied with the intervention • most common concerns in discussions of interdisciplinary care meetings and educational session were physical and psychosocial needs

Author	Setting	Sample	Objective	Methods	Results
Frick et al., 2017	USA	n=117 patients with pancreatic cancer or proxies; convenience sampling of people who used an Internet-based tool	To describe treatment patterns and related side effects, surveillance care patterns, and perceptions of a publicly available Internet-based tool for creating survivorship care plans	Descriptive	• 5% had been previously offered a supportive care plan • 83% of those who responded to a follow-up satisfaction survey indicated they would share the plan with a health care provider

2.7.1 Clinical Trials in Progress

Although the number of published studies is limited, it is promising that there are currently a number of active and completed clinical trials of supportive care interventions for people affected by pancreatic cancer conducted, according to the international registry of privately and publicly funded clinical studies (clinicaltrials.gov) (see Table 2). Supportive care interventions include nutritional support, physical activity, integration of early palliative care, and other behavioural and educational interventions. The majority of these trials are focused on specific outcomes or goals (*e.g.,* reducing distress or postoperative complications, or improving physical function or nutritional status). Among the registered clinical trials listed, there are few that target those affected by pancreatic cancer specifically, and even fewer interventions that include both patients and family members.

Table 2. Registered clinical trials of non-pharmacological interventions for people affected by pancreatic cancer

Intervention Type	Population	Primary Outcome	Location
Completed Trials			
Embedded supportive care	Pancreatic cancer (patients; locally advanced or metastatic)	Feasibility	USA
Exercise intervention	Pancreatic cancer (patients; all stages)	Physical functioning	Germany
Nutritional support	Pancreatic cancer (patients; all stages)	Nutritional status	Germany
Nutritional support	Hepatobiliary cancer (patients)	Postoperative complication	Korea
Palliative care	Pancreatic cancer (patients; borderline resectable, locally advanced resectable/ unresectable, metastatic; newly diagnosed)	Feasibility	USA
Nutritional support	Pancreatic cancer (patients; undergoing GI elective surgery)	Postoperative complications	Denmark
Supportive care	Pancreatic or other GI cancers (stage III/IV) or ALS (patient-family dyads)	Decision-making self-efficacy	USA
Walking programme	Pancreatic or periampullary cancers (patients; stage I-III)	Fatigue	USA
Dignity therapy and life plan	Pancreatic or advanced lung cancer (patients)	Psychological distress	USA
Collaborative care management intervention	Hepatobiliary cancer (patients)	Depression	USA
Integrated early palliative care	Pancreatic or biliary tract cancers (patients; locally advanced or metastatic)	Pain and depression	Korea
Integrated early palliative care	Pancreatic, gastric, biliary tract, or lung cancer (patients; metastatic; newly diagnosed)	Quality of life	
Integrated early palliative care	Pancreatic, gastric, or lung cancer, or mesothelioma (patients; newly diagnosed)	Feasibility	Italy

Intervention Type	Population	Primary Outcome	Location
Integrated early palliative care	Pancreatic, other GI, genitourinary, lung, and breast cancer (patients; advanced stage)	Quality of life, symptom management, health care utilization	USA
Recruiting			
Nutritional support	Pancreatic cancer (patients; unresectable)	Weight and body composition	USA
Health care coaching support	Pancreatic and other cancers (patients; advanced stage)	Health care utilization	USA
Diet and exercise counselling	Pancreatic cancer (patients; resectable)	Feasibility	USA
Walking programme	Pancreatic cancer (patients)	Quality of life	USA
Diet and exercise counselling	Pancreatic cancer (patients; undergoing surgical resection)	Quality of life	USA
Perioperative geriatrics intervention	Pancreatic, esophageal, or gastric cancer (patients; will receive surgical resection)	Hospital length of stay	USA
Prehabilitation pre- and post-surgery walking programme	Pancreatic, other GI, or lung cancers (patients)	Feasibility	USA
Prehabilitation (nutrition and physical conditioning)	Pancreatic or hepatobiliary cancers (patients; will receive surgical resection)	Functional walking capacity	Canada
Personal resilience empowerment program	Pancreatic or other hepatobiliary cancers, lung cancer (patients; will undergo surgical procedures)	Quality of life	USA
Perioperative rehabilitation programme	Hepatobiliary cancer (patients)	Incidence and severity of general complication	Korea
Multimodal: exercise, nutrition, and nurse-led supportive and motivational counselling	Pancreatic, biliary tract, or non-smell lung cancers (patients; locally advanced or metastatic; newly diagnosed)	Lower body strength	Denmark
Oncologist training programme for goals of care discussions	Oncologists; pancreatic and other cancers (patients; advanced stage)	Increased and improved goals of care discussions	USA
Active, not recruiting			

Intervention Type	Population	Primary Outcome	Location
Preoperative exercise intervention	Pancreatic cancer (patients; borderline resectable; will receive surgery)	Physical functioning	USA
Home based exercise and nutrition programme	Pancreatic cancer (patients; scheduled for pancreatectomy and neoadjuvant chemotherapy and/or chemoradiation)	Feasibility	USA
Integrated early palliative care	Pancreatic or gastric cancers (patients; locally advanced and/or metastatic; newly diagnosed)	Quality of life	Italy
Computer-assisted intervention	Pancreatic, gastric, colorectal, or liver cancers (patients; scheduled to undergo surgery)	Feasibility	
Family caregiver education intervention and telephone counselling support	Pancreatic and other solid tumour cancers (family caregivers)	Caregiver burden, quality of life, preparedness, psychological distress	USA
Integrated early palliative care	Pancreatic and other non-colorectal GI cancers, and lung cancers (patients; advanced stage; newly diagnosed; family caregivers)	Quality of life	USA

2.7.2 Community- and Organization-Based Support Programmes

In addition to the ongoing active and completed clinical trials for supportive care interventions for people affected by pancreatic cancer, it is also encouraging that there are a number of programmes offered through government and community agencies to help support people affected by pancreatic cancer. For example, the *Pancreatic Cancer Action Network* offers one-to-one support through the Pancreatic Cancer Action Network's Survivor & Caregiver Network, connecting survivors and caregivers affected by pancreatic cancer. Other services offered include in-person support and networking groups, toll-free telephone and online support groups, and free educational events presented by medical professionals to provide relevant information and new discoveries. The range of programmes offered by organizations like the *Pancreatic Cancer Action Network* include support groups (in-person and online), toll-free telephone services, educational programming, and financial support services. An environmental scan was conducted to determine the programmes currently available to support people affected by pancreatic cancer (see Table 3 for a summary of programmes).

In-person support and networking groups are mostly facilitated by a nurse, social worker, or professional counsellor. These groups offer an opportunity to meet, share, and connect with other patients and loved ones in person. Online support communities hosted by public and private organizations are widely accessible. These support services can provide information and resources to educate people affected by pancreatic cancer about the disease, treatment options and effects, and strategies to manage living with the disease.

Table 3. Summary of community- and organization-based support programmes

Organization	**Location**	**Services Offered**
Avner Pancreatic Cancer Foundation	Australia	- educational materials - fundraising events
Cancer*Care*, Inc.	USA	- 15-week online support group for caregivers, led by a social worker - counseling services with oncology social workers - financial assistance programs - Connect Education workshops
Craig's Cause Pancreatic Cancer Society	Canada	- information/support group - financial support grants - educational materials
Herb Kosten Pancreatic Cancer Support	USA	- in-person support groups - events and symposia
Hirshberg Foundation for Pancreatic Cancer Research	USA	- financial support - patient advocates for legal and insurance issues - counseling and support groups - children support programs - educational materials
John E. Sabga Foundation for Pancreatic Cancer	Trinidad and Tobago	- educational materials - fundraising events
Macmillan	UK	- free support line - in-person support groups
National Pancreatic Cancer Foundation	USA	- educational materials - fundraising events
PanCare Foundation: Pancreatic Cancer Organisation	Australia	- educational materials - in-person support groups
Pancreatic Cancer Action Network	Online	- Pancreatic Cancer Action Network's Survivor & Caregiver Network - in-person support and networking groups - toll-free telephone and online support groups - educational events

Organization	Location	Services Offered
Pancreatic Cancer Canada	Canada	- peer support programme (Pancreatic Cancer Peer Support Program, with Wellspring) - educational materials
Pancreatic Cancer UK	UK	- free support line with specialist nurse - online discussion forum - in-person support groups - peer-to-peer support service, Side by Side
Rolfe Pancreatic Cancer Foundation	USA	- in-person support groups - educational materials
The Lustgarten Foundation for Pancreatic Cancer Research	USA	- online social network (through Pancreatic Cancer Connections, partnership with Let's Win and Inspire) - educational materials
World Pancreatic Cancer Coalition	International	- educational materials - financial support - fundraising events - support groups
Online Support Communities		
Cancer Compass	Online	- online discussion boards
CancerConnect	Online	- online social network
Facebook	Online	- online social communities for people affected by pancreatic cancer (*e.g.,* Pancreatic Cancer Canada) and for specific subgroups (*e.g.,* Whipple Surgery Survival Group)
Inspire	Online	- moderated online cancer support network supported by nonprofit community partners - *Pancreatic Neuroendocrine Tumor (PNET) Support Community* to connect patients and families and provide resources
Johns Hopkins Medical Institutions Pancreatic Cancer Chat Room	Online	- unmoderated discussion forum

Organization	Location	Services Offered
Smart Patients, Inc.	Online	- online social network - includes specific subgroups (*e.g., Pancreatic neuroendocrine Tumor Community*)

2.8 Psychoeducation

The dearth of published studies and registered clinical trials underscores the need for more targeted interventions to address the range of informational and supportive care needs that have been identified in this population. Recognizing that pancreatic cancer is a public health crisis with a rising incidence, appropriate and sustainable ways to provide psychosocial support as a standard of care are required. Indeed, there have been calls for innovative and acceptable ways to provide evidence-based psychosocial support for those facing pancreatic cancer (Beesley et al., 2016a).

Multidisciplinary psychoeducation programs have been put forth as an opportunity to weave education and psychological care into medical treatment pathways (Garchinski et al., 2014; Schofield & Chambers, 2015; Sagar, 2016). Psychoeducation is a treatment modality designed to synergize psychotherapeutic and educational approaches, to reduce the sense of helplessness that individuals may experience due to uncertainty and lack of knowledge (Fawzy, 1995). Psychoeducation includes both illness-specific information and strategies for managing the disease and its impact. It is broadly intended to prepare people with adequate knowledge and skills to manage physical and psychosocial outcomes, to ultimately improve quality of life. This is useful as people may use information seeking as a coping strategy to reduce the uncertainty associated with the onset of serious illness (Berlyne, 1977; Mishel, 1990). When individuals and families are confronted with a major illness, psychoeducational techniques can be used to help digest and interpret emotionally loaded information and to use the information proactively (Lukens & McFarlane, 2004). These overall goals are facilitated by the promotion of self-management, empowerment, and preparedness (Fawzy, 1995).

The clinical applications of psychoeducation are broad, owing to the flexibility of the psychoeducation model. In our context, psychoeducation may be most useful and feasible when considered within a stepped care framework. Psychoeducation can represent the first level of supportive care provided to all people affected by pancreatic cancer, thereby embedding psychosocial care into routine care. Such programs could serve to help people understand the disease and its implications, to manage symptoms and distress, and to make informed decisions about treatment and the future. Psychoeducation could then function as an assessment or referral point for those with heightened and complex symptoms and requiring more specialized care, establishing a tiered model of supportive care delivery (Hutchison et al., 2006).

Psychoeducational interventions have been applied in a wide range of settings for acute and chronic illnesses, and have been particularly established as an adjunctive treatment for cancer (Lukens & McFarlane, 2004). Psychoeducation has been used to address disease-specific related concerns, symptom management, adjustment, and survivorship. In a meta-analysis of 116 studies, Devine and Westlake (1995) found that patients with mixed cancer types that participated in some form of psychoeducational intervention reported improvements in psychological symptoms (*e.g.,* anxiety, depression), physical symptoms (*e.g.,* nausea, vomiting, pain), and knowledge. In more recent systematic reviews, diverse positive outcomes of psychoeducational interventions have been demonstrated (Chambers, Pinnock, Lepore, Hughes, & O'Connell, 2011; McLoone, Menzies, Meiser, Mann, & Kasparian, 2013; Matsuda, Yamaoka, Tango, Matsuda, & Nishimoto, 2014; Chow, Chan, Chan, Choi, & Sui, 2016; Xiao Chow, So, Leung, & Chan, 2016). These include improvements in physical symptoms, psychosocial outcomes, adjustment and coping with illness, and quality of life. In one systematic review, three studies reported that psychoeducation significantly improved symptom clusters, such as fatigue, anxiety, gastrointestinal symptoms (*e.g.,* nausea, vomiting, loss of appetite, diarrhea), in mixed cancer populations (Xiao et al., 2016). Improvements have been reported in quality of life in patients with gynecological cancer (Chow et al., 2016) and prostate cancer (Chambers et al., 2011), physical and psychosocial symptoms in patients with breast cancer (Matsuda et al., 2014), and knowledge, self-efficacy, and satisfaction with care in patients with melanoma (McLoone et al., 2013).

Compared to other supportive care interventions, psychoeducation has been shown to yield significant and sustained benefits on psychological outcomes and quality of life (Edelman, Craig, & Kidman, 2000; Zimmermann, Heinrichs, & Baucom, 2007; Faller et al., 2013; Wang et al., 2017).

Despite the supporting evidence for psychoeducation to improve health-related outcomes and management in cancer, comprehensive psychoeducational interventions targeting the unique needs of people affected by pancreatic cancer have not yet been established.

2.9 The Research-to-Practice Gap and Implementation Science

Many tools and interventions in the fields of psychosocial oncology and supportive care have demonstrated clinical efficacy, yet they are often under-utilized and fail to reach broad clinical implementation (Hack et al., 2011). There is often inattention to the various barriers that impede implementation, including structural (*e.g.,* lack of financial resourcing), organizational (*e.g.,* lack of intervention support from those in positions of administrative authority), and social barriers (*e.g.,* lack of support from oncologists and nurses). The challenge in executing full-scale implementation of empirically promising interventions is not unique to supportive care efforts, and has been a longstanding issue across health care. It has been estimated that it takes an average time lag of 17 years between research evidence and clinical practice (Morris, Wooding, & Grant, 2011). An underlying reason for the research-to-practice gap in may lie in the assumption that implementation research naturally flows from successful efficacy research (Glasgow, Lichtenstein, & Marcus, 2003). In an effort to narrow the research-to-practice gaps in health care practice, a blend of design components of clinical effectiveness and implementation research is being increasingly used (Curran, Bauer, Mittman, Pyne, & Stetler, 2012). Such hybrid designs can dually aim to evaluate the impact of interventions and the implementation strategies in "real world" settings. In contrast to traditional research paradigms with step-wise progressions from efficacy to implementation, hybrid designs can improve uptake and external validity, and provide useful information for researchers and decision makers. The growing recognition and utility of implementation theories can greatly improve the timely and successful implementation of promising interventions into routine clinical practice. The overall goal of implementation research is to elucidate the processes and factors that promote uptake, application, and sustainability of evidence in a specific context.

As the landscape of implementation research is multifactorial and complex, there have been calls for the use of mixed methods designs (Palinkas et al., 2011; Landsverk et al., 2012). The rationale for mixed methods designs is similar to other areas of research, as the triangulation of qualitative and quantitative data can provide a more comprehensive understanding than either approach alone (Teddlie & Tashakkori, 2003). In implementation research, quantitative methods can be used to measure intervention and implementation outcomes. Qualitative methods are used to explore and understand the process of implementation through detailed descriptions from various perspectives (*i.e.,* relevant stakeholders). Qualitative inquiry also allows us to acknowledge the dynamic nature of the implementation process and the complexity of real world settings in implementation research, unlike the controlled contexts of efficacy studies. The scope of utility of qualitative research can range from addressing questions related to intervention content and delivery, trial design and conduct, to selection of outcome and measures (O’Cathain et al., 2015).

Chapter 3: Rationale

The profound disease burden and unique psychosocial concerns faced by people affected by pancreatic cancer can have a significant impact on their wellbeing and quality of life. The need for improved knowledge and understanding early in the disease course can help to reduce uncertainty and promote preparedness. With the increasing incidence of pancreatic cancer, there have been calls for innovative and sustainable ways to provide psychosocial care as part of routine care for the people affected. However, standardized and comprehensive supportive care interventions uniquely targeted for people affected by pancreatic cancer have been limited. This thesis project was therefore intended to develop and evaluate the implementation of an interdisciplinary-led group psychoeducational intervention into routine care of people affected by pancreatic cancer. This presents an opportunity to improve quality of life and quality of care, and to facilitate adjustment and reflection on the physical and psychosocial practical issues that arise near the end of life. This work ultimately aims to inform future efforts and approaches to care by understanding the clinical value of implementing supportive care intervention into routine care in this population. Our goals are aligned with the increasing imperative of integrating early palliative and supportive care into routine care of people affected by life-limiting illness.

Chapter 4: Research Aims

The research aims of this thesis project were:

(1) To develop an interdisciplinary psychoeducational intervention for people affected by pancreatic cancer;

(2) To prospectively assess the feasibility, acceptability, and preliminary efficacy of implementing an interdisciplinary psychoeducational intervention for this population.

Chapter 5: The development of a psychoeducational intervention for people affected by pancreatic cancer

5.1 Background

Pancreatic cancer is one of the most aggressive malignancies, with an overall 5-year survival rate of only 8% (Canadian Cancer Society, 2017; American Cancer Society, 2017). It is most often diagnosed at an advanced and incurable stage, since early symptoms are largely absent, and it is the fourth leading cause of cancer-related death in North America (Canadian Cancer Society, 2017). The threat of impending mortality can be highly disturbing. Patients affected by this disease demonstrate elevated rates of anxiety and depression in comparison to other types of cancers (Zabora et al., 2001; Clark et al., 2010). Family members are also affected and show similar or even greater levels of distress than their patient counterparts (Janda et al., 2017).

Those affected by pancreatic cancer have high informational and supportive care needs regarding symptom management, communication with health care professionals (HCPs), worry about loved ones, and uncertainty about the future (Beesley et al., 2016a). These needs are often unmet, despite clinical practice guidelines calling for psychosocial and educational support and for early palliative care (Beesley et al., 2016a; Gooden et al., 2016; Ferrell et al., 2017). This is consistent with evidence that the majority of patients with metastatic cancer, including those with clinically significant psychological distress, are not referred for specialized psychosocial and palliative care (Ahmed et al., 2004; Ellis et al., 2009; Fann, Ell, & Sharpe, 2012; Wentlandt et al., 2012). This gap in health care may be related to stigma and misunderstanding about the potential benefit of psychosocial and palliative care services (Bruera & Hui, 2010; Zimmermann et al., 2016), or limited accessibility and availability (Hui et al, 2010).

Psychoeducation refers to a treatment modality that provides information for self-management within a supportive social context and embeds both education and psychological care into routine care (Sagar, 2016; Garchinski et al., 2014; Thompson & Young-Saleme, 2015). Multidisciplinary psychoeducation programs may be well-suited to address the early information and support needs for patients with pancreatic cancer. Several systematic reviews of studies with mixed cancer populations have shown that there are significant and sustained benefits of psychoeducational interventions in relation to emotional distress and quality of life (Zimmermann et al., 2007; Faller et al., 2013; Wang et al., 2017). Psychoeducation may be particularly useful when implemented within a stepped-care framework or tiered model of service delivery (Bower & Gilbody, 2005; Chambers, Hutchison, Clutton, & Dunn, 2014). From this perspective, psychoeducation would be the first level of supportive care provided to all patients with advanced or aggressive disease and could serve as an initial assessment and referral point for those requiring more specialized treatment (Hutchison et al., 2006).

Psychoeducation has often been conceptualized as an intervention for patients with early or non-advanced cancer, but may be equally or even more important for those with incurable or advanced disease (Ferrell et al., 2017). Such patients suffer from significant symptoms of depression and demoralization (Rodin et al., 2009) that progress over time without intervention (Lo et al., 2010). Psychotherapeutic (Rodin et al., 2018) and palliative (Zimmermann et al., 2014) interventions have value in this population, but access is often limited, particularly in the period immediately following diagnosis. Therefore, we developed a brief psychoeducational intervention with the goal of improving: (a) patient and family knowledge about pancreatic cancer and its anticipated impact; (b) access to palliative and supportive care; and (c) adjustment to disease and treatment.

Barriers to the implementation of psychosocial and palliative interventions have been attributed to the lack of resources, leadership, and advocacy (Hack et al., 2011). Frameworks and theories emerging from implementation science can help to improve the translation and dissemination of knowledge and uptake of interventions in the clinical setting (Eccles & Mittman, 2006). Implementation science addresses the processes by which empirically-supported interventions can be tailored for specific clinical contexts (Eccles & Mittman, 2006). Although these comprehensive frameworks are useful tools to consider, it may be unclear to many researchers how to apply these to diverse contexts with differing purposes, disciplines, and populations they aim to address. To improve the utility of implementation science frameworks and ideas, further demonstrations of their application in the clinical setting are needed.

We describe here the process of developing a psychoeducational intervention to address the informational and supportive care needs of people affected by pancreatic cancer. The principles of implementation science were applied to optimize uptake and sustainability in the clinical context. Our purpose was to illustrate the major decision points in the tailoring of psychoeducational materials and to detail a roadmap for scientists and clinicians seeking to implement similar initiatives in their settings.

5.2 Methods

We used Schofield & Chambers' (2015) framework to inform the development of our intervention's content and format. This framework seeks to promote effective and sustainable self-management interventions in cancer care. It emphasizes the targeting of interventions to cancer type and stage and tailoring them to individual needs. It also prioritizes evidence-based content, low-intensity delivery, and stakeholder acceptability.

We used the Consolidated Framework for Implementation Research (CFIR) as an overarching guide of the whole implementation process (Damschroder et al., 2009). The CFIR attends to five main domains: (I) intervention characteristics (*e.g.,* evidence strength, and intervention quality and complexity); (II) the outer setting (*i.e.*, external factors that may affect implementation, including the wider state of knowledge and policy climate); (III) the inner setting (*i.e.*, internal organizational factors associated with readiness to implement); (IV) individual characteristics (*e.g.,* personal attributes of stakeholders, beliefs about intervention, self-efficacy); and (V) the process of implementation itself, which includes planning and forethought, engaging champions, executing the plan, and evaluating the success of the intervention and implementation. CFIR encourages formative evaluation, which is “a rigourous assessment process designed to identify potential and actual influences on the progress and effectiveness of implementation efforts” (Stetler et al., 2006). Such evaluation allows continuous quality improvement in intervention content and delivery, spanning across the phases of development and implementation.

