

Addressing Fear of Cancer Recurrence: A Cognitive-Existential Psychosocial Intervention for
Cancer Survivors

Christina Tomei

Thesis submitted to the School of Psychology in partial fulfillment of the requirements for the
degree of Doctor of Philosophy in Clinical Psychology

School of Psychology
Faculty of Social Sciences
University of Ottawa

© Christina Tomei, Ottawa, Canada, 2017

Acknowledgements

To my incredible thesis supervisor, Dr. Sophie Lebel – thank you, from the bottom of my heart, for your boundless support, encouragement, and faith throughout my graduate studies. Because of your unwavering guidance, I have grown both professionally and personally over the past few years. I attribute my growing confidence as a scientist-practitioner to you, as you have continually taught me to trust myself. I will always treasure the memories in our lab, and our shared interests outside of clinical psychology. Thank you for providing me the opportunity to adapt your novel therapeutic intervention for my own dissertation. I admire you tremendously and have learned so much from you, and cannot thank you enough for everything you have done. Thank you for your kindness, genuineness, and enthusiasm, and for always being by my side throughout this marathon. I am truly blessed to have you as my supervisor.

To Dr. Monique Lefebvre, thank you for effortlessly wearing multiple hats as a clinical supervisor, research supervisor, and principal investigator for my dissertation. I admire your authenticity, attentiveness, and convivial nature. Thank you for teaching me to trust the therapeutic process, to rely on my clinical acumen, and for instilling confidence in me. I am so fortunate to have been privy to your clinical expertise.

To Dr. Cheryl Harris, thank you for your involvement in my dissertation, as both a principal investigator and clinical supervisor. Thank you for your gentle demeanour, your warmth, your therapeutic guidance, and for always providing me with a safe, supportive environment. It has been a privilege to work alongside you.

To Dr. Christine Maheu, thank you for generously granting me the privilege of adapting your therapeutic intervention for my dissertation, and for your guidance, support, and willingness to consult with research-related endeavours. It means so much to me.

To the wonderful staff at the Psychosocial Oncology Program and the Wellness Beyond Cancer Program at The Ottawa Hospital, thank you for your generous help with recruitment of my study participants. A special thanks to Lynne Jolicoeur, Josée Charlebois, Dr. Caroline Gérin-Lajoie, Robin Morash, Carrie Liska, and Gail Larocque.

I extend my heartfelt thanks to all of my study participants. Your willingness to participate in my research serves as the foundation for my clinically informed dissertation. I admire your courageousness, dedication, and openness to experience. Thank you all for trusting the process, and for trusting me as your therapist. Thank you to Caroline Séguin Leclair and Taylor Hatchard for their role as therapists in the second phase of this dissertation.

Thank you to my Psychosocial Oncology labmates, both past and present, for all the wonderful memories: Megan McCallum, Sara Beattie, Andrea Feldstain, Caroline Séguin Leclair, Danielle Petricone-Westwood, Georden Jones, and Brittany Mutsaers. Thank you to my volunteers, Chelsea Moran and Shannon Bedford, for your help and commitment.

Thank you to the University of Ottawa and the School of Psychology program for providing me with solid, high quality training as both a researcher and clinician. I am eternally grateful for this gift of achieving my lifelong goal of becoming a clinical psychologist. Thank you to Drs. Pierre Ritchie and John Hunsley for your guidance; to my thesis committee, Drs. Paul Greenman, Jean Grenier, and Elisa Romano, for your expertise, encouragement and support; and to Dr. Dwayne Schindler and Angeline Tsui, for your statistical proficiency.

I am truly grateful to my family and friends, both in Toronto and Ottawa, who have supported me throughout the program. Thank you all for your endless support.

To my “little” brother, Rob, thank you for your boundless positivity and encouragement. I truly appreciate all of your feedback and reassurance over the past few years. Your supportive

messages, sense of humour, and well wishes throughout my graduate studies have meant so much to me. You have steadily demonstrated that I can always count on you, and for that, I am truly grateful. Thank you for everything.

To my two pillars of strength, my wonderful parents, Rose and Joseph Tomei. You have been my personal cheerleaders from the very beginning, and never cease to remind me (and everyone) of your pride in me. You have been there every step of the way, throughout every scholarly endeavour and otherwise. You have been my driving force throughout this marathon of earning a Ph.D. Thank you both, from the bottom of my heart, for your wisdom, encouragement, trust, and support. You mean the absolute world to me.

Finally, thank you to my best friend and husband, Paul. I am forever grateful for your perpetual support, encouragement, and nurturance. Thank you for always reminding me of my strengths and attributes, for teaching me how to slow down, and for being my limitless source of comfort and protection. Words defy description for my gratitude towards you. I love you infinitely.

Preface

This thesis is manuscript-based, containing a general introduction, two studies, and a general discussion/conclusion. The core research team of this dissertation research includes Dr. Sophie Lebel, Dr. Christine Maheu, Dr. Monique Lefebvre, Dr. Cheryl Harris, and myself. In both studies, I was primarily responsible for conducting a thorough literature review; preparing all study documents (ethics review board applications, consent forms and information sheets, etc.); liaising with team members; data collection, entry, and analysis; and writing the manuscripts. I am especially grateful for the support, direction, and feedback of my collaborators. The role of each co-author is summarized below.

Dr. Sophie Lebel, Associate Professor at the University of Ottawa and my research supervisor, guided all of my research activities and contributed to the aforementioned responsibilities in our weekly supervision meetings. More specifically, she offered permission for the adaptation of her FCR clinical intervention, and assisted me with study design, ethics review board applications, selection of measures, data collection, analysis and interpretation, dissemination of research findings, and manuscript preparation. She also served as a clinical supervisor in all phases of these research studies.

Dr. Christine Maheu, Associate Professor at the Ingram School of Nursing at McGill University and Clinical Scientist at Princess Margaret Cancer Centre, collaborated in both the first and second phase of this dissertation research. She provided her expert knowledge in quantitative and qualitative research, provided permission for the adaptation of her FCR clinical intervention, and assisted with data analysis, interpretation, and manuscript preparation.

Dr. Monique Lefebvre, clinical, health and rehabilitation psychologist in the Department of Psychology at The Ottawa Hospital, collaborated in the second phase of this dissertation

research. Specifically, she served as a principal study investigator and clinical supervisor, and assisted me with ethics review board applications, study recruitment, liaising with team members, organizing team meetings, and manuscript editing and preparation.

Dr. Cheryl Harris, clinical, health and rehabilitation psychologist in the Department of Psychology at The Ottawa Hospital, collaborated in the first phase of this dissertation research. Specifically, she served as a principal study investigator and clinical supervisor, and assisted me with ethics review board applications, study recruitment, liaising with team members, and manuscript preparation.

Ms. Brittany Mutsaers, fellow doctoral candidate in the Psychosocial Oncology Lab, collaborated in the first phase of this dissertation research. Ms. Mutsaers assisted me with qualitative data collection, data entry, coding and interpretation, and manuscript editing.

The following research ethics boards approved these studies: The Ottawa Health Science Network Research Ethics Board (Study 1 Protocol #20140374-01H; Study 2 Protocol #20150013-01H), and the University of Ottawa Office of Research Ethics and Integrity (Study 1 File #A10-14-01; Study 2 File #A03-15-01). Furthermore, as study 2 is a randomized controlled trial, this trial has been registered on <http://www.clinicaltrials.gov> (Identifier: NCT02382315).

One of these two studies has been published in a peer-reviewed journal. The pilot study entitled “Addressing Fear of Recurrence: Improving Psychological Care in Cancer Survivors” was published as a commentary article in *Supportive Care in Cancer* in February 2016 (Tomei, Lebel, Maheu & Mutsaers, 2016). Since the pilot study was published as a commentary article, for the purposes of this dissertation, I have subsequently written the methods, results, and conclusions of study 1 in further detail, to accurately capture the outcome of the study. The published commentary article has been included in Appendix K for additional review). The study

2 article, entitled “Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized Controlled Clinical Trial Pilot Study”, has been submitted to the journal of *Supportive Care in Cancer*. For the purposes of this dissertation, I have written the methods of study 2 in further detail, to ensure the details of the study are captured. The submitted article has been included in Appendix L for additional review.

General Abstract

Fear of cancer recurrence (FCR) is defined as “fear, worry, or concern relating to the possibility that cancer will come back or progress (Lebel et al., 2016, p. 3266). FCR is the most frequently reported concern identified among cancer survivors (Baker, Denniston, Smith, & West, 2005; Lebel, Rosberger, Edgar, & Devins, 2007). Although approximately 50% of cancer survivors experience moderate-to-high levels of FCR (Simard et al., 2013), few psychosocial interventions exist that directly target this construct. The overarching study objectives were: (a) to adapt a manualized, 6-week, cognitive-existential group therapy intervention for FCR to an individual format; (b) to pilot-test the feasibility, acceptability, and satisfaction of this individual intervention on $n=3$ participants; and (c) to further pilot-test the efficacy of the individual intervention on $n=25$ participants, via a randomized controlled trial (RCT). In study 1, $n=3$ cancer survivors (1 male, 2 females) completed the one-on-one therapy intervention for the psychological treatment of FCR. Sessions were 60-90 minutes long, and included cognitive restructuring exercises, behavioural experiments, relaxation techniques, existential processing of the here-and-now, and finding meaning in life post-diagnosis. Participants completed questionnaire packages throughout the intervention and an exit interview to determine their overall feedback on the intervention. Quantitative analyses revealed downwards trends in fear of cancer recurrence and cancer-specific distress across participants. Qualitative analyses of the exit interviews revealed that all participants found the intervention useful, and that the sessions had favourable pacing and length.

In study 2, the FCR intervention was further pilot-tested via an RCT. Twenty-five female cancer survivors were randomized to an experimental group or a wait-list control group. Sessions included cognitive restructuring techniques, behavioural experiments, confronting existential

distress, and relaxation exercises. Nineteen women (n=9 intervention, n=10 control) completed the 6-week therapy intervention, and completed questionnaire packages at pre-, post- and 3-month follow-up. Between-within ANOVAs revealed significant interactions in the primary outcome measure of FCR, and secondary outcome measures of cancer-specific distress and uncertainty in illness for participants in the experimental group. Repeated measures ANOVAs revealed reductions in FCR, cancer-specific distress, uncertainty in illness, reassurance-seeking, cognitive avoidance, and intolerance of uncertainty, and revealed improvements in positive reinterpretation and growth, use of emotional support and mental health (improved quality of life) for participants in the experimental group, as compared to the wait-list control group. The variables that changed either maintained or improved at follow-up. Results from this study demonstrate promising results in addressing FCR in cancer survivors via a cognitive-existential intervention. Future research should continue investigating the specific therapeutic ingredients that are most effective for the psychological treatment of FCR.

List of Tables and Figures

General Introduction	1
Figure 1. Model of Fear of Cancer Recurrence	22
Study 1: A Cognitive-Existential Intervention to Address Fear of Recurrence in Men and Women with Cancer: A Feasibility Study	43
Table 1. Description of the Individual Cognitive-Existential Intervention	74
Figure 1. Flow Diagram of Patient Recruitment	75
Figure 2. Participants' FCRI Total Scores	76
Figure 3. Participants' IES Total Scores	77
Study 2: Examining the Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized Controlled Clinical Trial Pilot Study	78
Figure 1. CONSORT Flow Diagram	116
Figure 2. Summary of Time Points Across Experimental Group and Wait-List Control Group	117
Table 1. Participant Characteristics	118
Table 2. Mixed Between-Within ANOVAs Examining Psychological Outcomes at Baseline (T1) and Post-Intervention (T2)	119
Table 3. Repeated Measures ANOVAs Examining Psychological Outcomes at Pre-Intervention (T1), Post-Intervention (T2), and 3-Month Follow-up (T3) ..	120
Figure 3. Between-Within ANOVA Examining FCRI Scores over Time	121
Figure 4. Between-Within ANOVA Examining IES Scores over Time	122
Figure 5. Between-Within ANOVA Examining MUIS Scores over Time	123
Figure 6. Repeated Measures ANOVA Examining FCRI Scores over Time	124
Figure 7. Repeated Measures ANOVA Examining IES Scores over Time	125
Figure 8. Repeated Measures ANOVA Examining MUIS Scores over Time	126
Figure 9. Repeated Measures ANOVA Examining BRIEF COPE: Positive Reinterpretation and Growth Scores over Time	127
Figure 10. Repeated Measures ANOVA Examining BRIEF COPE: Acceptance Scores over Time	128
Figure 11. Repeated Measures ANOVA Examining CAQ Scores over Time	129
Figure 12. Repeated Measures ANOVA Examining RQ Scores over Time	130
Figure 13. Repeated Measures ANOVA Examining IUS Scores over Time	131
Figure 14. Repeated Measures ANOVA Examining SF-8: Mental Health Quality of Life Scores over Time	132
Figure 15. Between-Within ANOVA Examining BRIEF COPE: Acceptance Scores Across Therapists over Time	133

Table of Contents

Acknowledgments.....	ii
Preface.....	v
General Abstract	viii
List of Tables and Figures.....	x
General Introduction	1
Overview	1
Cancer Types	1
Breast Cancer	1
Colorectal Cancer.....	2
Uterine/Endometrial Cancer	4
Ovarian Cancer	4
Cervical Cancer.....	5
Ocular Melanoma Cancer	6
Fear of Cancer Recurrence	7
Prevalence	8
Predictors and characteristics.....	9
Psychosocial outcomes	10
Clinical presentations.....	11
Measuring clinical FCR	12
FCR and distress	12
Review of Empirical Interventions for Patients with Cancer	13
Previous Interventions that Address FCR.....	16
Guiding Intervention	19
Theoretical Models	19
Current Studies	23
Rationale for Current Studies.....	24
Study 1 Rationale.....	24
Study 2 Rationale.....	25
References	27
Study 1: A Cognitive-Existential Intervention to Address Fear of Recurrence in Men and Women with Cancer: A Feasibility Study	43
Abstract.....	44
Introduction	45
The Current Study	45
Methods	47
Participants.....	47
Procedure	48
Outcome Measures.....	50
Demographic Form	51
Fear of Cancer Recurrence Inventory	51
Impact of Events Scale.....	52
Post-Session Feedback Questionnaires.....	52

Qualitative Exit Interviews	53
Results	54
Participants.....	54
Changes in Outcome Measures.....	55
FCRI Scores.....	56
IES Scores	56
Post-Session Feedback Questionnaires	56
Results of Qualitative Analyses	58
Qualitative Exit Interviews.....	58
Theme 1: Overall Experience in Therapy	58
Theme 2: Experience with FCR Pre-intervention.....	60
Theme 3: Mechanisms of Change	61
Theme 4: Overall Improvement in FCR	62
Discussion.....	63
Feasibility.....	63
Acceptability	65
Satisfaction.....	66
Limitations	67
Summary of Hypotheses	68
Clinical Implications	69
References	70
Study 2: Examining the Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized Controlled Clinical Trial Pilot Study	78
Abstract.....	79
Introduction	81
The Current Study.....	83
Hypotheses	84
Method.....	85
Participants.....	85
Procedure	87
Sample Size.....	88
Randomization	89
Therapists.....	90
Outcome Measures.....	91
Demographic Form	91
Primary Outcome Measure	91
Fear of Cancer Recurrence Inventory	91
Secondary Outcome Measures.....	92
Impact of Events Scale.....	92
SF-8 Health Survey.....	93
Intolerance of Uncertainty Scale.....	94
Mishel Uncertainty in Illness Scale: Community Form	94
Why do People Worry about Health?	94

Cognitive Avoidance Questionnaire	95
Reassurance Questionnaire	95
BRIEF COPE	96
Statistical Analyses	96
Results	97
Participants	97
Changes in Outcome Measures	98
Significance & Effect Size	98
Mixed Between-Within Subjects ANOVAs	98
Repeated Measures ANOVAs	100
Individual Therapist Differences	100
Discussion	101
Limitations	104
Future Directions	105
Clinical Implications	107
References	109
General Discussion	134
Thesis Rationale	134
Study 1: Review of Objectives and Hypotheses	135
Study 1: Main Pilot Findings	135
Study 2: Review of Objectives and Hypotheses	137
Study 2: Main Pilot Findings	138
Integration of Findings within Theoretical Models	139
The Common-Sense Model	140
Uncertainty in Illness Theory	143
Cognitive Models of Worry	144
Thesis Limitations	150
Thesis Strengths	152
Clinical Implications	153
Future Directions	154
References	158
Appendix A. Telephone Screening and Eligibility Script, Study 1	165
Appendix B. Consent Form, Study 1	173
Appendix C. Fidelity Checklist, Study 1 & 2	179
Appendix D. Questionnaire Package, Study 1	191
Appendix E. Post-Session Feedback Questionnaires, Study 1	199
Appendix F. Qualitative Exit Interview Guide, Study 1	215
Appendix G. Telephone Screening and Eligibility Script, Study 2	218
Appendix H. Mini Screener, Study 2	226
Appendix I. Consent Form, Study 2	229
Appendix J. Questionnaire Package, Study 2	235
Appendix K. Accepted Commentary Article, Study 1	258
Appendix L. Submitted Article, Study 2	265

General Introduction

Overview

Cancer is defined as “a disease characterized by any of various malignant tumours composed of abnormal cells that tend to proliferate rapidly, invade surrounding tissues, and metastasize to new body sites” (*American Heritage Dictionary*, 2002). According to the Canadian Cancer Society (2016a), 42% of Canadian women and 45% of Canadian men will be diagnosed with some form of cancer. It is estimated that approximately 196,900 new cases of cancer have occurred in Canada in 2015, resulting in approximately 539 Canadians receiving a cancer diagnosis every day (Canadian Cancer Society, 2016a). Cancer is the leading cause of death in Canada, and accounts for approximately 30% of all Canadian deaths. However, with improvements in cancer treatment and early detection, many individuals diagnosed with cancer can expect to live many years post-diagnosis (Canadian Cancer Society, 2016a). The five-year relative survival rate for all types of cancers diagnosed in Canada is 63%, indicating that 63% of people diagnosed with cancer can expect to be living five years later (Canadian Cancer Society, 2016a). With the exception of non-melanoma skin cancers, the most common cancer types are lung, breast, colorectal and prostate cancer, respectively, and these specific types account for 51% of all new cancer cases (Canadian Cancer Society, 2016a).

Cancer Types

For the purposes of this dissertation, the cancer types described below are representative of those diagnosed in our study participants.

Breast cancer. As the most common cancer diagnosed among Canadian women (Canadian Cancer Society, 2016b), breast cancer is defined as a malignant tumour that begins in the cells of the breast. The most common types of breast cancer are ductal carcinoma and lobular

carcinoma. Ductal carcinoma consists of cancer detected in areas associated with transporting milk from the glands to the nipple, and lobular carcinoma consists of cancer within the lobules, which are the glands that produce milk (Canadian Cancer Society, 2016b). In 2015, approximately 25,000 women were diagnosed with breast cancer, representing just over one quarter of all new cancer cases in women (Canadian Cancer Society, 2016b). While significantly less common in men, approximately 220 men were diagnosed with breast cancer in 2015, with almost all of the breast cancers found in men being ductal carcinoma (Canadian Cancer Society, 2016b). On average, 68 Canadian women will receive a breast cancer diagnosis daily (Canadian Cancer Society, 2016b).

Breast cancer is the second leading cause of death from cancer in Canadian women (Canadian Cancer Society, 2016b), accounting for 14% of all cancer deaths in women in 2015. More specifically, 14 Canadian women will die from breast cancer every day (Canadian Cancer Society, 2016b). However, the death rates for breast cancer have been declining since the mid-1980s, reflecting the impact of early screening procedures and improved treatments. While relative survival rates vary contingent on age, approximately 88% of Canadian women diagnosed with breast cancer are expected to survive for five years or more post-diagnosis (Canadian Cancer Society, 2016b). Five-year relative survival rates are slightly lower for women diagnosed with breast cancer under the age of 40 (85%), or over the age of 79 (79%; Canadian Breast Cancer Foundation, 2016). Treatment options for breast cancer include chemotherapy, radiation, surgery, and hormonal therapy.

Colorectal cancer. As the third most commonly diagnosed cancer in Canada (Canadian Cancer Society, 2016c), colorectal cancer is characterized by the development of malignant cells in the large intestine or colon, including the rectum. In terms of incidence rates, it is estimated

that 25,100 Canadians were diagnosed with colorectal cancer in 2015, representing 13% of all new cancer cases (Canadian Cancer Society, 2016c). Colorectal cancer affects more men than women each year, with approximately 14,000 men and 11,100 women being diagnosed with colorectal cancer in 2015. Approximately 69 Canadians will receive a colorectal cancer diagnosis every day (Canadian Cancer Society, 2016c).

In terms of mortality rates, colorectal cancer is the second leading cause of death from cancer in Canadian men, and the third leading cause of death from cancer in Canadian women. In 2015, colorectal cancer accounted for approximately 12% of all cancer deaths, with an estimated total of 5,100 men and 4,200 women succumbing to the disease. Approximately 25 Canadians will die from colorectal cancer every day (Canadian Cancer Society, 2016c). While these statistics are alarming, incidence and mortality rates for colorectal cancer have been declining for both sexes over the past ten years (Canadian Cancer Society, 2016c). With scientific advancements in cancer research, the vast majority of individuals with cancer will complete treatment and survive. Approximately 65% of Canadians diagnosed with colorectal cancer are expected to survive for five years or more post-diagnosis (Canadian Cancer Society, 2016c). Various colorectal cancer treatments are available, including surgery, chemotherapy, radiation, and targeted therapy.

Gynecological cancer. Gynecological cancers consist of the uncontrolled growth and spread of abnormal cells originating in the female reproductive system, including the cervix, ovaries, uterus, vagina, and vulva (Foundation for Women's Cancers, 2016). Gynecological cancer is diagnosed in over 10,000 Canadian women per year (Statistics Canada, 2015). The most common types, respectively, are uterine/endometrial, ovarian, and cervical cancer, and each cancer type is unique in symptom presentation and subsequent treatment.

Uterine/Endometrial cancer. Uterine/endometrial cancer is characterized by the development of malignant tumours that begin in the cells of the uterus. In more than 95% of cases, uterine cancer starts in the endometrium, or the lining of the uterus; thus the interchangeable use of the terms uterine and endometrial cancer. Uterine cancer is the most commonly diagnosed gynecological cancer. In 2015, approximately 6,300 Canadian women were diagnosed with uterine cancer, accounting for 6.9% of new cancer cases (Canadian Cancer Society, 2016d). Uterine cancer is most common in postmenopausal women, although it can occur in younger women as well (Ovarian Cancer Canada, 2016). Based on 2010 estimates, approximately 1 in 36 Canadian women are expected to develop uterine cancer in their lifetime (Canadian Cancer Society, 2016d).

In terms of mortality rates, it is estimated that approximately 1,050 Canadian women will die from uterine cancer (Canadian Cancer Society, 2016d). Fortunately, uterine cancers are often detected early, as signs and symptoms include unusual vaginal bleeding, which is highly abnormal in postmenopausal women (Ovarian Cancer Canada, 2016). As a result of early detection, approximately 85% of Canadians diagnosed with uterine cancer are expected to survive for five years or more post-diagnosis (Canadian Cancer Society, 2016d).

Treatment modalities for uterine cancer often include surgical interventions, such as a total hysterectomy (i.e., removal of the uterus and cervix) and a bilateral salpingo-oophorectomy (i.e., removal of the ovaries and fallopian tube). Treatment for more advanced or recurrent uterine cancer often includes radiation therapy, hormonal therapy, and/or chemotherapy (Canadian Cancer Society, 2016d), along with more extensive surgical procedures.

Ovarian Cancer. Ovarian cancer is defined as malignant tumours that begin in the cells of the ovaries. It is estimated that in 2015, approximately 2,800 Canadian women were

diagnosed with ovarian cancer, representing 2.9% of all new cancer cases in Canadian women (Canadian Cancer Society, 2016e). Based on 2010 estimates, approximately 1 in 71 Canadian women are expected to develop ovarian cancer during their lifetime. Similarly to uterine cancer, ovarian cancer is most commonly diagnosed in post-menopausal women. However, unlike uterine cancer, one's risk for developing ovarian cancer increases with age (Statistics Canada, 2015).