5.3 Initial Development of the Intervention

5.3.1 Outer and Inner Setting

There has been global recognition of the importance of integrated supportive and palliative care throughout the illness trajectory from diagnosis to the end of life, as reflected in recent clinical practice guidelines (Ferrell et al., 2017; WHO, 2014; Knaul et al., 2017). Despite such recommendations and clear clinical need, available support services are often minimal for patients with pancreatic cancer and their families (Beesley et al., 2016a).

The Wallace McCain Centre for Pancreatic Cancer (WMCPC) was established in 2013 at the Princess Margaret Cancer Centre (PM) in Toronto, Canada to advance the quality of care provided for this population and to develop new and innovative ways to improve outcomes and reduce the burden of disease. The WMCPC provided a unique opportunity to develop an improved model for the delivery of psychosocial care as part of usual oncology care. This centre offers a comprehensive interprofessional and multidisciplinary clinic that promotes early referral to specialized psychosocial and palliative care services. Although formulating a comprehensive treatment plan is important to patients and their families, an early psychoeducational intervention in this context could also be of value to provide information and support and to promote use of such evidence-based specialized services.

5.3.2 Stakeholder Involvement

The success of the development and implementation process of an intervention depends on the early involvement of key stakeholders (Schofield & Chambers, 2015; Damschroder et al., 2009). This ensures clinical relevance and commitment, and engages champions within the organization to take leadership and responsibility for sustainability. We therefore recruited an interdisciplinary team from the pancreatic oncology and supportive care clinics at our comprehensive cancer centre to develop the intervention. The content developers included representatives from nursing, an oncology clinical nurse specialist (n=1, SM), social work (n=2, KA, AH), dietetics (n=1, SB), and psychology (n=1, CL). An expert from patient education (n=1, LL) ensured that the language and presentation of information was appropriate for individuals with different educational backgrounds. Implementation support was provided by research administration (n=5, ET, AR, AD, SC, AF) and clinical administration (n=1, VK). Conceptual oversight was provided by clinician representatives from psychology (n=1, GMD), psychiatry (n=1, GR), palliative care (n=1, CZ), and oncology (n=1, SG). These stakeholders were involved from the time of project conception, and participated in group and individual meetings to develop the intervention from September 2016 to September 2017.

5.3.3 Available Resourcing

The clinical nurse specialist, social worker, and dietitian from our team agreed to deliver the intervention jointly, with each taking primary responsibility for his or her area of expertise. As part of usual care, these professionals had been providing individualized assessments and care regarding pain and symptoms, nutrition, advance care planning, and how to live well with pancreatic cancer. However, they recognized the greater efficiency and potential value of working together to deliver the intervention. A group intervention format was considered to be the most clinically feasible and cost- and time-efficient to provide information to patients and families. The ongoing role of the team members within the WMCPC programme would also allow the intervention to be sustained subsequently as part of routine care. Early consultation with these professionals suggested compatibility between their perceived clinical roles and the goals of the intervention. As we continued to develop the intervention and to conduct practice sessions, the team became increasingly more invested in and felt shared ownership of this implementation effort. Such strengthening of interpersonal ties has been found to be necessary for sustainable implementation (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004).

There was debate during the development process about the intervention “dose,” or the number of sessions needed for optimal clinical benefit. The degree of benefit people receive from interventions is typically associated with the number of sessions they receive (Faller et al., 2013), but this also may increase the costs and burden of delivery and participation. For this reason, low-intensity designs are being increasingly adopted in stepped-care models of psychological care, to provide services efficiently that respond to need, to improve access and maximize cost-effectiveness (Hutchison et al., 2006). Balancing these factors, we created an intervention prototype consisting of a single session lasting 1.5 hours. The first hour focused on delivering content; the last half hour was reserved for questions. We offered the intervention on a rotating, biweekly basis to accommodate space and time constraints. This low-intensity model could be integrated easily into the flow of usual care.

5.3.4 Establishing the Evidence Base for the Content of the Intervention

Considerable evidence demonstrates that patients with advanced cancers experience a range of physical and psychosocial challenges (Gooden et al., 2016; Muircroft & Currow, 2016). In pancreatic cancer, these include: 1. problems with digestion and diet, rapid weight loss, and poor appetite (Tang et al., 2018); 2. physical symptoms such as abdominal and back pain, nausea, jaundice, and diarrhea (Labori et al., 2006; Kanji & Gallinger, 2013); 3. fears and concerns about the future (Tong et al., 2016); and 4. adaptation to the impact of progressive disease on themselves and close others (Lo et al., 2010; Rodin & Gillies, 2009; Rodin et al., 2009). The encouragement of open communication and partnership with the health care team early in the disease trajectory may improve symptom management and facilitate timely and appropriate referral and acceptance of specialized psychosocial and palliative care services (Greer, Jackson, Meier, & Temel, 2013).

The experience of cancer affects not only patients, but also their intimate others (Veach, Nicholas, & Barton, 2013). Family members fulfill many important caregiving duties, yet their roles and unique supportive care needs are often underestimated. Without adequate support, the burden of caregiving and worry about losing a loved one can lead to poor health and distress (Sharpe et al., 2005; Braun et al., 2007; Janda et al., 2017), especially as disease worsens (Dumont et al., 2006). Supportive interventions that treat patients and families as a single group implicitly acknowledge interdependencies among members of the family system (Lo et al., 2013), which is consistent with the principles of palliative care (WHO, 2014).

5.3.5 Tailoring the Intervention

The intervention was designed to welcome all interested family members and friends to attend with the patient. It was designed to be easily comprehensible to a wide audience without overwhelming them with detail. The script was phrased in plain language with a Flesch Reading Ease (FRE) Score of 65.1% (Flesch, 1948) and

Flesch-Kincaid Reading Grade Level of 8.8 (Kincaid, Fishburne, Rogers, & Chissom, 1975), indicating an 8th grade reading level. The group format and circular seating arrangement of the group was chosen to encourage interactive discussion among attendees and facilitators, allowing for interjections and requests for clarification throughout the session. We included print handouts for note-taking to reduce the burden of recall. We focused on building a sense of trust and rapport with the health care team and offered to meet for individualized consults post-session.

Table 4 presents the key content areas of the intervention (see Appendix A for the *Living Well with Pancreatic Cancer* Intervention Manual). Participants received a folder that included printed slides, informational pamphlets, and details about hospital- and community-based programs that provide relevant support. The first author (ET) and education specialist (LL) assembled the PowerPoint presentation and developed the accompanying script, to ensure the quality of content and design. In particular, they emphasized the use of plain language, readability, and developed an appropriate layout that included both text and graphic content.

The order in which topics were introduced was organized to commence with material that was more practical and to proceed to more future-oriented topics associated with mortality. The intervention first addressed practical issues involving nutrition and self-management of symptoms, including tips on how to eat and maintain weight during treatment, pain management, and how to cope with disease and treatment-induced nausea using both dietary and medication monitoring. This was followed by information about palliative care and advance care planning. To dispel myths surrounding the term palliative care, we defined it as focusing on improving the quality of life in patients and families, and including pain and symptom management for individuals at any age or point in illness trajectory, regardless of the course of treatment. We explained that adapting to advanced disease requires engaging in and living life meaningfully, while simultaneously planning and preparing for all eventualities, including death. This challenge was described as similar to following two, divergent paths at the same time. This analogy of a “double road” or “double awareness” has been found to be clinically useful (Rodin & Zimmermann, 2008; MacArtney, Broom, Kirby, Good, & Wootton, 2017; Jacobsen et al., 2018).

The last issues to be discussed were the impact of cancer on patients and their families, and available supportive-care services, including hospital-based services (*e.g.* social workers, psychologists, psychiatrists, spiritual care workers, mindfulness-based cognitive therapy, psychotherapy tailored for advanced cancer (Rodin et al., 2018) and community-based services (*e.g.,* Gilda’s Club, Wellspring, Canadian Cancer Society, Pancreatic Cancer Canada, Craig’s Cause Pancreatic Cancer Society). We emphasized that patients and families face illness together, and discussed both the importance and difficulty of sustaining open communication about physical, emotional, and existential concerns when they arise. Attendees were encouraged to seek and accept help from others. Throughout the session, we sought to engage patients and family in honest, supportive dialogue as a demonstration of the value of professional support (Thorne et al., 2014).

Table 4. Key content areas of *Living Well with Pancreatic Cancer*

Key Content Areas	Discussion Points
Disease management	• Describe nutrition goals to maintain physical function and quality of life, and when a dietitian consultation may be required • Discuss how to manage common symptoms related to pancreatic cancer, promote partnership with the health care team for symptom management, clarify the role and goals of palliative care services
Planning for the future	• Explain the importance of advance care planning
Personal and family impact of cancer	• Discuss the impact of cancer on personal and family emotions and relationships, and the importance of maintaining a balance between hopes and fears, and continuing to live life meaningfully
Supportive care services	• Describe the available supportive care services offered within the hospital and in the community for the patient and family

Communication with loved ones and health care professionals	• Emphasize the importance of open communication with loved ones and health care professionals throughout discussions of other key content areas

5.3.6 Formative Evaluation

To assess the success of our implementation effort and to provide strategic information that may guide its further improvement, the intervention described in this paper was tested in a feasibility study using a mixed-methods approach (Chapter 6). Outcomes include rate of referral to the intervention and number of patients and family members who attend; the effectiveness of the intervention to improve knowledge and reduce uncertainty about illness based on self-reported measures; feedback from interviews of attendees about the timing, acceptability, and value of the intervention, and their suggestions for its improvement; and feedback from HCPs in the clinic about the process and feasibility of intervention implementation. This study will aim to characterize the feasibility, acceptability, and preliminary efficacy of the intervention and its implementation process in an ambulatory pancreatic oncology clinic at a large tertiary cancer centre.

5.4 Conclusion

Pancreatic cancer remains a highly challenging diagnosis for both patients and their loved ones. Many people present with advanced disease, a cluster of rapidly progressive symptoms, and poor performance status upon diagnosis. It has one of the highest mortality rates of any malignancy and may epitomize the general public's worst fears about having cancer because of its sudden onset, limited treatment options, and rapid course of deterioration. Given the lethality of illness, there is an urgency to promote adaptation and preparation and to provide support during a period of heightened distress and uncertainty.

We report here on the initial development and implementation of a group psychoeducational intervention to meet the informational and supportive care needs of individuals following recent diagnosis of pancreatic cancer (see Figure 1 for a visual fishbone diagram of the development and implementation process). The intervention addresses nutrition guidelines for this population and the commonly experienced symptoms and side effects. The content and delivery were tailored to broach difficult future-oriented topics in a supportive and non-threatening way. Our team acknowledged the urgency and perceived threat of discussions of advance care planning and palliative care for this population. As such, we introduced these topics as relevant to all patients regardless of staging of disease, aligning with recent clinical recommendations (Zimmermann et al., 2016; Zwakman et al., 2018).

Living Well with Pancreatic Cancer was developed by embedded HCPs and based on their clinical experiences and the research literature. *Living Well with Pancreatic Cancer* is consistent with guidelines to provide early, dedicated palliative and supportive care concurrently with oncology care to improve the overall standard of care (Ferrell et al., 2017). Its implementation into routine practice disseminates knowledge and promotes reflection about the foreseeable physical and psychosocial concerns that arise over the course of this illness. Psychoeducation may constitute the first line of supportive intervention, with more specialized individual treatment provided subsequently within a tiered model of supportive care delivery (Hutchison et al., 2006).

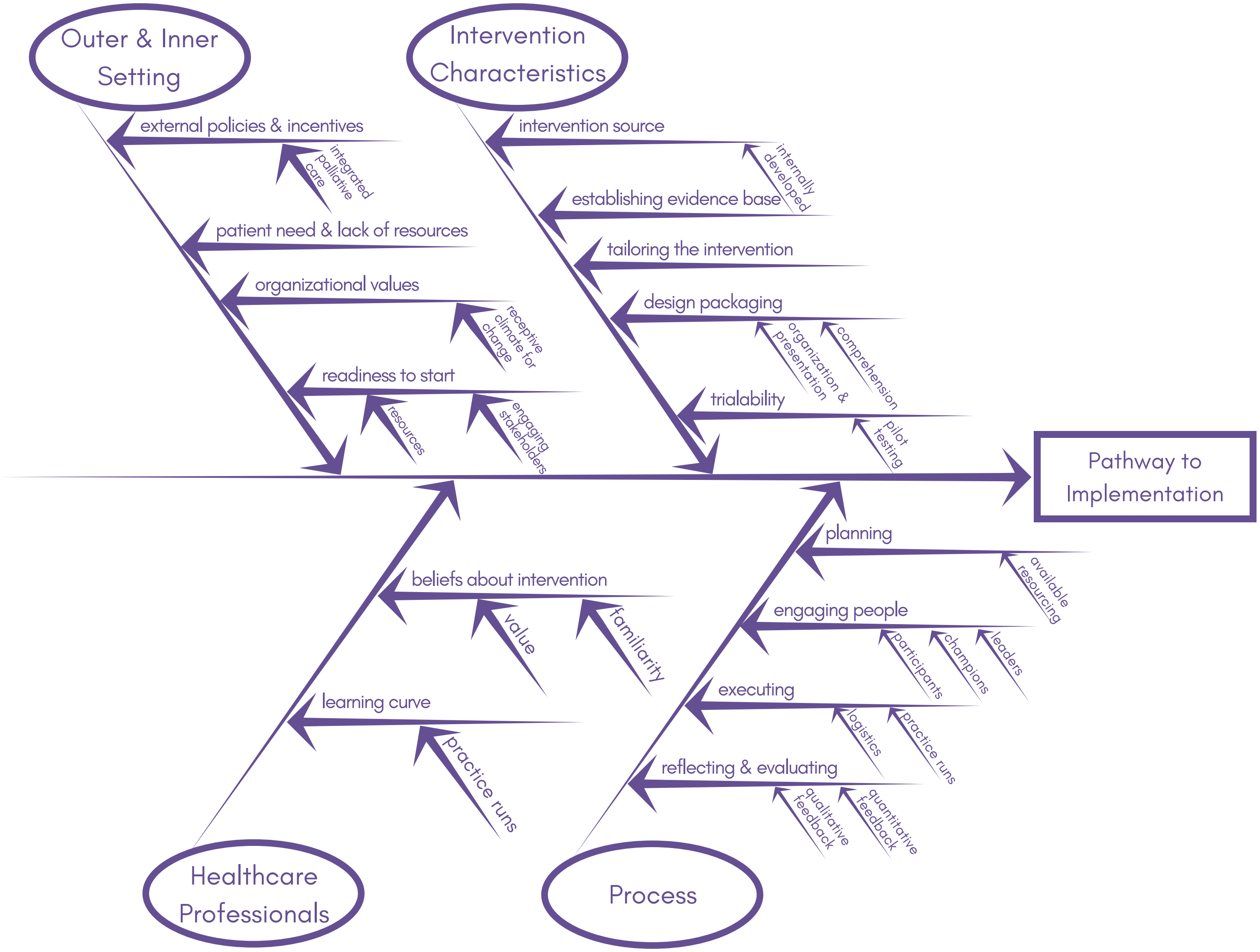

Figure 1. Pathway to implementation of a psychoeducational intervention for people affected by pancreatic cancer.

Chapter 6: Implementing an interdisciplinary psychoeducational intervention for people affected by pancreatic cancer: a mixed methods feasibility study

6.1 Background

Pancreatic cancer is one of the most fatal diseases, with a 5-year survival rate of less than 10% (Canadian Cancer Society, 2017). Prevention and early detection efforts have seen limited progress over time, relative to other cancers. Approximately 80% of those newly diagnosed have unresectable disease, either locally advanced or metastatic (Kanji & Gallinger, 2013), for which there are no curative options. The clinical management of those who have had or not had resection is complex, due to significant symptom burden including pain, nausea and vomiting, fatigue, poor appetite, and rapid weight loss. The informational and psychosocial needs of people affected by this disease are great and are amplified by concerns about the impact of disease on families and by uncertainty and fears about the future (Beesley et al., 2016). Rates of anxiety and depression are often higher than in other cancers (Zabora et al., 2001; Clark et al., 2010). Given the rapidity of disease onset and deterioration, the introduction of palliative and supportive care services is a critical priority in this population. Early detection and intervention for physical and psychosocial distress may improve quality of life and preparation for the end of life.

We have developed a psychoeducational intervention to address the supportive care needs of people affected by pancreatic cancer. *Living Well with Pancreatic Cancer* is an empirically-based, single session, manualized group intervention focused on education and discussion of the physical and psychosocial concerns common in this population (see Chapter 5). It lasts 1.5-hours and is jointly led by an interdisciplinary team of clinicians embedded in the pancreatic oncology clinic (*i.e.,* nurse, social worker, and dietitian). Topics include nutrition and symptom management, planning for the future (*e.g.,* advance care planning), personal and family impact of disease, and availability of supportive care services. *Living Well with Pancreatic Cancer* encourages partnership and communication with health care professionals (HCPs) and family members, who are invited to attend with patients.

The purpose of this study was to examine the early phase implementation of *Living Well with Pancreatic Cancer* as part of routine care in a pancreatic oncology clinic. We applied implementation science principles throughout the planning, development, and evaluation of *Living Well with Pancreatic Cancer*. This perspective focuses on issues of real world effectiveness and sustainability, and recognizes the multifactorial determinants that can affect the success of implementation. It encourages the use of mixed methods designs to provide a comprehensive understanding of the processes on the ground (Palinkas et al., 2011; Landsverk et al., 2012). It also encourages early and ongoing evaluation to improve effectiveness, uptake and scalability of an intervention. In the present study, we report on the initial acceptability, feasibility, and self-reported benefit of our intervention to address the early informational and supportive care needs of pancreatic cancer patients. We used both qualitative and quantitative data to assess the implementation of *Living Well with Pancreatic Cancer* into routine care, combining perspectives from patients, family members, and HCPs.

6.2 Methods

This study was approved by the Research Ethics Board of the University Health Network (UHN REB #17-5028) (Appendix B). We used a concurrent triangulation mixed methods design with pre-post outcome assessments collected at baseline (t0) and 1 month later (t1) (Creswell, Plano Clark, Gutmann,, & Hanson, 2003). Concurrent refers to simultaneous collection of quantitative and qualitative data in this study, and triangulation refers to the joint and complementary interpretation of both data sources. We collected quantitative (*e.g.,* attendance rate, consent rate, completion rate, and self-report measures) and qualitative data (*i.e.,* interviews and field notes) concerning feasibility, acceptability, and effectiveness.

6.2.1 Participants and Procedure

Eligible participants were patients diagnosed with adenocarcinoma of the pancreas, their family members, and HCPs involved in routine care of patients with pancreatic cancer. Inclusion criteria included age ≥18 years and English fluency.

Participant recruitment occurred between October 2017 to June 2018 at the Princess Margaret Cancer Centre (PM), a comprehensive cancer centre in Toronto, Canada and part of the University Health Network (UHN). The clinical team at the Wallace McCain Centre for Pancreatic Cancer (WMCPC) invited all new patients in the clinic to participate in a session of *Living Well with Pancreatic Cancer* as part of their standard of care. Patients receiving follow-up care in the clinic were also encouraged to attend. Patients and family members could also self-enroll after learning about *Living Well with Pancreatic Cancer* from the UHN website, UHN Patient Education calendar, and printed flyers provided in the clinic. Participants were enrolled into the session by the clinic administrative assistant. Eligible HCPs were invited by email, telephone, or in person to provide feedback in a semi-structured interview with the study coordinator and lead author (ET).

At the start of each session, the facilitators introduced the study coordinator who described the research study. Patients and family members who agreed to participate in the study gave written informed consent (Appendix C). Baseline self-report measures were collected at the start of the session, and follow-up measures were collected 4 weeks later. Participants were also invited at follow-up to participate in a semi-structured interview. Patients and family members could participate in the interview as a dyad (Morgan, Ataie, Carder, & Hoffman, 2013).

HCP participants provided written informed consent and completed a demographic information form prior to being interviewed. All participants (*i.e.,* patients, family members, HCPs) were informed that the interviews would be audio-recorded and transcribed verbatim. A member of the research team verified the transcriptions for accuracy and removed identifying information.

6.2.2 Measures

Demographics collected at baseline included age, gender, marital status, education, employment status, and living situation. Clinical characteristics were extracted from the patient's electronic medical record and included time since diagnosis. Demographics collected from HCP participants included profession and years working in cancer care.

6.2.2.1 *Feasibility Outcomes*

These included rates of attendance (% of eligible patients who attend the session), study consent (% of attendees who consent to the study), and study completion (% of consenting participants who complete the follow-up assessment). To assess feasibility, we used the following criteria based on prior work (Temel et al., 2007): 50% attendance for eligible patients, which equates to having ≥39 patients over 6 months, assuming 3 new patient consults per week who meet eligibility; and 60% study consent and completion rates. Interview data, field notes, and non-participant observations by the study coordinator were also examined for information related to feasibility and acceptability.

6.2.2.2 *Semi-Structured Interviews*

Patient and family member participants were asked to share their feedback about the intervention (*e.g.,* relevance, timing, impact, format) and overall disease experience. HCP participants were asked about their experience of the intervention and thoughts about its feasibility and sustainability (see Appendix D for interview guides).

6.2.2.3 *Self-Reported Outcome Measures*

The experience of uncertainty was measured using the *Mishel Uncertainty in Illness Scale Community Form (MUIS-C)* (Mishel, 1981; Appendix E). This 23-item self-report scale assesses perceptions of ambiguity and unpredictability with regards to illness and its treatment. The scale generates a summed score ranging from 23 to 115, with higher scores indicating greater uncertainty. The form was adapted to also allow for assessment of caregiver ratings of illness uncertainty.

The 16-item *Family Satisfaction with Advanced Cancer Care- Patient* (FAMCARE-P16) scale (Lo et al., 2009; Appendix E) was used to assess patient satisfaction with information-sharing, availability and quality of care. Scores range from 16 to 80, with higher scores indicating greater satisfaction with care. The FAMCARE-P16 has demonstrated high internal reliability and has shown responsiveness to change in an early palliative care team intervention in patients with advanced cancer (Lo et al., 2009; Zimmermann et al., 2014). Family satisfaction with care was assessed using the original 20-item FAMCARE (Kristjanson, 1993; Appendix E), which had been designed for use with caregivers. Scores range from 20 to 100, with higher scores indicating greater satisfaction with care.