Ovarian cancer is often diagnosed at more advanced stages, due to the subtle nature of its symptoms. Subsequently, diagnoses of ovarian cancer often result in poorer prognosis (Canadian Cancer Society, 2016e). Ovarian cancer is the deadliest gynecological cancer, with one in nine women dying from the disease. Mortality rates indicate that approximately 1,750 Canadian women will die from ovarian cancer. However, despite a relatively high mortality rate, the risk of death due to ovarian cancer has decreased over time (Statistics Canada, 2015). The five-year relative survival rate for ovarian cancer is 45% (Canadian Cancer Society, 2016e).

Surgery is the primary treatment for all stages and types of ovarian cancer (Canadian Cancer Society, 2016e). In most cases, chemotherapy is offered after surgical procedures for most stages of ovarian cancer, whereas radiation is rarely used in treatment (Canadian Cancer Society, 2016e).

Cervical cancer. Cervical cancer is characterized by the development of cancerous lesions on the cervix. In 2015, approximately 1,500 women were diagnosed with cervical cancer, accounting for 1.5% of new cancer cases in Canadian women. It is estimated that approximately 1 in 152 Canadian women are expected to develop cervical cancer in their lifetime (Canadian Cancer Society, 2016f). Cervical cancer is more likely to affect younger women, as compared to ovarian or uterine cancer. The median age of diagnosis with cervical cancer was 47 years, and

28.7% of all new cases occurred in women under the age of 40 (Statistics Canada, 2015).

Mortality rates indicate that approximately 380 Canadian women will succumb to cervical cancer in 2016. However, since the introduction of the Pap test as a means of early detection, the number of deaths from the disease has declined significantly, with a rate of 2.2 deaths per 100,000 Canadian women (Statistics Canada, 2015). Subsequently, the five-year relative survival rate for cervical cancer is 74% (Canadian Cancer Society, 2016f).

Treatment for cervical cancer may include a total hysterectomy or radical hysterectomy, depending on the stage of the cancer (Canadian Cancer Society, 2016f). Radiation therapy may be used in treatment as well, with women usually receiving a combination of external beam radiation therapy and brachytherapy (i.e., internal radiation). Chemotherapy may be offered for patients with more advanced stages of cervical cancer (Canadian Cancer Society, 2016f).

Ocular Melanoma. Ocular melanoma arises from malignant tumours in the pigmented cells of the eye. It is a type of noncutaneous melanoma that affects the intraocular space, accounting for 5% of all melanomas, and is the second most common location of melanoma on the body after cutaneous melanoma (Canadian Cancer Society, 2016g). In 2015, approximately 6,800 Canadians were diagnosed with melanoma (Canadian Cancer Society, 2016h). Although considered to be a rare form of cancer, ocular melanoma is the most common type of primary eye cancer in adults. In most cases, ocular melanoma affects only one eye, and 95% of tumours originate in the uvea (choroid, ciliary body and iris; Canadian Cancer Society, 2016i).

The most recent Canadian statistics on ocular melanoma are from 2010, when 355 Canadians were diagnosed with the disease (Canadian Cancer Society, 2016j). Ocular melanoma is generally more prevalent in men, but Canadian statistics show almost equal proportion of men and women being diagnosed with this form of cancer (Canadian Cancer Society, 2016j). Risk

factors for this disease include having light skin and eyes, and long-term exposure to artificial UV radiation, such as welding or indoor tanning (Canadian Cancer Society, 2016i). Most ocular melanomas grow slowly, and incidence increases with age (McLaughlin et al., 2005). In 2010, 40 Canadians died from ocular melanoma (Canadian Cancer Society, 2016j).

Earlier diagnosis and treatment of this cancer type are related to better outcomes. Treatment of ocular melanoma originating in the uvea varies from active observation to complete removal of the eye, depending on the site and size of the tumour (Jovanovic et al., 2013). In addition to surgery, radiation and chemotherapy treatments are also common. Prognosis of ocular melanoma varies with the size and location of the tumour at diagnosis. Less than 4% of patients have metastatic disease at diagnosis, however, approximately half of patients will develop metastases during the course of the illness (Jovanovic et al., 2013). The five-year survival rates for tumours located in the iris and in the choroid are 95% and 35%, respectively. The survival rate of tumours originating in ciliary body is difficult to determine due to tumour rarity, but generally, prognosis is poor (Canadian Cancer Society, 2016j).

Fear of Cancer Recurrence

Despite increasing survival rates and treatment efficacy, the survivorship phase can be difficult for cancer survivors. Studies have shown that cancer survivors have a variety of unmet needs, with fear of cancer recurrence (FCR) being the most frequently reported concern (Baker, Denniston, Smith, & West, 2005; Lebel, Rosberger, Edgar, & Devins, 2007). Unmet needs are services or resources related to psychosocial care that patients view as both important and unsatisfied (Soothill et al., 2001). More specifically, unmet needs are perceived as essential for one's wellbeing, but are viewed as unavailable in the amount that is considered necessary (Lopez, 2016; Sanson-Fisher et al., 2000; Soothill et al., 2001; Waller, Boyes, Carey & Sanson-

Fisher, 2015). When left unaddressed, unmet needs (i.e., addressing FCR) increase psychological morbidity and subsequently reduce quality of life over time (Hodgkinson et al., 2007).

FCR is defined as “fear, worry or concern relating to the possibility that cancer will come back or progress” (Lebel et al., 2016, p. 3266). FCR is a psychosocial concern that has been described as the sword of Damocles that hangs over patients’ heads for the rest of their lives (Muzzin, Anderson, Figueredo, & Gudelis, 1994). As a relatively new phenomenon, FCR has only garnered research attention over the last two decades.

Prevalence of FCR. Studies have shown that moderate-to-high levels of FCR affect 22 to 87% of cancer patients (Crist & Grunfeld, 2013; Koch, Jansen, Brenner, & Arndt, 2013; Llewellyn, Weinman, McGurk, & Humphris, 2008; Simard et al., 2013; Thewes et al., 2012; Vickberg, 2003), and can persist for several years after diagnosis (Crist & Grunfeld, 2013). Simard et al. (2013) found that an average of 49% of cancer survivors reported moderate to high levels of FCR, and an average of 7% reported high levels of FCR. Furthermore, FCR is associated with maladaptive coping strategies such as hyper-vigilance, excessive bodily checking, and reassurance-seeking, which is the tendency to excessively seek reassurance from others in an effort to assuage anxiety (e.g., frequent contact with one’s physician or follow-ups with one’s cancer care team; Armes et al., 2009; Lebel et al., 2007; Lebel et al., 2013). Reassurance-seeking can be detrimental in the long-term amongst anxious patients, as it may reinforce maladaptive coping strategies and promote enduring anxiety (Lebel et al., 2013). Koch et al. (2014) conducted a study of 2,671 breast cancer survivors, and found that a small (but relevant) portion of survivors reported moderate (11%) to severe (6%) levels of FCR. Custers et al. (2015) found that 52% of gastrointestinal stromal tumour (GIST) patients reported high levels of FCR. These discrepant percentages in FCR may be attributed to the variety of different

measures used to assess FCR, and the lack of validated clinical cut-off scores for measuring FCR.

Given that a recurrence of cancer is a realistic possibility, patients' fears are not unfounded (Herschbach & Dinkel, 2014). In a study conducted with 1,721 cancer patients with mixed cancer sites and tumour stages, the most distressing problem reported was fear of disease progression/recurrence, which was endorsed by 68% of patients (Herschbach et al., 2004). Further studies with cancer survivors have indicated that FCR either did not decrease over time (Llewellyn et al., 2008), or remained stable over time (Mehta, Lubeck, Pasta, & Litwin, 2003). Simard and Savard (2009) found that time was not related to the degree of FCR reported by participants. Furthermore, Simard et al. (2013) conducted a systematic review, and found 20 cross-sectional studies that did not report significant changes in FCR over time.

Predictors and characteristics of FCR. Predictors of FCR include younger age (Crist & Grunfeld, 2013; Koch et al., 2014; Lebel, Beattie, Ares & Bielajew, 2013; Simard et al., 2013, van de Wal et al., 2015), and the presence of somatic symptoms, such as fatigue or pain (Simard et al., 2013). Additionally, Simard et al. (2013) found that women tend to experience more FCR than men, and that loved ones of cancer patients, such as caregivers and/or partners, can also experience the impact of FCR. Nevertheless, while more than 40 predictors of FCR have been studied (Crist & Grunfeld, 2013), few have been identified as strong predictors of FCR. Researchers have examined factors such as coping strategies, optimism and social support, although results have been contradictory across various studies (Simard et al., 2013). Some studies have found low self-esteem, denial, and avoidance-oriented coping to be predictors of future FCR (Stanton, Danoff-burg & Huggins, 2002; Wade, Nehmy & Koczwara, 2005). Thewes

et al. (2012) conducted a systematic review and found that clinically high FCR levels at baseline are a stronger predictor of higher and long-term FCR.

With regards to presence of FCR severity across cancer types, results appear to be mixed. van de Wal, van de Poll-Franse, Prins, and Gielissen (2015) conducted a study with 2,615 survivors with mixed cancer types and tumour stages, and found no significant differences in severity of FCR between any of the cancer types. Similarly, a relationship between FCR and cancer type was not detected in other studies (Deimling, Bowman, Sterns, Wagner & Kahana, 2006; Mellon, Kershaw, Northouse & Freeman-Gibb, 2007). However, Savard and Ivers (2013) found that as compared to survivors with other cancer types, higher FCR was found in head and neck cancer survivors. Other studies report disparate findings, suggesting that prostate cancer survivors experience lowest levels of FCR, whereas FCR is comparable across breast, colorectal and lung cancer patients (Simard & Savard, 2009; Simard, Savard & Ivers, 2010). Results from these studies suggest that FCR is a universal construct, experienced by survivors of various cancer types.

Psychosocial outcomes. Despite the aforementioned findings, there is little evidence that current medical management is addressing FCR among cancer survivors. Clinical levels of FCR have been associated with impaired functioning, psychological distress, stress-response symptoms, lower quality of life (Vickberg, 2003), and increased use of health care resources (Lebel, Tomei, Feldstain, Beattie, & McCallum, 2013). When left untreated, FCR can increase health care utilization demands and costs. Specifically, FCR was significantly related to outpatient visits, emergency department visits, and amount of medications used. These outcomes are partially due to the lack of a well-defined process for directing patients struggling with FCR (Lebel et al., 2013). Additionally, there is evidence that patients with cancer who endorse high

levels of FCR are more likely to refuse discharge from a cancer centre and follow-up with a primary care provider, and are more likely to seek re-admission to a specialized cancer centre (Glynne-Jones, Chait, & Thomas, 1997). Furthermore, higher levels of FCR can negatively impact quality of life, with overall well-being and functioning in social, emotional, physical and cognitive areas all significantly affecting FCR (Crist & Grunfeld, 2013; Koch et al., 2014; Simard et al., 2013). In sum, it is apparent that the clinical manifestations of FCR are highly debilitating, and therefore require extensive study (Thewes et al., 2014). Given that high levels of FCR predict long-term FCR, this further justifies the need for therapeutic interventions to address this common concern.

Clinical presentations of FCR. FCR can manifest in a number of symptomatic ways. High levels of FCR are often characterized by frequent rumination and anxious preoccupation about a potential cancer recurrence, ongoing efforts to monitor for potential recurrences, and an attempt to avoid any reminders of cancer (Lee-Jones, Humphris, Dixon, & Hatcher, 1997). Other hallmarks of FCR include the excessive use of maladaptive coping strategies (e.g., body checking and reassurance-seeking) and the presence of intrusive thoughts. Additionally, physical sensations that are not indicative of recurrence (e.g., aches and pains) may be misinterpreted as the return of cancer, and may subsequently evoke negative feelings initially experienced upon diagnosis and treatment (Lee-Jones et al., 1997). Moreover, persistent moderate-to-high levels of FCR significantly interfere with everyday living, affecting quality of life, causing uncertainty about the future (Beesley et al., 2008), straining social supports (Armes et al., 2009), disturbing planning for the future (Lee-Jones et al., 1997), and leading to significant psychological burden (Thewes et al., 2012). Custers et al. (2015) found that patients with high levels of FCR reported higher levels of psychological distress, difficulty planning for the future, and functional

impairment than did patients with lower levels of FCR. Studies have also indicated that clinical FCR is associated with other clinical mental health concerns, including depression, anxiety, and higher levels of psychological morbidity (i.e., distress; Koch et al., 2014; Simard et al., 2013). The aforementioned findings illustrate the impact and consequences of FCR on cancer survivors. As a result, this construct requires further study (Thewes et al., 2014).

Measuring clinical FCR. At the present time, there is no consensus on what constitutes “clinical” versus “non-clinical” FCR. The absence of a consensus on the differentiating characteristics may be inhibiting the formulation of a definition and accurate measurement (Herschbach & Dinkel, 2014; Simard & Savard, 2015; Thewes et al., 2012). Furthermore, a clinical cut-off level of FCR has not been established. While some FCR instruments propose cut-off scores to identify “high” or “clinical” FCR (Simard et al., 2013; Thewes, Zachariae, Christensen, Nielsen, & Butow, 2015), the absence of a gold-standard clinical interview or measure makes validating cut-off scores difficult (Lebel et al., 2016). For example, the recommended clinical cut-off score on the Fear of Cancer Recurrence Inventory-Short Form (FCRI; Simard & Savard, 2009), which corresponds to the severity subscale of the FCRI, is currently being debated (i.e., a score of 13 versus a score of 22; Fardell et al., 2016). However, efforts have been made to measure clinical levels of FCR with cancer survivors using purpose-designed clinical interviews, such as the Semi-Structured Interview for Fear of Cancer Recurrence (SIFCR; Simard & Savard, 2015), although further validation of its content is necessary (Lebel et al., 2016).

FCR and distress. While there is clearly an association between FCR and distress, these constructs are not synonymous. As previously noted, FCR is “fear, worry or concern relating to the possibility that cancer will come back or progress” (Lebel et al., 2016, p. 3266), and FCR

consists of cognitions (e.g., “this pain means the cancer has come back for sure”), emotions (e.g., anxiety, sadness), and behaviours (e.g., hypervigilance towards one’s bodily symptoms).

Conversely, distress is a “multi-factorial unpleasant emotional experience which extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fear, to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crises” (Holland et al., 2007). The difference between both constructs illustrates how specific treatment must be for cancer survivors, and brings forth the question of which psychological treatments are most effective for this patient population.

Review of Empirical Interventions for Patients with Cancer

In regards to evidence-based psychological treatments, Cognitive Behavioural Therapy (CBT) is a structured, short-term, present-oriented form of psychotherapy, directed towards solving current problems and modifying dysfunctional thinking and behaviour (Beck, 1964). Moorey and Greer (2002) developed one of the first CBT intervention programs specifically for cancer patients, entitled Adjuvant Psychological Therapy (APT). This brief psychotherapeutic intervention was modelled on Beck’s (1964) cognitive therapy, and is designed for use with various therapeutic modalities (including individual therapy, group therapy, and couples therapy; Moorey & Greer, 2002). APT is to be used in conjunction with patients’ medical oncology treatments (e.g., adjuvant chemotherapy), and consists of four specific therapeutic components: cognitive techniques (e.g., thought monitoring, cognitive restructuring), behavioural techniques (e.g., relaxation exercises, behavioural experiments), emotional expression techniques (i.e., addressing feelings associated with a cancer diagnosis), and interpersonal elements (e.g., encouraging effective communication between partners). The authors maintain a flexible

approach to treatment, and suggest tailoring the treatment depending on the specific needs and therapeutic goals of the patient (Moorey & Greer, 2002).

Numerous studies have illustrated that CBT interventions can have positive outcomes for individuals living with cancer. Patients with cancer who participated in CBT groups showed a reduction in depression and anxiety (Edelman, Bell, & Kidman, 1999; Greer et al., 1992; Herschbach et al., 2010; Qiu et al., 2013) and symptom-related distress (Breitbart et al., 2012), an increase in coping skills and self-growth (Kissane et al., 2003), and an increase in quality of life (Breitbart et al., 2012; Lee, Lim, Yoo, & Kim, 2011; Penedo et al., 2006; Qiu et al., 2013; Simpson, Carlson, & Trew, 2001). Furthermore, CBT interventions for cancer patients have successfully reduced insomnia (Fiorentino et al., 2010) and symptom burden (Breitbart et al., 2012), and increased emotional well-being, positive affect, and benefit finding (i.e., a range of positive psychological changes that result following a traumatic event, such as enhanced sense of purpose, changes in life priorities, and enhanced spirituality; Antoni et al., 2006; Kissane et al., 2003; Helgeson, Reynolds & Tomich, 2006; Penedo et al., 2006). It is worth noting that the interventions discussed are not an exhaustive list of CBT treatments for cancer survivors, as this is beyond the scope of this dissertation. For extensive reviews of the efficacy of CBT interventions for cancer survivors, please see Osborn, Démoncada and Feuerstein's (2006) meta-analysis on psychosocial interventions for depression, anxiety, and quality of life in adult cancer survivors, Tatrow and Montgomery's (2006) meta-analysis on CBT techniques for managing distress and pain in breast cancer patients, and Faller et al.'s (2013) systematic review and meta-analysis on various psycho-oncologic interventions for emotional distress and quality of life.

While CBT treatments can be effective for patients with cancer, it appears that most therapeutic interventions are offered in a group therapy format, and are sex-specific. As

evidenced in the literature, many therapeutic interventions for patients with cancer are typically group therapies, and most of these interventions have specifically been tailored for patients with breast cancer (Classen et al., 2001; Kissane et al., 2003; Lee et al., 2011; Qiu et al., 2013; Simpson et al., 2001). Additionally, most group interventions for individuals with cancer are sex-specific, as the groups are available to males only or females only (Edelman et al., 1999; Penedo et al., 2006; Qiu et al., 2013, Simpson et al., 2001). While there are some mixed-sex group interventions (Breitbart et al., 2012; Greer et al., 1992), these interventions are often not specific to *one* type of cancer (i.e., mixed-sex therapy groups are typically available to males and females with different cancer diagnoses).

While there are numerous group therapy options available, there appears to be an absence of *individualized* clinical interventions for patients with cancer. As a result, patients may not have access to the necessary therapeutic modality of their choice. Indeed, patients who receive the treatment modality of their preference report better therapeutic outcomes by the end of treatment (Carlson et al., 2014). Individual therapy interventions can also provide access to care for patients who are less comfortable in group therapy settings, or, where comprising a therapy group may not be possible (e.g., rural settings). Additionally, results from Osborn et al.'s (2006) meta-analysis revealed that individually-based interventions for cancer patients have been found to be more effective than group-based interventions. Specifically, various CBT approaches provided in an individual format assisted cancer survivors in reducing emotional distress and improving quality of life (Osborn et al., 2006), further suggesting the importance of developing individualized intervention protocols.

While there are interventions that adequately address distress amongst cancer patients, there are limited published interventions that specifically address FCR within this population.

Given the detrimental impact of FCR on cancer survivors, there appears to be a growing need for treatment protocols addressing this construct.

Previous interventions that address FCR. To date, there are limited published interventions that have examined fear of disease progression, a concept related to FCR. Herschbach et al. (2010) examined the effects of a CBT group intervention and a supportive existential group therapy for patients with cancer or arthritis. Results indicated that both interventions successfully reduced fear of disease progression in patients when compared to a control group. However, the interventions were only effective for cancer patients, particularly for individuals whose cancer had recurred or metastasized. A secondary analysis of this data showed superior cost-effectiveness of the group CBT as compared to the supportive existential group therapy for patients with high fear of disease progression (Sabariego, Brach, Herschbach, Berg & Stucki, 2011). Subsequent analyses demonstrated that patients with higher education were more likely to report a reliable decrease in FCR (Dinkel et al., 2012).

Humphris and Ozakinci (2008) developed the Adjustment to the Fear, Threat, or Expectation of Recurrence (AFTER) intervention to address FCR in head and neck cancer patients, although results of this study are yet to be published. Furthermore, there are several study protocols for the treatment of FCR that have been or are currently being tested in ongoing randomized controlled trials (RCTs). Lewis et al. (2013) conducted an RCT on 76 breast cancer patients, who were randomized to either a 15-session FCR exposure group or a 15-session support group. The researchers found that as compared to patients who attended the support group, patients in the FCR exposure group showed a significantly greater reduction in psychological distress associated with FCR (Lewis et al., 2013). Additionally, Butow et al. (2013) developed and pilot-tested the Conquer Fear Intervention, an individual therapy that aims

to address FCR in breast and colorectal cancer patients. The Conquer Fear Intervention is delivered in 5 sessions consisting of 60-90 minutes each, and meta-cognitive and Acceptance and Commitment (ACT) techniques are utilized throughout the intervention. The pilot study ($n=8$) demonstrated clinically and statistically significant reductions in FCR and cancer-specific distress, and demonstrated clinically significant improvements in quality of life post-intervention (Smith et al., 2015). Butow et al. (2013) are presently testing the Conquer Fear Intervention in a multicentre RCT, with patients randomized into the intervention group or relaxation-training group. Results of the study are yet to be published. Furthermore, van de Wal et al. (2015) are presently testing the Survivors Worries of Recurring Disease (SWORD) intervention as compared to a treatment as usual (TAU) group in 104 breast, prostate and colorectal cancer patients. The SWORD intervention consists of a combined online and face-to-face CBT approach, and is delivered over 9 sessions ranging from 15 minutes (e-consultation or telephone session) to 90 minutes (face-to-face session). Results of this RCT are yet to be published.

While few studies exist in which FCR is a primary outcome variable, there are group intervention studies for survivors of cancer in which FCR is a secondary outcome variable. Specifically, Lengacher et al. (2009) assessed whether a mindfulness-based stress reduction (MBSR) group therapy had a positive effect on breast cancer survivors' emotional outcomes via an RCT, and found a significant decrease in participants' FCR levels upon completion of the intervention. Lengacher et al. (2011) also conducted an RCT with a similar MBSR group, and found significant improvement in FCR after patients completed an 8-week MBSR program. Shields et al. (2010) assessed the efficacy of a telephone-based intervention, designed to improve communication between breast cancer patients and physicians and increase participants' self-efficacy. The researchers found that the intervention was not successful in decreasing survivors'

FCR levels. Cameron, Booth, Schlatter, Zingskas, and Harman (2007) assessed whether a group intervention could alter emotional regulation and increase adjustment in women with breast cancer. The researchers found a significant decrease in FCR post-intervention, although these results were not maintained at the 6 and 12-month follow-up. Seitz et al. (2014) conducted a pilot study of an internet-based CBT intervention for long-term pediatric cancer survivors. The online intervention consists of written exercises and expressive communication with therapists. The researchers found significant decreases for Fear of Progression/Relapse at the end of the intervention, with an effect size of 0.48, and the effects were maintained at 3-month follow up (Seitz et al., 2014). Therefore, while the existing interventions are informative and can help assuage cancer patients' distress, there is a growing need for the development and rigorous testing of evidence-based interventions studies that target FCR (Thewes et al., 2014), specifically, individually-based interventions.

In summary, there is only one RCT that has been published in a very different health care system with cancer inpatients (Herschbach et al., 2010), and other studies on FCR have either been pilot studies (Smith et al., 2015) or addressed FCR as a secondary outcome (Cameron et al., 2007; Lengacher et al., 2009; Lengacher et al., 2011; Seitz et al., 2014; & Shields et al., 2010). As a result, there is a pressing need for a new, individualized FCR intervention that a) addresses FCR as a primary outcome variable, b) is grounded in evidence-based treatment; c) is manualized, to ensure consistency in the delivery of the therapeutic content across patients, and d) can be made available for patients living with this concern. Therefore, the intervention tested in this dissertation, which was guided by Lebel and Maheu's (2009) group FCR intervention, sought to address these gaps in the literature. Lebel and Maheu's (2009) intervention is further described below.