We developed a *Psychoeducation Knowledge Questionnaire* (PKQ) to assess participant understanding about the topics covered by *Living Well with Pancreatic Cancer* (Appendix E). The PKQ is a 5-item self-report measure that assesses subjective understanding of illness, its management and impact, and available support services. The scale generates a summed score ranging from 5 to 25, with higher scores indicating increased knowledge. Separate forms tailored to patients and family members were used. Internal consistency was high in the present study (Cronbach's alpha = 0.84).

6.2.3 Analysis

6.2.3.1 Qualitative Analysis

Qualitative data was integrated from all sources (*i.e.,* interviews with patients, family members, and HCPs; and field notes collected throughout the study, including during sessions, research meetings, multidisciplinary case conferences, debriefs, and informal discussions). We used conventional content analysis, a systematic approach including open coding and categorization of text, to understand participant experiences and to suggest methodological refinements to the intervention (Hsieh & Shannon, 2005; Elo & Kyngäs, 2008). We used an inductive approach when examining issues of participant acceptability and self-reported benefit. We used a deductive approach for issues related to feasibility and sustainability, based on the Consolidated Framework for Implementation Science (CFIR) (Damschroder et al., 2009), which we had used to guide the development of the intervention (see Chapter 5). Coding was conducted by the lead author (ET) and checked by other research team members (AD, CL). Techniques to enhance the trustworthiness and credibility of analysis were employed, including triangulation (*i.e.,* the comparison of results from different data sources) and peer auditing (Lincoln & Guba, 1985).

6.2.3.2 Quantitative Analysis

Descriptive statistics are reported to characterize the sample. Rates of attendance, consent, and completion were assessed against a priori feasibility criteria described earlier. Means were calculated for all outcome data and we report pre-post differences on illness uncertainty, satisfaction with care, and knowledge. Given the small sample size, nonparametric tests were used to calculate pre-post differences (Wilcoxon signed-rank test for knowledge and illness uncertainty outcomes; sign test for satisfaction with care).

6.2.3.3 Mixed Methods Analysis

Triangulation was accomplished as follows: upon analyzing both qualitative and quantitative data sources separately, the two sets of results were explicitly merged into a combined analysis allowing for fuller comparisons and interpretations to be made.

6.3 Results

6.3.1 Participants

Twenty-eight participants were recruited, consented, and provided baseline assessment data. Of these, 21 were attendees (*n*=14 patients; *n*=7 caregivers) (see Table 5) and 7 were HCPs (see Table 6). Among participants who attended the session, 33.3% (7/21) completed the post-intervention follow-up questionnaire package and participated in a qualitative interview (*n*=5 patients; *n*=2 caregivers) (see Table 7). All HCPs who consented to participate in the study provided brief demographic information and completed the qualitative interview. The mean age of attendee participants was 64 years (SD=12.6; range=28-83) and the majority were female (*n*=13; 61.9%), Caucasian (*n*=19; 90.5%), highly educated with a college/ university education or above (*n*=19; 90.5%), and indicated English as their primary language (*n*=16; 76.2%). The mean duration of illness for patients was 102.6 days (SD=118.0; range=8-410).

Table 5. Attendee participant characteristics at baseline (*n*=21)

Variable	**Mean (*SD*) or *n* (%)**	**Range**
Attendee participant type		
Patient	14/21 (66.7%)	
Caregiver	7/21 (33.3%)	
Spouse/common-law	3/7 (42.9%)	
Child	2/7 (28.6%)	
Friend	2/7 (28.6%)	
Age (years)	64.2 (12.6)	28-83
Time since diagnosis (days)	102.6 (118.0)	8-410
Female	13/21 (61.9%)	
Married/common-law	13/21 (61.9%)	
Primary language English	16/21 (76.2%)	
Caucasian	19/21 (90.5%)	
Education		
High school or less	2/21 (9.5%)	
College/university education or above	19/21 (90.5%)	
# children	1.4 (1.0)	
Ages of children	33.8 (13.6)	10-64
Combined family household income		
$15,000-$59,999	7/17 (41.2%)	
$60,000-$99,999	2/17 (11.8%)	
$100,000-$199,999	5/17 (29.4%)	
$200,000+	3/17 (17.6%)	
Knowledge (PKQ)	15.8 (3.7)	5-21
1. Your disease and how to manage your systems	3.6 (1.0)	1-5
2. How you and your family can cope with your disease	3.1 (0.9)	1-5
3. How to partner with your health care team	3.3 (1.1)	1-5
4. How to plan for the future	2.9 (0.9)	1-4
5. Where to find support services	3.0 (0.8)	1-4
Satisfaction with care (FAMCARE)		

Patient (n=13)	59.3 (10.7)	37.9-96.3
Caregiver (n=7)	75.7 (18.6)	37.9-94.7
Uncertainty (MUIS-C) (n=21)	63.0 (11.0)	40.0-87.7

Table 6. Health care professional participant demographics (*n*=7)

Variable	**Mean (*SD*) or *n*(%)**	**Range**
Age in years	38 (6.3)	32-50
Involved in research study	6 (85.7%)	
Discipline		
Nursing	2 (28.6%)	
Allied health	3 (42.9%)	
Research	1 (14.3%)	
Administration	1 (14.3%)	
Primary role in the WMCPC		
Clinical	6 (85.7%)	
Research	1 (14.3%)	
Duration of employment in discipline (years)	12.3 (8.6)	4-28
Duration of employment in oncology care (years)	8.5 (6.5)	5-23
Duration of employment at the WMCPC (years)	3.4 (1.5)	1-5

Table 7. Attendee participant characteristics at baseline and follow-up (*n*=7)

Variable	**Baseline (t0)**		**Timepoint 1 (t1)**	
	Mean (*SD*) or *n* (%)	**Range**	**Mean (*SD*) or *n* (%)**	**Range**
Knowledge (PKQ) (n=7)	14.6 (2.9)	10-18	18.3 (4.5)	13-24
Satisfaction with care (FAMCARE)				
Patient (n=4)	59.8 (10.0)	48-69	59.5 (11.5)	59-73
Caregiver (n=2)	78.5 (6.4)	74-83	88.4 (13.5)	79-98
Uncertainty (MUIS-C) (n=6)	68.7 (7.1)	56-77	53.8 (13.2)	35-69

6.3.2 Findings

Our qualitative analysis identified respondent feedback on the acceptability of *Living Well with Pancreatic Cancer*, perceived benefits of the session, and ideas on the feasibility of implementation, including suggestions for continued sustainability of the program. Themes were generated based on qualitative data analysis; findings are presented within each of the topic areas related to the feasibility, acceptability, self-reported benefit, and sustainability of the program. To further articulate the theme, descriptive quantitative results are presented alongside each area of focus. All potentially identifying characteristics were excluded to maximize confidentiality of our participants, and direct quotations are indicated by their participation type (*i.e.,* patient, caregivers, and HCPs). See Table 8 for an overview of the mixed methods findings from patient and caregiver participants, HCP participants, and researcher observation and field notes.

Table 8. Summary of mixed methods findings

Areas of Focus	Qualitative Findings			Quantitative Outcomes
	Attendee Interviews	Health Care Professional Interviews	Researcher Observations & Field Notes	
Feasibility of Implementation	Becoming part of standard care			Feasibility outcomes Session attendance rates
	Early delivery			Time from diagnosis to session attendance
Acceptability	Comprehension and organization			-
	Applicability of content			
	Interactive face-to-face panel of experts			
	Group format			
Self-Reported Benefit	Receiving information			Knowledge (PKQ)
	Relationship building with the team			Satisfaction with care (FAMCARE)
	Knowledge of palliative and supportive care			Knowledge (PKQ)
	Planning for the future			Illness uncertainty (MUIS-C)
Sustainability of Implementation	-	Shared ownership and commitment		-
	-	Research as catalyst		
	-	Concerns about sustainability		

6.3.3 Feasibility of Implementation

Ten sessions were conducted over seven active months of operation. The attendance rate was 76%. Of 37 registrants, 28 attended the full duration of the session. Seventy-five percent of attendees (21 of 28) consented to the research study. The 21 attendee participants that consented provided demographic information (see Table 5). Thirty-three percent of consented participants (7 of 21) completed the follow-up assessment (see Table 7).

6.3.3.1 Becoming part of standard care

Participants described the intervention as a program that had the potential to make a difference in the care of all people affected by pancreatic cancer. This theme highlights the importance participants placed on offering the session as part of standard care, as they “think everybody would benefit, because everybody’s overwhelmed.” They emphasized their support for integrating the program into routine clinical care for future patients:

> You kind of have to know how things work and how your diet’s going to be affected, advance care planning, all these topics, right? One way or another, the patient has to learn these things. I think if I were your team, I would place it like: as part of our care pathway, we have this education session we’d like you to come to. (Patient 1)

The clinic team (*e.g.,* oncologists, nurses, administrative staff, research staff, etc.) proposed to integrate this program into routine care of their patients from the start of the implementation process. The program was intended to be offered as a clinical service for patients and families; and HCPs felt that “all patients can benefit.” To introduce the program, a flyer was added to a pre-assembled package that was distributed to all new medical oncology patients in the WMCPC (Field notes, September 2017). Members of the health care team were responsible for encouraging patients to attend the session when they met with them during clinic appointments. People could also self-refer to the session, through flyers posted around the clinic waiting area, on patient education class schedules in the hospital, and on the institution's website. Contact information for the clinic administrative staff was provided on all program materials, to facilitate registration for the next available session.

Although recruitment was initially targeted towards patients in the weekly clinic for new patients, it became apparent over time that a multi-pronged strategy was needed. Patients attending this clinic were assessed by an interprofessional team to discuss treatment plans and to ensure that coordinated care plans were in place. Some then did not remain at the centre to receive treatment, while a proportion of those who stayed to receive care travelled long distances to do so. The ideal recruitment strategy, as articulated by a member of the team, then became "anybody who lives in the Toronto area or within an hour and getting treatment for advanced pancreas cancer should be attending this." The team member elaborated, "some won't and or don't want to. So say that's 50% of what we see. Then there's a group that's just so sick. There are just too many other things to be dealing with. We have to deal with that in clinic. It's tough because of the competing priorities of all the other appointments."

Because of these complexities, self-referral to the program was limited for the first few months despite efforts to encourage registration. As such, the clinical team decided to incorporate the program into the institution's patient electronic scheduling system (Field notes, November 2017). Upon implementation, scheduling access was granted to administrative staff, and the session was offered in the scheduling system as a clinical service for people receiving care at the WMCPC. The scheduled session was visible to patients through the institution's online portal as it was registered as a clinic appointment. The portal is a secure website that allows patients to view all appointments and diagnostic testing results, and can be accessed anytime with a computer, smartphone, or tablet. The number of people registered for the sessions steadily increased over time after the program was integrated into the patient scheduling system (see Figure 2). The clinical team recognized this particular procedural change as an important step for routinizing the program:

> Opening up a grid was very key for these patients because a lot of them depend on the portal and seeing that appointment. I noticed that when we automatically booked them once they had a care plan in place, participation rose immensely, whereas when we don't and we wait for patients to voluntarily enroll, clinics are cancelled because of lack of participants. (Health care professional 7)

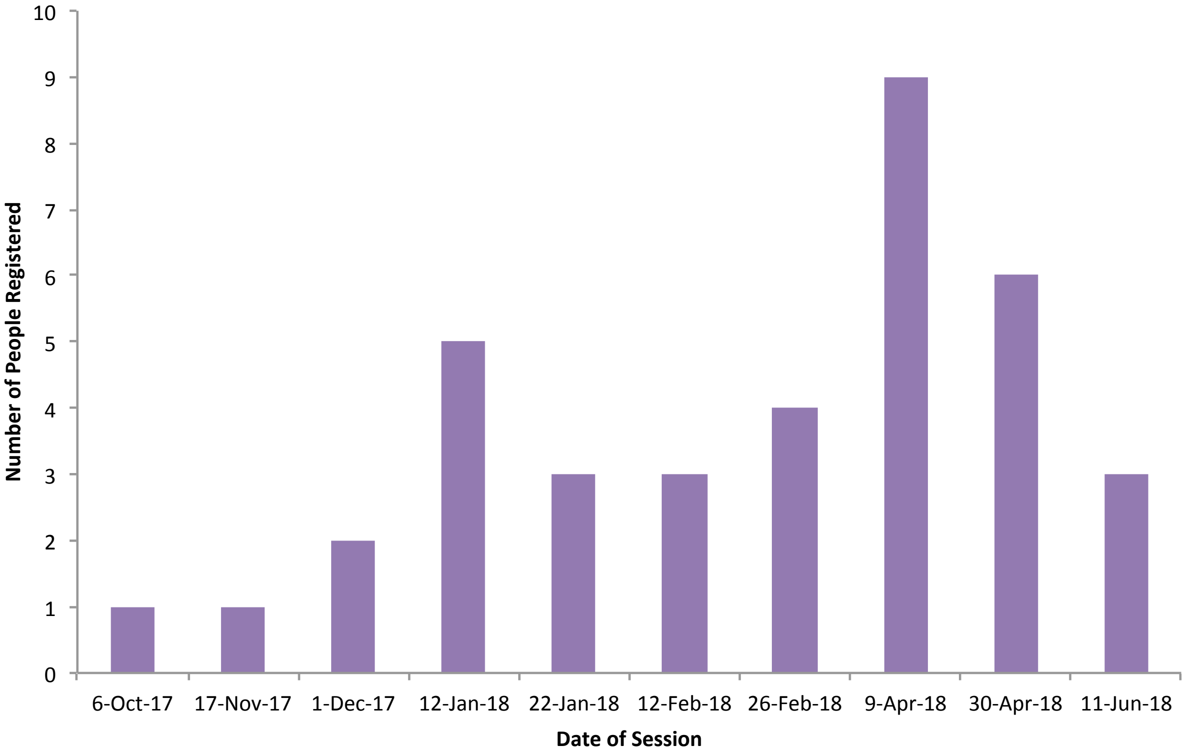

Figure 2. Number of participants registered for the session over time.

6.3.3.2 Early delivery

The median time from diagnosis to program attendance for patients was 67 days (IQR=25-112), with a range of 8 to 410 days. Despite the variability, one consistent message received was that participants wished for early timing of intervention delivery, ideally “within the first month” after diagnosis. This theme of early delivery underscored the value participants described of accessing relevant information as early as possible to improve their understanding of the disease and their capacity to cope with side effects. Those who had attended the session early in their disease course acknowledged the session as a way to receive helpful information at a time when the “whole thing is very new,” and some “would have liked it on day one.” As one patient who attended the session with her partner one week after receiving her diagnosis explained:

> That time was early, so we were trying to go for everything that’s offered, hoping something will help. My husband and I both wanted to go, to join, to see, because the whole thing is very new. So anything we can get information on will be helpful. (Patient 2)

Participants further discussed early delivery in relation to their capacity to participate in the session prior to commencing treatment; a time associated with minimal symptom burden and greater mobility and functioning. Participants suggested that the optimal strategy was to offer the session earlier in the disease course and to everyone affected:

> I think offering it to everyone is the best way to go, because it doesn’t sound like anything aggressive. It doesn’t sound like anything that’s going to be more harmful than helpful. I don’t think you’re going to get patients who are offended by the offer. I think offering it to everyone would still be the best way to go and at the beginning, especially. (Caregiver 1)

In retrospective accounts from those who attended the session further along their disease course, the desire for the option of early delivery was expressed. As recalled by a patient who attended 3 months after receiving her diagnosis:

> I think that an education session within a few weeks after that would've even been helpful. I think you do need education content probably within the first month, because, it's such a new thing. (Patient 1)

The health care team similarly agreed that early delivery of *Living Well with Pancreatic Cancer* was optimal for patients and families. Despite this concordance with the attendee participants, HCPs characterized early delivery as being a time when patients had a confirmed diagnosis, a treatment care plan in place, and once they were settled into treatment and started to feel better. The team felt that having a confirmed diagnosis and care plan before session attendance was important, since patients and family members may not fully understand their situation in order to benefit from the intervention. They were also concerned with burdening participants, and so the aim was to target patients after they had commenced treatment. However, participants felt that having the session "at the beginning" offered an additional source of support and reassurance during a time of heightened uncertainty.

6.3.4 Acceptability

6.3.4.1 Comprehension and organization

The use of plain language was carefully considered during intervention development, and patient education experts were consulted for all patient-facing materials to account for varying health literacy levels and a range of educational and language backgrounds. Participants appreciated how information was "laid out in basic terms" and that "nothing was particularly science jargon, so it was very accessible in terms of that." Participants that did not indicate English as their primary language (19.0%;

see Table 5) were observed to comprehend the information presented and follow along.

In terms of the organization of the presentation, participants commented favourably on the structured format (*i.e.,* presentation slides) to help “reinforce what we were talking about,” while the focus on interactive discussion made room to “stray away from what was being talked about to give anecdotes and feedback as we went.” Facilitators echoed this emphasis on “listening to what they’re saying” to “meet that individual’s need in that moment or just make it a bit more geared towards them.” One facilitator expanded:

> I like the class the way it is because if they do ask questions, it kind of takes it away from the structured presentation we have. I feel like that’s what makes it personalized and individualized and that’s what makes it better for patients. I’m glad we have a structure but I like that we can meet their needs as we go along. (Health care professional 1)

6.3.4.2 Applicability of content

Participants agreed about the applicability of topics covered in the session, ranging from nutrition and symptom management, to planning for the future, which were all described as content that was “useful and necessary to know.” These content areas reflected the informational needs that were frequently encountered by the health care team in their daily clinical practice, including palliative care and advance care planning. These topics were agreed amongst clinical staff as being relevant to include in the session, particularly earlier in the disease course, as one facilitator elaborated: “I think everyone kind of tiptoes around the sensitive topics and subjects but those conversations have to be had and if we start having them early on, my hope is that it normalizes it a little bit.” However, they were still worried that such conversations could be too distressing for patients and families. Despite these concerns, participants acknowledged that the topics described as being more “difficult” were critical to discuss:

> [Advance care planning] was a difficult conversation, but a necessary one I’m sure. You should have to go for the education content, and I would suggest within the first month, because even the advance care planning, which might be shocking for people, like having to talk about that, it’s good to put it in your head, even if you’re not prepared to actually decide everything at the moment. (Patient 1)

Other topics that the health care team felt were important to discuss included the emotional and family impact of cancer. In doing so, they hoped to normalize these experiences and emphasize the goal of “living well and having good quality of life” while “balancing” the disease and the “world of cancer.” For example, people were encouraged to “speak to your health care team if there is something that you want to do that is meaningful to you, whether that may be a wedding, a family trip, or a class. We can work together to adapt your treatment schedules. We will try our best to work around the things that you want to do.” When these ideas were articulated during the sessions, attendees were observed to be surprised and relieved to hear that such changes were possible and that living well and having the best quality of life possible were clear priorities of their medical team.

6.3.4.3 Interactive face-to-face panel of experts

Clinical staff agreed that patients and caregivers often repeatedly asked similar questions that “touch on different things” where “there’s a lot of overlap” between disciplines, given the complex nature of issues encountered. Therefore, there had been longstanding value in having an “interdisciplinary clinic” led by allied health and nursing professionals. Having the panel of experts all “there to answer the questions at one time” would provide an opportunity for each expert to answer questions from their own perspective, while being complemented by opinions from other experts. As elaborated by one staff member:

> My belief is that, in cancer care, working interprofessionally is really important based on the complex needs of patients and families with advanced or palliative cancers, which pancreatic cancer is one. Within the first months [of working in this clinic], I realized the burden of the cluster of symptoms and the high supportive care needs in this population, and thought that we should do something differently. Getting to know the team members and building professional relationships with them, and with the repetitive nature of some of the education, teaching, and learning for patients and families, I thought that doing an interprofessional clinic and taking patients and families out of the clinic to deal with those issues, as well as advanced care planning, may have been a better approach. (Health care professional 2)

Facilitators recognized that this session presented a unique clinical encounter—it was a first in their respective clinical practices when they were delivering care together across allied health and nursing disciplines, as well as caring for more than one family unit at a time. When the sessions first began, facilitators felt “nervous” to “present” and perform in this context and they were observed to feel more comfortable facilitating with their designed script (Appendix A). As sessions progressed, facilitators gained repeated practice and learned techniques from each other. Over time, facilitators were observed to show increased comfort with the content and mediation of group processes:

> I think it’s worked out well and the more we do it, the more comfortable we’re going to get with it. From the first few times we started doing it, I was like, what am I supposed to say again? […] I generally don’t love presenting. It makes me very nervous. (Health care professional 1)

As sessions continued, facilitators were observed to learn from each other and to develop a fuller understanding of issues encountered across disciplines. They were then observed to provide complementary and more comprehensive answers to participants. Besides these self-directed benefits, facilitators predicted how the informal, interdisciplinary-led format could also be of benefit to participants. As one commented:

> I think it’s better for the patients because I think it’s easier if it feels like a conversation versus a presentation. They’re probably going to be more likely to participate because it’s like, okay, this is informal, we’re just chatting, no big deal. Versus, I’m sitting at a chair looking this way, not looking this way, who’s sitting next to me, just listening to the person in front of me talk. (Health care professional 1)

To further enable this kind of supportive environment, facilitators emphasized at the start of each session that “this will be a safe environment, and any questions that may be asked will remain in the room and stay confidential. No questions are too simple or too stupid to ask.” Participants acknowledged their appreciation for a safe atmosphere for communication and support. In the excerpt below, one participant recounted her experience with the session as compared to other clinic visits in the hospital:

> Coming to the session was nice, because it was different than the clinic. It was kind of nice to go to an information session where you’re going to sit down with people who know what they’re talking about and are able to provide feedback and support. It’s not as busy as the clinic, so it makes it a lot more relaxing almost, like you’re just kind of in a class almost, like an interesting class. It was nice having it available, but not really associated with the clinic, but kind of. (Caregiver 1)

Participants described their overall experience with the session as one that provided face-to-face delivery of accessible and reliable information by the HCPs on their team. As one participant said: “I just think it’s much better to sit in a room with people who have the information and to talk to them, so I think it’s a better way to deliver education, like in person.”

6.3.4.4 Group format

The group format was considerably discussed as a distinct benefit of the session amongst participants, as they expressed their desires to meet others in a similar situation, to share experiences, and to seek and provide support. This was of importance as they also recognized the difficulties in bringing together a group of patients and families, given the poor prognosis of disease. In one scenario, a daughter caregiver attended a session months after her mother was diagnosed with pancreatic cancer, and was joined by a son caregiver of a patient diagnosed only a few weeks prior, and a patient who had been living with the disease for 3 months. Throughout the session, the son caregiver seemed overwhelmed as he was still adjusting to the realities of the disease. The other caregiver responded by offering advice about what he might encounter and ways to support his mother, and in turn, he was observed to be appreciative of the support received. After the session, further exchanges were observed between the patient and the daughter caregiver, as the patient gave advice to help her in supporting her mother. Indeed, when this daughter caregiver was interviewed, she expressed the benefits of meeting others to not “feel like you’re alone” and the synergistic effects of a group session. She described further, “It allowed for communication between patients and family members who are experiencing the same thing. You can also provide feedback for them and they can provide feedback to you.”

The desire to connect with others in a similar situation was likewise expressed by an individual who came to a session alone, and in the absence of other participants, a group session may have helped to address her wishes. As articulated through her accounts of her experiences coming to the hospital: “I never know who’s there, who’s like me. You’re just in your own chair and there’s not a lot of conversation going on.” From her further perspectives:

> I know that there are not a whole lot of survivors, so it’s difficult to buddy people up, but it would help people to be able to talk to somebody who had the disease […] I just

> think some kind of buddy system or some way to link the patients to somebody who had [pancreatic cancer]. (Patient 1)

Clinical staff similarly acknowledged the benefits of a group setting as “it kind of works as a buddy system” and it “takes away some of the isolation of being alone in a diagnosis that is scary and people would have comfort in knowing that there are other people with the diagnosis and you’re kind of in it together.” At the same time, facilitators were aware of its potential disadvantages, such as discussions derailing into specific treatment plans, which “you can’t stop from happening”; “comparisons” between personal situations (*e.g.,* “well, I’m on this and you’re on that and why is your doctor doing this”); or provoking anxiety (*e.g.,* one says, “I’m considering treatment but I’m worried about the cancer coming back,” while someone else says, “well, that’s it, I had surgery and now my cancer is back.”). In considering the makeup of groups, some hesitation from the facilitators was observed. Yet, these hypothesized scenarios did not appear to manifest as frequently or to its anticipated magnitude in the group sessions. The facilitators were often observed to manage group dynamics expertly, and to diffuse discussions before much derailing could occur. Moreover, as a session would progress, the nature of being with others in a similar situation was observed to calm individuals who were perhaps more overwhelmed with their personal situations at the start. So on the “positive end,” there was a “real synergy” and supportiveness observed in the interactions between patients and family members, which fostered some hope of living well:

> There were a couple of people there who gave me some positive feedback in the sense that they’d obviously gone through some of this already and had surgery and seemed to be quite well, which made me think that there was some hope sort of thing. (Patient 7)

A facilitator made a parallel observation when reflecting on these group dynamics:

> I’ve kind of thought it’s been in our favour or the patient’s favour when we’ve had an individual in the class who has done pretty well in treatment, obviously still has

> disease, but is living well and I feel like it gives those newly diagnosed patients that piece of hope. Like, obviously we don't know what's going to happen, but in the class, we're telling people, be hopeful but let's plan for the worst or the future. But, seeing those people, I think, gives them that hope. (Health care professional 1)

The group dynamic was also observed to allow mutual understanding of circumstances and lived experiences to be shared in a safe space, while also being supported and given accurate information by HCPs as needed. In one interaction, a patient and her daughter attended a week after receiving a provisional diagnosis, and were joined by a patient with her spouse who was on treatment and diagnosed 6 months prior. The first family was deciding whether to pursue chemotherapy or forgo treatment, and expressed it may be helpful to talk to someone who had been through it. The spouse caregiver jumped in, "You mean someone who's been in chemotherapy? Well here you are!" as he referred to his wife, who continued, "Everybody is different. But for me, life has continued and I've had a good quality of life. My general wellbeing improved radically. I've been much much better." The first family seemed grateful to have had the opportunity to hear from others who had been through chemotherapy. The nurse facilitator interjected, "And the goal of chemotherapy is not to be in bed sick, and just know, you can also delay your decision. But, you also won't know until you try. You can always give it a try then stop if you don't like it."

6.3.5 Self-Reported Benefit

The main themes that emerged to indicate impact of the session experience on participants were: (i) *receiving information* – information to aid comprehension and understanding; (ii) *relationship building with the team* – building relationships with members of their health care team; (3) *knowledge of palliative and supportive care* – learning about the range of services available to support patients and families; and (4) *planning for the future*. These reactions to the session experience and their self-reported impacts are detailed below.

6.3.5.1 Receiving information

Participants commonly commented on the “piles and piles of information out there, coming from all different directions.” They felt quite overwhelmed by the vast amounts of information that seemed to be readily available to them, with sources ranging from the health care team, web-based resources, and anecdotal advice from personal support circles. Given these experiences, participants acknowledged that some of the information in the session did “overlap” with information they already knew. However, participants expressed their appreciation for receiving “tidbits of information” in the session. This repeated exposure helped them continue to process information, which cumulated over time. As one participant commented, “I think there are always bits and pieces that you learn as you go along, and in a way, that’s really the best that can happen.” In turn, this process led to greater levels of understanding over time and may be particularly important in this disease context, as one’s physical and emotional condition is dynamic:

> And just getting the information more than once is, you know, you get something every time somebody says something, you get something different and your own condition changes and your own level of acceptance with where you’re at, so you can receive more. (Caregiver 2)

In the clinic, there was a dedicated weekly combined interprofessional new patient clinic to allow timely assessments by various specialists. Although this integrated interdisciplinary approach was optimal in managing patients and clinical outcomes, clinical staff described their observations of family experiences in the clinic as a “fog for people” where they were “stricken with fear and anticipatory grief.” Similar to the attendees’ accounts, clinical staff found that “most information” they provide “goes in one ear, out the other” or that people just “forget so much of what they hear in that first new patient clinic.” They recognized the benefits of providing an “educational class at a different time” to “help patients grasp information”:

> I find in that [new patient] clinic, people are in such shock and are so upset that they can’t process things. I

> think when social work has to go in, there's a specific thing that you're doing. So maybe you're providing emotional support, maybe someone's freaking out about resources, but because you're meeting with them one-on-one you can tailor it to them. Whereas, the class is more general and you don't do the one-on-one piece so much. So I think the class is a complement to the clinic because you can't cover everything in the clinic and everyone needs that information […] I think half the time of when I'd give things to people, like brochures, my card, whatever it may be, they somehow don't know where everything is anymore; they can't remember what we talked about; they don't know how to reach me. (Health care professional 4)

These benefits were similarly reflected in the self-report outcome data. A Wilcoxon signed-rank test showed that participants reported greater levels of knowledge after attending the session (median 20) than before (median 16) and this change was statistically significant (*Z*(7)=-1.997, *p*=.046) (see Table 7 for mean scores).

6.3.5.2 Relationship building with the team

Participants regarded the opportunity to meet with and receive support from their health care team as an important component of the session, as one patient put it, "I think you're trying to make clear that these are contactable people, so I liked that idea." They expressed that the opportunity to build relationships with the "people who are working behind the scenes" helped them identify the "people that I can talk to are if I need to talk to them." As one acknowledged:

> I think part of it is relationship building, you know, seeing the dietitian, the social worker, and the nurse associated with the clinic time after time, can sort of help the patient build a relationship with them […] Things will be better for these patients if they have some sort of relationship. For me, I feel like I have some relationship with HCP X that I feel comfortable to email her or ask her questions. I also have developed a relationship with HCP X by going to see her one-on-one. And these are things that will change the patient experience. (Patient 1)

Facilitators were perceived to be distinct supportive figures, and participants described that this helped them “not feel alone; you feel supported.” Such interactions made them feel that it was “much easier to call them later” when they needed to. Participants expressed their further gratitude for how the facilitators aimed to normalize difficult circumstances in a realistic yet supportive way. This was clearly articulated by one patient-caregiver dyad:

> Caregiver 2: What’s interesting is to normalize the experience of having a very bad disease with a terrible name that everybody’s afraid of. So, seeing other people with it that look kind of normal and together is helpful, too, and it’s very nice to have people talk about it not as a, “I’m so sorry you’re doing…” So just being very matter of fact about it and talking about this period of your life as just another part of your life; it’s not your life is over, now you’re just waiting to die. It’s not what you want.
>
> Patient 5: This is such a good thing that to show, to show people, people that care about you’re, you know, like…
>
> Caregiver 2: You’re not alone. Yeah, it was very well done. And from that perspective, it was nice to have the different areas represented.
>
> Patient 5: Oh, just that. Put a note somewhere it’s a very good thing. It showed, yes, we’re there. I don’t know how to say it…
>
> Caregiver 2: You felt supported, I think.
>
> Patient 5: Yes, you feel supported, and I feel like this with my family, but then there is a professional help. They’re support, too. And I like the way things are said and it’s not like, “That’s okay; don’t worry.” It’s not like that. They put you in front of a situation and then try to say “we’re here; we’re here,” like my family does. “Yeah, it’s a difficult situation, but we’re here with you.”

The increased comfort felt by participants in knowing who to reach out to when subsequent support was needed was further reported by the facilitators, as they were sought out for professional support through self-referrals later on:

> A family member came [to the session] and then when her mother died, she has been in touch with me a lot. She comes in once a week since her mom died because that was the connection that was valuable and it led to her feeling like she knew who to call when she needed help. (Health care professional 5)

Facilitators expressed that the session offered the opportunity to reach and care for more people than they perhaps otherwise would have. This also helped them identify those with complex needs or elevated distress, which was described as a positive outcome of the session:

> We're probably reaching more patients than we normally would because not everyone needs to see a dietitian. Not everyone needs to see a social worker. So this way I think we're getting to see a lot more patients, which is good and hopefully, it'll also help, if everyone were going to it, hopefully it would pick out or help us figure out the people who are well and will get what they need from the class and go on, and then the people who would really benefit and need the one-on-one, they can get it. (Health care professional 1)

In some scenarios, they found it useful to be able to attend to the issues with a multi-pronged approach together in one room. Others were addressed after the session or were flagged for follow-up, as the subsequent care of one particular patient-caregiver dyad was described by a facilitator:

> That was an excellent catch because he was so distressed that it was impacting her. He's actually connected to psychiatry here through that meeting and he's actually very stable now and very calm. It's her actually who's been more anxious, but he's in a better position to support her. So that was a very good outcome to having them come that early on, because we identified a need, addressed it through the

> psychosocial care, and then it's led to helping her. She was the really emotionally stable person at the beginning and then as her disease progressed, she got symptoms, and she became very anxious herself. That's a really good outcome because without the class… I mean I think it would have been identified in clinic, but not in the same way maybe. (Health care professional 5)

Despite these benefits expressed by participants, there was no significant improvement in satisfaction with care at the follow-up assessment (*p*=.875) (see Table 7 for mean scores). The two-tailed sign test of the FAMCARE and FAMCAREP16 revealed 4 positive observations and 2 negative observations.

6.3.5.3 Knowledge of palliative and supportive care

Participants were observed to be relieved to be given information about available supportive care resources at the hospital and in the community, and expressed interest in pursuing them. One caregiver appreciated being able to then relay this information to the patient who was unable to attend:

> It was nice to have the community support recommendations up there, because she did start going to some of the sessions that were available through Princess Margaret after that. She went to the meditation classes and stuff like that. She went to another one. I completely forget what it is, but while she was able to travel around, it was kind of nice for her to have something to do, because after her treatment and towards the end of her treatment, she was kind of bored and she was looking for things to do. So it was nice to know where the resources were and to know what was available and stuff that's available for free to patients. (Caregiver 1)

Participants often expressed their desire to seek supportive care services after learning about the various options. However, some experienced logistical conflicts and wished the programs offered more flexibility in attendance ability. For example, one patient recounted her frustration and difficulties in committing to a yoga program, despite her desire to attend:

> Part of the problem, is that this yoga, I think it was on Day Xs, were my chemo days so I couldn’t go to that one. The other tricky thing is they wanted you to agree to go to every session, and for me, that was hard because my first week is really terrible where I don’t feel well at all. I really don’t feel like driving because my hands are shaking and my legs are shaky. Community Organization X does have a general yoga drop-in and stuff like that, so there are things I could access there. But I feel like both of these programs didn’t work out for me just because of the day or the timing and the requirement to be at every session. (Patient 1)

HCPs found that introducing the idea of palliative care often led to patients thinking they were not being told the whole truth and that they were being referred for EOL care. As it was a “delicate topic,” they carefully explained what palliative care meant to participants in an effort to destigmatize the term. Participants acknowledged their preexisting beliefs about palliative care and found comfort in learning that palliative care did not equate to care for those only at the very end of life. Some then self-referred to palliative care:

> Initially I thought palliative care was all about relieving pain until you die but I understand that, in fact, they do treat people who are not at death’s door or who just need help with things. So, that’s why I contacted them but it takes a month to get that going. That actually was one thing that I did learn about in the information session that I attended, so that was good. (Patient 7)

6.3.5.4 Planning for the future

The health care team felt that the discussion points were important to discuss with patients and families, and even if one was feeling overwhelmed, the session served to “gently start those conversations.” They hoped that the session could help participants learn how to plan for the future and know what to expect, which may help to relieve some fears and distress:

> I think it would be awful for patients to be sitting at home with so many questions and having so many unknowns when you could just get the information in a straightforward way. Because at the end of the day, if they get that information and those answers, hopefully anxiety would go down and then that also helps the whole impact of the team because then you don't have patients calling in crisis because they have no idea what's going on or how to cope. I think that impacts everyone. That's nursing and the triage in clinic, that's the doctors, that's social work, it's across the board. And for patients, to feel empowered to get information so that they have a bit of control, because you get that diagnosis and you lose so much control. So I would hope that they felt confident in what they learned to move forward. (Health care professional 4)

Indeed, participants noted that the content helped them "have a better idea of what they're facing" and "what to expect and resources," while also helping to "cut down on some questions in the future." These benefits were recognized by participants as a way to help address some of the uncertainty they felt about their future. As one participant claimed: "This is the future, I just wanted to know, what should I do to help myself cope, and help me to cope." These findings were aligned with the quantitative data. A Wilcoxon signed-rank test showed that participants reported a reduction in the levels of illness uncertainty. Median scores on the MUIS-C before and after the session were 70.5 and 55.5, respectively (see Table 7 for mean scores). This change was statistically significant ($Z(6)=-2.201$, $p=.028$).

6.3.6 Sustainability of Implementation

6.3.6.1 Shared ownership and commitment

The most striking observation throughout the implementation process was the shared commitment displayed by all stakeholders involved. The motivation to create and implement this kind of interdisciplinary program for this population had been longstanding amongst team members. The value in constructing this was articulated as a means to provide additional support to patients and families, to help them understand how to manage their disease and to live well, and to help ease the entire team's workload. One facilitator noted, "At the beginning I was a little reluctant about the time commitment and all the work, but you just have to decide that you're going to do it and start planning the program. So that was my thinking, that the patients and families needed some extra meeting time with nursing and allied health." Beyond simply supporting the facilitation of the session itself, team members dedicated additional time and effort:

> When you're already so clinically-based and most of your day is already eaten up by just the day in and day out processes, and like with any project, you end up doing it after hours. So it's not a huge issue, you just have to commit to it and I guess it was good to be pushed about the timelines and just know that you had to have it done and then getting together and stuff like that. (Health care professional 2)

Through field observations and health care professional accounts, it became apparent that such collective enthusiasm and volunteerism was instrumental in driving the creation of this program:

> I think the good thing about the way this was we didn't need extra resources to do it. Like we created something that was within our means. Yes, it was a bit of work in the beginning because we had a lot of meetings and trying to figure everything out. But then, we found space to do it. We have the people here to do it. I think we created something that is sustainable. I don't think we needed extra money to make this happen. We're doing something that we should be able to keep going with. (Health care professional 1)

The learning process of presenting the content and delivering the session together became "easier" and "more relaxed" as they continuously supported and encouraged one another. This gradual shift to developing a strong synergy between facilitators was clearly observed. And as they continued to learn together, their personal confidence and team intimacy and trust was observed to enhance over time as well. One of them expressed:

> I think the fact that we're sitting at the table with them [participants] and [HCP X] and [HCP X] are there, essentially supporting me while I'm doing my part. That makes me feel more comfortable. Like, if I forget to say something, I know [HCP X] will jump in with something brilliant to say, which is always nice to know. Having you guys there and having it be an informal setting makes me feel a lot more comfortable. (Health care professional 1)

6.3.6.2 Research as catalyst

Despite the pre-existing motivation by the clinical team to develop an interdisciplinary clinic "since the inception of WMCPC," it had been challenging for them to organize the resources required alongside their clinical workload:

> With all the other responsibilities in the clinic, finding the time and space was a bit challenging. So it was always a thought I had, I just hadn't put a process or started to really think about a protocol to figure out how to do that. Then, Dr. X came to the pancreas group and he was looking at a psychoeducational program to trial this, it seemed a good fit. (Health care professional 2)

The promise of a research study then served to facilitate the development of such an intervention and procedures required to execute its implementation. The contribution of time and resources from researchers helped to centrally coordinate and organize the clinical team, intervention development, conceptual oversight, and program logistics. Research collaboration was recognized as a forefront consideration when beginning a clinic initiative, as one health care professional explained:

> Bringing in any new anything [into the clinic], it's so much easier to do it through research, because then, it's

> protocolized, and it’s like bold clarity, it’s cemented and defined and all those things […] like, the step-by-step granularity of what needs to be done. So I think that we learned something for sure, that we just need to, even if it's just quote unquote, psychosocial or non-drug intervention or non-correlative study, we still need to follow the same sort of process. (Health care professional 3)

6.3.6.3 Concerns about sustainability

The continued sustainability of the program in the clinic was a matter of considerable dialogue throughout the entire implementation process. Despite the joint commitment to the program, the main challenge to its long-term sustainability, as raised by HCPs, was inadequate human resources. This challenge was discussed in relation to time and funding. As described earlier, they valued the support offered from the research component, and questioned how the conclusion of the research study would affect the continuation of the program:

> You’re spending collectively eight to ten hours of human resource time for three or four [participants]. If you really think about it, it’s two hours each, that’s eight upwards of ten hours for all the pre-booking and getting ready for two patients plus a family member seems like a lot. It’s a lot of resources to run it and we have some support because it’s research-driven at the moment. What’s going to happen when that’s gone? So, I’m already thinking about that. Like, is there anything we can do differently? (Health care professional 2)

Team members commented on their difficulties balancing volunteered time to the program alongside all their other clinical duties. One facilitator remarked, “I think it is always hard in a hospital, because everyone’s time is stretched so thin.” Dedicating allocated time to prepare for and facilitate the session was a constant issue, as another described:

> The challenge, depending on your day, is committing the time. And it’s not like not wanting to commit the time; it’s just the reality and pace of the day in a hospital. So, I think that’s another thing that can be a challenge depending on the week. (Health care professional 4)

Deciding on an optimal number of people to have in a session was an ongoing discussion between team members. Through trialing over time (see Figure 2), the team recognized that having only one patient in the session was not sufficient to justify the use of two or more hours of volunteered time of three HCPs:

> I think about other group work that I’ve done and I would say, consistently from what I know in the community, is having cutoffs. So, a group doesn’t run if two people are coming, which really stinks for those two people. And I think by having larger groups, you justify it more in using staff time. I think the numbers thing is probably something that would, that I would think about in making a case to sustain it or if you needed extra money and you were advocating. I think numbers have to be there to make it grow. (Health care professional 4)

After one particular session with 10 participants, the team debriefed that it had been more time-consuming and personally draining to facilitate such a large group and to address many different concerns in the room altogether. As one pointed out, “Figuring out what the ideal cap is: if 10 is too much and 2 is too little, what number in between would be the ideal state?” From these experiences, the team collectively decided that the optimal parameters for running a session would a minimum of 2 patients and a maximum of 8 participants.

As mentioned above, the program was integrated into the patient electronic scheduling system and registration improved. The placement of appointments on peoples’ schedules also helped because it is much “easier for them to see things electronically, as about 90% of our population is on the patient portal.” At the same time however, the resourcing required to track and register patients and families increased as well:

> It’s been more active. I think putting it on their schedule is not a cookie-cutter approach, because they may not have their diagnosis, so it takes some extra human resources to track who’s ready and then to offer it to them. So who has… where are the human resources to do that? (Health care professional 2)

Aspects that were described as necessary upfront and ongoing work included: planning and preparing presentation materials; booking and setting up the room for the session; and tracking, registering, checking-in, activating clinic visits in the electronic scheduling system, and following up with those that attend. In relation to the continued sustainability of the program, team members suggested the need for additional support or funding for administration, as many of these demanding duties required administrative support:

> After opening up the grid and finally getting that established, I created a registration sheet and I’ve had to book patients in, create MRNs for family members and patients too, and identify that they were seen here at Hospital X by this service. I’ve booked their visits, I’ve set up a room, I’ve checked them in, and I’ve activated their visits. (Health care professional 7)

Facilitators were observed to manage multiple factors simultaneously when conducting group sessions, which were distinct from their daily clinical encounters. Facilitators noticed how they had to be constantly aware of making everyone feel comfortable and heard, while also making sure “everything is covered” and that they were “saying the right things and doing the right things” and not “getting off track.” They experienced this to be quite demanding of their own personal resources:

> It’s quite exhausting. It’s easy to facilitate, but at the end, you’re tired and then you have to go back and do more clinical work. I may make it seem easy in some way, but it is actually quite mindfully exhausting. (Health care professional 2)

6.4 Discussion

Our findings suggest that the implementation of an interdisciplinary-led group psychoeducational intervention in a pancreatic cancer oncology clinic is potentially feasible. Following our trialing efforts of implementation procedures, establishing the program as a clinical service and integrating the *Living Well with Pancreatic Cancer* sessions into the clinical setting led to improved participation rates over time. The value in offering the program as part of standard care was articulated from all perspectives, from patients, caregivers, to HCPs. Early timing of session attendance was preferred by attendee participants, and this was related to the early accessibility of knowledge and support. Optimal timing of intervention delivery will require a balance of attendees' wishes for early timing and clinical judgement. Attendee participants expressed their desire for receiving digestible information in this kind of forum, despite the overlap with what was already known, underscoring that information assimilation and understanding occurs as a dynamic process over time (Nissim et al., 2017).