Guiding Intervention

As a result of the lack of published interventions to treat FCR, Lebel and Maheu (2009) created a manualized cognitive-existential group intervention for patients with FCR. Their intervention was adapted from Kissane's (2003) cognitive-existential group therapy for women with breast cancer, and further adapted to include existential elements, such as authentic living and freedom and responsibility (Yalom, 2005), processing of the here-and-now, and finding meaning in life post-diagnosis. The intervention consists of six consecutive, 120-minute weekly group therapy sessions; with homework exercises assigned each week. Lebel et al. (2014) pilot-tested their intervention with breast and ovarian cancer participants ($n=56$). Participants were recruited from the Division of Gynecologic Oncology at The Ottawa Hospital in Ottawa, Ontario, and the Cancer Survivorship Program at Princess Margaret Cancer Centre in Toronto, Ontario. All group leaders were health care professionals (i.e., psychologists, social workers, and nurses; $n=8$) with previous training in psychotherapy. Results of the study demonstrated significant improvement, with a moderate effect size between pre-and post-testing in FCR ($\eta^2=0.73$), cancer-specific distress ($\eta^2=0.38$), quality of life ($\eta^2=0.54$), uncertainty ($\eta^2=0.41$), and coping strategies ($\eta^2=0.16-0.27$). This intervention is currently being further tested in a multi-site RCT.

Theoretical models. Lebel and Maheu's (2009) cognitive-existential intervention is theoretically guided by the following models: the Common Sense Model (CSM; Lee-Jones, Humphris, Dixon & Hatcher, 1997; Leventhal, Diefenbach & Leventhal, 1992), Mishel's Uncertainty in Illness Theory (Mishel, 1988), and cognitive models of worry (Dugas, Gagnon, Ladouceur & Freeston, 1998; Ladouceur et al., 2000; Langlois, Ladouceur, Patrick, & Freeston, 2004).

The CSM (Leventhal et al., 1992) was initially proposed to explain adherence to medical regimens, and was further expanded by Lee-Jones et al. (1997) in the most exhaustive and comprehensive theoretical formulation of FCR to date (Fardell et al., 2016). According to the CSM, experiencing internal and external triggers increases the perception that one is at risk of recurrence, which in turn heightens FCR. Examples of internal triggers include fatigue and pain, and examples of external triggers include medical appointments, anniversary date of diagnosis, and media exposure to cancer. These triggers function as reminders of the disease, or as evidence that the disease may have returned. Once the perception of being at risk for recurrence is activated, patients focus even more on physical sensations, interpreting these sensations as further evidence of a recurrence. In cases of clinical FCR, this can result in anxious preoccupation, personal checking behaviours, and over-seeking reassurance from doctors and/or family members (Lee-Jones et al., 1997). These inappropriate coping strategies (e.g., avoidance, checking behaviours) provide temporary relief from FCR by providing immediate reassuring feedback. However, this relief is often short-lived, and ultimately increases FCR over time (Lee-Jones et al., 1997).

According to the Uncertainty in Illness Theory (Mishel, 1988), uncertainty is generated when components of illness and illness-related events possess the characteristics of inconsistency, complexity, unpredictability, and lack of information in situations of importance to the individual. Uncertainty, in turn, increases psychological distress and perceived risk of recurrence, thereby increasing FCR and reducing quality of life (Lee-Jones et al., 1997; Mishel, 1988). Illness uncertainty is also compounded by the possibility that the cancer could recur at any time, and that triggers or reminders of the cancer experience are often unpredictable.

According to this model, cancer survivors who possess better knowledge of the signs and symptoms of recurrence should experience less uncertainty, and therefore less FCR.

Cognitive models of worry (Dugas et al., 1998; Ladouceur et al., 2000; Langlois et al., 2004) suggest that one of the functions of worry is to avoid feared outcomes by interfering with emotional processing. Furthermore, cognitive models of worry suggest that people who worry tend to hold faulty beliefs about the benefits of worry (e.g., “If I do not worry about my health, I will miss early signs of recurrence”), and that people who worry have lower tolerance for uncertainty than do people who do not worry excessively (Ladouceur et al., 2000). Many of the characteristics of FCR are similar to those of Generalized Anxiety Disorder (GAD), a psychological disorder characterized by excessive anxiety or worry about several routine things (e.g., intrusive thoughts, persistent worry about health, and faulty beliefs about the benefit of worry; Simard et al., 2010). Dugas et al.’s (1998) conceptual model of GAD maintains that intolerance of uncertainty, faulty beliefs about the benefit of worry, poor problem orientation, and cognitive avoidance are key components in the maintenance of GAD. Similarly, individuals with elevated levels of FCR may consider anything less than complete certainty that they are cancer-free as inadequate, which may explain their increased use of coping strategies (e.g., personal checking behaviours, seeking medical reassurance). While FCR has been found to be different than GAD, there are shared underlying mechanisms between these constructs (Simard et al. 2015). It is also important to differentiate between the constructs of uncertainty and intolerance of uncertainty: While uncertainty measures the ambiguity associated with cancer and its treatment, intolerance of uncertainty reflects a difficulty in tolerating and coping with even small amounts of ambiguity or uncertainty when facing cancer.

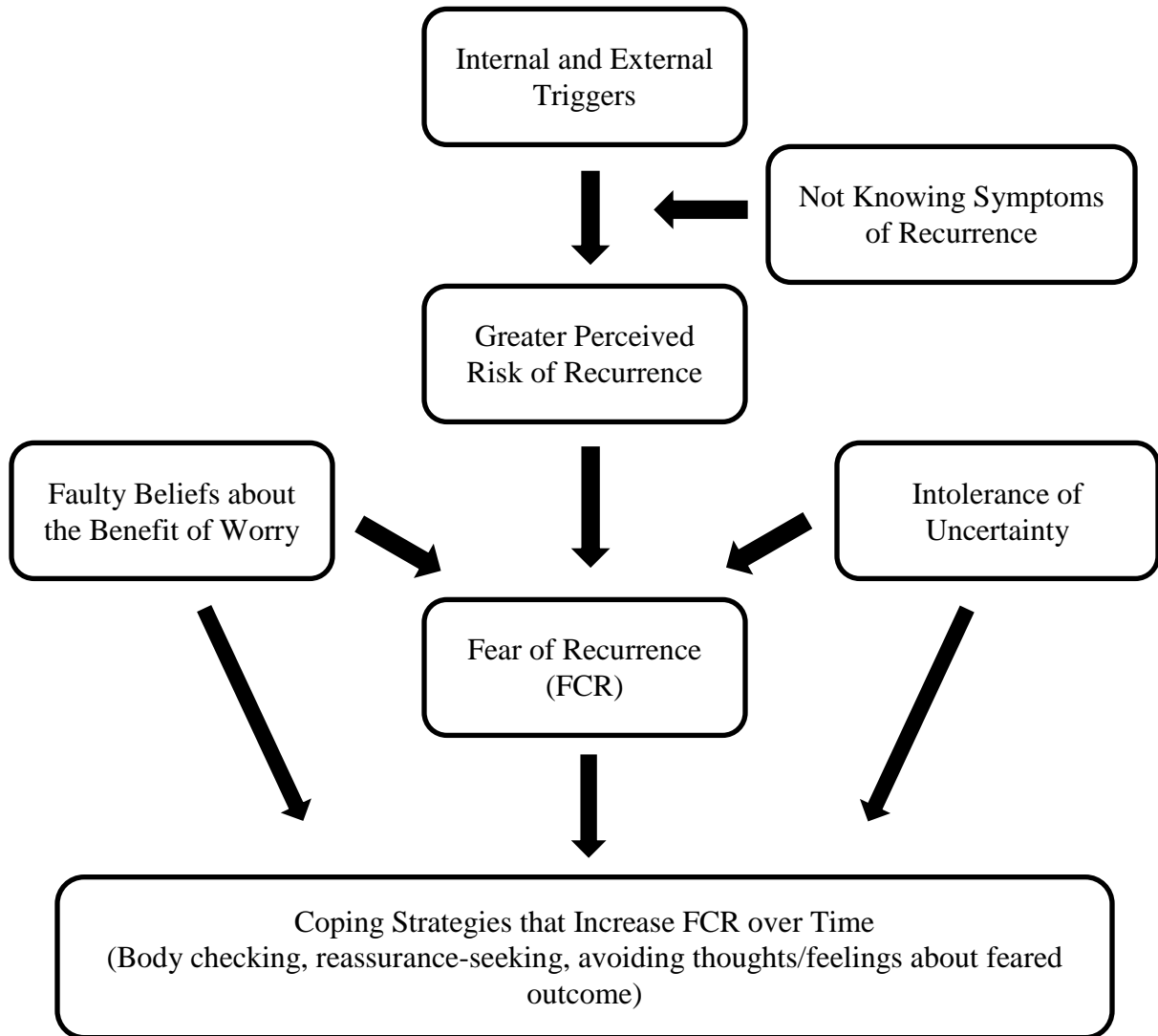


Figure 1. Model of Fear of Cancer Recurrence (Lebel et al., 2014; adapted from Lee-Jones et al., 1997).

Current Studies

This dissertation consists of two studies. The objectives of the first study, a small-scale pilot investigation, were to: 1) adapt and standardize Lebel and Maheu's (2009) cognitive-existential group intervention to an individual format; and 2) pilot-test the feasibility, acceptability, and satisfaction with the individual FCR intervention. The objective of the second proposed study, an RCT, was to pilot-test the efficacy of the same individual FCR intervention as compared to a wait-list control group.

The current studies were conducted with the support and assistance of members of the Psychosocial Oncology Program, the Wellness Beyond Cancer Program, and the Psychology Department, all located at The Ottawa Hospital, General Campus. The Psychosocial Oncology Program provides support and rehabilitation for individuals living with cancer, from diagnosis to treatment to palliative care, if necessary. The Psychosocial Oncology Program consists of a multidisciplinary team, including a clinical psychologist, psychiatrists, social workers, nurses, and occupational therapists, who offer a range of services for patients, including psychological, emotional, social, and practical support. The Wellness Beyond Cancer Program consists of a multidisciplinary team of health care providers who provide patients at the end of their cancer treatment with appropriate follow-up care and resources based on their needs. The Wellness Beyond Cancer program is comprised of oncologists, primary care providers, and nurse practitioners. The Psychology Department consists of approximately 38 psychologists, who are involved in clinical services, research, and training activities.

As previously mentioned, approval was obtained from the Institutional Research Ethics Boards of all affiliated investigators: The University of Ottawa and The Ottawa Hospital.

Rationale for current studies. Adapting, standardizing, and pilot-testing the individual therapy version of the existing FCR group intervention served to facilitate participation for survivors less inclined to participate in group therapy, and allowed for therapeutic services where organizing and implementing a group intervention may not be feasible. Unfortunately, the lack of interventions designed to address FCR leaves clinicians unequipped in helping cancer survivors experiencing these fears. While intervention research on FCR is emerging (Thewes et al., 2012), it appears that very few *individual* therapeutic interventions exist that specifically target FCR. Furthermore, to date, it appears that limited interventions exist for both men and women living with FCR. Thus, the current studies intended to address the gaps in the literature by adapting the aforementioned FCR group intervention to an individual therapy format.

Study 1. The following manuscript entitled “A Cognitive-Existential Intervention to Address Fear of Recurrence in Men and Women with Cancer: A Feasibility Study” describes the outcome of administering the individual FCR intervention to $n=3$ cancer survivors with moderate-to-high FCR. Study 1 was based on the following hypotheses: 1) Participants would find the intervention feasible, acceptable, and satisfactory; 2) Participants would show a reduction in their FCR and cancer-specific distress immediately after completing the intervention.

Originally, the intent was to recruit colorectal cancer survivors who had completed cancer treatments ($n=2$ females and $n=2$ males) for participation in study 1. Colorectal cancer patients were chosen for two reasons: 1) Colorectal cancer patients represent the largest mixed sample cancer group; 2) Colorectal cancer patients are the third most prevalent group after breast and prostate cancer (Canadian Cancer Society, 2016c). Despite exhaustive recruitment efforts over a period of five consecutive months, it was not feasible to solely recruit colorectal cancer

survivors. As a result, recruitment was opened to all cancer sites, and two breast cancer survivors were subsequently included in the sample. One male colorectal cancer survivor completed the FCR intervention.

As previously noted, for the purposes of this dissertation, the methods, results, and discussion for study 1 were written in further detail, as the original manuscript was accepted as a brief commentary in the journal of *Supportive Care in Cancer* (Tomei, Lebel, Maheu & Mutsaers, 2016). Due to the 1,000-word limit of the commentary, the paper has been revised to include the necessary details of the study. The published commentary is included in Appendix K for further review.

Study 2. The manuscript entitled “Examining the Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized Controlled Clinical Trial Pilot Study” illustrates the results of an RCT with 25 female cancer survivors. The goal of the study was to examine the efficacy of the individual FCR intervention, with participants randomized to either an experimental group or a wait-list control group. Study 2 was based on the following hypotheses:

- 1) Participants in the experimental group would have lower scores on the primary outcome measure of FCR after treatment than would participants in the wait-list control group;
- 2a) Participants in the experimental group would have lower scores on secondary outcome measures of cancer-specific distress, intolerance of uncertainty, uncertainty in illness, cognitive avoidance, reassurance-seeking, and faulty beliefs about worrying than would participants in the wait-list control group;
- 2b) Participants in the experimental group would demonstrate enhanced coping skills in positive reinterpretation and growth, acceptance, and use of emotional support, and report better mental and physical quality of life after treatment, than would participants in the wait-list control group;

3) When grouped together, all participants (both experimental group and wait-list control group) would have lower scores on the primary outcome measure of FCR after treatment, and these effects would be maintained at 3-month follow-up;

4a) When grouped together, all participants (both experimental group and wait-list control group) would have lower scores on the secondary outcome measures of cancer-specific distress, intolerance of uncertainty, uncertainty in illness, cognitive avoidance, reassurance-seeking, and faulty beliefs about worrying; and these effects would be maintained at 3-month follow-up;

4b) When grouped together, all participants (both experimental group and wait-list control group) would demonstrate enhanced coping skills in positive reinterpretation and growth, acceptance, and use of emotional support, and report better quality of life after treatment, and these effects would be maintained at 3-month follow-up.

Originally, the intent was to recruit $n=10$ men and $n=10$ women for study 2, in order to address the gaps in the literature for individual therapy targeting FCR for mixed sexes. However, despite extensive recruitment efforts over a period of six months, it was not possible to recruit 10 male survivors. Due to recruitment time restraints, the remaining sample was opened to all female cancer survivors of mixed cancer sites.

As previously noted, the methods in study 2 have been written in further detail, as the paper has been submitted to the journal of *Supportive Care in Cancer*. Due to the word limit of the journal submission, the paper has been revised for the purposes of this dissertation to include the necessary details of the study. The submitted article has been included in Appendix L for additional review.

References

- The American Heritage Dictionary of the English Language*. (3rd ed). (2002). Boston: Houghton Mifflin Company.
- Antoni, M. H., Lechner, S. C., Kazi, A., Wimberly, S. R., Sifre, T., Urcuyo, K. R. . . . Gluck, S. (2006). How stress management improves quality of life after treatment of breast cancer. *Journal of Consulting and Clinical Psychology, 74*(6), 1143-52. doi: 10.1037/0022-006X.74.6.1143
- Armes, J., Crowe, M., Colbourne, L., Morgan, H., Murrells, T., Oakley, C., . . . Richardson, A. (2009). Patients' supportive care needs beyond the end of cancer treatment: A prospective, longitudinal survey. *Journal of Clinical Oncology, 27*(36), 6172–6179. doi: 10.1200/JCO.2009.22.5151
- Baker, F., Denniston, M., Smith, T., & West, M. (2005). Adult cancer survivors: How are they faring? *Cancer, 104*(11), 2565-2576. doi: 10.1002/cncr.21488
- Beck, A. T. (1964). Thinking and depression II: Theory and therapy. *Archives of General Psychiatry, 10*(6), 561-571. doi:10.1001/archpsyc.1964.01720240015003
- Beesley, V., Eakin, E., Steginga, S., Aitken, J., Dunn, J., & Battistutta, D. (2008). Unmet needs of gynaecological cancer survivors: Implications for developing community support services. *Psycho-Oncology, 17*(4), 392–400. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/17680554>
- Breitbart, W., Poppito, S., Rosenfeld, B., Vickers, A. J., Li, Y., Abbey, J., . . . Cassileth, B. R. (2012). Pilot randomized controlled trial of individual meaning-centered psychotherapy for patients with advanced cancer. *Journal of Clinical Oncology, 30*(12), 1304-1309. doi: 10.1200/JCO.2011.36.2517

- Butow, P. N., Bell, M. L., Smith, A. B., Fardell, J. E., Thewes, B., Turner, J., . . . Mihalopoulos, C. (2013). Conquer fear: protocol of a randomized controlled trial of a psychological intervention to reduce fear of cancer recurrence. *BMC Cancer*, *13*, 201. doi: 10.1186/1471-2407-13-201
- Cameron, L. D., Booth, R. J., Schlatter, M., Zingskas, D., & Harman, J. E. (2007). Changes in emotion regulation and psychological adjustment following use of a group psychosocial support program for women recently diagnosed with breast cancer. *Psycho-Oncology*, *16*(3), 171-80. doi: 10.1002/pon.1050
- Canadian Breast Cancer Foundation. (2016). Breast cancer in Canada, 2015. *Canadian Breast Cancer Foundation*. Retrieved from <http://www.cbcf.org/ontario/AboutBreastCancerMain/FactsStats/Pages/Breast-Cancer-Canada.aspx>
- Canadian Cancer Society. (2016a). Cancer statistics at a glance. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from <http://www.cancer.ca/en/cancer-information/cancer-101/cancer-statistics-at-a-glance/?region=on>
- Canadian Cancer Society. (2016b). Breast cancer statistics. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from <http://www.cancer.ca/en/cancer-information/cancer-type/breast/breast-cancer/?region=on>
- Canadian Cancer Society. (2016c). Colorectal cancer statistics. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from <http://www.cancer.ca/en/cancer-information/cancer-type/colorectal/statistics/?region=on>

Canadian Cancer Society. (2016d). Uterine cancer statistics. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/uterine/statistics/?region=on>

Canadian Cancer Society. (2016e). Ovarian cancer statistics. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/ovarian/statistics/?region=on>

Canadian Cancer Society. (2016f). Cervical cancer statistics. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/cervical/statistics/?region=on>

Canadian Cancer Society (2016g). Intraocular melanoma. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/eye/eye-cancer/intraocular-melanoma/?region=on>

Canadian Cancer Society (2016h). Eye cancer statistics. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/eye/statistics/?region=on>

Canadian Cancer Society (2016i). Risk factors for eye cancer. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/eye/risks/?region=on>

Canadian Cancer Society (2016j). Survival statistics for eye cancer. *Canadian Cancer Society's Advisory Committee on Cancer Statistics*. Retrieved from

<http://www.cancer.ca/en/cancer-information/cancer-type/eye/prognosis-and-survival/survival-statistics/?region=on>

- Carlson, L. E., Tamagawa, R., Stephen, J., Doll, R., Faris, P., Dirkse, D., & Speca, M. (2014). Tailoring mind-body therapies to individual needs: patients' program preference and psychological traits as moderators of the effects of mindfulness-based cancer recovery and supportive-expressive therapy in distressed breast cancer survivors. *Journal of the National Cancer Institute Monographs*, *50*, 308-314. doi: 10.1093/jncimonographs/lgu034
- Classen, C., Butler, L. D., Koopman, C., Miller, E., DiMicieli, S., Giese-Davis, J., . . . Spiegel, D. (2001). Supportive-expressive group therapy and distress in patients with metastatic breast cancer. *Archives of General Psychiatry*, *58*, 494-501. doi:10.1001/archpsyc.58.5.494
- Crist, J. V., & Grunfeld, E. A. (2012). Factors reported to influence fear of recurrence in cancer patients: a systematic review. *Psycho-Oncology*, *22*, 978-986. doi: 10.1002/pon.3114
- Custers, J. A., Tielen, R., Prins, J. B., de Wilt, J. H., Gielissen, M. F., & van der Graaf, W. T. (2015). Fear of progression in patients with gastrointestinal stromal tumors (GIST): Is extended lifetime related to the Sword of Damocles? *Acta Oncologica*, *54*(8), 1202-1208. doi: 10.3109/0284186X.2014.1003960
- Deimling, G. T., Bowman, K. F., Sterns, S., Wagner, L. J., & Kahana, B. (2006). Cancer-related health worries and psychological distress among older adult, long-term cancer survivors. *Psycho-Oncology*, *15*(4), 306-320. doi: 10.1002/pon.955
- Dinkel, A., Herschbach, P., Berg, P., Waadt, S., Duran, G., Engst-Hastreiter, U., . . . Book, K. (2012). Determinants of long-term response to group therapy for dysfunctional fear of progression in chronic diseases. *Behavioral Medicine*, *38*(1), 1-5. doi: 10.1080/08964289.2011.640364

- Dugas, M. J., Gagnon, F., Ladouceur, R., & Freeston, M. H. (1998). Generalized anxiety disorder: A preliminary test of a conceptual model. *Behaviour research and therapy*, 36(2), 215-226. Retrieved from www.ncbi.nlm.nih.gov/pubmed/9613027
- Edelman, S., Bell, D. R., & Kidman, A. D. (1999). A group cognitive behaviour therapy programme with metastatic breast cancer patients. *Psycho-Oncology*, 8, 295-305. doi: 10.1002/(SICI)1099-1611(199907/08)8:4<295::AID-PON386>3.0.CO;2-Y
- Faller, H., Schuler, M., Richard, M., Heckl, U., Weis, J., & Küffner, R. (2013). Effects of psycho-oncologic interventions on emotional distress and quality of life in adult patients with cancer: systematic review and meta-analysis. *Journal of Clinical Oncology*, 31, 782-793. doi: 10.1200/JCO.2011.40.8922
- Fardell, J. E., Jones, G., Smith, A. B., Lebel, S., Thewes, B., Costa, D., . . . Butow, P. (2016). *Screening for clinical fear of cancer recurrence using the Fear of Cancer Recurrence Inventory-Severity Scale*. Manuscript in preparation.
- Fardell, J. E., Thewes, B., Turner, J., Gilchrist, J., Sharpe, L., Smith, A. B., . . . Butow, P. (2016). Fear of cancer recurrence: a theoretical review and novel cognitive processing formulation. *Journal of Cancer Survivorship*, 10, 663-673. doi: 10.1007/s11764-015-0512-5
- Fiorentino, L., McQuaid, J. R., Liu, L., Natarajan, L., He, F., Cornejo, M. . . . Ancoli-Israel, S. (2010). Individual cognitive behavioral therapy for insomnia in breast cancer survivors: a randomized controlled crossover pilot study. *Nature and Science of Sleep*, 2, 1-8. doi:10.2147/NSS.S8004

- Foundation for Women's Cancers (2016). About Gynecologic Cancers. *Foundation for Women's Cancer*. Retrieved from <http://www.foundationforwomenscancer.org/about-gynecologic-cancers/>
- Freeston, M. H., Rheaume, J., Letarte, H., Dugas, M. J., & Ladouceur, R. (1994). Why do people worry? *Personality and Individual Differences, 17*, 791–802. doi: 10.1016/0191-8869(94)90048-5
- Glynn-Jones, R., Chait, I., & Thomas, F. (1997). When and how to discharge cancer survivors in long term remission from follow-up: The effectiveness of a contract. *Clinical Oncology, 9*, 25-29. doi: 10.1016/S0936-6555(97)80055-6
- Gosselin, P., Langlois, F., Freeston, M. H., Ladouceur, R., Dugas, M. J., & Pelletier, O. (2002). Le questionnaire d'évitement cognitif (QEC): Développement et validation auprès d'adultes et d'adolescents. *Journal de Thérapie Comportementale et Cognitive, 12*, 24-37. Retrieved from: <http://psycnet.apa.org/psycinfo/2003-03161-004>
- Greer, S., Moorey, S., Baruch, J. D., Watson, M., Robertson, B., & Mason, A. (1992). Adjuvant psychological therapy for patients with cancer: A prospective randomised trial. *British Medical Journal, 304*(6828), 675–680. doi: 10.1136/bmj.304.6828.675
- Helgeson, V. S., Reynolds, K. A., & Tomich, P. L. (2006). A meta-analytic review of benefit finding and growth. *Journal of Consulting and Clinical Psychology, 74*(5), 797-816. doi: 10.1037/0022-006X.74.5.797
- Herschbach, P., Keller, M., Knight, L., Brandl, T., Huber, B., Henrich, G., ... Marten-Mittag, B. (2004). Psychological problems of cancer patients: A cancer distress screening with a cancer-specific questionnaire. *British Journal of Cancer, 91*, 504-511. doi: 10.1038/sj.bjc

- Herschbach, P., Berg, P., Waadt, S., Duran, G., Engst-Hastreiter, U., Henrich, G., . . . Dinkel, A. (2010). Group psychotherapy of dysfunctional fear of progression in patients with chronic arthritis or cancer. *Psychotherapy and Psychosomatics*, *79*(1), 31-38. doi: 10.1159/000254903
- Herschbach, P. & Dinkel, A. (2014). Fear of progression. In U. Goerling (Ed.), *Psycho-Oncology* (pp. 11-29). doi: 10.1007/978-3-642-40187-9
- Hodgkinson, K., Butow, P., Fuchs, A., Hunt, G. E., Stenlake, A., Hobbs, K. M., . . . Wain, G. (2007). Long-term survival from gynecologic cancer: Psychosocial outcomes, supportive care needs and positive outcomes. *Gynecologic Oncology*, *104*(2), 381-389. doi: <http://dx.doi.org/10.1016/j.ygyno.2006.08.036>.
- Holland, J. C., Andersen, B., Breitbart, W. S., Dabrowski, M., Dudley, M. M., Fleishman, S., . . . Zevon, M. A. (2007). Distress management. *Journal of the National Comprehensive Cancer Network*, *5*(1), 66-98. Retrieved from <http://www.jnccn.org/content/8/4/448.full.pdf+html>
- Humphris, G. & Ozakinci, G. (2008). The AFTER intervention: a structured psychological approach to reduce fears of recurrence in patients with head and neck cancer. *British Journal of Health Psychology* *13*, 223-230. doi: 10.1348/135910708X283751
- Jovanovic, P., Mihajlovic, M., Djordjevic-Jocic, J., Vlajkovic, S., Cekic, S., & Stefanovic, V. (2013). Ocular melanoma: an overview of the current status. *International Journal of Clinical and Experimental Pathology*, *6*(7), 1230-1244. Retrieved from <http://www.ijcep.com> /ISSN:1936-2625/IJCEP1304033

- Kissane, D. W., Bloch S., Miach, P., Smith, G. C., Seddon, A., & Keks, N. (2003). Cognitive-existential group psychotherapy for women with primary breast cancer: A randomised controlled trial. *Psycho-Oncology*, *12*(6), 532-546. doi: 10.1002/pon.1280
- Koch, L., Jansen, L., Brenner, H., & Arndt, V. (2013). Fear of recurrence and disease progression in long-term (≥ 5 years) cancer survivors-a systematic review of quantitative studies. *Psycho-Oncology*, *22*(1), 1-11. doi: 10.1002/pon.3022
- Ladouceur, R., Dugas, M. J., Freeston, M. H., Léger E., Gagnon F., & Thibodeau, N. (2000). Efficacy of a cognitive-behavioral treatment for generalized anxiety disorder: Evaluation in a controlled clinical trial. *Journal of Consulting and Clinical Psychology*, *68*(6), 957-964. doi: 0.1037/0022-006X.68.6.957
- Langlois, F., Ladouceur, R., Patrick, G., & Freeston, M. H. (2004). Characteristics of illness intrusions in a non-clinical sample. *Behavior Research and Therapy*, *42*, 683-696. doi: 10.1016/S0005-7967(03)00191-8
- Lebel, S., Beattie, S., Ares, I., & Bielajew, C. (2013). Young and worried: age and fear of recurrence among breast cancer survivors. *Health Psychology*, *32*(6), 695-705. doi: 10.1037/a0030186
- Lebel, S. & Maheu, C. (2009). *Development of a cognitive-existential intervention to address fear of cancer recurrence in women with cancer*. Unpublished manuscript, Department of Psychology, University of Ottawa, Ottawa, Canada.
- Lebel, S., Maheu, C., Lefebvre, M., Secord, S., Courbasson, C., Singh, M., . . . Catton, P. (2014). Addressing fear of cancer recurrence among women with cancer: A feasibility and preliminary outcome study. *Journal of Cancer Survivorship*, *8*, 485-496. doi: 10.1007/s11764-014-0357-3

- Lebel, S., Ozakinci, G., Humphris, G., Thewes, B., Prins, J., Dinkel, A., ... Butow, P. (2016). Current state and future prospects of research on fear of cancer recurrence. *Psycho-Oncology*. doi: 10.1002/pon.4103
- Lebel, S., Rosberger, Z., Edgar, L., & Devins, G. M. (2007). Comparison of four common stressors across the breast cancer trajectory. *Journal of Psychosomatic Research*, 63, 225-232. doi: 10.1016/j.jpsychores.2007.02.002
- Lebel, S., Tomei, C., Feldstain, A., Beattie, S., & McCallum, M. (2013). Does fear of cancer recurrence predict cancer survivors' health care use? *Supportive Care in Cancer*, 21(3), 901-906. doi: 10.1007/s00520-012-1685-3
- Lee, H., Lim, Y., Yoo, M. S., & Kim, Y. (2011). Effects of a nurse-led cognitive-behaviour therapy on fatigue and quality of life of patients with breast cancer undergoing radiotherapy. *Cancer Nursing*, 34(6), 22-30. doi: 10.1097/NCC.0b013e31820d1734
- Lee-Jones, C., Humphris, G., Dixon, R., & Hatcher, M. B. (1997). Fear of cancer recurrence – A literature review and proposed cognitive formulation to explain exacerbation of recurrence fears. *Psycho-Oncology*, 6(2), 95-105. doi: 10.1002/(SICI)1099-1611(199706)6:2<95::AID-PON250>3.0.CO;2-B
- Lengacher, C. A., Shelton, M. M., Reich, R. R., Barta, M. K., Johnson-Mallard, V., Moscoso, M. S., ... Lucas, J. (2014). Mindfulness based stress reduction (MBSR (BC)) in breast cancer: evaluating fear of recurrence (FOR) as a mediator of psychological and physical symptoms in a randomized control trial (RCT). *Journal of Behavioral Medicine*, 37(2), 185-195. doi: 10.1007/s10865-012-9473-6

- Lengacher, C. A., Johnson-Mallard, V., Barta, M., Fitzgerald, S., Mostcoso, M. S., Post-White, J., . . . Kip, K. E. (2011). Feasibility of a mindfulness-based stress reduction program for early-stage breast cancer survivors. *Journal of Holistic Nursing, 29*(2), 107-117. doi: 10.1177/0898010110385938
- Lengacher, C. A., Johnson-Mallard, V., Post-White, J., Mostcoso, M. S., Jacobsen, P. B., Klein, T.W., . . . Kip, K. E. (2009). Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer. *Psycho-Oncology, 18*(12), 1261-72. doi: 10.1002/pon.1529
- Lewis, F., Merckaert, I., Caillier, M., Delevallez, F., Libert, Y., Lienard, A., . . . Razavi, D. (2013). Reducing breast cancer patients' psychological distress related to fear of recurrence: A randomized study comparing the efficacy of a therapy group and a support group [Abstract]. *Psycho-Oncology, 22*, 74.
- Leventhal, H., Diefenbach, M., & Leventhal, E. A. (1992). Illness cognition: Using common sense to understand treatment adherence and affect cognition interactions. *Cognitive Therapy and Research, 16*(2), 143-163. doi: 10.1007/BF01173486
- Llewellyn, C. D., Weinman, J., McGurk, M., & Humphris, G. (2008). Can we predict which head and neck cancer survivors develop fears of recurrence? *Journal of Psychosomatic Research, 65*, 525-532. doi:10.1016/j.jpsychores.2008.03.014h
- Lopez, A. L. (2016). *Assessing the psychosocial needs of women with gynaecological cancers: The development and psychometric evaluation of the gynaecological cancer needs questionnaire*. (Unpublished doctoral dissertation). The University of Sydney, Sydney, AU.

- McLaughlin, C. C., Wu, X. C., Jemal, A., Martin, H. J., Roche, L. M., & Chen, V. W. (2005). Incidence of noncutaneous melanomas in the US. *Cancer, 103*(5), 1000-1007. doi: 0.1002/cncr.20866
- Mellon, S., Kershaw, T. S., Northouse, L. L., & Freeman-Gibb, L. (2007). A family-based model to predict fear of recurrence for cancer survivors and their caregivers. *Psycho-Oncology, 16*(3), 214-223. doi: 10.1002/pon.1074
- Mehta, S. S., Lubeck, D. P., Pasta, D. J., & Litwin, M. S. (2003). Fear of cancer recurrence in patients undergoing definitive treatment for prostate cancer: results from CaPSURE. *Journal of Urology, 170*(5), 1931-1933. doi: 10.1097/01.ju.0000091993.73842.9b
- Mishel, M. H. (1988). Uncertainty in illness. *Journal of Nursing Scholarship, 20*, 225-231. doi: 10.1111/j.1547-5069.1988.tb00082.
- Moorey, S., & Greer, S. (2002). *Cognitive behavioral therapy for people with cancer*. New York: Oxford University Press Inc.
- Muzzin, L. J., Anderson, N. J., Figueredo, A. T., & Gudelis, S. O. (1994). The experience of cancer. *Social Science and Medicine, 38*, 1201-1208. doi: 10.1016/0277-9536(94)90185-6
- Osborn, R. L., Demoncada, A. C., & Feuerstein, M. (2006). Psychosocial interventions for depression, anxiety, and quality of life in cancer survivors: meta-analyses. *The International Journal of Psychiatry in Medicine, 36*(1), 13-34. doi: 10.2190/EUFN-RV1K-Y3TR-FK0L
- Ovarian Cancer Canada. (2014). Other gynecological cancers. *Ovarian Cancer Canada*. Retrieved from <http://www.ovariancanada.org/about-ovarian-cancer/disease-basics/other-gynecological-cancers>

- Penedo, F. J., Molton, I., Dahn, J. R., Shen, B. J., Kinsinger, D., Traeger, L., . . . Antoni, M. (2006). A randomized clinical trial of group-based cognitive-behavioral stress management in localized prostate cancer: development of stress-management skills to improve quality of life and benefit finding. *Annals of Behavioral Medicine, 31*(3), 261-270. doi: 10.1207/s15324796abm3103_8
- Qiu, J., Chen, W., Gao, X., Xu, Y., Tong, H., Yang, M., . . . Yang, M. (2013). A randomized controlled trial of group cognitive behavioral therapy for Chinese breast cancer patients with major depression. *Journal of Psychosomatic Obstetrics & Gynecology, 34*(2), 60-67. doi: 10.3109/0167482X.2013.766791
- Sabariego, C., Brach, M., Herschbach, P., Berg, P., & Stucki, G. (2011). Cost-effectiveness of cognitive-behavioral group therapy for dysfunctional fear of progression in cancer patients. *The European Journal of Health Economics, 12*(5), 489-497. doi:10.1007/s10198-010-0266-y
- Sanson-Fisher, R., Girgis, A., Boyes, A., Bonevski, B., Burton, L., & Cook, P. (2000). The unmet supportive care needs of patients with cancer. *Cancer, 88*(1), 226-237. doi: 10.1002/(SICI)1097-0142(20000101)88:1<226::AID-CNCR30>3.0.CO;2-P
- Savard, J., & Ivers, H. (2013). The evolution of fear of cancer recurrence during the cancer care trajectory and its relationship with cancer characteristics. *Journal of Psychosomatic Research, 74*, 354-360. doi: <http://dx.doi.org/10.1016/j.jpsychores.2012.12.013>
- Seitz, D. C., Knaevelsrud, C., Duran, G., Waadt, S., Loos, S., & Goldbeck, L. (2014). Efficacy of an internet-based cognitive-behavioral intervention for long-term survivors of pediatric cancer: A pilot study. *Supportive Care in Cancer, 22*, 2075-2083. doi: 10.1007/s00520-014-2193-4

Shields, C. G., Wagler Ziner, K., Bourff, S. A., Schilling, K., Zhao, Q., Monahan, P., . . .

Champion, V. (2010). An intervention to improve communication between breast cancer survivors and their physicians. *Journal of Psychosocial Oncology*, 28(6), 610-29. doi: 10.1080/07347332.2010.516811.

Simard, S., & Savard, J. (2015). Screening and comorbidity of clinical levels of fear of cancer recurrence. *Journal of Cancer Survivorship*, 9(3), 481-491. doi: 10.1007/s11764-015-0424-4

Simard, S., Thewes, B., Humphris, G., Dixon, M., Hayden, C., Mireskandari, S., & Ozakinci, G. (2013). Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *Journal of Cancer Survivorship*, 7(3), 300-22. doi: 10.1007/s11764-013-0272-z.

Simard, S., Savard, J., & Ivers, H. (2010). Fear of cancer recurrence: specific profiles and nature of intrusive thoughts. *Journal of Cancer Survivorship*, 4(4), 361-371. doi: 10.1007/s11764-010-0136-8

Simard, S., & Savard, J. (2009). Fear of cancer recurrence inventory: Development and initial validation of a multidimensional measure of fear of recurrence. *Supportive Care in Cancer*, 17(3), 241-251. doi: 10.1007/s00520-008-0444-y

Simpson, J. S., Carlson, L. E., & Trew, M. E. (2001). Effect of group therapy for breast cancer on healthcare utilization. *Cancer Practice*, 9(1), 19-26. doi: 10.1111/j.1523-5394.2001.91005.pp.x

- Smith, A. B., Thewes, B., Turner, J., Gilchrist, J., Fardell, J., Sharpe, L., Bell, M. L., . . . Butow, P. (2015). Pilot of a theoretically grounded psychologist-delivered intervention for fear of cancer recurrence (Conquer Fear). *Psycho-Oncology*, *24*(8), 967-970. doi: 10.1002/pon.3775
- Soothill, K., Morris, S., Harman, J., Francis, B., Thomas, C., & McIllmurray, M. (2001). The significant unmet needs of cancer patients: probing psychosocial concerns. *Supportive Care in Cancer*, *9*(8), 597-605. doi: 10.1007/s005200100278
- Stanton, A. L., Danoff-burg, S., & Huggins, M. E. (2002). The first year after breast cancer diagnosis: hope and coping strategies as predictors of adjustment. *Psycho-Oncology*, *11*(2), 93-102. doi: 10.1002/pon.574
- Statistics Canada. (2015). Trends in the incidence and mortality of female reproductive system cancers. Retrieved from <http://www.statcan.gc.ca/pub/82-624-x/2015001/article/14095-eng.htm>
- Tatrow, K., & Montgomery, G. H. (2006). Cognitive behavioral therapy techniques for distress and pain in breast cancer patients: a meta-analysis. *Journal of Behavioral Medicine*, *29*(1), 17-27. doi: 10.1007/s10865-005-9036-1
- Thewes, B., Brebach, R., Dzikowska, M., Rhodes, P., Sharpe, L & Butow, P. (2014). Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. *Psycho-Oncology*, *23*, 390-396. doi: 10.1002/pon.3423
- Thewes, B., Butow, P., Bell, M. L., Beith, J., Stuart-Harris, R., Grossi, M., . . . Dalley, D. (2012). Fear of cancer recurrence in young women with a history of early-stage breast cancer: A cross-sectional study of prevalence and association with health behaviours. *Supportive Care in Cancer*, *20*, 2651-2659. doi: 10.1007/s00520-011-1371-x

- Thewes, B., Butow, P., Zachariae, R., Christensen, S., Simard, S., & Gotay, C. (2012). Fear of cancer recurrence: A systematic literature review of self-report measures. *Psycho-Oncology*, 21(6), 571-587. doi: 10.1002/pon.2070
- Thewes, B., Zachariae, R., Christensen, S., Nielsen, T., & Butow, P. (2015). The Concerns About Recurrence Questionnaire: Validation of a brief measure of fear of cancer recurrence amongst Danish and Australian breast cancer survivors. *Journal of Cancer Survivorship*, 9(1), 68-79. doi: 10.1007/s11764-014-0383-1
- Tomei, C., Lebel, S., Maheu, C., & Mutsaers, B. (2016). Addressing fear of recurrence: improving psychological care in cancer survivors. *Supportive Care in Cancer*, 1-4. doi: 10.1007/s00520-016-3103-8
- van de Wal, M., Gielissen, M., Servaes, P., Knoop, H., Speckens, A., E. M., & Prins, J. B. (2015). Study protocol of the SWORD-study: a randomised controlled trial comparing combined online and face-to-face cognitive behaviour therapy versus treatment as usual in managing fear of cancer recurrence. *BMC Psychology*, 3(12), 1-13. doi:10.1186/s40359-015-0068-1
- van de Wal, M., van de Poll- Franse, L., Prins, J., & Gielissen, M. (2015). Does fear of cancer recurrence differ between cancer types? A study from the population- based PROFILES registry. *Psycho-Oncology*, 25(7), 772-778. doi: 10.1002/pon.4002
- Vickberg, S. (2003). The concerns about recurrence scale (CARS): A systematic measure of women's fears about the possibility of breast cancer recurrence. *Annals of Behavioral Medicine*, 25, 16-24. doi: 10.1207/S15324796ABM2501_03
- Wade, T. D., Nehmy, T., & Koczwara, B. (2005). Predicting worries about health after breast cancer surgery. *Psycho-Oncology*, 14(6), 503-509. doi: 10.1002/pon.866

- Waller, A., Boyes, A., Carey, M., & Sanson-Fisher, R. (2015). Screening and assessment for unmet needs. In J. C. Holland, W. S. Breitbart, P. N. Butow, P. B. Jacobsen, M. J. Loscalzo, & R. McCorkle (Eds.), *Psycho-Oncology* (3rd ed.) (pp. 369-377). New York: Oxford University Press.
- Yalom, I. D. (2005). *The theory and practice of group psychotherapy*, 5th edition. New York, NY: Basic Books.

RUNNING HEAD: FEAR OF RECURRENCE IN MEN AND WOMEN

Study 1

A Cognitive-Existential Intervention to Address Fear of Recurrence in Men and Women with
Cancer: A Feasibility Study

Christina Tomei¹, Sophie Lebel¹, Christine Maheu², & Brittany Mutsaers¹

¹ *School of Psychology, University of Ottawa*

² *Ingram School of Nursing, McGill University*

Abstract

The current study explored the feasibility, acceptability, and satisfaction of an individualized, manualized, 6-week cognitive-existential intervention for fear of cancer recurrence (FCR). The current study also focused on addressing gaps in the literature regarding the absence of therapeutic interventions for FCR. In this pilot study, $n=3$ cancer survivors (1 male, 2 females) completed a one-on-one therapy intervention for the psychological treatment of FCR. Sessions were 60-90 minutes long, and included cognitive restructuring exercises, behavioural experiments, relaxation techniques, existential processing of the here-and-now, and finding meaning in life post-diagnosis. Participants completed questionnaire packages including the Fear of Cancer Recurrence Inventory (FCRI) and the Impact of Events Scale (IES), during a 4-week baseline period and throughout the 6-week intervention. Participants also completed post-session feedback questionnaires inquiring about their opinions on each session, and completed an exit interview to determine their overall feedback on the intervention. Line graphs revealed that the individual intervention may have helped survivors living with elevated FCR. While participants remained in the clinical range for FCR at discharge, line graphs indicated downward trends in the expected direction for both FCR and cancer-specific distress. Furthermore, $n=2$ participants were no longer in the clinical range on the IES, suggesting decreases in cancer-specific distress. Content and thematic analysis of the exit interviews revealed that all participants found the intervention useful and that the sessions had favourable pacing and length. A larger scale randomized controlled trial (RCT) is needed to further test the effectiveness of this FCR intervention.

A Cognitive-Existential Intervention to Address Fear of Recurrence in Men and Women with Cancer: A Feasibility Study

Fear of cancer recurrence (FCR) is defined as “the fear or worry that the cancer will return or progress in the same area or another part of the body” (Vickberg, 2003). FCR can result in psychological distress, impaired functioning, and lower quality of life (Vickberg, 2003). A recent literature review estimated that about 49% of cancer survivors experience moderate-to-high levels of FCR (Simard et al., 2013).

Despite a growing interest in FCR, there are few published psychological interventions that specifically address this construct (Herschbach et al., 2010; Thewes et al., 2012), and none that are available in more than one therapeutic modality, despite evidence suggesting that patients who receive the treatment modality of their choice report better therapeutic outcomes by the end of treatment (Carlson et al., 2014). As a result, clinicians are left with limited tools to address this concern. To address this paucity in the literature, the second and third author developed a manualized, six-week cognitive-existential (CE) group intervention. The CE intervention is specifically aimed to help reduce FCR, and involves cognitive restructuring and emotional processing exercises. Recently, Lebel et al. (2014) pilot-tested the CE group intervention on $n=56$ women with breast or gynecological cancers. The intervention demonstrated significant improvement in FCR (with an effect size of 0.73), immediately post-therapy and at a 3-month follow-up (Lebel et al., 2014).

The Current Study

With the success of the aforementioned study by Lebel et al. (2014), and the absence of individual therapeutic interventions addressing FCR, the first and second author adapted the CE group intervention to a one-on-one format. There are limited therapeutic interventions that exist

to address FCR that are available in an *individual* format, for both men *and* women living with FCR. Therefore, this pilot study of the individual CE intervention included male and female cancer survivors ($n=3$) experiencing moderate-to-high FCR. The goal of the study was to test the feasibility, acceptability, and satisfaction of the individual FCR intervention.

Feasibility is defined as the ease or convenience of study execution (Soanes & Stevenson, 2005; as cited in Feeley & Cossette, 2009). For the purposes of this study, feasibility was measured by the research team's ability to successfully execute the proposed research plan and study procedures, and deliver the intervention to participants as intended (Feeley & Cossette, 2009). Specifically, feasibility was assessed by examining the time needed to reach the desired sample size, the number of participants screened for eligibility and enrolled in the intervention, whether male and female colorectal cancer survivors could successfully be recruited and retained in the intervention, whether the intervention could be delivered to participants as planned, the number of dropout rates, and questionnaire compliance (i.e., if participants were able to complete the questionnaires in a timely manner – once a week for 10 weeks, including a baseline period and after each intervention session). Feasibility was assessed to determine whether this intervention was appropriate for further testing in a larger pilot randomized controlled trial (RCT).

Acceptability has a number of definitions, including whether the intervention is suitable according to the clinical population of interest and the intervention provider (Feeley & Cossette, 2009); whether participants find the treatment fair, reasonable, or intrusive (Kazdin, 1980); or how well the treatment is received by a target population (Ayala & Elder, 2011). Acceptability was measured through the use of post-session feedback questionnaires and a qualitative exit interview for participants to complete at the end of therapy.

For the purposes of this study, patient satisfaction was measured by the extent to which patients were pleased with the care they received from the intervention provider. The measures used to determine patient satisfaction included the aforementioned post-session feedback questionnaires and qualitative exit interview.

The authors hypothesized that it would be feasible to deliver the FCR individual intervention as intended, and that participants would find the intervention to be acceptable and satisfactory. Furthermore, the authors hypothesized that participants' results on the outcome measures would show downward trends in FCR and cancer-specific distress after completing the intervention. A mixed methods design (i.e., the inclusion of both quantitative and qualitative data collection) was chosen in order to enhance the richness of data collected.

Methods

Participants

Participants were recruited from The Ottawa Hospital's (TOH) Psychosocial Oncology Program (PSOP) via study posters and referrals from health care professionals employed at TOH. Participants included in this study were the first consecutively assessed individuals who met study inclusion criteria. As this study is a pilot intervention, $n=4$ cases was determined to be an appropriate amount for assessment of acceptability, feasibility, and satisfaction in participant ratings, as seen in FCR-related pilot studies (Smith et al., 2015).

Study inclusion criteria included the following: a) men and women diagnosed with cancer (stages I-III), b) fluency in English, c) 18 years of age or older, d) clinical level of FCR as indicated by a score of 13 or greater on the severity subscale of the FCRI (Simard & Savard, 2009; range 0-36), e) clinical distress level as indicated by a score of at least 24 on the IES (Horowitz, Wilner & Alvarez, 1979; range 0-75), and f) completion of cancer treatment (e.g.,

chemotherapy, radiation, and/or surgery). Exclusion criteria were as follows: a) the refusal to provide informed consent; b) non-understanding of the English language, c) Stage IV cancer (as these individuals are facing end-of-life issues, are often too sick to complete treatment, and/or are dealing with active disease, as opposed to threat of recurrence), d) previous cancer recurrence (as the study focused on individuals with a first occurrence of cancer), e) current enrollment in group or individual psychotherapy for cancer issues during the treatment; and f) self-disclosure of unmanaged mental health disorder (as any pre-existing mental health concern may interfere with the psychological treatment of FCR).