The intervention content and format was acceptable to patients, caregivers, and HCPs. As sessions progressed, facilitators came to develop a more comprehensive understanding of issues across disciplines, and became more comfortable with the content and mediation of group processes. This finding highlights the importance of individual beliefs in one's own capabilities within a particular context to achieving implementation goals (Bandura, 1977). Participants reported benefits from the session, including feeling that they had more knowledge and understanding of their circumstance, palliative and supportive care resources, and of planning for their future. They appreciated the support received from their health care team and expressed their desire to continue building those relationships. The relevancy of information presented and support needs for participants are consistent with previous studies on unmet needs of people affected by pancreatic cancer (Beesley et al., 2016a) and advanced cancer more broadly (Moghaddam, Coxon, Nabarro, Hardy, & Cox, 2016; Nissim et al., 2017). The constructs of quantitative outcomes selected for this feasibility study corresponded well to the benefits identified by participants. However, participants reported that items from the measures of illness uncertainty and satisfaction with care were not relevant or appropriate, and this was related to the timing or nonspecificity of items. This suggests that careful consideration is needed when selecting outcome measures for these constructs in future studies.

Shared commitment to the implementation effort catalyzed with a research study allowed for the launch of this testing phase and continued interest in its sustainability. There remained concerns about time and funding for the sustainability of this program within the clinical setting. Moving forward, these concerns will need to be carefully considered and co-designed, recognizing the environmental context and available capacity and infrastructure.

Limitations to our study included the use of a single group, non-randomized design, that does not allow determination of differences between those who attended the intervention from those who did not. The time lag between intervention attendance and post-assessment and circumstances that can occur during the intervening time may influence the assessment. Future work should seek to determine the optimal timing of assessment. The sample size and lack of a control group in this feasibility study did not allow for sufficient statistical power to assess the impact of the intervention based on the self-report measures. The potential for recall bias due to the subjective ratings of self-report measures is a further limitation. In addition, our purpose-built *Psychoeducation Knowledge Questionnaire* is a subjective evaluation of knowledge, and therefore could be influenced by subject bias and demand characteristics. For future research, we recommend the development of an additional, psychometrically sound, measure to assess content knowledge. In order to minimize practice effects, this scale should include parallel forms of equal levels of difficulty that assess the same concepts. The generalizability of our findings is unclear, as individuals who attended may have been more motivated to participate and have some basic understanding of English. Future research should carefully document all eligible patients in the clinic to accurately reflect program enrolment rates, which can further influence administrative buy-in and sustainability. Despite these limitations, our early phase implementation study highlighted the facilitators and barriers to achieving implementation success within a complex disease setting.

6.5 Conclusions and Implications

The findings from this study are encouraging and demonstrate that early phase implementation within the clinical setting is feasible. Commitment and volunteerism from all stakeholders involved are critical to begin an implementation endeavour. The catalyst of resource support from the current research study facilitated a platform to mobilize the endeavour. In order to continue sustaining the program, however, additional human resourcing is required, such as dedicated allocation of resources to program operations. This would involve ongoing efforts of advocacy and planning to establish support for administrative and supportive care needs. The lack of such resources may reflect a broader under-prioritization of supportive care, compared to other aspects of cancer care, at higher levels of organization and decision-making (Rodin, 2018).

This early phase mixed methods implementation research allowed us to explore multiple perspectives and articulate the nuances of implementation efforts within a complex clinical setting. We obtained valuable information that can be used to strategically influence the iterative tailoring of this intervention to enhance its relevance to clinical practice. Overall, our findings lend support for a next phase of testing with more stringent feasibility criteria, implementation strategies, and a randomized design. These methodological considerations will allow us to understand the effectiveness of the intervention and their underlying mechanisms in improving knowledge, reducing uncertainty, and improving satisfaction with care.

Chapter 7: General Discussion

We developed *Living Well with Pancreatic Cancer* using principles of implementation science to create an interprofessional and sustainable model of supportive care education. By reporting on intervention development and early phase evaluation, as articulated in this thesis, we aim to advance the field of implementation science. Our intervention development model emphasizes rapid and relevant knowledge translation to maximize opportunities for integration of team and user feedback. Our iterative development and evaluation process grounded in implementation science frameworks offers an innovative design for complex interventions. This thesis presents a novel approach to promote systematic uptake of complex interventions in routine clinical practice. Ultimately, this thesis outlines an approach to intervention development, evaluation, and reporting that may help us to address complex health care problems in different contexts to improve delivery of care.

7.1 Methodological Contributions

This thesis project detailed two articles: (i) the rationale, decision-making processes, and methods for intervention development used for *Living Well with Pancreatic Cancer;* and (ii) an early phase evaluation of the feasibility of this complex intervention. This thesis offers important methodological contributions to the burgeoning application of implementation science in clinical research. Although not commonly represented in the literature, reporting this type of research is necessary in efforts to unpack the “black box” of intervention development (Hoddinott, 2015). Despite methodological guidance for best practices of complex intervention development and evaluation (Medical Research Council, 2000), there continues to be inadequate detailing of complex intervention components and processes in the literature. Transparent reporting is imperative for clinical research, including the documentation and rationale behind decision-making in intervention development and evaluation (Craig et al., 2008). These efforts are in the spirit of the current movement for transparency in clinical research, including increased mandatory use of standardized reporting guidelines, open-access peer-reviewed publications, and data sharing for clinical trials (Taichman et al., 2017). The documentation of all phases of research detailed in these two articles is aimed to align with efforts for transparency: to enhance scientific rigour, facilitate knowledge exchange, minimize research waste, and make reproducible and measurable impacts on health care.

Over the past decade, scholars have advanced a surge of frameworks, theories, and models to guide the field of implementation science, such as the Knowledge-to-Action (KTA) Model (Graham et al., 2006), the Promoting Action on Research Implementation in Health Services (PARiHS) framework (Kitson et al., 2008), and the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009). These aids were developed to elucidate the mechanisms by which implementation strategies succeed or fail (Nilsen, 2015). While a greater understanding of theoretical underpinnings were required to advance this new field of science, there is now an abundance of approaches that may make it difficult for researchers to select and apply an appropriate framework. To address the lack of guidance on implementation science frameworks in practice, we demonstrated and reported the principles of implementation science as applied in the present intervention development study. Informed by Schofield and Chambers' (2015) framework and the CFIR (Damschroder et al., 2009), we developed an evidence-based, manualized psychoeducational intervention to support people affected by pancreatic cancer. Decisions to achieve a feasible and both cost- and time-efficient intervention led to a prototype consisting of a single 1.5 hour group interactive education session, to be delivered by interprofessional team members positioned within the implementation site.

Following the intervention development process, an implementation feasibility study was conducted. Reporting of early stage implementation results are rarely documented in the literature given the challenges associated with interpreting preliminary data; however, such documentation can be of benefit. Specifically, factors and trends that affect uptake of evidence into practice can be highlighted at an early stage and may thereby influence subsequent planning and program development (Stetler et al., 2006). For example, preliminary feasibility and efficacy data can inform the potential to achieve desired outcomes, gain momentum and buy-in, and inform the sustainability of the strategies employed. This is an important methodological contribution of this thesis; iterative feedback allows for the optimization of the intervention in real time by refining implementation strategies in a proactive fashion. Formative evaluation was used to explicitly study the processes and effectiveness of our initial implementation of *Living Well with Pancreatic Cancer*, with the goal of optimizing its integration in the pancreatic oncology clinic. The analysis identified informative and suitable strategies such as shared ownership and commitment to the intervention among stakeholders and research resource support.

Moreover, this thesis provides highlights the importance of collecting qualitative and quantitative data that can complement or challenge each other, to generate a more complete understanding of a phenomenon (Teddlie & Tashakkori, 2003). Mixed methods designs may be particularly valuable in supportive care research, which involves complex behavioural interventions that lie at the intersection between science and art. Implementation researchers also support the use of mixed method designs (Palinkas et al., 2011; Landsverk et al., 2012), recognizing that the process of implementation is inherently complex and multifactorial. As such, the success or failure of outcomes depend on structural, organizational, social, and individual factors.

7.2 Implications for Practice and Health Systems

7.2.1 Living well and planning for the future

Our findings revealed that the format and content of *Living Well with Pancreatic Cancer* were acceptable to participants. They also reported benefits such as feeling they had more knowledge of how to manage their disease, a better understanding of palliative and supportive care, and how to plan for the future. These findings highlight that people are receptive to and may benefit from discussions that encompass all aspects of facing life-threatening disease, from the relevant physical, psychological, to social aspects of their condition. It is possible that this openness reflects a desire of patients and families to engage authentically with their circumstance, to share experiences with others in a similar situation, and to receive support from their health care team. This may be reflective of the therapeutic potential of redefining hope, through focusing on living well while simultaneously planning for the future (Jacobsen et al., 2017). This is an important consideration, as the capacity to balance between engaging in life and tolerating the awareness of death is considered essential for psychological adaptation in the context of life-threatening disease (Rodin & Zimmermann, 2008; MacArtney et al., 2017).

7.2.2 Palliative care

The findings from our analysis suggest that our approach to discussing palliative and supportive care was acceptable to participants. This may be a useful strategy to consider as we continue efforts to educate patients, families, HCPs, and the public of a broadened definition of palliative care—one that emphasizes its necessity for high quality care. These efforts are imperative as there remains much stigma attached to palliative care, with its perceived association with EOL care and death (Zimmermann et al., 2016). Although initially conceived as care at the end of life, pioneered by prominent figures like Cicely Saunders and Elizabeth Kubler-Ross, palliative care has since evolved and expanded rapidly upstream to care at the point of diagnosis of a serious life-limiting illness (Zimmermann & Wennberg, 2006; Clark, 2007). This global evolution to how we define palliative care is reflected in clinical recommendations (WHO, 2002) and increasing evidence for early palliative care to improve quality of life and satisfaction with care, and reduce distress (Bakitas et al., 2009; Temel et al., 2010; Zimmermann et al., 2014).

Efforts to promote education about palliative care may be optimal at this time, in the context of serious progressive illness and at the crux of a changing societal landscape. Persisting stigma attached to palliative care partly rests on a greater societal stigma and fear of death (Zimmermann & Rodin, 2004); however, societal attitudes towards death and dying are changing. Contributions to this shift include a worldwide demographic change in population ageing, increased openness and awareness to discussion about death, attention to the EOL experience and topic of a "good death" (Ellershaw, Dewar, & Murphy, 2010), and legalization of medically-assisted dying in countries around the world (Emmanuel, Onwuteaka-Philipsen, Urwin, & Cohen, 2016). These educational goals reflect a broader health care movement from reactive to proactive approaches of care to facilitate adjustment, management, and planning.

7.2.3 Integration and sustainability of supportive care intervention in oncology care

People affected by pancreatic cancer and advanced cancers continue to experience considerable unmet informational and supportive care needs (Beesley et al., 2016a; Moghaddam et al., 2016). This gap in service delivery partly lies on the notable challenges of integrating supportive care into oncology (Hack et al., 2011). Successful implementation of supportive care interventions requires proactive integration into health systems and standards of care (Rodin, 2018). Although such recommendations for comprehensive cancer care are valuable and may even serve as prerequisites, these alone are not sufficient to fully achieve integration of supportive care in the cancer care system (Van Beek et al., 2016). Additional necessary considerations include shared recognition and values within professional networks to support integration of palliative and supportive care interventions into cancer care (Hack et al., 2011; den Herder-van der Eerden et al., 2018). The commitment from multidisciplinary champions, leaders, and advocates (*e.g.,* physicians, nurses, allied health providers, researchers, patients, families, administrators, and policy makers) across cancer care is warranted for integration and sustainability of supportive care interventions. Funding and support at the local or ministry levels are also needed, as competing priorities of resource allocation are implicit. From our findings, the early stage implementation of *Living Well with Pancreatic Cancer* into routine care was feasible with the support and buy-in from champions and leaders. Despite our preliminary successes, strategies to leverage the human resource capital (*i.e.,* clinical and administrative) are required to support continued sustainability.

7.3 General Limitations

The interpretation of the findings from this thesis should be considered in light of the following limitations, in addition to those highlighted previously. First, local contexts underpins the field of implementation research, therefore, our specific findings may or may not be generalizable to other contexts. However, the aim of our findings and interpretations is to shed light on aspects that may be useful to consider for implementation and evaluation of similar interventions.

Moreover, a limitation of the feasibility study was the small sample size, owing to the high attrition rate. This may be attributed to factors such as burden of illness and death. It is possible that participants who completed the follow-up assessment were more likely to be relatively well and more motivated to share their experiences. The feasibility study also highlighted weaknesses of the selected outcome measures, including the MUIS-C and FAMCARE, as some items of the questionnaires may not have been appropriate. Reasons indicated by participants included inapplicability of items, in relation to their circumstance or timing. However, the constructs were overall consistent with our qualitative findings. Future studies may therefore benefit from paying particular attention to the selection of appropriate measures for their target population or tailoring of outcome measures according to their study context.

By nature, implementation research and hybrid designs were meant to address the weaknesses of efficacy-based research paradigms. Their aim was to enhance traditional designs to reflect implementation challenges. However, the pitfall of implementation and hybrid approaches is an uncertainty of the effectiveness of specific intervention components and implementation strategies. Future research is required to identify the aspects of the intervention and implementation process that are effective, and to determine their mechanisms of effect, to promote reproducibility and widespread benefit of implementation research.

Chapter 8: Future Directions

The reports generated from this thesis may help serve as a guide for HCPs and administrators interested in replicating or tailoring initiatives for other sites. Our findings suggest that psychoeducation can represent a supportive care model that is standardized, evidence-based, tailored, and feasible. Models of care that fit these criteria are needed to further the operationalization of supportive care in routine oncology care. Worthwhile endeavours for future research can include implementation of psychoeducation into multiple pancreatic oncology clinics, or the tailoring of the intervention for testing in other advanced tumour sites. Moreover, psychoeducation can constitute the first line of supportive care intervention within a tiered model of care delivery (Hutchison et al., 2006), in which individuals requiring further care can be assessed and referred for specialized treatment as deemed appropriate. Tiered or stepped models of care can confer clinical and economic benefits, representing an efficient use of health care resources (Bower & Gilbody, 2005). Online adaptations of psychoeducation are also avenues worthy of future exploration. They may allow us to expand service delivery and improve access to supportive care, to reach people living in remote areas or who may be too ill to attend services in-person. Innovative technological approaches to consider may include online internet-based applications such as Zoom or Skype. Interactive use designs may also be designed by the team, for patients and family members to use on their mobile devices. These potential applications of psychoeducation are promising areas for future research, given the impetus for the “scale-up” of innovations to achieve maximal clinical impact and widespread adoption in health systems. Indeed, underlying the emergence of implementation science was the desire to increase the translation of research into practice, to improve the rapidity of impact on clinical care, public health, and policy.

Chapter 9: Conclusions

In the spirit of the evolution from a biomedical model to person-centred care, we require innovative strategies to promote integration of standardized supportive care. This can help us to support patients and families in the human dimensions of medical care to achieve highest quality care. This thesis highlights the acceptability, context-specific feasibility, and preliminary benefits of integrating psychoeducation as a first line of supportive care into the routine care of people affected by pancreatic cancer. This thesis also demonstrates the potential utility of implementation science frameworks in informing intervention development and evaluation to improve uptake and sustainability in the clinical setting. However, it also underscores the need to consider resource allocation, especially human capital, for the scale-up and sustainability of such interventions. These findings have compelling broad clinical and research implications.

Amidst the medical advances of scientific knowledge, innovation, and technology, we must not fail to acknowledge the cultures of the people we care for; that is, how meaning and values are socially constructed (Napier et al., 2014). In order to enhance wellbeing, we must therefore strive to understand wellbeing as both a biological and social construct. This includes an emphasis on empathy, personal values, and interpersonal commitment in models of health care delivery. In doing so, we can focus on improving quality of life and relieving suffering in the care of people affected by life-threatening illness. This is the essence of modern palliative care. This philosophy is at the core of our efforts to promote standardized supportive care in oncology. Rapidly developing over recent decades, the modern palliative care revolution has brought us back to the historic origins of medicine—the power in providing comfort and relieving pain and suffering with no means to cure.

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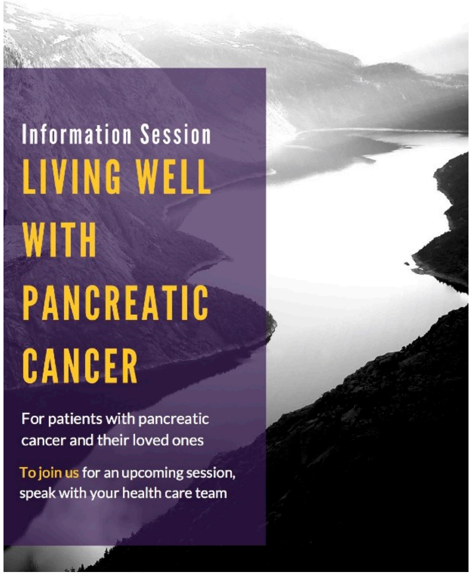
Appendix A: Living Well with Pancreatic Cancer Intervention Manual

Living Well with Pancreatic Cancer
Intervention Manual


Information Session
LIVING WELL
WITH
PANCREATIC
CANCER

For patients with pancreatic cancer and their loved ones

To join us for an upcoming session, speak with your health care team

Developed by: Tong, Moura, Antes, Henderson, Buchanan, Lee, Lo & Rodin,
Princess Margaret Cancer Centre, 2018

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TABLE OF CONTENTS

Introduction

Chapter 1 · Session Introduction

Chapter 2 · Nutrition Management

Chapter 3 · Managing Symptoms

Chapter 4 · Planning for the Future

Chapter 5 · Caring for Yourself & Your Loved Ones

Introduction

What is *Living Well with Pancreatic Cancer?*

Living Well with Pancreatic Cancer is a single group psychoeducational intervention designed to focus on the tailored physical and psychosocial concerns common in people affected by pancreatic cancer. The 1.5-hour session is jointly led by an interdisciplinary group of health care providers that provide care in the site (*i.e.,* nurse, social worker, and dietitian). The sessions are pre-scheduled and offered on a biweekly basis. The session provides information about nutrition and symptom management (including the role of palliative care services), planning for the future (*e.g.,* advance care planning), personal and family impact of disease, supportive care services available in the hospital and in the community, and encourages partnership and open communication with health care providers and loved ones. Handout materials outlining the content of the session and available resources are provided for participants to take home.

Introduction

Rationale: *Living Well with Pancreatic Cancer*

People affected by pancreatic cancer have high emotional distress, and informational and supportive care needs, including symptom management, communication with health care providers, worry about loved ones, and communication with health care providers (Beesley *et al.*, 2016).

Psychoeducational intervention aims to provide information about the disease and its management in a standardized format within a supportive and therapeutic milieu. This treatment modality has been widely used in early staged cancers and in non-cancer populations (Faller *et al.,* 2013; Zimmermann *et al.,* 2007), and has been shown to improve quality of life and emotional distress. The incorporation of a psychoeducational program into routine care of patients with pancreatic cancer presents an opportunity to: (i) integrate education and resources from various disciplines (*e.g.,* dietetics, nursing, social work) about the foreseeable physical and psychosocial concerns that may arise; (ii) standardize the approach to information delivery; and (iii) establish trust and communication of patients and families with their health care team. These efforts are also consistent with the goal to provide early, dedicated palliative and supportive care concurrently with oncology care for those diagnosed with life-threatening disease (Ferrell *et al.,* 2017).

We have developed an intervention manual of a group psychoeducational intervention for people affected by pancreatic cancer to provide information and to encourage thinking about supportive care needs from the point of diagnosis. The intervention was developed through integration of empirical knowledge, anecdotal evidence, and extensive clinical experience of expert stakeholders.

CHAPTER CONTENTS

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Introduction

How to Use the Intervention Manual

This intervention manual is designed to help guide health care providers to use the available educational resources, including a PowerPoint presentation and additional handout materials, in their role as a facilitator of the group psychoeducational session. This manual is intended to provide a guided script of the session alongside the slide deck, all written in plain language to be comprehensible to a wide audience. The script has a Flesch Reading Ease Score of 65.1% (Flesch, 1948)and Flesch-Kincaid Reading Grade Level of 8.8, indicating a 8th grade reading level (Kincaid *et al.*, 1975).

It is important to note that facilitators are not required to follow this script strictly. This manual offers an organized structure to the session, but there is equal emphasis on interactive discussion. Therefore, facilitators are free to respond to individual patient and family member needs by tailoring the content to meet those needs. Throughout the session, facilitators should pause to ask if there areas that require further clarification or if any questions arise. Facilitators are also encouraged to interject and support each other during all discussion areas, given the complex and interdisciplinary nature of problems encountered in this clinical context.

Chapters 2-5 will focus on key content areas, and each of them will have an allotted time frame of approximately 15 minutes, including 10 minutes for material presentation and 5 minutes for questions. This time structure is flexible however, and can be adjusted depending on group dynamics and members' levels of interaction.

CHAPTER CONTENTS

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Introduction

Structure of the Intervention Manual

CHAPTER CONTENTS

The first chapter, **Session Introduction**, will provide an overview of introductions and welcoming remarks, as well as suggestions to the facilitators for setting the stage for the group session. The subsequent chapters, **Nutrition Management; Managing Pain and Other Symptoms & Early Palliative Care; Planning for the Future; and Caring for Yourself and Your Loved Ones** will consist of the guided scripts for discussion points, with additional examples and probes to stimulate discussion if needed, and handout resources for reference.

Introduction

CHAPTER CONTENTS

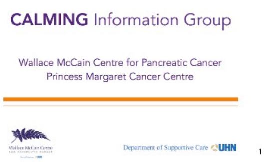
Acknowledgments

The intervention was collaboratively developed by the Wallace McCain Centre for Pancreatic Cancer and the Department of Supportive Care at the Princess Margaret Cancer Centre based on principles of psychoeducational and supportive care intervention development, empirical findings, extensive clinical experience, and anecdotal observations from patients and families.

This intervention manual was compiled through joint efforts by the interdisciplinary team. Eryn Tong was primarily responsible for the writing and compilation of this manual, with conceptual oversight by Dr. Chris Lo, research psychologist, and Dr. Gary Rodin, Head, Department of Supportive Care, Princess Margaret Cancer Centre. The manual was supported by content provided by Shari Moura, clinical nurse specialist, Kelly Antes and Ali Henderson, social workers, and Sarah Buchanan, registered dietitian, Wallace McCain Centre for Pancreatic Cancer, Princess Margaret Cancer Centre. Louise Lee, education specialist in the Department of Supportive Care, was instrumental in ensuring plain language readability of the intervention and manual.

Chapter 1: Session Introduction

Welcoming Group



CALMING Information Group

Wallace McCain Centre for Pancreatic Cancer
Princess Margaret Cancer Centre

Department of Supportive Care UHN

Instructions for Facilitator(s): Open the session by welcoming all group participants and providing introductions. Introduce the team of facilitators that will be delivering the session, and offer the opportunity for each group member to introduce themselves, (*e.g.,* names, identification as patient or caregiver if they are comfortable with sharing, and what they hope to learn from the session).

Explain that this session will be an opportunity to discuss different topics that may be relevant for people affected by pancreatic cancer, including patients, families, and friends. Emphasize that this is a safe environment, and any questions that may be asked will remain in the room and stay confidential, and that no questions are too simple to ask.

Program Overview

Nutrition Tips

Managing symptoms

Planning for the future

Caring for yourself and others

Begin the presentation by offering reassurance, telling patients and families that they are not alone in this journey. The Wallace McCain Centre for Pancreatic Cancer has a lot of experience treating patients, and the health care team is there to support them.

In the program overview slide, explain that the session will cover topics such as how to control side effects and symptoms with appropriate diets and medications, and then how to prepare yourself and loved ones for this diagnosis practically, mentally, and emotionally.

Chapter 2: Nutrition Management

*Discussion in this content area is ideally led by a **registered dietitian** with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Overview: Nutrition

Guided Script for Facilitator(s): When it comes to nutrition, there is a lot to talk and think about. It can be very easy to find conflicting information about the best diet and foods on the web and in books, and because of this, it is common for individuals to feel as though there is one right diet or a few specific foods that need to be included or avoided. In reality, each person's food ideas and diets will be different and this is okay because there is no "one-size fits all."

The overall nutrition goals should include making sure enough fluid, calories, protein, vitamins and minerals is taken. This will help you keep one's weight stable, which will help maintain energy levels. People are encouraged to make healthy food and diet choices as tolerated.

Chapter 2: Nutrition Management

Discussion in this content area is ideally led by a ***registered dietitian*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Nutrition Goals

Nutrition Goals

- Improve tolerance to treatment
- Maintain strength, energy levels, and physical function
- Improve quality of life

6

Healthy eating is important while you are going through this journey because it can improve your tolerance to treatments – this can mean fewer interruptions to treatment schedules and maintaining treatment doses.

We want to help you maintain or improve your nutrition so you feel you have good energy, strength and physical function. Along with this, we want to ensure that your weight is within a healthy range.

When you have more energy, you are able to do more things you enjoy. This, like nutrition, will look different for each person. For some it might be continuing to attend the gym or going for walks, and for others, this could be maintaining a social schedule.

Changes to your diet and nutrition after a diagnosis can be used to help manage symptoms.

Questions to probe discussion:

- Has anyone noticed a change in appetite? Feeling less hungry maybe? Taking smaller portions at meal times compared to usual?

Chapter 2: Nutrition Management

Discussion in this content area is ideally led by a ***registered dietitian*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

What Should You Focus On?

If you are able to eat well without any side effects or changes to digestion or absorption, it is reasonable to continue with your usual diet. We want you to choose the healthiest diet possible, as tolerated. Just because you have a new diagnosis and treatment doesn't mean you need to overhaul your diet.

What should I focus on?

- Consume whole foods
- Fluid, calories, and protein
- Eat small, frequent meals
- Adjust your diet to manage side effects
- Diets may look different – that is okay!

5

As mentioned at the beginning of this discussion, we want to make sure you consume a good amount of fluid, calories, protein, vitamins and minerals. This means you may have to make small adjustments to your diet to meet these requirements, but this does not mean an entirely new diet.

1. **Consume whole foods** to get all of the vitamins, minerals, and nutrients your body needs. Limit refined carbohydrates as long as you can maintain adequate nutrition without incorporating these foods into the diet.

2. **Fluid needs** will be different for everyone, but you may want to aim for about 6-10 cups from all fluid sources (*e.g.,* water, tea, juice, milk, oral nutrition supplements, etc.). With regards to protein and calorie needs, the way your body uses the nutrients you take in can be different after a diagnosis of pancreatic cancer. You may need more **calories and protein** as compared to your usual intake. Our bodies require more protein to help the immune system repair, to keep our muscles strong, etc. To achieve this, include a protein source with meals and snacks. These can be plant or animal-based proteins or a combination of both. If your appetite is poor and you and are finding it hard to eat, always focus on eating the

protein at your meal first, than the grain or starch and then fill up on what is left (the vegetables!).

3. With pancreatic cancer, it is very common to lose your appetite or feel full after eating a small amount of food. To help manage this, **eat small, frequent meals**. In other words, take smaller meals more often, and include the protein! Smaller meals doesn't have to mean less intake. Each time you are eating something, think about what you can add that will increase the calorie content without increasing the portion size. For example, you could put some avocado on your sandwich, add nuts or seeds to salads, have a snack of fruit with a few spoonful's of cottage cheese, etc. Also, remember to eat slowly and chew your food well, which will help make digestion easier for your body.

   Accept help from family and friends – if they offer to prepare meals, tell them exactly what you want or don't want, and provide grocery lists or recipes to tolerated foods. If it is an option, request large batches of food to be portioned into smaller portions so that meals are ready if you are having difficulty with meal preparation.

4. **Adjust your diet to manage side effects:** If you are experiencing side effects and are unable to take your usual diet, be kind to yourself and give permission to take the foods you can tolerate. For example, it is okay if you have to reduce your intake of higher fibre foods to manage diarrhea or nausea. You can still get everything you need in terms of fluid, calories, and protein, even if you are not taking your usual diet.

5. **Diets may look different:** Your diet may not look like your families or even someone else you know with cancer *but that is okay.* Your diet, and any changes to it, need to be individualized so that you can feel your best during your treatment. Eating well will support you while you are on treatment. *Eating is your most important job.*

Chapter 2: Nutrition Management

Discussion in this content area is ideally led by a ***registered dietitian*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

When Should You Contact the Dietitian?

This will be your opportunity to go through examples of when it will be important to contact the dietitian for further consultation or attention.

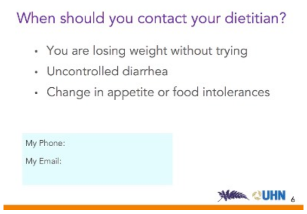
1. **If you are losing weight without trying:** A dietitian can help you determine if you need to make change to your diet based on the amount of weight loss you have experienced and the reason for your weight loss. For example, did you lose weight because you stopped eating sweets, removed animal products from your diet, or because you feel nauseated all the time and are skipping your afternoon snack and dinner?

2. **Uncontrolled diarrhea:** This can be a side effect of some treatments, and diet changes can be beneficial. Diarrhea can also be a symptom of pancreatic insufficiency, which your health care team would need to address. Your dietitian can help you identify which dietary changes will be most helpful in managing this symptom.

3. **Changes in appetite/food intolerances**, including:
   - Finding certain food consistencies hard to manage (*e.g.,* dry, solid foods), sensation of foods getting stuck in the throat
   - Losing your appetite and noticing that you are skipping meals and snacks
   - Usual foods are causing gas, diarrhea, heartburn

Contact information for the dietitian is provided on this slide as well as at the end of the presentation.

Resource Provided: Pancreatic Cancer Action Network Diet and Nutrition Book



When should you contact your dietitian?

- You are losing weight without trying
- Uncontrolled diarrhea
- Change in appetite or food intolerances

My Phone:
My Email:

Key Messages:

The main goals of nutrition and dietary changes are to prevent or improve poor nutritional status, maintain your dose and treatment schedule, help manage side effects effects from treatment or from the cancer itself, and to maintain or improve your weight, energy, and strength.

Chapter 3: Managing Symptoms

*Discussion in this content area is ideally led by a **nurse** with expertise in treating patients with pancreatic cancer.*

Overview: Managing Symptoms

We are now going to focus on how to manage symptoms you may be experiencing now or may experience during treatment. You may have few to many symptoms and over time, you will learn to manage these with the support of your health care team.

Please know that your symptom experience can change over time. Keep in mind that many of these will improve once you start treatment, some may temporarily need better management if it is related to cancer treatment.

The overall goal is to try and *be proactive* with a mild to moderate symptom experience using the pills and instructions you have been given. Keep the information on how to manage symptoms in a place that you can access easily.

The goal of care is to control your pain and symptoms, so that you can carry out day-to-day activities as normal as possible and have good quality of life.

CHAPTER CONTENTS

Chapter 3: Managing Symptoms

Discussion in this content area is ideally led by a ***nurse*** *with expertise in treating patients with pancreatic cancer.*

Bowel Movements

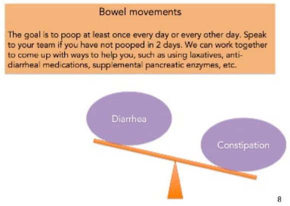
Many patients experience changes in their bowel movements, such as constipation (*i.e.,* not being able to poop) or diarrhea (*i.e.,* having to frequently poop). This may have started before you were diagnosed and will continue as you start treatment.

The overall goal is to poop at least once every day or every other day. Let a member of your health care team know if you are having challenges pooping.

You will develop the art to balance between diarrhea and constipation. We can work together to come up with ways to help you, such as using laxatives, anti-diarrheal medications, supplemental pancreatic enzymes, etc.

Resource Provided: University Health Network 1-page sheet "Bowel Medication Guide"

CHAPTER CONTENTS



Bowel movements

The goal is to poop at least once every day or every other day. Speak to your team if you have not pooped in 2 days. We can work together to come up with ways to help you, such as using laxatives, anti-diarrheal medications, supplemental pancreatic enzymes, etc.

Chapter 3: Managing Symptoms

Discussion in this content area is ideally led by a ***nurse*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Nausea

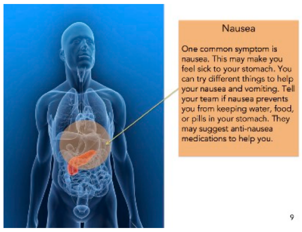
A common symptom of pancreatic cancer and its treatment is nausea. This may make you feel sick to your stomach. Some describe it as feeling like your stomach is off or you feel nausea to the extreme that causes taste changes and leads to vomiting.

It is important that you let your nurse and/or doctor know if what you have been prescribed to manage is not working. Our goal is to keep your nausea intermittent and mild so you can continue to eat and drink as best as possible.

Tell your team if nausea prevents you from keeping water, food, or pills in your stomach. They may suggest adding or changing anti-nausea medications to help you.

You can try different things to help your nausea and vomiting, such as:

- Eat more meals more often
- Eat foods that are easy on the stomach
- Sip small amounts of liquids throughout the day
- Take one of the "as needed or PRN" medications prescribed and see if you feel better
- If nausea is more constant, try taking an anti-nausea pill 30 minutes prior to having a meal.



Nausea

One common symptom is nausea. This may make you feel sick to your stomach. You can try different things to help your nausea and vomiting. Tell your team if nausea prevents you from keeping water, food, or pills in your stomach. They may suggest anti-nausea medications to help you.

Resource Provided: Cancer Care Ontario booklet "How to manage your nausea and vomiting"

Chapter 3: Managing Symptoms

*Discussion in this content area is ideally led by a **nurse** with expertise in treating patients with pancreatic cancer.*

Abdomen (Belly) and Back Pain

Another common symptom experienced before and after diagnosis is pain. Many people describe this as an uncomfortable, dull, achy pain in the stomach or under the rib cage. Some describe it as a band-like type pain across the abdomen and it may radiate to the back. If you are experiencing back pain, you may notice this pain may be worse at night when you lay down to rest or sleep.

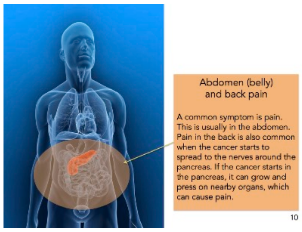
For some, it is common to have pain after eating or drinking large amounts. Eating small and frequent meals may help manage this.

You can also try taking a pain medication 30 minutes before eating a meal and this may help prevent diarrhea as well.

We may not be able to take all of your pain away, but your pain level should be at a point where you can eat and drink comfortably and do the activities that you want to do.

We know that all pain medications with opioids are constipating. This is not a reason to avoid your pain pills, but we do need to ensure you have a good plan in place to manage your goal to poop every other day and to not be constipated (such as a laxative).

CHAPTER CONTENTS



Abdomen (belly) and back pain

A common symptom is pain. This is usually in the abdomen. Pain in the back is also common when the cancer starts to spread to the nerves around the pancreas. If the cancer starts in the pancreas, it can grow and press on nearby organs, which can cause pain.

10

Chapter 3: Managing Symptoms

Discussion in this content area is ideally led by a ***nurse*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Partnering with Your Team to Manage Pain & Symptoms

As you start treatment, we hope that many of your symptoms will get better and you will start to feel better. *This is our goal.* However, if you start to notice changes in your symptoms, including those that are not controlled well, it is important to talk to your health care team before they get worse. Talk to your health care team if you have any symptoms that are affecting your quality of life or making it difficult to eat, drink, maintain weight, or sleep.

You can also manage your pain and other symptoms by taking your medications as instructed. Some patients think that their pills cause more harm than good. But, in fact, each pill that has been prescribed has a specific purpose. Taking these medications will help you maintain strength for your treatment. If you are concerned or have side effects from your medications, talk to your health care team. Your health care team can work with you to come up with a plan. For example, opioids are commonly given for pain, but a major side effect is constipation, which we previously talked about. We can work together to discuss and come up with ways to help manage the symptoms and side effects.

Another way to manage pain and other symptoms is to partner with palliative care services available in the hospital. Your health care team may suggest a consultation with the palliative care team. We know that the term ‘palliative care’ can mean different things to everyone and can be quite scary for some. However, it is important to know that palliative care does not mean that you are giving up treatments or preparing to die.

Partnering with your team to manage pain and symptoms

Be proactive

Take medications (e.g., opioids)

Early palliative care consultation/ symptom management

Goal of Care
To control pain and symptoms, so that you can carry out day-to-day activities

11

Chapter 3: Managing Symptoms

*Discussion in this content area is ideally led by a **nurse** with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

What Does Palliative Care Mean?

Palliative care helps you and your loved ones improve your quality of life. We often work with palliative care services to help us manage your symptoms so that you can continue on treatment. The better your symptoms are managed, the more likely you will be strong enough to continue on treatment. The goal is to manage and control your pain and symptoms as best as possible.

What does palliative care mean?

Palliative care helps you and your loved ones improve your quality of life. The goal is to manage and control your pain and symptoms as best as possible. It is offered to people of any age and at any point in their illness.

Chapter 3: Managing Symptoms

*Discussion in this content area is ideally led by a **nurse** with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Early Palliative Care

Dr. Camilla Zimmermann, the Head of Palliative Care here at the Princess Margaret Cancer Centre, has conducted studies on the effect of early palliative care. Her studies have shown that early palliative care improves patient's quality of life and satisfaction with their care, and also reduces distress for both patients and their family members.

The Palliative Care team offers many services to patients and families to meet their physical, emotional and spiritual needs. They help patients to be actively involved in their care and support early and frequent conversations about goals of care. They can also help you talk about difficult issues to prepare for all possibilities.

Early palliative care

- Studies show improved quality of life, satisfaction with care, and reduced distress for patients and family members.
- The Palliative Care team offers many services to patients and families to meet their physical, emotional, and spiritual needs.

Chapter 3: Managing Symptoms

*Discussion in this content area is ideally led by a **nurse** with expertise in treating patients with pancreatic cancer.*

What do Other Patients Say about Palliative Care?

“Palliative care is an ongoing care and I’m very grateful to have it when I am feeling well and feeling strong and able to do things.”

“Palliative care is about the quality of living, and what you can do to help with that quality of living. It’s living the best you can with the issues you’re dealing with.”

“In fact, palliative care is not just end-of-life. It’s the whole symptom management, potentially through all phases it is available, and I didn’t know that.”

Resource Provided: University Health Network Patient Education booklet: "The Palliative Care Program: What you should know”

CHAPTER CONTENTS

What do other patients say about palliative care?

*"**Palliative care is an ongoing care**, and I’m very grateful to have it when I am feeling well and feeling strong and able to do things.”*

*"**Palliative care is about the quality of living**, and what you can do to help with that quality of living. It’s living the best you can with the issues you’re dealing with."*

*"**In fact, palliative care is not just end-of-life**. It’s the whole symptom management, potentially through all phases it is available, and I didn’t know that."*

Chapter 4: Planning for the Future

Discussion in this content area is ideally led by a ***social worker*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Advance Care Planning

There are two questions that are useful to frame our discussion about advance care planning: "*If I don't talk about it and it's not written down, how will anyone know my wishes?*" and "*If I were unable to communicate with anyone, and there were things that I really wanted or didn't want, how would I feel?*"

These are things that are important for all of us to think about, for example, once we start to make a little bit of money, own property, have children, etc. But, these are also conversations that we tend to avoid in our society. We encourage everyone, whether we are healthy or not, to think about these questions and ideas at some point, regardless of type or severity of illness.

Planning for the future

Advance Care Planning

If I don't talk about it and it's not written down, how will anyone know my wishes?

If I were unable to communicate with anyone, and there were things that I really wanted or didn't want, how would I feel?

Chapter 4: Planning for the Future

Discussion in this content area is ideally led by a ***social worker*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Defining Advance Care Planning

Advanced care planning is a process of thinking about and sharing your wishes for future health and personal care. It can help you tell others what would be important if you were ill and unable to communicate.

Advanced care planning is a process of thinking about and sharing your wishes for future health and personal care.

Chapter 4: Planning for the Future

CHAPTER CONTENTS

*Discussion in this content area is ideally led by a **social worker** with expertise in treating patients with pancreatic cancer.*

Advance Care Planning: Speak Up Ontario

“The Advance Care Planning Quick Guide” from Speak Up Ontario is a useful resource. It outlines the five steps of advance care planning in more detail:

- ***Think***: What are your values, wishes, and beliefs about understanding specific medical procedures?
- ***Learn***: Learn more about what the procedures can do or cannot do.
- ***Decide***: Who will be your substitute decision maker? Someone who is willing and able to speak for you if you cannot speak for yourself?
- ***Talk***: About your wishes with your substitute decision maker, loved ones and your doctor.
- ***Record and communicate***: Your wishes. It is a good idea to write down or make a recording of your wishes so it is known to all.

Advance Care Planning Booklet

1. Think
2. Learn
3. Decide
4. Talk
5. Record

Speak Up

18

Please feel free to complete the guide and discuss with myself about your plan and any questions you may have. This is the beginning of creating a supportive plan for all.

Resource Provided: Speak Up Ontario 1-page sheet “The Advance Care Planning Quick Guide”

Chapter 5: Caring for Yourself & Your Loved Ones

Discussion in this content area is ideally led by a ***social worker*** *with expertise in treating patients with pancreatic cancer.*

The Emotional Impact of Cancer

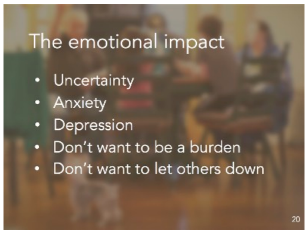
When you are diagnosed with cancer, you may experience very powerful emotions and can feel overwhelmed, scared about the uncertainty of the situation, can't make sense of the situation, anxious, or depressed.

You may also feel the need to protect or to not burden others. This can be experienced as not letting others down.

We want to talk about these in this session because we want to acknowledge that these emotions are common and normal, and we also want to help support you if you need additional support.

CHAPTER CONTENTS

Caring for yourself and your loved ones



The emotional impact

- Uncertainty
- Anxiety
- Depression
- Don't want to be a burden
- Don't want to let others down

Chapter 5: Caring for Yourself & Your Loved Ones

*Discussion in this content area is ideally led by a **social worker** with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

The Impact on Family and Relationships

We also want to acknowledge that cancer affects both the patient and everyone around them, including those in the room. This is a shared experience.

With that being said, family members can experience distress that can often be greater than the distress experienced by patients, since they provide emotional, physical, and medical support for their loved ones. It is important to ask questions, and to share your thoughts and concerns with your social worker or any other member of your health care team.

Relationships are impacted by cancer, but we can work together to ensure any relationship concerns are addressed and supported. This can involve supportive counselling for the patient and for loved ones. We can also discuss how to have conversations around how to tell your children or other family members and friends.

The impact on family and relationships

Family members can experience more distress than the patients themselves.

ILLUSTRATION : KARINE DAISAY

21

Chapter 5: Caring for Yourself & Your Loved Ones

Discussion in this content area is ideally led by a ***social worker*** *with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Walking on a Double Path of Hope and Fear

As you may have already felt, this experience can often feel like a roller coaster of emotions. It is completely normal to be feeling a range of emotions. We often encourage patients and their loved ones to get in the mind frame of "hoping for the best, but preparing for the worst."

Another way of seeing this would be, "being able to balance both your hopes and your fears." We feel that patients and family members often are able to cope better when they think of their situation in this way.

Walking on a double path

HOPE

and Fear

22

Chapter 5: Caring for Yourself & Your Loved Ones

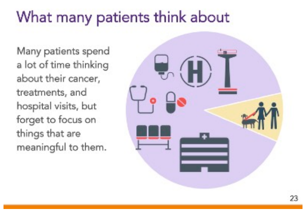
CHAPTER CONTENTS

> *Discussion in this content area is ideally led by a* ***social worker*** *with expertise in treating patients with pancreatic cancer.*

What Many Patients Think About

We find showing this pie chart useful to show that sometimes, it can be easy for the "world of cancer" to take up most of your time, and it can be difficult when there is too much focus on the disease. We want to encourage all of you to remember to focus on other aspects of life, to continue to do the things you love and enjoy and things that are meaningful to you. These will look different for everyone, and can be something like going on a family trip, or as simple as walking a dog or reading a book.

The goal is to try to balance out this pie chart and to make more time for the things that you would like to do. It can be helpful to talk to your loved ones and health care team, to explore different possibilities and to manage this balance. For example, even though you may be on treatment with a schedule, it is important for you to know that we can work with you to change your treatment plans or appointment schedules so that you can continue to do the things that are meaningful to you.



What many patients think about

Many patients spend a lot of time thinking about their cancer, treatments, and hospital visits, but forget to focus on things that are meaningful to them.

Chapter 5: Caring for Yourself & Your Loved Ones

*Discussion in this content area is ideally led by a **social worker** with expertise in treating patients with pancreatic cancer.*

CHAPTER CONTENTS

Hospital & Community Support

There are many services within the Department of Supportive Care here at the hospital that are offered to you if you that would like additional support. The Department has a range of professionals that can help, including: social work, psychology, psychiatry, spiritual care, music therapy, etc. Our goal is to help patients and families cope with diagnosis, reduce distress, improve emotional wellbeing, and help navigate difficult decisions. This can also include practical assistance, such as transportation to treatment, finances, *drug coverage*, community resources, etc.