Procedure

Interested potential participants were asked to contact the first author for additional information on the study. Prior to receiving the treatment, participants were screened in an initial telephone meeting by the first author (see Appendix A for telephone screening and eligibility script). For those individuals who met inclusion criteria, a pre-therapy meeting was organized between the first author and the participant. During these meetings, the first author administered research consent forms, discussed general expectations, addressed any relevant questions, and prepared participants for the onset of the intervention. The pre-therapy meeting was also used to determine if patients were suitable for this intervention (e.g., inquiring about substance abuse, determining pervasiveness of any existing mental health concerns, and assessing interpersonal suitability for participation). The first author also administered the Mini International Neuropsychiatric Interview (MINI; Sheehan & Lecrubier, 2006; available upon request) with each participant in the pre-therapy meeting. The MINI is a structured diagnostic interview instrument used to assess for major Axis I psychiatric disorders. The MINI was administered in order to determine if potential participants had any pre-existing/comorbid Axis I diagnoses that

might interfere with the treatment of FCR. Upon explaining the limits of confidentiality and signing research consent forms, each participant was provided with a unique participant ID number.

All participants were assigned to a 4-week baseline period prior to commencing the therapy. The purpose of the baseline period was to determine if there were any changes in FCR or cancer-specific distress as a function of time alone. Participants were asked to fill out an online questionnaire package once a week, during the baseline period and also after each intervention session (i.e., a total of 10 measurement time points, including the 4-week baseline period and 6 intervention sessions). Participants were provided with a link to complete a weekly online questionnaire package via Fluid Survey, an online survey software, and were asked to use their respective participant ID number for identification purposes when completing the questionnaires. Participants were informed that they were allowed to miss one session and reschedule one session, as the presumed effectiveness of the intervention was contingent on session attendance. To maximize attendance, all participants were reimbursed for their parking/transportation fees for each session.

Approval was obtained from the two Institutional Research Ethics Boards of all affiliated investigators: The Ottawa Hospital Health Science Network Research Ethics Board and The University of Ottawa Research Ethics Board (see Appendix B for the approved consent form). The first and second author discussed the process for adapting the group intervention therapist and patient manuals (for more information on the original CE intervention, please see Lebel et al., 2014). Changes from the group format included reducing the sessions from 120 to 60-90 minutes, having participants prepare a list of questions about recurrence in session 1, and

extended discussion of existential concerns and processing the participants' worst-case scenarios in sessions 4 and 5.

The first author facilitated the adapted intervention with all study participants, for a total of 18 therapy sessions (6 therapy sessions x 3 participants). The sessions were conducted at PSOP at TOH Cancer Centre. All therapy sessions were video-recorded using a secure closed-circuit camera, where video sessions were safely stored and reviewed on the hospital's server. The second author reviewed video recordings of all therapy sessions, in order to assess treatment integrity and fidelity. A systematic fidelity checklist was created to ensure adherence to treatment protocol (see Appendix C). Dr. Sophie Lebel rated the sessions according to the fidelity checklist, and adherence to the therapist manual ranged from 82-94% across all therapy sessions. Drs. Cheryl Harris and Sophie Lebel provided weekly clinical supervision for the first authors' therapy sessions.

The strictest confidentiality was ensured when storing participant data. All participants were informed that their involvement in the study was known only by members of the research team, and that all identifying information was kept in Dr. Cheryl Harris' secured, locked office. The video recordings of the therapy sessions were kept on TOH's secured server, and were deleted once the study was completed. Online questionnaire responses were saved in a password-protected folder, and tangible copies of the questionnaire packages were stored in a secured, locked filing cabinet at TOH.

Outcome Measures

Participants were asked to complete a series of online questionnaires via Fluid Survey within 24 hours after each therapy session. In order to ensure the questionnaires were completed in a timely fashion, the first author reminded each participant to fill out their questionnaire at the

end of each therapy session (which resulted in a 100% response rate within the specified time frame). The study questionnaire packages included the following inventories:

Demographic information form. Participants were given a demographic information form package to complete at baseline (i.e., during the pre-therapy meeting). The demographic form includes information about participants' current marital status, highest education level, current occupational status, ethnic background, age, annual income level, and medical history.

The *Fear of Cancer Recurrence Inventory* (FCRI; Simard & Savard, 2009) is a 42-item multidimensional instrument that has been used to examine FCR in previous studies (Savard & Ivers, 2013; Thewes et al., 2012). The FCRI is a comprehensive measure that uses a 5-point Likert scale, ranging from 0 (Not at all or Never) to 4 (A great deal or All the time) to measure patients' concerns about cancer recurrence. The FCRI contains seven subscales: Triggers (8 items, $\alpha=.90$, "Generally, I avoid situations or things that make me think about the possibility of a cancer recurrence"), Severity (9 items, $\alpha=.89$, "When I think about the possibility of cancer returning, other unpleasant thoughts or images come to mind (death, suffering, consequences for my family)"), Psychological Distress (4 items, $\alpha=.86$, "When I think about the possibility of cancer recurrence, I feel worry, fear, or anxiety"), Coping Strategies (9 items, $\alpha=.89$, "I try to get the idea out of my mind, to not think about it"), Functioning Impairment (6 items, $\alpha=.91$, "My thoughts or fears about the possibility of cancer recurrence disrupt my relationship with my partner, my family, or those close to me"), Insight (3 items, $\alpha=.80$, "I think that I worry more about the possibility of cancer recurrence more than other people who have diagnoses of cancer"), and Reassurance (3 items, $\alpha=.75$, "I go to the hospital or clinic for an examination"), as well as a total FCR score (Simard & Savard, 2009). The total FCR score ranges from 0-168, with higher scores indicating greater FCR. Based on a study of mixed cancer patients ($n=600$), a score

of 13 or greater on the nine-item severity subscale (range 0–36) was found to reliably identify respondents who experience a clinical level of FCR (Simard & Savard, 2009). The total FCR score has demonstrated excellent internal consistency ($\alpha=0.95$; Simard & Savard, 2009) and temporal stability (test-retest=0.89; Thewes, et al., 2012). Internal consistency on the total FCR score is higher than that of the individual scales, and therefore the total FCR score was used for the current study. The concurrent validity of the FCRI has been supported by positive correlations with other measures of FCR and cancer-related symptoms (Simard & Savard, 2009).

The *Impact of Events Scale* (IES; Horowitz et al., 1979) is a 15-item scale that measures the frequency of intrusive and avoidant thoughts associated with stressful life events over the past 7 days. The IES uses a 4-point Likert scale, ranging from 1 (Not at all) to 4 (Often). The IES has two subscales: Intrusion (7 items, $\alpha=.78$, “I had waves of strong feelings about it”), and Avoidance (8 items, $\alpha=.82$, “I stayed away from things or situations that might remind me of it”). Items have been modified to reflect participants’ cancer experience (i.e., “I had waves of strong feelings about my cancer experience; “I stayed away from reminders of my cancer experience”). The total IES score was used in the current study by summing all the items, and scores range from 0 to 75. The scale has good internal consistency ($\alpha=0.84 - 0.91$), and good test-retest reliability (Total $r=0.87$; Horowitz et al., 1979). Please see Appendix D for a copy of the questionnaire package.

Post-session feedback questionnaires. The first author created post-session feedback questionnaires to assess participants’ satisfaction with the intervention, and the second author reviewed the content of the questionnaires before administration to the participants. All participants were asked to provide their opinion on the content of each respective session. Participants were asked to comment on how helpful the specific in-session exercises were, with

response options ranging from 1 (Strongly Disagree) to 5 (Strongly Agree). Participants were also asked to identify and comment on which exercises they liked most and least, and how frequently they practiced the in-between session exercises each week. These feedback questionnaires were provided to participants after each therapy session, and were to be completed before the onset of the next therapy session. All participants who completed the intervention provided feedback on each respective therapy session (Please see Appendix E for copies of the 6 post-session feedback questionnaires).

Qualitative exit interviews. The first author created the qualitative exit interviews questions, and the second author reviewed the content of the questions before administration to the participants. Following completion of the intervention, the fourth author conducted in-depth, semi-structured qualitative telephone exit interviews with each participant. The exit interviews were conducted in order to obtain participant feedback about the value and usefulness of the intervention, whether the intervention impacted their FCR, whether the exercises were useful, and whether participants were satisfied with their treatment. The qualitative exit interviews were approximately 20-30 minutes long (Please see Appendix F for a copy of the qualitative exit interview guide). The qualitative exit interviews were audio-recorded, transcribed and analyzed. Content and thematic analysis of the exit interviews was performed using NVivo 10, a qualitative data analysis software. Content analysis involves the analysis of how frequently a topic is found within a dataset (Joffe, 2012). Thematic analysis involves the analysis of commonalities and similarities in experiences found in the data, with respect to the topic being studied. Thematic analysis can be viewed as an extension of content analysis, as it goes beyond how frequently an idea is present, and links ideas together to form themes (Joffe, 2012).

Exchanges between the first, second, and fourth author occurred to discuss results and patterns observed in the interviews, and to obtain consensus on final themes detected.

Results

Participants

The original intent for this study was to recruit $n=4$ colorectal cancer patients (2 males and 2 females). As previously mentioned, $n=4$ participants was determined to be an appropriate amount for assessment of acceptability, feasibility, and satisfaction in participant ratings. From October 2014 to March 2015, a total of $n=6$ individuals expressed interest in the FCR intervention. Of the 6 individuals, a total of $n=3$ completed the intervention, $n=1$ had a cancer recurrence (thus rendering her ineligible to participate in the study), and $n=2$ dropped out. Of the dropouts, both individuals expressed they were no longer interested in participating (see figure 1 for study flowchart).

Participants who did not complete the intervention.

Participant 100, a married, retired 61-year old Caucasian female who was diagnosed with stage 3 colorectal cancer in early 2010 and treated with chemotherapy. She did not endorse any major Axis I psychiatric disorders during her MINI interview. She elected to no longer participate in the study after session 1.

Participant 103, a widowed, employed 60-year old Caucasian female who was diagnosed with stage 3 colorectal cancer in mid-2014 and treated with radiation, chemotherapy and surgery. She endorsed a past major depressive episode during her MINI interview. She experienced a cancer recurrence prior to the start of the intervention.

Participant 105, a single, retired 65-year old Caucasian male who was diagnosed with a stage 3 soft-tissue sarcoma in late 2013 and treated with surgery. He endorsed a past major

depressive episode, social phobia, and alcohol dependence (current) during his MINI interview. He reported that he relied on alcohol to cope with his emotions, and was not receiving any treatment for his alcohol use. He elected to no longer participate in the study after session 2.

All participants who did not complete the intervention were provided with contact information for PSOP, in the event they required additional psychological services.

Participants who completed the intervention.

Participant 101, a single 66-year old Caucasian male who was diagnosed with stage 2 colorectal cancer in mid-2013. He completed chemotherapy, radiation, and surgical treatment for his cancer. During the course of the intervention, he was employed full-time. He did not endorse any major Axis I psychiatric disorders during his MINI interview.

Participant 102, a divorced 52-year old Caucasian female who was diagnosed with stage 1 breast cancer in mid-2014. She completed radiation treatment for her cancer. During the course of the intervention, she was employed part-time. She endorsed a past major depressive episode during her MINI interview.

Participant 104, a married 43-year old Caucasian female who was diagnosed with stage 2 breast cancer in late 2013. She completed chemotherapy, radiation and surgical treatment for her cancer. During the course of the intervention, she was employed part-time. She did not endorse any major Axis I psychiatric disorders during her MINI interview.

Changes in Outcome Measures

Given the small sample size, a qualitative approach was taken to evaluate change across sessions. Line graphs were created using weekly total scores for the FCRI and the IES. Data points were visually inspected to examine whether decreases in FCR and cancer-specific distress occurred for each participant by the end of treatment.

FCRI scores. FCRI total scores varied during baseline period across all participants. Participant 101's scores were relatively stable throughout the beginning of treatment, followed by a sharp decrease after session 4. Participant 102's scores showed a decreasing slope in early treatment sessions, followed by an increase after session 4, and then displayed a declining slope again. Participant 104's scores showed slight decreases in early treatment, followed by a sharp peak after session 4, and then decreased again. Increases in FCRI total scores immediately after session 4 may be attributed to the content of that specific session (i.e., exposure to one's worst-case scenario, thereby heightening anxiety levels). Despite FCRI scores remaining in the clinical range (≥ 13 ; Simard & Savard 2015), the graphs display a trend towards a decrease in total FCRI scores by several points across each participant (see figure 2).

IES scores. At baseline, all participants' cancer-specific distress scores showed an initial decrease, followed by an increasing slope. By the end of treatment, participant 101 was still in the clinical range for cancer-specific distress, although it is worth noting that his IES score was at the lowest point by the final session of the intervention. Participants 102 and 104 were no longer in the clinical range on the IES following the end of treatment, suggesting a decrease in cancer-specific distress (see figure 3).

Post-session Feedback Questionnaires

Results from the post-session feedback questionnaires revealed general similarities in session preferences across participants. In terms of whether the in-session exercises were helpful for session 1, responses across participants ranged from Agree to Strongly Agree. All three participants reported that the relaxation exercises were the most helpful aspects of homework. Participants completed their homework exercises between 3-4 times throughout the week following session 1. In terms of helpfulness of in-session exercises in session 2, responses across

participants ranged from Neutral to Strongly Agree. All three participants reported that the most helpful aspects of the session included focusing on elements of their life they could control, along with the calming self-talk exercises. Completion of homework exercises ranged from 0-4 times throughout the week following session 2. In terms of whether the in-session exercises were helpful for session 3, responses across participants ranged from Agree to Strongly Agree. Participants reported that the most helpful aspects of the session included learning to challenge the need for worry, and learning about the difference between adaptive and maladaptive coping strategies. Participants completed their homework exercises between 3-4 times throughout the week following session 3. In regards to session 4, participants unanimously responded Strongly Agree for helpfulness across all in-session exercises. All three participants reported that the most helpful aspect of the session was confronting their worst fear/worst-case scenario. Completion of homework exercises ranged from 3-7 times throughout the week following session 4. In terms of helpfulness of in-session exercises in session 5, responses across participants ranged from Neutral to Strongly Agree. All three participants reported that the most helpful aspects of the session included identifying the parts of their lives they had put on hold, and concretizing goals and priorities for the future. Completion of homework exercises ranged from 1-7 times throughout the week following session 5. The post-feedback questionnaire for session 6 served as a summary for participants to identify the sessions and homework exercises that were most and least helpful throughout the intervention, and which particular session was most salient for them. Overall, participants found session 4 to be most helpful, and found the worst-case scenario homework exercise to be most useful. Two participants reported that they did not find any particular session to be least helpful. One participant reported that session 6 was least useful, only because it served as a wrap-up session and did not add any specific FCR-related content.

Results of Qualitative Analyses

Qualitative exit interviews. Content and thematic analysis of the transcribed interviews revealed four broad themes: 1) overall experience in therapy, 2) experience with FCR pre-intervention, 3) perceptions of mechanisms of change, and 4) overall improvement in FCR. Coding of the transcribed interviews was conducted line-by-line by the fourth author. An open-coding method (i.e., the absence of a pre-determined coding scheme) was used for data analysis (Creswell, 2013). Throughout the interviews, words and phrases were coded based on the general meaning that was articulated or expressed. The fourth author conducted the descriptive, qualitative analysis on the data to find common themes among the interviews, and formulated categories and subcategories of coded information.

Theme 1: Overall experience in therapy. As a whole, the participants reported that their experience with the intervention was positive. The participants stated that they were grateful for the experience, found the intervention useful, and highly recommended the intervention to others with similar challenges post-diagnosis and treatment. Specific subthemes were found within the theme of overall experience in therapy: general feedback on the intervention structure, general appreciation of the therapy, most appreciated aspects of the intervention, and least appreciated aspects of the intervention. Overall, participants found the number of sessions (6) and length of sessions (90-120 minutes) to be appropriate:

It's the right time, it's not too long (...) It was an hour and a half almost each session (...)

I wouldn't have liked to go further too much and shorter would not have been enough probably, so it was perfect, 6 sessions. (Participant 102, female)

I think it was a well-rounded experience, long enough, not too long, not too short (...) it was a good pace. (Participant 104, female)

Participants also expressed their gratitude and appreciation for participating in the intervention, and noted how impactful the intervention was:

The overall experience was positive, worthwhile, and it certainly changed the way I feel about cancer. I found the sessions tremendously empowering and it was definitely an opportune time for me to do this. I wasn't doing very well (...) I am so grateful for what I have learned and for having the chance to do it. (Participant 101, male)

I think it's going to be very useful, not just for fear of cancer recurrence but for other issues in my life as well. So it was very productive for me to go through that. (Participant 102, female)

Overall, it helped me to be more aware about my feelings and the thoughts (...) and how to manage them and how to be realistic. (Participant 104, female)

Most appreciated aspects of the therapy included cognitive restructuring, calming self-talk, relaxation exercises, and learning how to plan for the future:

The one I remember that I liked the most was about planning for the future. What's my project, what's my plan and to make, you know, realistic goals that you can break them down each project or each plan to break it down in easy to do tasks. (Participant 102, female)

Well, what happened over the last six or seven weeks is that I've learned some really good strong tools to help me manage my emotions and my feelings (...) The most powerful tools were the ones which were cognitive and where I was able to put the fear in a sort of more realistic way, think about them as things that aren't as bad as they were (...) The other tools I've learned are the relaxation tools, like meditation, body scanning

and self-talk, all really powerful, supportive tools in learning to think calmly about fear.

(Participant 101, male)

Least appreciated aspects of the therapy were specific to components of the relaxation CD, such as mindfulness exercises and the pacing of the exercises on the CD. Participants indicated that any constructive feedback was due solely to personal preference, and that they understood how those aspects of the therapy could work very well for others in a similar situation:

The mindfulness exercise about eating (...) it could be useful (...) I didn't think it was relevant for me (...) except for learning to be aware of what's going on like in the present right now (...) so it may be useful for someone else but I didn't feel it useful for me. (Participant 102, female)

Theme 2: Experience with FCR pre-intervention. An overarching theme detected in the interviews was the participants' experience with FCR prior to the onset of the therapy. The participants reported that they experienced fear and anxiety about the possibility of the cancer returning. Furthermore, participants reported previously engaging in maladaptive coping strategies to deal with their fears, such as avoidance and putting their lives on hold:

If I had worried about something, I would tend to avoid it. If I had a fear of something, I would tend to avoid it (...) I guess the scariest part for me was learning how badly I had done. I had done really badly, I don't know how I got myself into this situation but I definitely, definitely needed help and I couldn't see my way through all this mess, I really couldn't, I couldn't see anything. (Participant 102, female)

Because I could see very clearly that for 2 years my normal life, my social life, my relationships and family and exercise and the things like that had actually been put on hold and I had become, I had become quite isolated (...) Imagine seeing, having all sorts

of goals and opportunities in your life but you can't see them, that they're not clear because you're all focused on this disease. (Participant 101, male)

Theme 3: Mechanisms of change. Participants identified learning new patterns of thinking, forming a trusting therapeutic relationship, and planning for the future as potential mechanisms of change. All of the participants reported that addressing their worst-case scenario in session 4 and 5 was especially helpful, despite the exercise being emotionally difficult. This exposure exercise gave the participants a greater sense of control, and demonstrated the importance of confronting one's fears:

It was then that I realized what really scared me. So what I did was I wrote down everything that scared me about it (...) The tipping point for me was when I started to see how fears can really make you irrational (...) so I read my worst case scenario every day for a week, and I measured my emotional state before and after, and within a week, I had sort of confronted it. And then for a whole week, I had to read the scenario that I had written (...) every day so I actually managed to see over the week how much I was changing. (Participant 101, male)

I don't see that [worst-case scenario] as tragic as before, because now I have some understanding of the layers of my situation. I got used to [the] scenario and I got familiar with it, [it] was not just something very bad there, out in the corner, waiting for me any time (...) I have some plan, some back up or I know more about it, and it's not just something heavy and fearful and tragic (Participant 104, female)

Developing adaptive, realistic thinking patterns in lieu of negative automatic thoughts was another important mechanism of change for participants:

The most powerful tools were the ones which were cognitive, and where I was able to put the fear in a sort of more realistic way, think about them as really things that aren't as bad as they were. I had problems in my life with thinking that things could possibly be bad. Often worse than they really could be and this manifested itself in the way I approached it. So my mental approach to fear of recurrence of cancer is more realistic and manageable, and I've adapted to it. I have learned adaptive strategies. (Participant 101, male)

Theme 4: Overall improvement in FCR. All participants reported improvements in their FCR upon completion of the intervention. Participants reported they developed a realistic attitude toward FCR, and learned tools to effectively manage their anxiety and uncertainty:

I feel relief, an enormous relief (...) I can say that I feel a lot lighter now. It was a huge weight lifted from myself (...) I'm not officially, 100% not afraid of cancer because that would be just irrational. But it's [now] manageable and it's controllable. So I would say that I've adapted -- no, I've confronted and adapted. (Participant 101, male)

I don't avoid it as much. I have tools now to deal with it, so I don't have to avoid. I don't have to pretend it's not there but I don't (...) exaggerate the problem either, you know, on both sides, I don't need to exaggerate and I don't need to avoid. (Participant 102, female)

The whole experience helped me to be more objective about my situation. The most important were the moments in which we found solutions about the most difficult [situations] (...) It was really helpful to ease it, that fear of cancer recurrence and [fear of] death. (...) .. I have learned lessons and am continuing to use those lessons. (Participant 104, female)

Discussion

The goal of this study was to test the feasibility, acceptability, and satisfaction of an individualized, manualized therapeutic intervention for the treatment of FCR. To the knowledge of the authors, this is one of the first interventions to target FCR using a one-on-one therapeutic approach. Both quantitative and qualitative findings from this pilot study tentatively suggest that this intervention can be helpful in decreasing survivors' FCR and cancer-specific distress.

Feasibility

Feasibility was assessed to determine whether this FCR intervention is appropriate for further testing in a larger pilot RCT. Based on the aforementioned results, it appears to be feasible to offer this intervention on an individual basis. However, while it was feasible to offer this intervention to patients of all cancer types, it was not feasible to offer this intervention only to colorectal cancer survivors, as initially intended. It was indeed feasible to recruit $n=4$ colorectal cancer patients (2 males and 2 females - participants 100, 101, 103 and 105), however, it was not feasible to retain 3 of the aforementioned individuals in the intervention, due to ineligibility and attrition.

Feasibility was also affected by time (i.e., the amount of time required to recruit participants). Over the course of the study, which commenced in October 2014 and ended in March 2015 (5 months), a total of 3 consecutive months were devoted solely to recruitment of colorectal cancer patients. Due to 1) ongoing efforts of attempting to recruit only colorectal patients and 2) subsequent recruitment time restraints, the intervention was opened to all cancer populations by the end of the third month (December 2014). Once the intervention was available to other cancer groups, it was feasible to recruit enough participants for the study. Moreover, multiple efforts were made to recruit and retain 2 male and 2 female participants of mixed cancer

sites in the intervention. While it was feasible to recruit 2 males and 2 females of mixed cancer types, one male dropped out (participant 105). As a result, a total of $n=3$ participants (1 male, 2 females) successfully completed the intervention.

In terms of questionnaire completion, it was feasible for the participants to complete questionnaires once a week for 10 consecutive weeks. Thus, from a design perspective, participants were able to complete the questionnaire packages in a timely manner, suggesting further feasibility of the proposed research plan.

Over the course of the recruitment time period, a total of 6 individuals expressed interest in the intervention, and those 6 individuals were recruited, with 3 participants completing the intervention, 1 no longer meeting eligibility criteria due to a cancer recurrence, and 2 electing to drop out of the intervention. The number of individuals who dropped out ($2/6$ enrolled participants = 33.3%) is slightly higher than the 22% overall dropout rate from outpatient mental health care in the United States of America (Olfson et al., 2009), along with the dropout rate of 20-24% reported by Herschbach et al. (2010). As discussed above, the participants tended to drop out early in the intervention (specifically, sessions 1 and 2). Participant 100 cited that her reason for dropping out was based on personal time restraints, whereas participant 105 reported that he was no longer interested in completing the intervention after session 2.

Participant motivation and situational events are important factors to consider in this particular context. Of the participants who dropped out of the intervention, participant 100 appeared to be preoccupied with other psychological concerns and was simultaneously managing other stressful life events, while participant 105 was concurrently dealing with a number of major Axis I psychiatric concerns, including alcohol dependence. Given that this intervention is very specific and targeted for the treatment of FCR, as opposed to an intervention addressing

general distress, goodness of fit is important in determining whether FCR is the most salient issue at the time.

Acceptability

Based on this pilot study, the acceptability of this intervention is mixed, given that two participants dropped out of the intervention in the early stages. However, the participants who completed the intervention indicated that it was helpful, fair, and reasonable in their post-session questionnaires and qualitative exit interviews. Acceptability of the intervention is also reflected in participant attendance and adherence to session material. The participants who completed the intervention attended all weekly therapy sessions and returned all of their questionnaire packages, resulting in an attendance rate of 100% and a response rate of 100%. Furthermore, the study participants completed the majority of their in-between session homework exercises throughout the timeframe of the intervention. This suggests that participants were willingly engaged throughout the therapeutic process, and were motivated to continue addressing their FCR, despite certain challenging and emotionally evocative sessions. Additionally, since the participants reported that they were satisfied with the intervention overall, this may have resulted in higher attendance and adherence rates, suggesting further acceptability of the intervention. Overall, based on the 100% response rates, attendance rates, adherence to session material, and reports of satisfaction with the intervention, the authors safely conclude that the intervention was not burdensome to the participants, and therefore, was acceptable.

Acceptability of the intervention was also measured based on the assessment made by the clinicians (in addition to the assessment of the intervention made by participants). Based on both quantitative and qualitative results, it is apparent that the FCR intervention is suitable for the

individuals who participated in this study. Additionally, it was possible to collect participant data in the intended time period, indicating that the selected time frame was acceptable.

Satisfaction

The qualitative component of the current study allowed for a more in-depth understanding of the participants' experience with the intervention. Results from the exit interviews suggest that the participants found the intervention treatment to be satisfactory. Consistent themes were found across all participants regarding general satisfaction of and appreciation for the intervention, learning adaptive tools and techniques to target their fears, and experiencing a substantial improvement in managing FCR. Additionally, the exit interviews revealed participants' appreciation for session 4. There was unanimous agreement across participants that the worst-case scenario in-session exercise was the most helpful. Overall, participants who completed the intervention explicitly verbalized their satisfaction with the intervention in their exit interviews, and noted significant improvements in their FCR. No differences in identified themes were noted with regard to cancer type and/or gender.

When considering the quantitative aspects of the study, the post-session feedback questionnaires also suggest that the participants found the intervention treatment to be satisfactory. Much like the findings from the exit interviews, the post-session feedback questionnaires revealed that session 4 was most helpful, as evidenced by the consistent Strongly Agree ratings across all participants, and the highest rate of weekly homework completion.

Changes in FCR and Cancer-Specific Distress

Qualitative examination of participants' quantitative data illustrates downward trends in FCR across all participants. However, participants remained in the recommended clinical range for FCR at discharge, and one participant remained in the recommended clinical range for

cancer-specific distress at discharge. These downward trends may suggest that there would be further improvement in FCR over time if the therapy intervention were longer (e.g., 8-12 weeks). It is possible that additional sessions addressing FCR over several weeks may provide more help for participants, and therefore continue to decrease their fears and cancer-specific distress.

While participants remained in the suggested clinical range for FCR, it is worth noting that a clinical cut-off level of FCR has not been established. While some FCR instruments propose cut-off scores to identify “high” or “clinical” FCR (Simard et al., 2013; Thewes, Zachariae, Christensen, Nielsen, & Butow, 2015), the absence of a gold-standard clinical interview or outcome measure makes validating cut-off scores difficult (Lebel et al., 2016). Efforts have been made to measure clinical levels of FCR with cancer survivors using purpose-designed clinical interviews, such as the Semi-Structured Interview for Fear of Cancer Recurrence (SIFCR; Simard & Savard, 2015), although further validation of this interview content is necessary (Lebel et al., 2016). Furthermore, as evidenced in Lebel et al.’s (2014) group pilot study, results indicated that by the end of the intervention, participants either improved or remained the same, but did not get worse. Results from this study are similar to those found in Lebel et al.’s (2014) study, and at this point in time, it is unclear as to who specifically improves and who does not.

Limitations

While this individual FCR intervention constitutes an original contribution to research, it is important to note some limitations. The first limitation to consider is the small sample size and scope of this pilot study. Given the absence of statistical power, the results of this study are interpreted with caution (i.e., interpreted as trends). Another important limitation is the sampling technique employed for this study. Given that a convenience sample was used, this may limit

whether the findings are applicable to a broader population. Thus, results of this study are only representative of the individuals under investigation, and may not represent the opinions of future participants. Lastly, the preliminary findings of downward trends may in part be explained by the selection of participants with clinically high levels of FCR and cancer-specific distress. It is possible that the changes could be due to the effects of time or regression to the mean, and in the absence of a control group, this cannot be ruled out. However, the results of this study are promising enough to justify the use of a more rigorous design to further test the intervention in a larger sample. At the present time, it is unknown if this intervention would be appropriate for individuals experiencing low levels of FCR - those individuals who represent 51% of cancer survivors (Simard et al., 2013).

Summary of Hypotheses

As previously mentioned, the authors hypothesized that it would be feasible to deliver the FCR individual intervention as intended, and that participants would find the intervention to be acceptable and satisfactory. Furthermore, the authors hypothesized that participants' results on the outcome measures would show downward trends in FCR and cancer-specific distress by the end of the intervention. Results of the current study indicate that it was feasible to offer the FCR individual intervention to study participants, once the study population was opened to patients of mixed cancer sites. Consistent with the second hypothesis, results suggest that the intervention is considered to be acceptable and satisfactory by the participants who completed the therapy. Lastly, participants' results on the outcome measures displayed downward trends in FCR and cancer-specific distress by the end of the intervention, indicating that the final hypothesis was confirmed.

Clinical Implications

This research has direct implications for clinical services to improve quality of life for cancer survivors, and may decrease the use of health care services by anxious individuals seeking reassurance. Furthermore, the results of this study may help inform intervention efforts in the emergent area of FCR. Based on the outcome of the current study, it appears that the intervention is indeed appropriate for further testing in a pilot RCT, which is the aim and focus of study 2.

References

- Ayala, G. X., & Elder, J. P. (2011). Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. *Journal of Public Health Dentistry, 71*, 569-579. doi: 10.1111/j.1752-7325.2011.00241.x
- Carlson, L. E., Tamagawa, R., Stephen, J., Doll, R., Faris, P., Dirkse, D., & Speca, M. (2014). Tailoring mind-body therapies to individual needs: patients' program preference and psychological traits as moderators of the effects of mindfulness-based cancer recovery and supportive-expressive therapy in distressed breast cancer survivors. *Journal of the National Cancer Institute Monographs, 50*, 308-314. doi: 10.1093/jncimonographs/lgu034
- Creswell, J. W. (2013). *Qualitative inquiry and research design: Choosing among five approaches*. Los Angeles: Sage.
- Feeley, N., Cossette, S., Côté, J., Héon, M., Stremler, R., Martorella, G., & Purden, M. (2009). The importance of piloting an RCT intervention. *Canadian Journal of Nursing Research, 41*(2), 84-99. Retrieved from <http://www.ingentaconnect.com/content/mcgill/cjnr/2009/00000041/00000002/art00007?crawler=true>
- Herschbach, P., Berg, P., Waadt, S., Duran, G., Engst-Hastreiter, U., Henrich, G., . . . Dinkel, A. (2010). Group psychotherapy of dysfunctional fear of progression in patients with chronic arthritis or cancer. *Psychotherapy and Psychosomatics, 79*(1), 31-38. doi: 10.1159/000254903
- Horowitz, M., Wilner, N., & Alvarez, W. (1979). Impact of events scale: a measure of subjective stress. *Psychosomatic Medicine, 41*(3), 209-218. doi: 10.1192/bjp.180.3.205

- Joffe, H. (2012). Thematic analysis. In D. Harper & A. R. Thompson (Eds.), *Qualitative research methods in mental health and psychotherapy: A guide for students and practitioners* (pp. 209-223). Chichester, West Sussex: John Wiley & Sons
- Kazdin, A. E. (1980). Acceptability of alternative treatments for deviant child behavior. *Journal of Applied Behavior Analysis, 13*, 259–273. doi: 10.1901/jaba.1980.13-259
- Lebel, S., Maheu, C., Lefebvre, M., Secord, S., Courbasson, C., Singh, M., . . . Catton, P. (2014). Addressing fear of cancer recurrence among women with cancer: A feasibility and preliminary outcome study. *Journal of Cancer Survivorship, 8*, 485-496. doi: 10.1007/s11764-014-0357-3
- Lebel, S., Ozakinci, G., Humphris, G., Thewes, B., Prins, J., Dinkel, A., . . . Butow, P. (2016). Current state and future prospects of research on fear of cancer recurrence. *Psycho-Oncology*. doi: 10.1002/pon.4103
- Olfson, M., Mojtabai, R., Sampson, N. A., Hwang, I., Druss, B., Wang, P. S., . . . & Kessler, R. C. (2009). Dropout from outpatient mental health care in the United States. *Psychiatric Services, 60*(7), 898-907. doi: 10.1176/appi.ps.60.7.898
- Savard, J., & Ivers, H. (2013). The evolution of fear of cancer recurrence during the cancer care trajectory and its relationship with cancer characteristics. *Journal of Psychosomatic Research, 74*, 354-360. doi: <http://dx.doi.org/10.1016/j.jpsychores.2012.12.013>
- Simard, S. & Savard, J. (2009). Fear of cancer recurrence inventory: Development and initial validation of a multidimensional measure of fear of recurrence. *Supportive Care in Cancer, 17*(3), 241-251. doi: 10.1007/s00520-008-0444-y

- Simard, S., & Savard, J. (2015). Screening and comorbidity of clinical levels of fear of cancer recurrence. *Journal of Cancer Survivorship*, 9(3), 481-491. doi: 10.1007/s11764-015-0424-4.
- Simard, S., Thewes, B., Humphris, G., Dixon, M., Hayden, C., Mireskandari, S., & Ozakinci, G. (2013). Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *Journal of Cancer Survivorship*, 7(3), 300-22. doi: 10.1007/s11764-013-0272-z.
- Sheehan, D., & Lecrubier, Y. (2006). Mini-international neuropsychiatric interview (M.I.N.I.) 5.0.0.c. Swedish version.
- Smith, A. B., Thewes, B., Turner, J., Gilchrist, J., Fardell, J., Sharpe, L., . . . Clutton, S. (2015). Pilot of a theoretically grounded psychologist- delivered intervention for fear of cancer recurrence (Conquer Fear). *Psycho-Oncology*, 24(8), 967-970. doi: 10.1002/pon.3775
- Thewes, B., Butow, P., Bell, M. L., Beith, J., Stuart-Harris, R., Grossi, M., . . . Dalley, D. (2012). Fear of cancer recurrence in young women with a history of early-stage breast cancer: A cross-sectional study of prevalence and association with health behaviours. *Supportive Care in Cancer*, 20, 2651-2659. doi: 10.1007/s00520-011-1371-x
- Thewes, B., Butow, P., Zachariae, R., Christensen, S., Simard, S., & Gotay, C. (2012). Fear of cancer recurrence: A systematic literature review of self-report measures. *Psycho-Oncology*, 21(6), 571-587. doi: 10.1002/pon.2070
- Thewes, B., Zachariae, R., Christensen, S., Nielsen, T., & Butow, P. (2015). The concerns about recurrence questionnaire: Validation of a brief measure of fear of cancer recurrence amongst Danish and Australian breast cancer survivors. *Journal of Cancer Survivorship*, 9(1), 68-79. doi: 10.1007/s11764-014-0383-1

Vickberg, S. (2003). The concerns about recurrence scale (CARS): A systematic measure of women's fears about the possibility of breast cancer recurrence. *Annals of Behavioral Medicine*, 25, 16–24. doi: 10.1207/S15324796ABM2501_03

Table 1. *Detailed Description of the Individual Cognitive-Existential Intervention (modified from Lebel & Maheu, unpublished manuscript)*

Session #	Session Description
1	<ul style="list-style-type: none"> - Introduction of participant with a focus on their experience with FCR - Introduce FCR model - Identification of internal and external triggers - Introduce notion of cognitive restructuring and triggers, handout of thinking errors - Coping skills teaching: Progressive muscular relaxation (PMR) - Homework: thought record, PMR record, prepare list of questions for oncologist
2	<ul style="list-style-type: none"> - Discuss questions list about signs of recurrence and follow-up care to ask oncologist at next visit - Discuss ways of regaining sense of control - Coping skills teaching: Calming self-talk phrases and use of relaxation CD - Homework: thought record, PMR record, self-talk log
3	<ul style="list-style-type: none"> - Explore reasonable levels of worry - Complete “Why Worry” questionnaire - Challenge faulty beliefs about benefits of worry - Review maladaptive coping strategies like reassurance-seeking and avoidance - Coping skills teaching: Guided imagery - Homework: Challenge worries, examine evidence, guided imagery log
4	<ul style="list-style-type: none"> - Provide psycho-education about worry and the need for exposure to underlying fears, write down worst-case scenario - Promote emotional expression and confront specific fears that underlie participant’s FCR - Coping skill teaching: Mindfulness exercise (body scan) - Homework: Review worst-case scenario daily, write down feelings before and after, body scan daily
5	<ul style="list-style-type: none"> - Review exposure to worst-case scenario - Discuss ways of coping with some of the feared outcomes - Encourage expression of feelings of demoralization - Encourage participants to become re-engaged with important life goals, people, or activities they may have given up - Discuss what the future and planning now means for each participant - Coping skills teaching: Mindfulness (eating meditation) - Homework: Write out plans for future, practice mindfulness
6	<ul style="list-style-type: none"> - Review all content covered to date - Discuss resource list - Discuss future goals - Set new priorities - Promote the expression of saying goodbye and provide closure

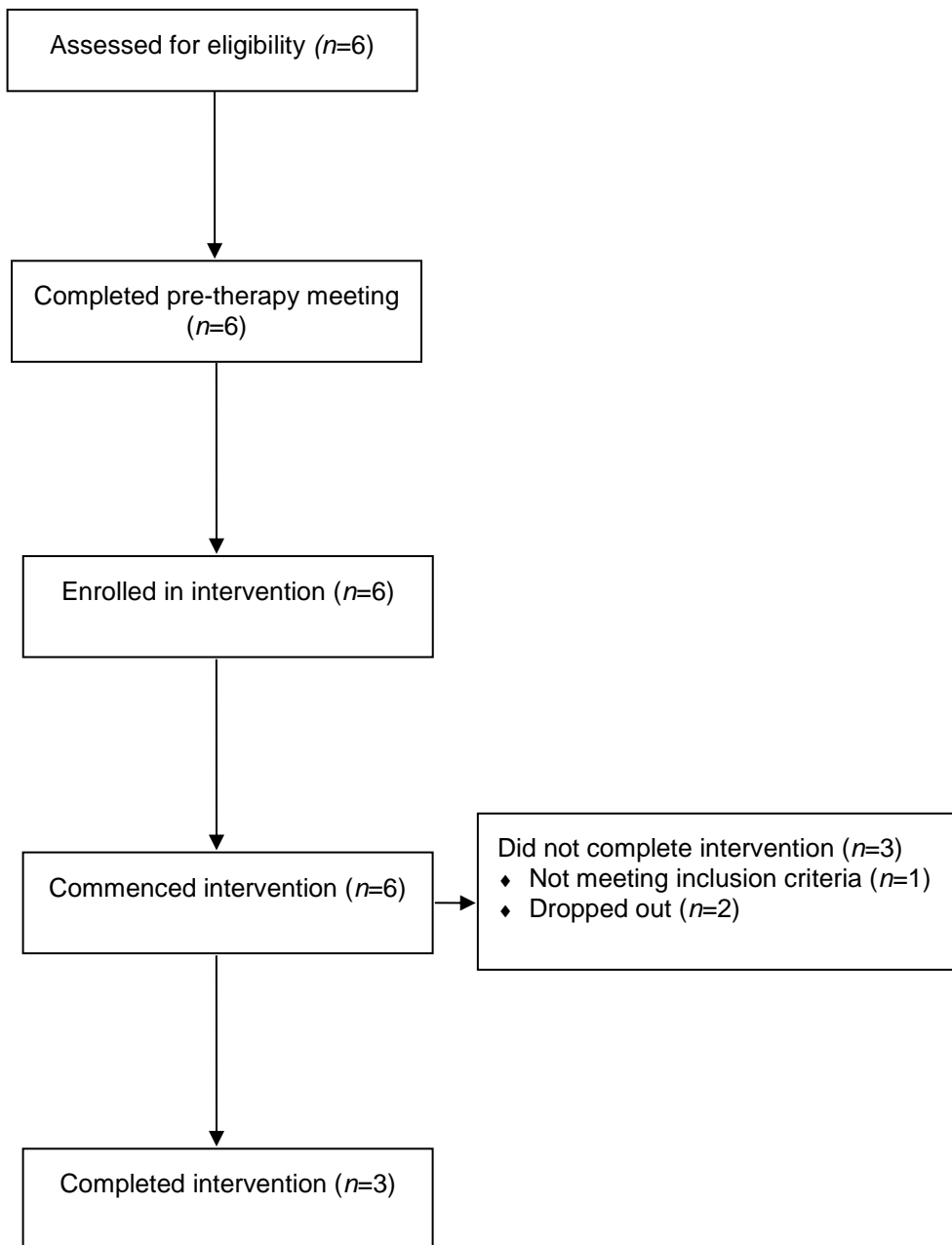


Figure 1. Flow diagram of patient recruitment.

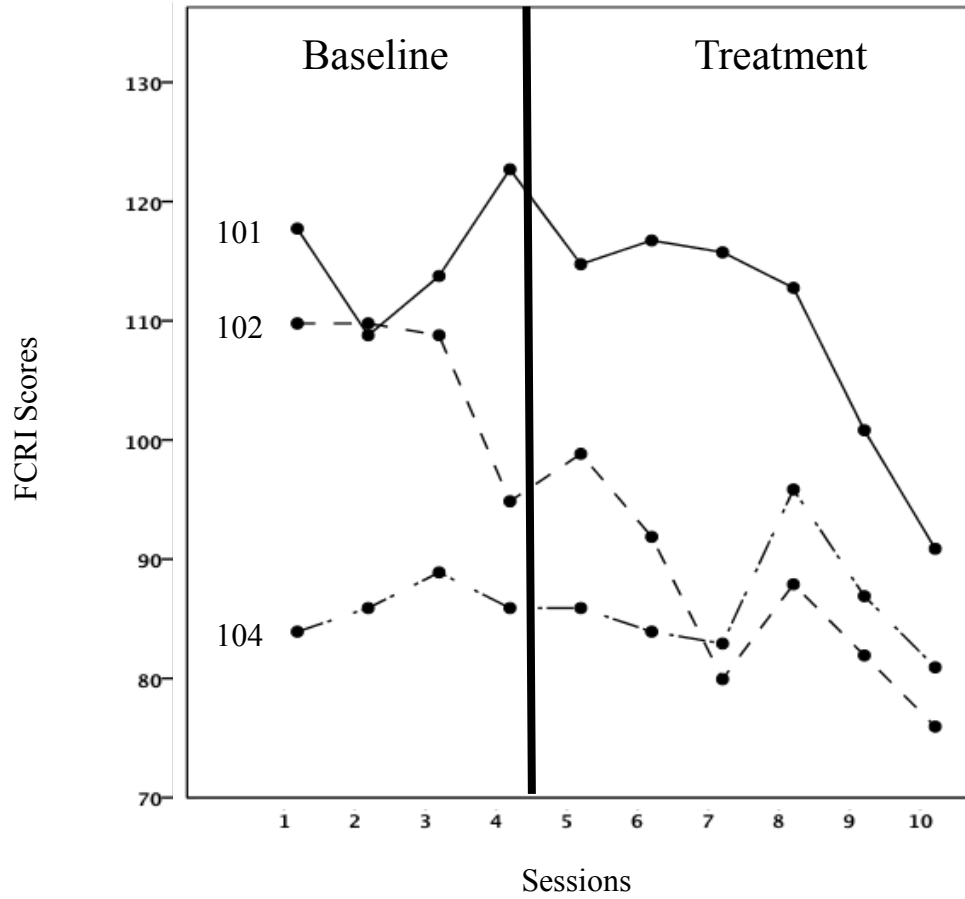


Figure 2. Participants' fear of cancer recurrence total scores from baseline to treatment completion.

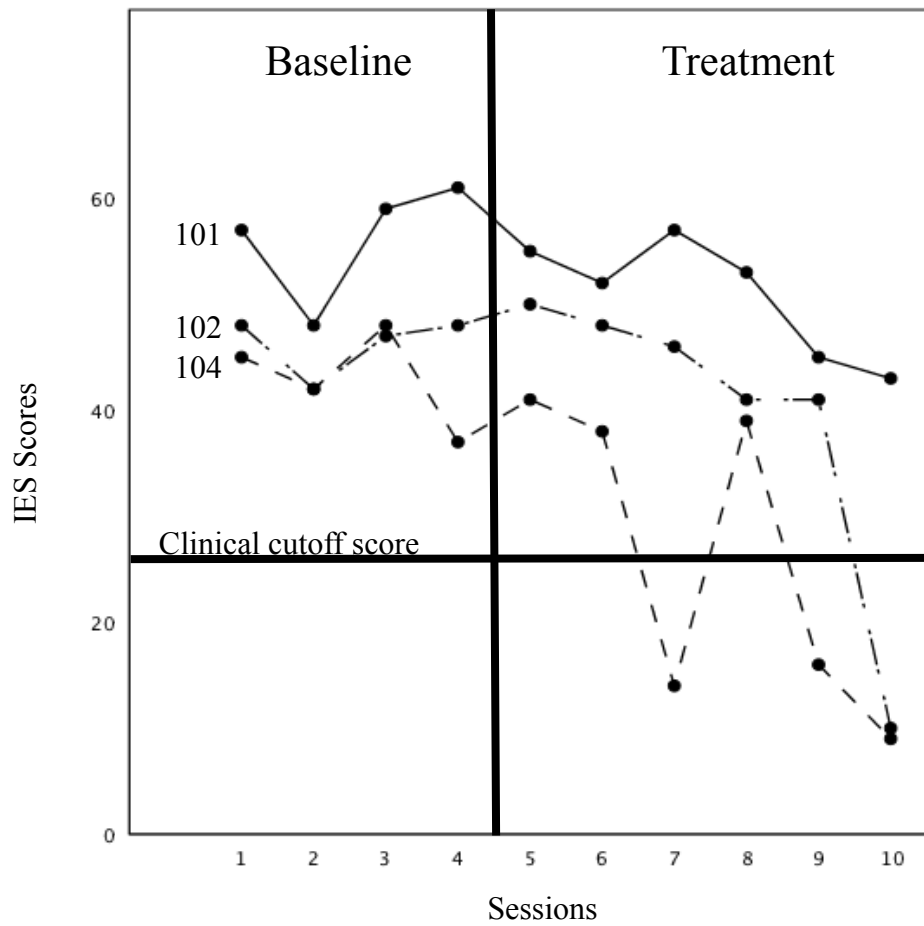


Figure 3. Participants' cancer-specific distress total scores from baseline to treatment completion.