In addition to these, the Department provides some specific programs, such as *Managing Cancer and Living Meaningfully (CALM), Mindfulness Based Cognitive Therapy (MBCT),* and *Integrative Restoration (iREST)*.

We also have excellent community support programs, including *Canadian Cancer Society*, *Gilda's Club*, *Wellspring Centre*, and *Craig's Cause Pancreatic Cancer Society*.

Supportive Care Clinic

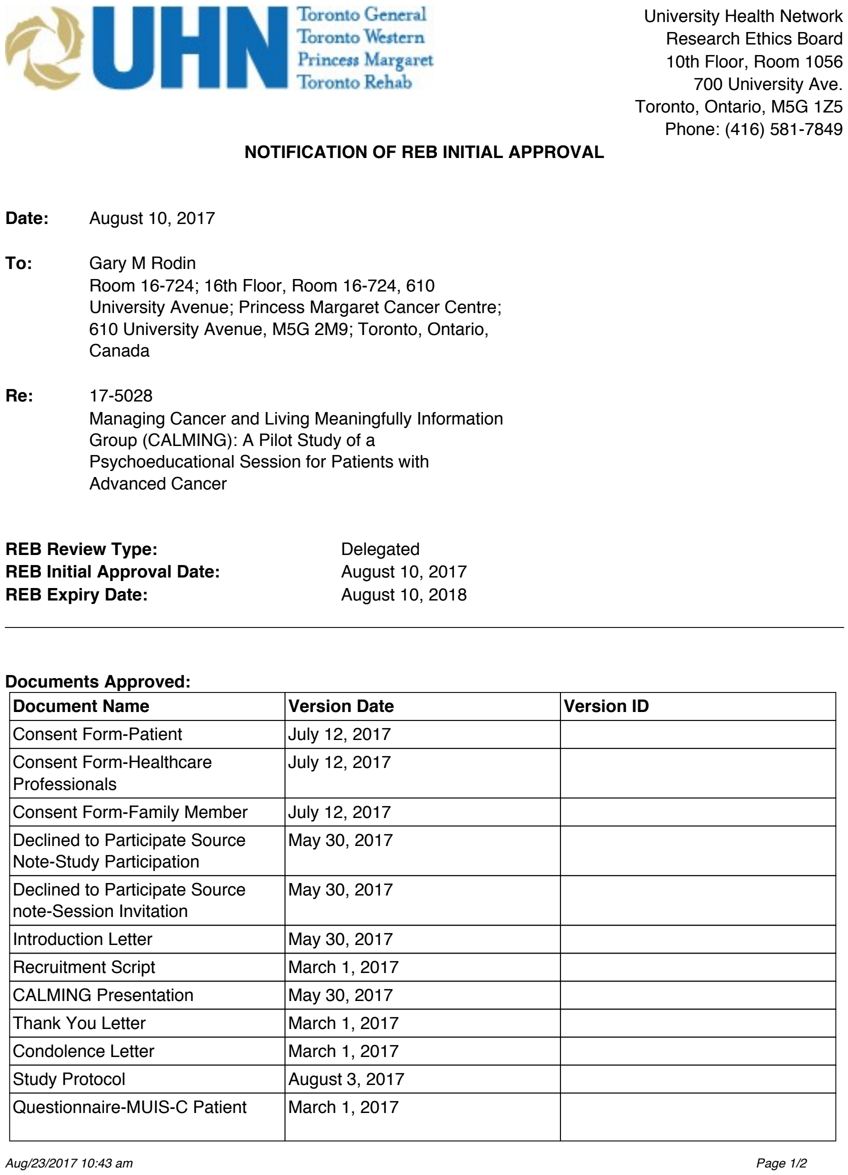
- CALM Therapy
- Mindfulness-based Cognitive Therapy
- iRest – Integrative Restoration

Community Supports

Resources Provided: Pamphlets for all hospital programs and community organizations listed.

Conclusions & Wrap-Up: *Provide contact information of all health care professional facilitators. Inquire if there are any other points that require clarification, if anyone has any questions, or if anyone would like to share any final thoughts before ending. Encourage patients and families to seek support from them or others from the team as required.*

Appendix B: University Health Network Research Ethics Board (REB) Initial Approval and Renewals for the Study



University Health Network
Research Ethics Board
10th Floor, Room 1056
700 University Ave.
Toronto, Ontario, M5G 1Z5
Phone: (416) 581-7849

NOTIFICATION OF REB INITIAL APPROVAL

Date: August 10, 2017

To: Gary M Rodin
Room 16-724; 16th Floor, Room 16-724, 610
University Avenue; Princess Margaret Cancer Centre;
610 University Avenue, M5G 2M9; Toronto, Ontario,
Canada

Re: 17-5028
Managing Cancer and Living Meaningfully Information
Group (CALMING): A Pilot Study of a
Psychoeducational Session for Patients with
Advanced Cancer

REB Review Type:	Delegated
REB Initial Approval Date:	August 10, 2017
REB Expiry Date:	August 10, 2018

Documents Approved:

Document Name	**Version Date**	**Version ID**
Consent Form-Patient	July 12, 2017	
Consent Form-Healthcare Professionals	July 12, 2017	
Consent Form-Family Member	July 12, 2017	
Declined to Participate Source Note-Study Participation	May 30, 2017	
Declined to Participate Source note-Session Invitation	May 30, 2017	
Introduction Letter	May 30, 2017	
Recruitment Script	March 1, 2017	
CALMING Presentation	May 30, 2017	
Thank You Letter	March 1, 2017	
Condolence Letter	March 1, 2017	
Study Protocol	August 3, 2017	
Questionnaire-MUIS-C Patient	March 1, 2017	

Aug/23/2017 10:43 am *Page 1/2*

Questionnaire-PKQ Patient	March 1, 2017	
Questionnaire-PKG Family Member	March 1, 2017	
Questionnaire-FAMCARE	March 1, 2017	
Qualitative Interview Guide-Patient	March 1, 2017	
Qualitative Interview Guide-Family Member	March 1, 2017	
Questionnaire-Demographic Patient and Family Member	March 1, 2017	
Questionnaire-Demographic Form Staff	March 1, 2017	
Questionnaire-FAMCAREP16	March 1, 2017	
Qualitative Survey/Interview Guide-Clinical Staff	March 1, 2017	
Questionnaire-MUIS-C Family Member	March 1, 2017	

The University Health Network Research Ethics Board approves the above mentioned study as it has been found to comply with relevant research ethics guidelines, as well as the Ontario Personal Health Information Protection Act (PHIPA), 2004.

Best wishes on the successful completion of your project.

Sincerely,
Jack Holland
Co-Chair, University Health Network Research Ethics Board

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada. The approval and the views of the REB have been documented in writing.
Furthermore, members of the Research Ethics Board who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

Toronto General
Toronto Western
Princess Margaret
Toronto Rehab

University Health Network
Research Ethics Board
10th Floor, Room 1056
700 University Ave.
Toronto, Ontario, M5G 1Z5
Phone: (416) 581-7849

NOTIFICATION OF REB RENEWAL APPROVAL

Date: August 9, 2018

To: Gary M Rodin
Princess Margaret Cancer Centre, 610 University
Avenue, 610 University Avenue, 16th Floor, Room
16-724, Toronto, Ontario, Canada, M5G 2M9

Re: 17-5028
Managing Cancer and Living Meaningfully Information
Group (CALMING): A Pilot Study of a
Psychoeducational Session for Patients with
Advanced Cancer

REB Review Type:	Delegated
REB Initial Approval Date:	August 10, 2017
REB Renewal Approval Effective Date:	August 10, 2018
Lapse In REB Approval:	N/A
REB Expiry Date:	August 10, 2019

The University Health Network Research Ethics Board has reviewed and approved the Renewal (17-5028.1) for the above mentioned study.

Best wishes on the successful completion of your project.

Sincerely,
Anthony Aqui
Ethics Coordinator, University Health Network Research Ethics Board

For: Jack Holland
Co-Chair, University Health Network Research Ethics Board

The UHN Research Ethics Board operates in compliance with the Tri-Council Policy Statement; ICH Guideline for Good Clinical Practice E6(R1); Ontario Personal Health Information Protection Act (2004); Part C Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations and the Medical Devices Regulations of Health Canada.

Appendix C: Consent Forms for Study Participation

Consent Form (Patient)

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title:	*CALMING*: A study to evaluate a psychoeducational session for patients with pancreatic cancer and their families
Principal Investigator:	**Dr. Gary Rodin**: Head, Department of Supportive Care, Princess Margaret Cancer Centre, Telephone: 416-946-4504

Introduction:

You are being asked to take part in a research study. Please read this explanation about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background:

We are conducting a research study to evaluate a new group psychoeducational session for patients with pancreatic cancer and their family members. The program is called CALMING, which is short for *Managing **C**ancer **A**nd **L**iving **M**eaningfully **In**formation **G**roup*.

This program involves 1 information session, which will be led by a nurse, social worker, and dietitian on your team. The psychoeducational program will cover topics such as disease management, communication with healthcare providers and loved ones, personal and family impact of cancer, preparing for the future, and supportive care resources. The purpose of this pilot study is to explore if this program can be suitable and meaningful for people living with your type of cancer and their family members.

You are being invited to participate in this study because you have received a diagnosis of pancreatic cancer, you are fluent in English, and you are over 18 years of age. The results of this study will help us plan how we test this program with a larger number of people living with different types of cancers and their family members. This pilot study is exploratory, which means that psychoeducational programs are not a routine part of cancer care in Canada for patients living with your type of cancer.

Procedures:

If you agree to participate in this study, this is what will happen:

1. You will be briefly interviewed to make sure you are eligible for the study.
2. You will be asked to complete a brief baseline questionnaire package that will take approximately 15-20 minutes to complete.
3. You will attend the psychoeducational session, which will last about 90 minutes. The session will be led by members of your clinical team. The session will be audio recorded.
4. Approximately 1 month after the session, you will be asked to complete a follow-up questionnaire package, either on paper to be mailed back, or over the phone with the help of research staff. The questionnaire package will take approximately 15-20 minutes to complete.
5. You may be invited to complete a brief interview to ask for your feedback about the program, the interview will be audio recorded. You may choose not to participate in the interview part of the study.

Risks:

There may be some risk associated with taking part in this research study. You may find some of the questions on the questionnaires or in the interview can cause emotional distress. You can choose not to answer any questions on the questionnaires or in the interview that you do not feel comfortable answering.

Benefits:

It is important to know that the knowledge that we gain from completing this study may not directly benefit you. However, information learned from this study may help guide psychoeducational programs for patients living pancreatic cancer and their family members in the future.

Confidentiality:

If you agree to participate in this study, the study doctor and his/her study team will look at your personal health information. They will collect only the information they need for the study.

What is personal health information?
It is any information that could be used to identify you and includes your name, address, and date of birth. It also includes new or existing medical records, for example; types, dates and results of medical tests or procedures.

How will the information be protected?

- You will be given an anonymous, study identification number. All study information collected, including collected transcripts of audio-recordings (if applicable), will be filed together in a research chart and kept in a locked and secure area or on secured UHN computers or encrypted and password protected devices. The study doctor will keep this information for 10 years after the study is completed, after which it will be destroyed.

- Audio-recordings, before transcription and verification, will be stored on secured UHN network computer servers or encrypted and password protected devices that, when not in use, will be stored in a locked and secure area. Audio-recordings will be professionally transcribed by an external company working with our research team.
- Your participation in this study will also be recorded in your medical record at this hospital. This is for clinical safety purposes.
- Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study follows proper laws and guidelines.
- All information collected during this study, including your personal health information, will be kept confidential. It will not be shared with anyone outside the study unless required by law. You will not be named or identified in any reports, publications, or presentations that may come from this study.

Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study. You may decide to be in the study now, and then change your mind later. You may leave the study at any time. It will not affect your care at Princess Margaret Cancer Centre. We will give you new information that is learned during the study that might affect your decision to stay in the study. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying “pass”.

Rights as a Participant:

By signing this consent form you do not give up any of your legal rights against the investigators or involved institutions for compensation, nor does this form relieve their legal and professional responsibilities.

Conflict of Interest:

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:

If you have any questions, concerns, or you would like to speak to the study team for any reason, please contact:

- **Dr. Gary Rodin** (Principal Investigator), at 416-946-4504
- **Ms. Eryn Tong** (Study Coordinator), at 416-340-4800 ext. 2708 or at eryn.tong@uhnresearch.ca

Please note that communication via e-mail is not absolutely secure. Therefore, please do not communicate personal sensitive information via e-mail.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a signed copy of this consent form.

Consent:

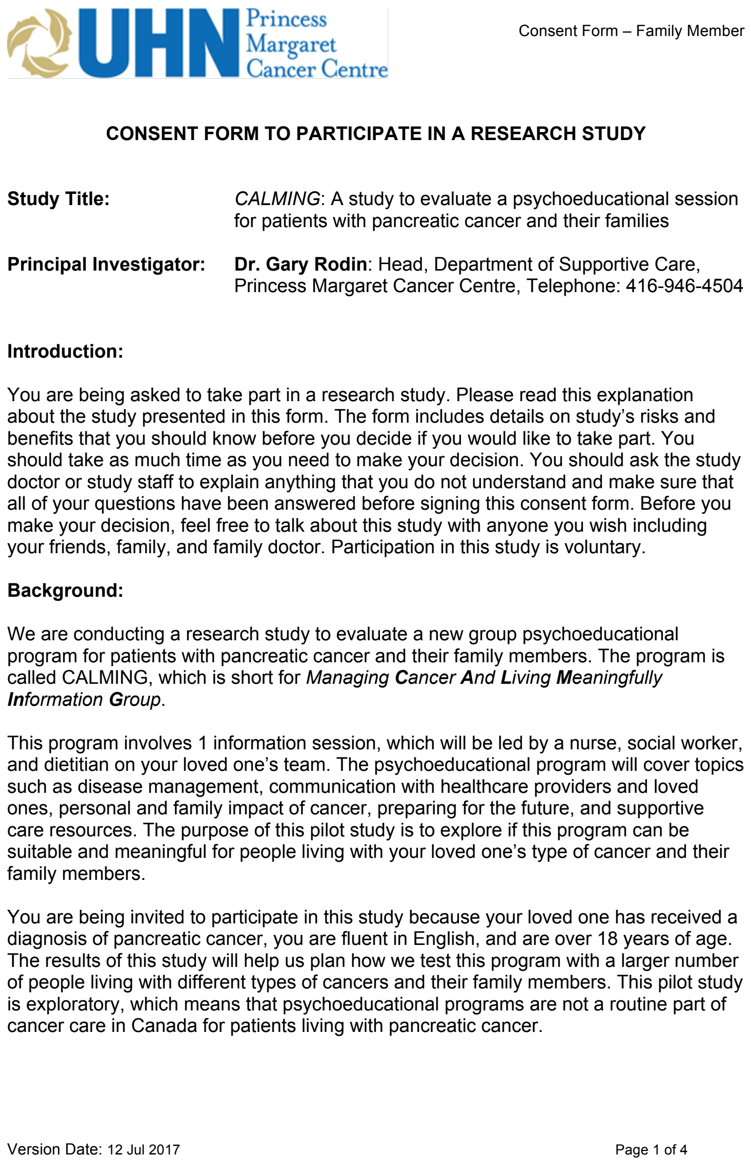
This study and the consent form have been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

____________________________ Print Study Participant’s Name	____________________ Signature	__________ Date

My signature means that I have explained this study to the participant named above. I have answered all questions.

____________________________ Print Name of Person Obtaining Consent	____________________ Signature	__________ Date

Consent Form (Family Member)



UHN Princess Margaret Cancer Centre

Consent Form – Family Member

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title:	*CALMING*: A study to evaluate a psychoeducational session for patients with pancreatic cancer and their families
Principal Investigator:	**Dr. Gary Rodin**: Head, Department of Supportive Care, Princess Margaret Cancer Centre, Telephone: 416-946-4504

Introduction:

You are being asked to take part in a research study. Please read this explanation about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background:

We are conducting a research study to evaluate a new group psychoeducational program for patients with pancreatic cancer and their family members. The program is called CALMING, which is short for *Managing **C**ancer **A**nd **L**iving **M**eaningfully **In**formation **G**roup*.

This program involves 1 information session, which will be led by a nurse, social worker, and dietitian on your loved one's team. The psychoeducational program will cover topics such as disease management, communication with healthcare providers and loved ones, personal and family impact of cancer, preparing for the future, and supportive care resources. The purpose of this pilot study is to explore if this program can be suitable and meaningful for people living with your loved one's type of cancer and their family members.

You are being invited to participate in this study because your loved one has received a diagnosis of pancreatic cancer, you are fluent in English, and are over 18 years of age. The results of this study will help us plan how we test this program with a larger number of people living with different types of cancers and their family members. This pilot study is exploratory, which means that psychoeducational programs are not a routine part of cancer care in Canada for patients living with pancreatic cancer.

Version Date: 12 Jul 2017 Page 1 of 4

Procedure:

As the patient's family member or companion, you have the opportunity to attend the session with the patient. If you agree to participate in this study, this is what will happen:

1. You will be briefly interviewed to make sure you are eligible for the study.
2. You will be asked to complete a brief baseline questionnaire package that will take approximately 15-20 minutes to complete.
3. You will attend the psychoeducational session, which will last about 90 minutes. The session will be led by members of your loved one's clinical team. The session will be audio recorded.
4. Approximately 1 month after the session, you will be asked to complete a follow-up questionnaire package, either on paper to be mailed back, over the phone, or on an online form. The questionnaire package will take approximately 15-20 minutes to complete.
5. You may be invited to complete a brief interview to ask for your feedback about the program, the interview will be audio recorded. You may choose not to participate in the interview part of the study.

Risks:

There may be some risk associated with taking part in this research study. You may find some of the questions on the questionnaires or in the interview can cause emotional distress. You can choose not to answer any questions on the questionnaires or in the interview that you do not feel comfortable answering.

Benefits:

It is important to know that the knowledge that we gain from completing this study may not directly benefit you. However, information learned from this study may help guide psychoeducational programs for patients living with pancreatic cancer and their family members in the future.

Confidentiality:

If you agree to participate in this study, the study doctor and his/her study team will look at your personal information. They will collect only the information they need for the study.

What is personal information?
It is any information that could be used to identify you. It includes your name, address, and date of birth.

How will your information be protected?

- You will be given an anonymous, study identification number. All study information collected, including collected transcripts of audio-recordings (if applicable), will be filed together in a research chart and kept in a locked and

secure area or on secured UHN computers or encrypted and password protected device. The study doctor will keep this information for 10 years after the study is completed, after which it will be destroyed.
- Audio-recordings, prior to transcription and verification, will be stored on secured UHN network computer servers or encrypted and password protected devices that, when not in use, will be stored in a locked and secure area. Audio-recordings will be professionally transcribed by an external company working with our research team.
- Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal information to check that the information collected for the study is correct and to make sure the study follows proper laws and guidelines.
- All information collected during this study, including your personal information, will be kept confidential. It will not be shared with anyone outside the study unless required by law. You will not be named or identified in any reports, publications, or presentations that may come from this study.

Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study. You may decide to be in the study now, and then change your mind later. You may leave the study at any time. It will not affect your loved one's care at Princess Margaret Cancer Centre. We will give you new information that is learned during the study that might affect your decision to stay in the study. You may refuse to answer any question you do not want to answer, or not answer an interview question by saying "pass".

Rights as a Participant:

By signing this consent form you do not give up any of your legal rights against the investigators or involved institutions for compensation, nor does this form relieve their legal and professional responsibilities.

Conflict of Interest:

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:

If you have any concerns or questions, or you would like to speak to the study team for any reason, please call:
- **Dr. Gary Rodin** (Principal Investigator), at 416-946-4504
- **Ms. Eryn Tong** (Study Coordinator), at 416-340-4800 ext. 2708 or at eryn.tong@uhnresearch.ca

Please note that communication via e-mail is not absolutely secure. Therefore, please do not communicate personal sensitive information via e-mail.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a signed copy of this consent form.

Consent:

This study and the consent form have been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

__________________________ Print Study Participant's Name	____________________ Signature	__________ Date

My signature means that I have explained this study to the participant named above. I have answered all questions.

__________________________ Print Name of Person Obtaining Consent	____________________ Signature	__________ Date

Consent Form (Health Care Professional)

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title:	Managing **C**ancer **A**nd **L**iving **M**eaningfully **In**formation **G**roup (CALMING): A Pilot Study of a Psychoeducational Session for Patients with Advanced Cancer
Principal Investigator:	**Dr. Gary Rodin**: Head, Department of Supportive Care, Princess Margaret Cancer Centre, Telephone: 416-946-4504

Introduction:

You are being asked to take part in a research study. Please read this explanation about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the Principal Investigator or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background:

The research team, in collaboration with the McCain Centre for Pancreatic Cancer, has developed a psychoeducational intervention for patients diagnosed with pancreatic cancer and their family members. The intervention is called CALMING, which is short for *Managing **C**ancer **A**nd **L**iving **M**eaningfully **In**formation **G**roup*.

This program is a single, group session, which will be led by a nurse, social worker, and dietitian from the McCain Centre. The psychoeducational session will cover topics such as disease management, communication with healthcare providers and loved ones, personal and family impact of cancer, preparing for the future, and supportive care resources. The purpose of this pilot study is to evaluate the feasibility and acceptability of delivering this intervention for patients with advanced disease and their families. We aim to receive ongoing feedback from the point of view of the clinical staff, both those involved in the study and those who interact with the patients and families who will attend the session.

You are being invited to participate in this study because you are a health care professional working in the McCain Centre. The results of this study will be used to refine CALMING and to plan the conduct of a subsequent randomized controlled trial.

Procedure:

If you agree to participate in this study, this is what will happen:

1. You will be asked to complete a brief demographics questionnaire that will take approximately 1-5 minutes to complete.
2. You will take part in the online survey. The survey will take approximately 20-60 minutes to complete.
3. If you wish, you may take part in an interview instead. The interview will last between 20-60 minutes and all interviews will be audio-recorded.

Risks:

There are no known risks associated with taking part in this research study. You may leave the interview at any time, and you can choose not to answer any questions in the interview that you do not feel comfortable answering.

Benefits:

It is important to know that the knowledge that we gain from completing this study may not directly benefit you. However, information learned from this study may help guide psychoeducational programs for patients living with your type of cancer and their family members in the future.

Confidentiality:

If you agree to participate in this study, the study doctor and his/her study team may collect personal information. They will collect only the information they need for the study.

What is personal information?
It is any information that could be used to identify you. It includes your name, age, and professional discipline.

How will your information be protected?