RUNNING HEAD: A THERAPY INTERVENTION FOR FEAR OF CANCER
RECURRENCE

Study 2

Examining the Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized
Controlled Clinical Trial Pilot Study

Christina Tomei¹, Sophie Lebel¹, Christine Maheu², Monique Lefebvre³, & Cheryl Harris³

¹ *School of Psychology, University of Ottawa*

² *Ingram School of Nursing, McGill University*

³ *Psychology Department, The Ottawa Hospital*

Abstract

Fear of cancer recurrence (FCR) is the most frequently reported concern identified in cancer survivors. Despite this, there is limited research on psychosocial interventions that target FCR. To address this gap in the literature, an individual cognitive-existential psychotherapy intervention for FCR was pilot-tested via a randomized controlled trial (RCT). Twenty-five female cancer survivors were randomized to an experimental group or a wait-list control group. Sessions included cognitive restructuring techniques, behavioural experiments, relaxation techniques, confronting existential distress, and finding meaning in life post-diagnosis. Nineteen women completed the 6-week therapy intervention, and completed questionnaire packages at pre-, post- and 3-month follow-up. Within the Linear Mixed Models (LMM) component of SPSS, mixed between-within subjects ANOVAs revealed significant interactions in the primary outcome measure of FCR, and secondary outcome measures of cancer-specific distress and uncertainty in illness for participants in the experimental group. Repeated measures ANOVAs revealed reductions in FCR, cancer-specific distress, uncertainty in illness, reassurance-seeking, cognitive avoidance, and intolerance of uncertainty, and revealed improvements in positive reinterpretation and growth, use of emotional support and mental health (improved quality of life) across all study participants. The variables that changed either maintained or improved at follow-up. With the exception of one coping subscale, no therapist differences were found. Results from this study demonstrate promising results in addressing FCR in female cancer survivors through a cognitive-existential intervention. Future research should continue to investigate the specific therapeutic ingredients that are most effective for the psychological treatment of FCR. This intervention responds to a need for the development of evidence-based

clinical services to improve quality of life in cancer survivors. Additional research is needed to further test this intervention on patients of mixed cancer sites.

Examining the Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized Controlled Clinical Trial Pilot Study

Psychosocial oncology research has consistently demonstrated that cancer survivors have a variety of unmet needs, with Fear of Cancer Recurrence (FCR) being the most frequently reported concern (Baker, Denniston, Smith, & West, 2005; Lebel, Rosberger, Edgar, & Devins, 2007). FCR is defined as “fear, worry or concern relating to the possibility that the cancer will come back or progress” (Lebel et al., 2016, p. 3266), and has been described as the sword of Damocles that hangs over patients’ heads for the rest of their lives (Muzzin, Anderson, Figueredo, & Gudelis, 1994). Nearly 50% of cancer survivors experience moderate-to-high FCR (Simard et al., 2013), and these individuals often engage in maladaptive coping behaviours, such as excessive bodily checking, reassurance-seeking, and avoidance of feared outcomes (Armes et al., 2009; Lebel et al., 2007; Lebel, Tomei, Feldstain, Beattie, & McCallum, 2013). Results from systematic reviews indicate that FCR tends to remain stable over time, and that high FCR at baseline is a strong predictor of higher long-term FCR (Simard et al., 2013; Thewes et al., 2012). Furthermore, female gender and younger age have been found to be predictors of moderate-to-high FCR (Simard et al., 2013; Thewes et al., 2012). FCR is also consistently associated with psychological distress, anxiety, depression, and stress-response symptoms, with correlations ranging from $r=.19$ to $.69$ (Simard et al., 2013), suggesting relations among these constructs. High levels of FCR are also associated with diminished physical and mental quality of life (Kim et al., 2012), including increased uncertainty and worry about the future, difficulties making decisions and planning for the future, and fear of death (Kim et al., 2012). Moreover, studies have shown that cancer patients who endorse high levels of FCR are more likely to refuse transfer from a cancer centre to follow-up by a primary care provider (Glynn-Jones, Chait, &

Thomas, 1997), express doubt about whether one's physician is thorough enough (Hart et al., 2008), are less satisfied with their care (Hart et al., 2008), and are more likely to seek readmission to a specialized cancer centre (Glynn-Jones et al., 1997). Furthermore, the need for reassurance is often cited as the reason for increased frequency of hospital visits (Llewellyn, Weinman, McGurk, & Humphris, 2008). Overall, there is clear evidence that a large portion of cancer survivors with moderate-to-high FCR tend to exhibit more psychological morbidities than survivors with low FCR.

Despite evidence that cancer patients with higher FCR have poorer psychological adjustment and may utilize health care resources excessively (Lebel et al., 2013), there are a few studies examining psychosocial interventions that address FCR. One particular published intervention has examined the notion of fear of disease progression. Herschbach et al. (2010) examined the effects of a cognitive-behavioural group therapy and a supportive-existential group therapy for patients with cancer or arthritis in a partially randomized study. Both interventions consisted of four 90-minute sessions, followed by two booster telephone calls at follow-up time points. Results indicated that both interventions successfully reduced fear of disease progression in cancer patients when compared to a control group, particularly for patients whose cancer had recurred or metastasized. Despite these findings, it is worth noting that neither intervention was based on theories of FCR. Humphris and Ozakinci (2008) developed the Adjustment to the Fear, Threat, or Expectation of Recurrence (AFTER) intervention for FCR in head and neck cancer patients, although results of this study have not been published.

In an effort to address the needs of patients with moderate-to-high FCR, Lebel and Maheu (2009) designed a cognitive-existential group intervention for the treatment of FCR. The intervention is theoretically guided by three models: The Common Sense Model (CSM; Lee-

Jones, Humphris, Dixon & Hatcher, 1997; Leventhal, Diefenbach & Leventhal, 1992), Mishel's Uncertainty in Illness Theory (Mishel, 1988), and cognitive models of worry (Dugas, Gagnon, Ladouceur & Freeston, 1998; Ladouceur et al., 2000; Langlois, Ladouceur, Patrick, & Freeston, 2004). Lebel et al. (2014) adapted components of the cognitive existential (CE) group intervention developed by Kissane and colleagues (1997), designed to address some of the existential issues related to living with cancer. Lebel et al.'s (2014) intervention consists of six consecutive, 1.5-hour weekly group therapy sessions. Patients completed a variety of in-session tasks, including cognitive restructuring exercises, behavioural experiments, and relaxation techniques. Patients were also encouraged to access their emotions, to tolerate their existential distress in the here-and now, and to confront specific fears regarding their FCR. The authors piloted the group intervention with breast and ovarian cancer participants ($n=54$), and results of the study demonstrated significant improvement, with a moderate effect size between in FCR ($\eta^2=0.73$), cancer-specific distress ($\eta^2=0.38$), quality of life ($\eta^2=0.54$), uncertainty ($\eta^2=0.41$), and coping strategies ($\eta^2=0.16-0.27$; Lebel et al., 2014). Almost all changes were sustained at 3-month follow-up.

The Current Study

While intervention research on FCR is emerging (Thewes et al., 2012), it appears that very few *individual* therapeutic interventions exist that specifically target FCR. This absence of one-on-one FCR interventions speaks to a growing need for such therapeutic services. Based on the success of our pilot study examining the feasibility, acceptability, and satisfaction of the individual FCR intervention, outlined above in study 1, the authors proceeded to further examine the efficacy of the individual FCR intervention with female cancer survivors ($n=25$), via a randomized controlled clinical trial pilot study. By offering this individual FCR intervention, the

authors served to meet the therapeutic needs and preferences of cancer survivors, and to provide therapeutic services where group interventions are not feasible. Notably, it is also favourable for cancer survivors to receive the treatment modality of their choice, as research suggests that this results in better therapeutic outcomes by the end of treatment (Carlson et al., 2014; Wu et al., 2014). Indeed, a meta-analysis revealed that individually-based interventions for cancer patients have been found to be more effective than group-based interventions (Osborn, Demoncada & Feuerstein, 2006), further suggesting the importance of developing individualized intervention protocols.

Hypotheses

The authors hypothesized that:

- 1) Participants in the experimental group would have lower scores on the primary outcome measure of FCR after treatment than would participants in the wait-list control group;
- 2a) Participants in the experimental group would have lower scores on secondary outcome measures of cancer-specific distress, intolerance of uncertainty, uncertainty in illness, cognitive avoidance, reassurance-seeking, and faulty beliefs about worrying than would participants in the wait-list control group;
- 2b) Participants in the experimental group would demonstrate enhanced coping skills in positive reinterpretation and growth, acceptance, and use of emotional support, and report better mental and physical quality of life after treatment, than would participants in the wait-list control group;
- 3) When grouped together, all participants (both experimental group and wait-list control group) would have lower scores on the primary outcome measure of FCR after treatment, and these effects would be maintained at 3-month follow-up;
- 4a) When grouped together, all participants (both experimental group and wait-list control

group) would have lower scores on the secondary outcome measures of cancer-specific distress, intolerance of uncertainty, uncertainty in illness, cognitive avoidance, reassurance-seeking, and faulty beliefs about worrying; and these effects would be maintained at 3-month follow-up;

4b) When grouped together, all participants (both experimental group and wait-list control group) would demonstrate enhanced coping skills in positive reinterpretation and growth, acceptance, and use of emotional support, and report better quality of life after treatment, and these effects would be maintained at 3-month follow-up.

Method

Participants

Female participants with various types of cancer (breast, gynecological and ocular melanoma) were recruited from The Ottawa Hospital's (TOH) Psychosocial Oncology Program (PSOP) and the Psychology department at TOH via study posters, referrals from health care professionals employed at TOH, and via TOH's electronic patient database, using a tool that searches for patients who had previously consented to be contacted for research purposes. The data was obtained using filters to create a list of patients who: were English speaking, over the age of 18, who had received a cancer diagnosis between stages I-III, were not currently receiving radiation, and were not currently receiving chemotherapy. Once this list of patients was obtained, their hospital charts were screened for eligibility, and they were contacted by members of the research team to assess their interest in participating. Those individuals who were interested in participating, expressed concerns with FCR, and met eligibility criteria were included in the study.

In order to partake in the study, all of the following inclusion criteria were required for participation: a) women diagnosed with cancer (stages I-III), b) fluency in English, c) 18 years of

age or older, d) clinical level of FCR as indicated by a score of 13 or greater on the severity subscale of the Fear of Cancer Recurrence Inventory (FCRI; Simard & Savard, 2009; range 0-36), e) clinical distress level as indicated by a score of at least 24 on the Impact of Events Scale (IES; Horowitz, Wilner, & Alvarez, 1979; range 0-75), and f) completion of cancer treatment (e.g., chemotherapy, radiation, and/or surgery). Exclusion criteria were as follows: a) the refusal to provide informed consent, b) non-understanding of the English language, c) Stage IV cancer (as these individuals are facing end of life issues, are often too sick to complete treatment, and/or are dealing with active disease, as opposed to threat of recurrence), d) previous cancer recurrence (as the study focused on individuals with a first occurrence of cancer), e) currently enrolled in group or individual psychotherapy for cancer issues during the treatment; and f) evidence of unmanaged mental health disorder that may interfere with the psychological treatment for FCR (as indicated by questions endorsed by participants on the Mini International Neuropsychiatric Interview screener tool (MINI; Sheehan & Lecrubier, 2006; see Appendix H).

Interested potential participants were asked to contact the first author for additional information on the study. Prior to receiving the treatment, participants were screened in an initial telephone meeting by one of the three therapists (see Appendix G for telephone screening and eligibility script). For those individuals who met inclusion criteria, a pre-therapy meeting was organized between the assigned therapist and the participant. During these meetings, the therapist administered research consent forms, discussed general expectations, addressed any relevant questions, and prepared participants for the onset of the intervention. The pre-therapy meeting was also used to determine if patients were suitable for this intervention (e.g., inquiring about substance abuse, determining pervasiveness of any existing mental health concerns, and assessing interpersonal suitability for participation). The therapists also administered the MINI

screener tool (Sheehan & Lecrubier, 2006) with each participant in the pre-therapy meeting. As previously mentioned, the MINI screener tool was administered in order to determine if potential participants had any pre-existing/comorbid Axis I diagnoses that might interfere with the treatment of FCR. For example, if participants endorsed symptoms consistent with any diagnosis indicated on the MINI, the therapist took additional precautions to inquire about how the symptoms were being managed, and if any impairment from this diagnosis would prevent the individual from engaging in treatment for FCR. In this study, only one participant endorsed symptoms consistent with heavy substance dependence, and thus, was referred elsewhere for services surrounding her dependence concerns. Upon explaining the limits of confidentiality and signing the research consent forms, each participant was provided with a unique participant ID number.

Participants were asked to complete a series of questionnaires during their involvement in the study. Participants were given the choice to complete questionnaires via paper-based copies or via Fluid Survey, an online survey software. Participants were asked to use their respective participant ID number for identification purposes when completing their questionnaires. Participants were informed that they were allowed to miss one session and reschedule one session, as the presumed effectiveness of the intervention was contingent on session attendance. To maximize attendance, all participants were reimbursed for their parking/transportation fees for each session.

Procedure

This pilot study consisted of a two-arm randomized controlled trial (RCT). Approval was obtained from the two Institutional Research Ethics Boards of the affiliated investigators: The Ottawa Hospital Health Science Network Research Ethics Board and The University of Ottawa

Research Ethics Board (see Appendix I for the approved consent form). This RCT has been registered on <http://www.clinicaltrials.gov> (Identifier: NCT02382315).

Sample size. G*Power 3.1.5 was used to calculate the necessary sample size for a repeated measures analysis of variance (ANOVA), between factors, with two groups (intervention group and wait-list control group), and three measurement time points (pre-, post-, and 3-month follow-up), using the effect size that was found in Lebel et al.'s (2014) pilot study of 0.73 ($\phi=.80$, $p < .05$). The sample size calculation was based on the effect size for the Fear of Recurrence Questionnaire (FRQ; Northouse, 1981). To obtain this effect size, a sample of 14 participants was required. While 14 participants was the minimum number to detect a difference between groups based on these parameters, a total of 25 participants were recruited, in order to account for the possibility of attrition. The attrition rate from Lebel et al.'s (2014) pilot study was 21%.

Participants included in this study were the first consecutively assessed individuals who met study inclusion criteria. Of potential participants meeting inclusion criteria, individuals were contacted consecutively. Over a recruitment time period of six months (January to July 2015), a total of $n=29$ individuals expressed interest in the intervention and were assessed for eligibility to participate in the study. Of this total, $n=4$ did not meet the aforementioned eligibility criteria, therefore, a total of $n=25$ individuals were enrolled in the intervention. Of the 25 participants who were randomized, $n=1$ was unable to be contacted after multiple attempts, and $n=2$ were deemed to be unsuitable for participation in the intervention prior to the onset of therapy (for reasons surrounding substance dependence and interpersonal concerns), and were directed to other psychological services. During the course of the intervention, $n=1$ dropped out during the intervention due to time restraints, and $n=2$ experienced cancer recurrences. This resulted in a

final sample of $n=19$ eligible participants. In the interest of ethical practice, the FCR intervention was still provided to the individuals who experienced cancer recurrences. All useable questionnaire data was retained for statistical analyses. Please see CONSORT diagram for further detail in figure 1.

Randomization. All enrolled participants were randomly assigned (50% likelihood) to one of two conditions, regardless of the outcome for the previous participant. Participants were randomly assigned to either the intervention arm ($n=11$), where they received the six-week FCR intervention within one week following their pre-therapy meeting, or the control arm ($n=14$), where they received standard medical care at TOH and were waitlisted to receive the FCR intervention 6 weeks later. Due to study timeline restrictions, wait-list times for participants in the control group varied between 2-6 weeks. While the authors initially intended for all control group participants to wait a full 6 weeks before receiving the intervention, the original wait-list timeline was reduced as a result of unanticipated job restructuring. Thus, the timeline of the study was significantly reduced, resulting in shorter wait-list times. Random assignment of participants to each group was implemented via an online random number generator (www.randomizer.org; Urbaniak & Plous, 2016). A statistical consultant affiliated with the School of Psychology (but outside of the research team) conducted the random assignment using this computerized procedure, and randomization outcomes were placed in individual sealed envelopes. During the pre-therapy meeting, the assigned therapist opened the sealed envelope in front of the participant, and revealed the group to which they were randomized (either the “intervention group”, or the “6-week wait-list control group”). Participants were notified of which group they were randomized to once the envelope was opened, and their first intervention session was scheduled accordingly.

Therapists. Christina Tomei and two University of Ottawa clinical psychology doctoral students fulfilling their practicum requirements served as the therapists. Of the 25 patients enrolled, Christina Tomei worked with 10 patients, one doctoral student worked with 9 patients, and one doctoral student worked with 6 patients. This setup was based on scheduling preferences and organization amongst all three therapists. All therapy sessions occurred at both PSOP and TOH's Psychology department. The first and second author provided a one-day training workshop for the two new therapists prior to the onset of the study. The workshop served to introduce the therapists to the intervention, and outlined the content of each session in detail.

All therapy sessions were video-recorded, and the second author reviewed random (pre-selected) sessions in order to assess treatment integrity and fidelity. Specifically, more than 20% of the videos were reviewed (2/6 sessions per therapist, per participant). A systematic fidelity checklist was created to ensure adherence to treatment protocol. Out of the 48 sessions that were viewed and rated, all sessions had an adherence rate above 80%, with the exception of 1 session. In that latter case, additional supervision was provided to the therapist prior to the next scheduled intervention session. The high adherence ratings suggest that the intervention was delivered systematically to all participants. Therapists corresponded and met directly with their own patients, and further correspondence surrounding the intervention was directed to the first author. Weekly clinical supervision was provided for the therapy facilitators by the second and fourth authors.

The strictest confidentiality was ensured when storing participant data. All participants were informed that their involvement in the study was known only by members of the research team, and that all identifying information was kept in the fourth author's secured, locked office at TOH. The video recordings of the therapy sessions were deleted once the study was

completed. Online questionnaire responses were saved in a password-protected folder, and tangible copies of the questionnaire packages were stored in a secured, locked filing cabinet at TOH.

Outcome Measures

Participants in the experimental group were asked to complete a series of self-administered questionnaires before the onset of the intervention (T1), after completing the intervention (T2), and at 3-month follow-up (T3). Participants in the wait-list control group completed the same series of self-administered questionnaires, with the addition of one time point. These time-points included a baseline period (T0), before the onset of the intervention (T1), after completing the intervention (T2), and at 3-month follow-up (T3). Please see figure 2 for a visual representation of the study time points. All participants were given a demographic information form to complete at baseline (i.e., during the pre-therapy meeting). The outcome measures below were selected based on the results from Lebel et al.'s (2014) pilot study, as the majority of these measures demonstrated improvements.

The study questionnaire packages included the following inventories:

Demographic information form. Participants were given a demographic information form to complete at baseline. The demographic form includes information about participants' current marital status, highest education level, current occupational status, ethnic background, age, annual income level, and medical history.

Primary outcome measure. The primary outcome was FCR, which was measured using the *Fear of Cancer Recurrence Inventory* (FCRI; Simard & Savard, 2009). The FCRI is a 42-item instrument that has been used to examine FCR in previous studies (Savard & Ivers, 2013; Thewes et al., 2012). The FCRI is a comprehensive measure that uses a 5-point Likert scale,

ranging from 0 (Not at all or Never) to 4 (A great deal or All the time). The FCRI contains seven subscales: Triggers (8 items, $\alpha=.90$, “Generally, I avoid situations or things that make me think about the possibility of a cancer recurrence”), Severity (9 items, $\alpha=.89$, “When I think about the possibility of cancer returning, other unpleasant thoughts or images come to mind (death, suffering, consequences for my family”), Psychological Distress (4 items, $\alpha=.86$, “When I think about the possibility of cancer recurrence, I feel worry, fear, or anxiety”), Coping Strategies (9 items, $\alpha=.89$, “I try to get the idea out of my mind, to not think about it”), Functioning Impairment (6 items, $\alpha=.91$, “My thoughts or fears about the possibility of cancer recurrence disrupt my relationship with my partner, my family, or those close to me”), Insight (3 items, $\alpha=.80$, “I think that I worry more about the possibility of cancer recurrence more than other people who have diagnoses of cancer”), and Reassurance (3 items, $\alpha=.75$, “I go to the hospital or clinic for an examination”), as well as a total FCR score (Simard & Savard, 2009). The total FCR score ranges from 0-168, with higher scores indicating greater FCR. Based on a study of mixed cancer patients ($n=600$), a score of 13 or greater on the nine-item severity subscale (range 0–36) was found to reliably identify respondents who experience a clinical level of FCR (Simard & Savard, 2009). The total FCR score has demonstrated excellent internal consistency ($\alpha=0.95$; Simard & Savard, 2009), and temporal stability (test-retest=0.89; Thewes et al., 2012). The concurrent validity of the FCRI has been supported by positive correlations with other measures of FCR and cancer-related symptoms (Simard & Savard, 2009). In the current study, Cronbach’s alpha for the FCRI at T1 was $\alpha=0.95$.

Secondary outcome measures. The *Impact of Events Scale* (IES; Horowitz et al., 1979) was used to measure cancer-specific distress. It is a 15-item scale that measures the frequency of intrusive and avoidant thoughts associated with cancer. The IES uses a 4-point Likert scale,

ranging from 1 (Not at all) to 4 (Often). The IES has two subscales: Intrusion (9 items, $\alpha=.78$, “I had waves of strong feelings about it”), and Avoidance (11 items, $\alpha=.82$, “I stayed away from things or situations that might remind me of it”). Items have been modified to reflect participants’ cancer experience (i.e., “I had waves of strong feelings about my cancer experience; “I stayed away from reminders of my cancer experience”). Scores on the IES range from 0 to 75. The scale has good internal consistency ($\alpha=0.84- 0.91$), and good test-retest reliability (Total $r=0.87$; Horowitz et al., 1979). In the current study, Cronbach’s alpha for the IES at T1 was $\alpha=0.74$.

The *SF-8 Health Survey* (Ware, Kosinski, Dewey, & Gandek, 2001) was used to measure health-related quality of life. The SF-8 is an 8-item health-related quality of life measure that provides an assessment of eight domains within a four-week recall period. The SF-8 utilizes a six-point Likert scale. For the purposes of this study, two domains will be assessed in this questionnaire: General physical health (Physical Component Summary; items 1-5 addressing general health, physical functioning, physical role limitation, bodily pain, vitality; “Overall, how would you rate your health during the past 4 weeks?”) and mental health (Mental Component Summary; items 6-8; social functioning, mental health, emotional role limitation; “During the past 4 weeks, how much have you been bothered by emotional problems (such as feeling anxious, depressed or irritable?”; Roberts, Browne, Ocaka, Oyok, & Sondorp, 2008). Each SF-8 item was weighted using norm-based scoring methods in the instrument guidelines. Scores above and below 50 are considered above and below the average general U.S. population. In the current study, Cronbach’s α for the PCS summary score at T1 was $\alpha=0.74$, and $\alpha=0.86$ for the MCS summary score. These items are referred to as “physical health” and “mental health” quality of life when reported in the findings.

The *Intolerance of Uncertainty Scale* (IUS; original French version: Freeston, Rheaume, Letarte, Dugas, & Ladouceur, 1994, English version: Buhr & Dugas, 2002) was used to measure uncertainty. The IUS is a 27-item self-report measure that assesses individuals' beliefs about uncertainty. The IUS uses a five-point Likert scale, ranging from 1 (Not at all characteristic of me) to 5 (Entirely characteristic of me). Sample items include: "Uncertainty stops me from having a firm opinion"; "It's unfair not having any guarantees in life"). The IUS has excellent internal consistency ($\alpha=.94$), acceptable test-retest reliability over a five-week period ($r=.78$), and convergent and divergent validity when assessed with measures of depression, anxiety, and worry (Buhr & Dugas, 2002; Dugas, Freestone, & Ladouceur, 1997). In the current study, the alpha for the IUS at T1 was $\alpha=0.96$.

The *Mishel Uncertainty in Illness Scale – Community form* (MUIS; Mishel, 1981) was also used to measure uncertainty. The MUIS is a 23-item self-report measure that examines uncertainty in relation to diagnosis, treatment, and planning for the future in patients with cancer (Mishel, 1981). Responses are rated on a five-point Likert scale, ranging from 1 (Strongly disagree) to 5 (Strongly agree). There are two factors in the MUIS, including multi-attributed ambiguity and unpredictability. Sample items include: "I am unsure if my illness is getting better or worse"; "My symptoms continue to change unpredictably"; "Because of the unpredictability of my illness, I cannot plan for the future." Construct and convergent validity of the MUIS has been previously established (Mishel, 1988). In the current study, the alpha for the MUIS at T1 was $\alpha=0.76$.