- You will be given an anonymous, study identification number. All study information, including collected transcripts of audio-recordings (if applicable), will be filed together in a research chart and kept in a locked and secure area or on secured UHN computers or encrypted and password protected devices. The Principal Investigator will keep this information for 10 years after the study is completed, after which it will be destroyed.
- Audio-recordings, prior to transcription and verification, will be stored on secured UHN network computer servers or encrypted and password protected devices that, when not in use, will be stored in a locked and secure area. Audio-recordings may be professionally transcribed by an external company working with our research team.

- Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal information to check that the information collected for the study is correct and to make sure the study follows proper laws and guidelines.
- All information collected during this study, including your personal information, will be kept confidential. It will not be shared with anyone outside the study unless required by law. You will not be named or identified in any reports, publications, or presentations that may come from this study.

Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission. If you refuse to take part or choose to leave the study at any time, this will in no way affect your professional standing at the Princess Margaret Cancer Centre or at UHN. We will give you new information that is learned during the study that might affect your decision to stay in the study.

Rights as a Participant:

By signing this consent form you do not give up any of your legal rights against the investigators or involved institutions for compensation, nor does this form relieve their legal and professional responsibilities.

Conflict of Interest:

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:

If you have any concerns or questions, or you would like to speak to the study team for any reason, please call:

- **Dr. Gary Rodin** (Principal Investigator), at 416-946-4504
- **Ms. Eryn Tong** (Study Coordinator), at 416-340-4800 ext. 2708 or at eryn.tong@uhnresearch.ca

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of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.
You will be given a signed copy of this consent form.

Consent:

This study and the consent form have been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

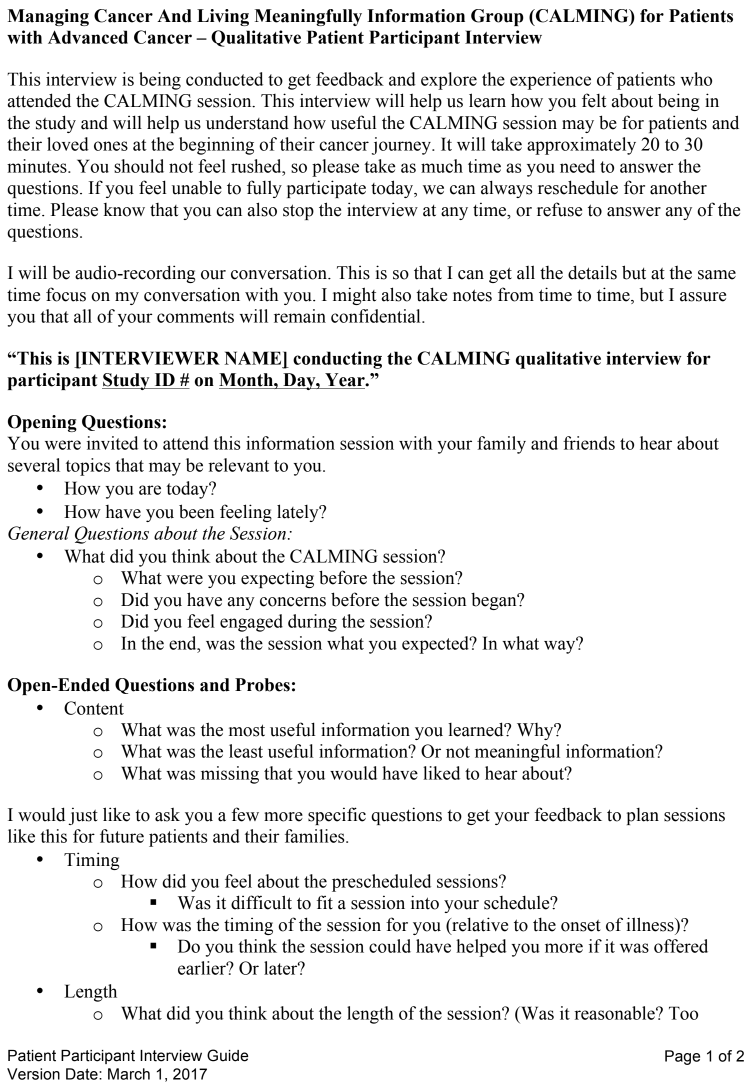
___________________________	____________________	__________
Print Study Participant's Name	Signature	Date

My signature means that I have explained this study to the participant named above. I have answered all questions.

___________________________	____________________	__________
Print Name of Person Obtaining Consent	Signature	Date

Appendix D: Interview Guides

Interview Guide (Patient)



Managing Cancer And Living Meaningfully Information Group (CALMING) for Patients with Advanced Cancer – Qualitative Patient Participant Interview

This interview is being conducted to get feedback and explore the experience of patients who attended the CALMING session. This interview will help us learn how you felt about being in the study and will help us understand how useful the CALMING session may be for patients and their loved ones at the beginning of their cancer journey. It will take approximately 20 to 30 minutes. You should not feel rushed, so please take as much time as you need to answer the questions. If you feel unable to fully participate today, we can always reschedule for another time. Please know that you can also stop the interview at any time, or refuse to answer any of the questions.

I will be audio-recording our conversation. This is so that I can get all the details but at the same time focus on my conversation with you. I might also take notes from time to time, but I assure you that all of your comments will remain confidential.

“This is [INTERVIEWER NAME] conducting the CALMING qualitative interview for participant Study ID # on Month, Day, Year.”

Opening Questions:
You were invited to attend this information session with your family and friends to hear about several topics that may be relevant to you.

- How you are today?
- How have you been feeling lately?

General Questions about the Session:

- What did you think about the CALMING session?
    - What were you expecting before the session?
    - Did you have any concerns before the session began?
    - Did you feel engaged during the session?
    - In the end, was the session what you expected? In what way?

Open-Ended Questions and Probes:

- Content
    - What was the most useful information you learned? Why?
    - What was the least useful information? Or not meaningful information?
    - What was missing that you would have liked to hear about?

I would just like to ask you a few more specific questions to get your feedback to plan sessions like this for future patients and their families.

- Timing
    - How did you feel about the prescheduled sessions?
        - Was it difficult to fit a session into your schedule?
    - How was the timing of the session for you (relative to the onset of illness)?
        - Do you think the session could have helped you more if it was offered earlier? Or later?
- Length
    - What did you think about the length of the session? (Was it reasonable? Too

    - long? Too short?)
    - If we had offered an additional information session or a follow-up question and answer session, would you have been interested in attending? Why/why not?
        - [If *yes*] What kind of benefits do you think you would have experienced from an additional information session and/or a question and answer session?
- Comprehension/Understanding
    - Was the presentation clear and easy to follow? Did it make sense?
    - Was there anything you did not understand or that you would have liked more explanation for?
- Delivery
    - What did you think about having the information session delivered in a group format with other patients and their family members present?
    - Did you have a family member or other loved one attend the session with you?
        - [If *no*] Do you think your experience with the session would have changed if a family member or friend had attended with you?
        - [If *yes*] Can you tell me more about this experience? In what way was it helpful/unhelpful to have your loved one attend with you?
    - What did you think about the delivery of the presentation (i.e., PPT presentation)?
        - Could the information have been delivered (delivered more clearly) in a different format (i.e., written materials/handouts, video format, other)?

Closing Questions:

- How did the session impact your cancer experience during this time, if at all?
    - Do you think the session helped you better manage your cancer? If no/yes, in what way?
    - Do you feel that the information (regarding symptom management, services, etc.) helped you cope better in any way, or helped you to know how/where to get help?
        - Do you feel that the information helped your loved ones cope better?
    - Did you seek out any help as a result of attending the CALMING session? If so, what type of help?
    - Did the session have an emotional impact on you?
- Thinking back over the past month, have you connected in clinic with the CALMING session facilitators?
    - Was it helpful to have made that connection earlier by attending the session?
- Is there anything you would like to add?
    - Are there any important issues about your participation in the session that we haven't talked about and that you would like to share with me?
- How have you felt about taking part in this interview?
    - Were there any questions you felt I should not have asked?
    - Were there any questions you felt I should have asked that I did not?
- Do you have any questions for me?

Thank you for taking the time to share your experiences with me. We appreciate you contributing to this study to help improve these sessions for other patients and their families in the future.

Interview Guide (Family Member)

Managing Cancer And Living Meaningfully Information Group (CALMING) for Patients with Advanced Cancer – Qualitative Caregiver Participant Interview

This interview is being conducted to get your feedback and explore the experience of family members/friends who attended the CALMING session. This interview will help us learn how you felt about being in the study and will help us understand how useful the CALMING session may be for patients and their loved ones at the beginning of their cancer journey. It will take approximately 20 to 30 minutes. You should not feel rushed, so please take as much time as you need to answer the questions. If you feel unable to fully participate today, we can always reschedule for another time. Please know that you can also stop the interview at any time, or refuse to answer any of the questions.

I will be audio-recording our conversation. This is so that I can get all the details but at the same time focus on my conversation with you. I might also take notes from time to time, but I assure you that all of your comments will remain confidential.

"This is [INTERVIEWER NAME] conducting the CALMING qualitative interview for participant Study ID # on Month, Day, Year."

Opening Questions:
You were invited to attend this information session with your loved one who is a patient at the Princess Margaret to hear about several topics that may be relevant to you.

- How you are today?
- How have you been feeling lately?

General Questions about the Session:

- What did you think about the CALMING session?
    - What were you expecting before the session?
    - Did you have any concerns before the session began?
    - Did you feel engaged during the session?
    - In the end, was the session what you expected? In what way?

Open-Ended Questions and Probes:

- Content
    - What was the most useful information you learned? Why?
    - What was the least useful information? Or not meaningful information?
    - What was missing that you would have liked to hear about?

I would just like to ask you a few more specific questions to get your feedback to help us plan sessions like this for future patients and their families.

- Timing
    - How did you feel about the prescheduled sessions?
        - Was it difficult to fit a session into your schedule?
    - How was the timing of the session for you (relative to the onset of illness)?
        - Do you think the session could have helped you more if it was offered earlier? Or later?
- Length

  - What did you think about the length of the session? (Was it reasonable? Too long? Too short?)
  - If we had offered an additional information session or a follow-up question and answer session, would you have been interested in attending? Why/why not?
    - [If *yes*] What kind of benefits do you think you would have experienced from an additional information session and/or a question and answer session?
- Comprehension/Understanding
  - Was the presentation clear and easy to follow? Did it make sense?
  - Was there anything you did not understand or that you would have liked more explanation for?
- Delivery
  - What did you think about the group format of the session, with other patients and their family members present?
  - Can you tell me about your experience with attending the session together with your loved one (and if applicable: other family members/friends)? In what way was it helpful/unhelpful to come together to have your loved one attend with you?
  - What did you think about the delivery of the presentation (i.e., PPT presentation)?
  - Could the information have been delivered (delivered more clearly) in a different format (i.e., written materials/handouts, video format, other)?

Closing Questions:

- How did the session impact your experience with your loved one's cancer experience during this time, if at all?
  - Do you think that the session helped your loved one better manage their cancer? If no/yes, in what way?
  - Do you feel that the information (regarding symptom management, services, etc.) helped you cope better in any way, or helped you to know how/where to get help?
    - Do you feel that the information helped your loved one cope better?
  - Did you or your loved one seek out any help as a result of attending the CALMING session? If so, what type of help?
  - Did the session have an emotional impact on you or your loved one?
- Thinking back over the past month, have you or your loved one connected in clinic with the CALMING session facilitators?
  - Was it helpful to have made that connection earlier by attending the session?
- Is there anything you would like to add?
  - Are there any important issues about your participation in the session that we haven't talked about and that you would like to share with me?
- How have you felt about taking part in this interview?
  - Were there any questions you felt I should not have asked?
  - Were there any questions you felt I should have asked that I did not?
- Do you have any questions for me?

Thank you for taking the time to share your experiences with me. We appreciate you contributing to this study to help improve these sessions for other patients and their families in the future.

Interview Guide (Health Care Professional)

CALMING Clinical Staff Survey/Interview Guide

Managing Cancer and Living Meaningfully Information Group (CALMING) for Patients with Advanced Cancer – Clinical Staff Survey

This survey is being conducted to get your feedback and explore the experience of CALMING from the facilitator/clinical staff perspective. This survey will help us learn how you felt about being a part of the development and implementation of the study and will help us understand how useful these sessions may be for patients at the beginning of their cancer journey. It will take approximately 20 to 30 minutes.

Open-Ended Questions:

- What information is the most valuable for your patients to know about their disease?
- How do you feel the CALMING session impacted your patients and families?
- How do you feel the CALMING session impacted your personal workload?
- How do you feel the CALMING session impacted the clinical flow?
- Did the CALMING session impact you personally? If so, please describe.

Closing Questions:

- Please feel free to share any other comments you have about the session or your experience.

Thank you for taking the time to share your experiences and feedback. We appreciate you contributing to this study to help improve these sessions for patients in the future.

Appendix E: Questionnaire Measures

Psychoeducation Knowledge Questionnaire (PKQ; Patient)

ID # _______________ Date: _______________
DD-MMM-YYYY

PKQ

1 = Not at all
2 = A little bit
3 = Moderately
4 = Quite a bit
5 = Very much

How much do you understand:	**1**	**2**	**3**	**4**	**5**
1. Your disease and how to manage your symptoms	☐	☐	☐	☐	☐
2. How you and your family can cope with your disease	☐	☐	☐	☐	☐
3. How to partner with your healthcare team	☐	☐	☐	☐	☐
4. How to plan for the future	☐	☐	☐	☐	☐
5. Where to find support services	☐	☐	☐	☐	☐

PKQ
Version Date: March 1, 2017

Page 1 of 1

Psychoeducation Knowledge Questionnaire (PKQ; Family Member)

ID # _______________

Date: _______________
DD-MMM-YYYY

PKQ

1 = Not at all
2 = A little bit
3 = Moderately
4 = Quite a bit
5 = Very much

How much do you understand:	**1**	**2**	**3**	**4**	**5**
1. Your loved one's disease and how to manage the symptoms	☐	☐	☐	☐	☐
2. How you and your family can cope with the disease	☐	☐	☐	☐	☐
3. How to partner with the healthcare team	☐	☐	☐	☐	☐
4. How to plan for the future	☐	☐	☐	☐	☐
5. Where to find support services	☐	☐	☐	☐	☐

Family Satisfaction with Advanced Cancer Care (FAMCARE-P16; Patient)

ID # _______________

Date: _______________
DD-MMM-YYYY

FAMCARE P16 Scale

1 = Very dissatisfied
2 = Dissatisfied
3 = Undecided
4 = Satisfied
5 = Very satisfied

How satisfied are you with:	1	2	3	4	5
1. Doctor's attention to your description of symptoms	☐	☐	☐	☐	☐
2. How thoroughly the doctor assesses your symptoms	☐	☐	☐	☐	☐
3. Information given about how to manage pain	☐	☐	☐	☐	☐
4. Information given about side effects	☐	☐	☐	☐	☐
5. Speed with which symptoms are treated	☐	☐	☐	☐	☐
6. Information given about your tests	☐	☐	☐	☐	☐
7. The way tests and treatments are performed	☐	☐	☐	☐	☐
8. The way tests and treatments are followed up by the doctor	☐	☐	☐	☐	☐
9. Information provided about your prognosis	☐	☐	☐	☐	☐
10. Answers from health professionals	☐	☐	☐	☐	☐
11. Referrals to specialists	☐	☐	☐	☐	☐
12. The availability of doctors to answer your questions	☐	☐	☐	☐	☐

ID # _______________ Date: _______________
DD-MMM-YYYY

13. The availability of nurses to answer your questions	☐	☐	☐	☐	☐
14. The way the family is included in treatment and care decisions	☐	☐	☐	☐	☐
15. Coordination of care	☐	☐	☐	☐	☐
16. The availability of doctors to your family	☐	☐	☐	☐	☐

Family Satisfaction with Advanced Cancer Care (FAMCARE; Family Member)

ID # _______________ Date: _______________
DD-MMM-YYYY

FAMCARE

1 = Very dissatisfied
2 = Dissatisfied
3 = Undecided
4 = Satisfied
5 = Very satisfied

How satisfied are you with:	1	2	3	4	5
1. The patient's pain relief	☐	☐	☐	☐	☐
2. Information provided about the patient's prognosis	☐	☐	☐	☐	☐
3. Answers from health professionals	☐	☐	☐	☐	☐
4. Information given about side effects	☐	☐	☐	☐	☐
5. Referrals to specialists	☐	☐	☐	☐	☐
6. Availability of a hospital bed	☐	☐	☐	☐	☐
7. Family conferences held to discuss the patient's illness	☐	☐	☐	☐	☐
8. Speed with which symptoms are treated	☐	☐	☐	☐	☐
9. Doctor's attention to patient's description of symptoms	☐	☐	☐	☐	☐
10. The way tests and treatments are performed	☐	☐	☐	☐	☐
11. Availability of doctors to the family	☐	☐	☐	☐	☐
12. Availability of nurses to the family	☐	☐	☐	☐	☐

ID # _______________ Date: _______________
DD-MMM-YYYY

13. Coordination of care	☐	☐	☐	☐	☐
14. Time required to make a diagnosis	☐	☐	☐	☐	☐
15. The way the family is included in treatment and care decisions	☐	☐	☐	☐	☐
16. Information given about how to manage the patient's pain	☐	☐	☐	☐	☐
17. Information given about the patient's tests	☐	☐	☐	☐	☐
18. How thorough the doctor assesses the patient's symptoms	☐	☐	☐	☐	☐
19. The way tests and treatments are followed up by the doctor	☐	☐	☐	☐	☐
20. Availability of the doctors to the patient	☐	☐	☐	☐	☐

Mishel Uncertainty in Illness Scale Community Form (MUIS-C; Patient)

ID # _______________ Date: _______________
DD-MMM-YYYY

MUIS-C Scale

Please read each statement. Take your time and think about what each statement says. Then place an "X" under the column that most closely measures how you are feeling TODAY. Please respond to every statement.

1 = Strongly Disagree
2 = Disagree
3 = Undecided
4 = Agree
5 = Strongly Agree

	1	2	3	4	5
1. I don't know what is wrong with me.	☐	☐	☐	☐	☐
2. I have a lot of questions without answers.	☐	☐	☐	☐	☐
3. I am unsure if my illness is getting better or worse.	☐	☐	☐	☐	☐
4. It is unclear how bad my pain will be.	☐	☐	☐	☐	☐
5. The explanations they give about my condition seem hazy to me.	☐	☐	☐	☐	☐
6. The purpose of each treatment is clear to me.	☐	☐	☐	☐	☐
7. My symptoms continue to change unpredictably.	☐	☐	☐	☐	☐
8. I understand everything explained to me.	☐	☐	☐	☐	☐
9. The doctors say things to me that could have many meanings.	☐	☐	☐	☐	☐
10. My treatment is too complex to figure out.	☐	☐	☐	☐	☐

ID # _______________ Date: _______________
DD-MM-YYYY

11. It is difficult to know if the treatments or medications I am getting are helping.	☐	☐	☐	☐	☐
12. Because of the unpredictability of my illness, I cannot plan for the future.	☐	☐	☐	☐	☐
13. The course of my illness keeps changing. I have good and bad days.	☐	☐	☐	☐	☐
14. I have been given many differing opinions about what is wrong with me.	☐	☐	☐	☐	☐
15. It is not clear what is going to happen to me.	☐	☐	☐	☐	☐
16. The results of my tests are inconsistent.	☐	☐	☐	☐	☐
17. The effectiveness of the treatment is undetermined.	☐	☐	☐	☐	☐
18. Because of the treatment, what I can do and cannot do keeps changing.	☐	☐	☐	☐	☐
19. I'm certain they will not find anything else wrong with me.	☐	☐	☐	☐	☐
20. The treatment I am receiving has a known probability of success.	☐	☐	☐	☐	☐
21. They have not given me a specific diagnosis.	☐	☐	☐	☐	☐
22. The seriousness of my illness has been determined.	☐	☐	☐	☐	☐
23. The doctors and nurses use everyday language so I can understand what they are saying.	☐	☐	☐	☐	☐

Mishel Uncertainty in Illness Scale Community Form (MUIS-C; Family Member)

ID # _______________ Date: _______________
DD-MMM-YYYY

MUIS-C Scale

Please read each statement. Take your time and think about what each statement says. Then place an "X" under the column that most closely measures how you are feeling TODAY. Please respond to every statement.

1 = Strongly Disagree
2 = Disagree
3 = Undecided
4 = Agree
5 = Strongly Agree

	1	2	3	4	5
1. I don't know what is wrong with my loved one.	☐	☐	☐	☐	☐
2. I have a lot of questions without answers.	☐	☐	☐	☐	☐
3. I am unsure if my loved one's illness is getting better or worse.	☐	☐	☐	☐	☐
4. It is unclear how bad my loved one's pain will be.	☐	☐	☐	☐	☐
5. The explanations they give about my loved one seem hazy.	☐	☐	☐	☐	☐
6. The purpose of each treatment is clear to me.	☐	☐	☐	☐	☐
7. My loved one's symptoms continue to change unpredictably.	☐	☐	☐	☐	☐
8. I understand everything explained to me.	☐	☐	☐	☐	☐
9. The doctors say things to me that could have many meanings.	☐	☐	☐	☐	☐
10. My loved one's treatment is too complex to figure out.	☐	☐	☐	☐	☐

ID # _______________

Date: _______________
DD-MMM-YYYY

11. It is difficult to know if the treatments or medications my loved one is getting are helping.	☐	☐	☐	☐	☐
12. Because of the unpredictability of the illness, I cannot plan for the future.	☐	☐	☐	☐	☐
13. The course of my loved one's illness keeps changing. He/she has good and bad days.	☐	☐	☐	☐	☐
14. I have been given many differing opinions about what is wrong with my loved one.	☐	☐	☐	☐	☐
15. It is not clear what is going to happen to my loved one.	☐	☐	☐	☐	☐
16. The results of my loved one's tests are inconsistent.	☐	☐	☐	☐	☐
17. The effectiveness of the treatment is undetermined.	☐	☐	☐	☐	☐
18. Because of the treatment, what my loved one can do and cannot do keeps changing.	☐	☐	☐	☐	☐
19. I'm certain they will not find anything else wrong with my loved one.	☐	☐	☐	☐	☐
20. The treatment my loved one is receiving has a known probability of success.	☐	☐	☐	☐	☐
21. They have not given my loved one a specific diagnosis.	☐	☐	☐	☐	☐
22. The seriousness of my loved one's illness has been determined.	☐	☐	☐	☐	☐
23. The doctors and nurses use everyday language so I can understand what they are saying.	☐	☐	☐	☐	☐