The *Why do people Worry about Health* questionnaire (WW-H; Pelletier, Gosselin, Langlois & Ladouceur, 2002) was used to measure positive beliefs about the benefit of worry. Responses are rated on a five-point Likert scale, ranging from 1 (Not at all true) to 5 (Completely

true). Sample items include: “By worrying, I can better prevent illness”; “The fact that I worry shows that I take responsibility for my health.” The WW-H has excellent internal consistency ($\alpha=.90$), and satisfactory temporal stability ($r=.71$; Pelletier et al., 2002). In the current study, Cronbach’s alpha for the WW-H at T1 was 0.81.

The *Cognitive Avoidance Questionnaire* (CAQ; Sexton & Dugas, 2008) was used to measure coping (i.e., cognitive avoidance). The CAQ is a 25-item self-report measure that assesses the tendency to employ cognitive avoidance strategies when encountering intrusive thoughts. The CAQ uses a five-point Likert scale, ranging from 1 (Not at all typical) to 5 (Completely typical). Higher scores on the CAQ indicate a greater tendency to cognitively avoid threatening events (Sexton & Dugas, 2008). The CAQ contains five subscales: Thought Suppression ($\alpha=0.86$), Thought Substitution ($\alpha=0.73$), Distraction ($\alpha=0.89$), Avoidance of Threatening Stimuli ($\alpha=0.87$), and the Transformation of Images into Thoughts ($\alpha=0.87$). Sample items include, “There are things that I would rather not think about”, “I often do things to distract myself from my thoughts”, and “I avoid actions that remind me of the things I do not want to think about.” The CAQ has excellent internal consistency ($\alpha=0.95$), and good test-retest reliability ($r =0.85$). In the current study, Cronbach’s alpha for the CAQ at T1 was 0.93.

The *Reassurance Questionnaire* (RQ; Speckens, Spinoven, Van Hemert, & Bolk, 2000) was also used to measure coping (i.e., reassurance-seeking). The RQ is a 10-item self-report questionnaire that assesses the extent to which individuals feel reassured by their physician. The RQ uses a four-point Likert scale, ranging from 1 (Not at all) to 4 (Most of the time). Factor analysis yielded a one-factor solution. Sample items on the RQ include, “Do you feel reassured by a visit to your physician if you are worrying about your health?”; “Do you think the diagnosis made by your physician is incorrect?”; and “Do you think that your symptoms should be

investigated more extensively (laboratory tests, X-rays, etc.)?” Cronbach’s alpha across populations ranged from satisfactory to moderate to excellent ($\alpha=0.66-0.83$), and test-retest reliability across populations was excellent ($r=0.83-0.87$). In the current study, the alpha for the RQ at T1 was 0.76.

Coping was also measured using 3 subscales of the *Brief COPE* questionnaire (Carver, 1997): (1) positive reinterpretation and growth (“I look for something good in what is happening”); (2) use of emotional support (“I’ve been getting comfort and understanding from someone”); and (3) acceptance (“I’ve been accepting the reality of the fact that it has happened”), consisting of a total of 6 items. These subscales were selected based on the findings from Lebel et al.’s (2014) pilot study, as these particular subscales were those that demonstrated changes. In the current study, Cronbach’s alpha for the positive reinterpretation and growth subscale at T1 was 0.87. Cronbach’s alpha for the use of emotional support subscale at T1 was 0.80. Lastly, Cronbach’s alpha for the acceptance subscale at T1 was 0.78. Please see Appendix J for a copy of the questionnaire package.

Statistical Analyses

Statistical analyses were performed using SPSS version 23. Demographic characteristics of the participants were generated (i.e., means, standard deviations) and are presented in Table 1. A mixed between-within subjects analysis of variance (ANOVA) and repeated measures ANOVAs were carried out within the linear mixed models (LMM) component of SPSS. The LMM approach was utilized to account for an unequal number of evaluations at each time point, and thus, preserved more values (Garson, 2012). The between-within subjects ANOVA was conducted to compare the experimental group’s T1 (pre-intervention) and T2 (post-intervention) with the wait-list control groups T0 (baseline period) and T1 (pre-intervention), and to assess for

differences over time between both groups. Following this, repeated measures ANOVAs were carried out to assess changes in the means across all participants over time (T1 – pre-intervention; T2 – post-intervention; and T3 – 3-month follow-up). Lastly, within LMM, a mixed between-within subjects ANOVA design was also performed to identify any individual therapist differences across outcome measures over time.

Within LMM, there are many ways to model covariance across time. Of the different ways in which one could model covariance, Singer (1998) suggested using simple covariance structures, such as unstructured, autoregressive, and compound symmetry structures. To determine which covariance structure best described this dataset, the authors employed the Akaike Information Criterion (AIC) in SPSS. The AIC assessed which mathematical model was the best fit for these analyses (Singer, 1998). Following Singer's (1998) suggestion, the authors used the lowest reported AIC value, as the lower the AIC value, the better that structure is in describing a particular dataset. For the between-within analyses, the autoregressive covariance structure yielded the lowest AIC values across the different dependent variables (DVs). For the repeated measures analyses and therapist differences analyses, the compound symmetry covariance structure yielded the lowest AIC values across the DVs. The statistical results below are based on the respective covariance structures mentioned above.

Results

Participants

A total of 25 women were enrolled in the study, and of these, $n= 19$ were breast cancer survivors, $n= 5$ were gynecological cancer survivors, and $n=1$ was an ocular melanoma cancer survivor. Of the 25 women enrolled in the study, data were collected, retained and analyzed on $n=24$ participants (as 1 participant dropped out prior to completing any questionnaires). After

accounting for attrition and ineligibility, $n=19$ women completed the intervention (13 breast, 5 gynecological, 1 ocular melanoma). The majority of participants were diagnosed with stage III breast cancer, and were diagnosed on average 1.5 years prior to participation. The average age of participants was 55 years old (range 34 -74 years). The average participant was university educated, employed full-time, and married or cohabiting. Pre-existing/co-morbid Axis I diagnoses across participants included Major Depressive Episode (past and current), Post-Traumatic Stress Disorder, and Social Anxiety Disorder, as evidenced by the MINI screener (Sheehan & Lecrubier, 2006).

Changes in Outcome Measures

Significance. Given the exploratory nature of this research, a Bonferroni correction to the alpha level was not applied, in the interest of reducing the probability of Type II errors occurring.

Effect size. Using a technique described by Peugh (2010), to obtain the variance accounted for in LMM, predicted values were calculated in SPSS, and those predicted values were correlated for our models against the dependent variables. This resulted in a correlation that when squared, provided the variance accounted for (r^2). Specifically, r^2 was used as our measure of effect size.

Mixed between-within subjects ANOVAs. Out of the 9 outcome measures in the between-within analyses, 3 variables showed significant interactions: FCRI (fear of cancer recurrence), IES (cancer-specific distress), and MUIS (uncertainty in illness). A LMM analysis (comparable to a mixed between-within subjects ANOVA) was conducted to assess the impact of RCT group (experimental group or wait-list control) on participants' scores on the FCRI across two time periods (experimental group: pre-intervention and post-intervention; wait-list control: baseline period (+/- 6 weeks) and pre-intervention). There was a main effect for time, F

(1, 15.18) = 8.04, $p = .012$, $r^2 = 0.12$. There was no main effect for RCT group, $F(1, 21.50) = .027$, $p = .871$, $r^2 = 0.92$. The mean difference across time for the control group was not significant, $p = .638$. There was a significant interaction effect between RCT group and time, $F(1, 15.18) = 4.57$, $p = .049$, $r^2 = 0.12$. Tests of simple main effects revealed that the mean difference across time for the experimental group was significant at $p = .003$.

Scores on the IES revealed that the main effect for time was not significant, $F(1, 14.63) = 3.33$, $p = .089$, $r^2 = 0.01$. There was no main effect for RCT group, $F(1, 20.96) = 20.96$, $p = .332$, $r^2 = 0.03$. The mean difference across time for the control group was not significant, $p = .611$. There was a significant interaction effect between RCT group and time, $F(1, 14.63) = 6.05$, $p = .027$, $r^2 = 0.03$. Tests of simple main effects revealed that the mean difference across time for the experimental group was significant at $p = .016$.

Scores on the MUIS revealed there was a main effect for time, $F(1, 13.71) = 6.38$, $p = .025$, $r^2 = 0.04$. There was no main effect for RCT group, $F(1, 22.50) = 1.50$, $p = .234$, $r^2 = 0.03$. The mean difference across time for the control group was not significant, $p = .323$. There was a significant interaction effect between RCT group and time, $F(1, 13.71) = 14.91$, $p = .002$, $r^2 = 0.08$. Tests of simple main effects revealed that the mean difference across time for the experimental group was significant at $p = .001$. The effect sizes of the observed changes on the aforementioned outcome measures are considered to be small effects (Cohen, 1992).

The aforementioned findings indicate that the experimental group reported a decrease on these three outcomes, while the control group did not report such a change. Please see figures 3-5 for the FCRI, IES and MUIS graphs. Please see Table 2 for the between-within results for all 9 outcome measures. The between-within analyses results were not significant for the remaining outcome variables (quality of life (physical health), quality of life (mental health), cognitive

avoidance, intolerance of uncertainty, reassurance-seeking, worry, and the following coping subscales: positive reinterpretation and growth, use of emotional support and acceptance).

Graphs for non-significant findings are available upon request.

Repeated measures ANOVAs. For all study participants, the means and standard deviations of the primary and secondary outcome variables at baseline (T1), post-intervention (T2) and 3-month follow-up (T3) are displayed in Table 3. A LMM analysis (comparable to a repeated measures ANOVA) was conducted and revealed significant time effects for FCR, cancer-specific distress, uncertainty in illness, cognitive avoidance, reassurance-seeking, intolerance of uncertainty, quality of life (mental health), and the following coping subscales: positive reinterpretation and growth, and acceptance. The effect sizes of the observed changes ranged from 0.04 -0.34 (small to medium effects; Cohen, 1992). The variables that were maintained at T3 include FCR, cancer-specific distress, positive reinterpretation and growth, reassurance-seeking, and quality of life (mental health). The variables that improved at T3 include uncertainty in illness, cognitive avoidance, intolerance of uncertainty, and acceptance. Non-significant findings include use of emotional support, worry, and quality of life (physical health). The repeated measures ANOVA results for all 9 outcome measures can be found in Table 3. Please see figures 6-14 for the FCRI, IES, MUIS, CAQ, RQ, IUS, BRIEF COPE subscales and SF-8 graphs. Graphs for non-significant findings are available upon request.

Individual therapist differences. A LMM analysis (comparable to a mixed between-within subjects ANOVA design) was performed to evaluate any individual therapist differences across outcome measures over time (i.e., if there were any differences in outcome measures achieved by different therapists). There were no therapist effects detected, however, there was one interaction between therapist and time on the acceptance coping subscale of the BRIEF

COPE, $F(4, 29.18) = 3.17, p = .028$. This interaction effect suggests that the patterns across therapists on the acceptance coping subscale changed as a function of time. Otherwise, no significant interactions between therapist and time emerged on the remaining outcome measures. These results suggest that as a whole, all three therapists were applying the same standard of treatment, and seeing the same effect. Please see figure 15 for the BRIEF COPE acceptance graph outlining therapist differences. Graphs for non-significant findings are available upon request.

Discussion

The goal of this study was to test the preliminary effects of this individualized, manualized FCR intervention. This is one of the first pilot intervention trials aimed at the treatment of FCR. Based on the results from this study, it appears that the intervention can be helpful in decreasing FCR in female cancer survivors. Hypothesis 1 was supported, in that participants assigned to the experimental group did have lower scores on the primary outcome measure of FCR after treatment than did participants in the wait-list control group. Hypothesis 2a was partially supported, in that participants in the experimental group had lower scores on secondary outcome measures of cancer-specific distress and uncertainty in illness than did participants in the wait-list control group, but not for intolerance of uncertainty, cognitive avoidance, reassurance-seeking and worry. Hypothesis 2b was not supported, as participants in the experimental group did not show improvements on coping subscales of positive reinterpretation and growth, acceptance coping, use of emotional support, and quality of life (physical health and mental health) as compared to participants in the wait-list control group. Hypothesis 3 was supported, in that all participants had lower scores on the primary outcome measure of FCR after treatment, and these effects were maintained at 3-month follow-up.

Hypothesis 4a was partially supported, in that participants had lower scores on cancer-specific distress, uncertainty in illness, cognitive avoidance, intolerance of uncertainty and reassurance-seeking, but not for worry. Hypothesis 4b was partially supported, in that participants showed improvements on quality of life (mental health), and coping subscales of positive reinterpretation and growth and acceptance coping, but not for use of emotional support and quality of life (physical health). The variables that changed either maintained or improved at the 3-month follow-up. Specifically, the variables that were maintained at T3 include FCR, cancer-specific distress, positive reinterpretation and growth, reassurance-seeking and quality of life (mental health). The variables that improved at T3 include uncertainty in illness, cognitive avoidance, intolerance of uncertainty, and acceptance. Overall, these findings provide evidence that the changes immediately observed from pre- to post-therapy are not just a result of the passage of time or other external events, but are indicative of the effects of the intervention, which appear to last, or improve, at least up to 3 months post-completion. The absence of a comparison group at the 3-month follow-up makes the maintenance of therapy gains tentative.

Results from this study generally indicate consistency across the theoretical models that guided this intervention. In line with Leventhal's Common Sense Model (Lee-Jones et al., 1997; Leventhal et al., 1992), significant reductions were found in FCR and coping subscales of positive reinterpretation and acceptance. However, the emotional support coping subscale was found to be non-significant. This may be due to participants feeling alone in their cancer journey, as feeling alone has been found to be a potential clinical feature of FCR (Mutsaers et al., 2016). Future interventions could address these beliefs and help patients increase their social supports. Consistent with the Uncertainty in Illness theory (Mishel, 1981), results indicated that there were significant reductions in illness uncertainty across participants over time. However, as the

relationship between change in FCR and illness uncertainty was not formally measured, further testing of the relationship between these two constructs is necessary. Consistent with cognitive models of worry (Dugas et al., 1998; Ladouceur et al., 2000; Langlois et al., 2004), results showed significant reductions in intolerance of uncertainty and cognitive avoidance. Contrary to our expectations, worry did not significantly decrease over time. One consideration is the possibility of one's predisposition to worry and anxiety. Given that all of the participants initially scored in the clinically high range for FCR (i.e., a form of anxiety), it is possible that these individuals may have a more anxious predisposition as compared to individuals who have low levels of FCR. Future studies could utilize different outcome measures to further examine worry and anxiety. For example, the State-Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983) measures anxiety as it relates to a specific element (i.e., state anxiety) and also longstanding anxiety consistent with one's predisposition (i.e., trait anxiety). Thus, the STAI may be a good tool to measure an individual's predisposition to worry and anxiety (J. Grenier, personal communication). Future intervention studies could focus on incorporating additional worry-based strategies, such as operationalizing the concept of worry to patients and increasing worry-targeted techniques.

In terms of feasibility, it does appear that this intervention is feasible. Over the course of 6 months, 25 study participants were successfully recruited. As previously mentioned, of these 25 participants, a total of 19 participants successfully completed the intervention (76%). Four of the 25 participants were deemed ineligible to continue participation (due to unsuitability or cancer recurrences), one participant could not be reached after enrolment, and one participant dropped out very early in the intervention due to time restraints (after session 2), resulting in one true dropout. Therefore, based on the number of individuals who completed the intervention, one

can infer that the intervention appealed to the majority of participants.

Limitations

While this intervention poses a unique contribution to research, there are limitations to this study. Primarily, this is a pilot RCT with a small sample size, which limits the generalizability of the findings. More specifically, the results are only representative of the participants in this study, and may not represent the opinions of future participants. Furthermore, this intervention was only tested on female patients with specific cancers, further limiting the applicability of the findings. Larger RCTs are necessary to continue establishing the efficacy of this intervention, particularly using a broader oncology population that includes males and individuals with different forms of cancer. If further studies replicate these findings, it will demonstrate broad intervention applicability.

As previously noted, the alpha level was not adjusted due to the exploratory nature of this study, indicating that these results should be interpreted with caution. These interesting research findings may be suggestive of future investigation in larger studies.

The original study timeline was significantly reduced due to unanticipated job restructuring. As a result of this change, the original 6-week waitlist for the control group was reduced to a 2-6 week waitlist, therefore compromising the initial study design. While this unanticipated change affected certain aspects of this study, efforts were made to ensure that participants assigned to the control group waited as long as possible before receiving the intervention. Of the participants assigned to the control group, $n=5$ waited 6 weeks, $n=2$ waited 5 weeks, $n=1$ waited 4 weeks, and $n=2$ waited 2 weeks. Thus, half of the control group participants were assigned to the originally intended 6-week waitlist.

Another limitation of the study is that some participants did not complete all timepoint evaluations. However, we retained data on all of the participants for our analyses, including participants who completed the intervention, who experienced recurrences, etc. Multiple efforts were made to follow-up with participants to request completion of questionnaires. Thus, future research should focus on an alternate strategy for successfully acquiring participant data.

Another noted limitation is the absence of a control group for the follow-up results at the 3-month time point. For ethical and practical reasons (i.e., retention of participants and completing the study in a timely manner), we limited the between comparisons to T1 and T2 only, and did not include T3.

The efficacy of this intervention may be partially explained by participants having had high levels of FCR and cancer-specific distress. At the present time, it is not known if the intervention would be appropriate, or as effective, in reducing FCR if individuals have lower levels of FCR and cancer-specific distress.

Future Directions

Results from this study suggest that it is possible to help cancer survivors manage their FCR. The steady recruitment rate and low dropout rate may also suggest participants' interest and motivation to complete the intervention. Interestingly, the recruitment and dropout rates for this study (the individual treatment modality) are different as compared from those found in Lebel et al.'s (2014) pilot study (the group treatment modality). In Lebel et al.'s (2014) study, recruitment of the 56 participants took 2 years (versus this study's recruitment rate of 6 months), and there was a 21% drop out rate (versus this study's dropout rate of 0.04%). This poses the question of whether the individual version of the intervention is perceived differently, or, is perhaps considered to be more acceptable, or less threatening, by participants than the group

version. Certainly, clinical experience suggests that female patients often decline group therapy for fear of being distressed by other patients' experiences and psychological distress (M. Lefebvre, personal communication). Furthermore, one of the benefits of the individual therapy is the flexibility in scheduling sessions. While the group therapy occurred at a specific day and time each week, participants in the individual intervention were able to select their preferred time and day for each weekly session. It is possible that the differences in recruitment rates and attrition rates across the group and individual interventions may in part be due to scheduling factors, as half of the participants who were considered dropouts in Lebel et al.'s (2014) study cited scheduling conflicts (i.e., needing to miss more than the one weekly session that the protocol allowed). A future study could compare the feasibility, acceptability and efficacy of the group intervention versus the individual intervention, to determine if the treatments are comparably effective, and for whom. Another approach would be to conceptualize the study by treatment preferences – to identify patient attributes that may influence engagement in treatment, adherence to treatment, and outcome achievement (Sidani & Braden, 2011).

This is the first FCR-related intervention to be validated in more than one therapeutic modality. As both group and individual modalities appear to be effective, this should encourage research offering both group and individual interventions targeting this phenomenon. Future research should also continue investigating the specific therapeutic ingredients that are most effective for the psychological treatment of FCR. Future studies could also examine whether cognitive techniques (e.g., targeting distorted thinking, cognitive restructuring), existential techniques (e.g., focusing on meaning, loss and identity and on promoting the experience of emotional expression of specific fears, processing one's worst-case scenario), and/or relaxation techniques (e.g., progressive muscular relaxation, calming self-talk phrases) are most helpful in

decreasing FCR.

Future studies building on this research may also consider the inclusion of a qualitative data component, in order to further supplement the findings from the existing quantitative data. Including a qualitative aspect could enable the identification of specific themes or elements, in order to help further interpret the quantitative data obtained (J. Grenier, personal communication). Future research could examine the existence of any themes or elements within the course of therapy that could account for individuals who did not benefit as much, or, whose worries were particularly challenging to overcome. For example, worries or concerns expressed by participants may fit under various themes, such as “body image”, “loss”, “sexuality”, “leaving family behind”, etc. (J. Grenier, personal communication). In research efforts as such, it would be prudent to assess if certain specific themes underlying the worry have a bigger impact than the actual “act” of engaging in worry. Thus, the utilization of a mixed-methods approach would undoubtedly add richness and comprehensiveness to this existing study, in an effort to further understand both the construct of FCR and the experience of study participants.

Clinical Implications

This individualized intervention has direct clinical implications for survivors living with FCR. This intervention can help cancer survivors reduce FCR and psychological distress through gentle confrontation of fear, loss and meaning, and through the use of adaptive coping strategies, such as cognitive reframing and planning for the future. Furthermore, this intervention can help participants replace existing maladaptive coping behaviours (i.e., avoidance and reassurance-seeking) with authentic connection, as well as helpful and realistic tools moving forward, therefore enhancing quality of life.

The results from this pilot RCT may continue to inform intervention efforts targeting

FCR. At the present time, several RCTs are underway to address FCR-related interventions, which may ultimately lead to evidence-based guidelines on how to manage FCR. Presently, it appears that oncology-related specialists refer only 21% of patients with high FCR for psychosocial services (Thewes et al., 2014), despite the high prevalence of FCR-related suffering. This finding clearly illustrates how these psychological services can be helpful to a wider population. Furthermore, a standard method for screening patients with FCR would be a helpful addition to current assessments within oncological-medical settings. Cost-efficacy studies should be conducted in the near future, as there is increasing evidence that these FCR interventions are effective and well received by patients, with potential benefit to the healthcare system as well as patients and loved ones.

References

- Baker, F., Denniston, M., Smith, T., & West, M. (2005). Adult cancer survivors: How are they faring? *Cancer, 104*(11), 2565-2576. doi: 10.1002/cncr.21488
- Buhr, K., & Dugas, M. J. (2002). The intolerance of uncertainty scale: psychometric properties of the English version. *Behaviour Research and Therapy, 40*, 931-945. doi: [http://dx.doi.org/10.1016/S0005-7967\(01\)00092-4](http://dx.doi.org/10.1016/S0005-7967(01)00092-4)
- Carlson, L. E., Tamagawa, R., Stephen, J., Doll, R., Faris, P., Dirkse, D., & Speca, M. (2014). Tailoring mind-body therapies to individual needs: patients' program preference and psychological traits as moderators of the effects of mindfulness-based cancer recovery and supportive-expressive therapy in distressed breast cancer survivors. *Journal of the National Cancer Institute Monographs, 50*, 308-314. doi: 10.1093/jncimonographs/lgu034
- Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the brief cope. *International Journal of Behavioral Medicine, 4*(1), 92-100.
- Cohen, J. (1992). A power primer. *Psychological Bulletin, 112*(1), 155.
- Dugas, M. J., Freeston, M. H., & Ladouceur, R. (1997). Intolerance of uncertainty and problem orientation in worry. *Cognitive Therapy and Research, 21*(6), 593-606. doi: 10.1023/A:1021890322153
- Dugas, M. J., Gagnon, F., Ladouceur, R., & Freeston, M. H. (1998). Generalized anxiety disorder: A preliminary test of a conceptual model. *Behaviour research and therapy, 36*(2), 215-226. Retrieved from www.ncbi.nlm.nih.gov/pubmed/9613027

- Freeston, M. H., Rheaume, J., Letarte, H., Dugas, M. J., & Ladouceur, R. (1994). Why do people worry? *Personality and Individual Differences*, *17*, 791–802. doi: 10.1016/0191-8869(94)90048-5
- Glynn-Jones, R., Chait, I., & Thomas, F. (1997). When and how to discharge cancer survivors in long term remission from follow-up: The effectiveness of a contract. *Clinical Oncology*, *9*, 25-9. Retrieved from:
<http://www.sciencedirect.com/science/article/pii/S0936655597800556>
- Hart, S. L., Latini, D. M., Cowan, J. E., & Carroll, P. R. (2008). Fear of recurrence, treatment satisfaction, and quality of life after radical prostatectomy for prostate cancer. *Supportive Care in Cancer*, *16*(2), 161-169.
- Herschbach, P., Berg, P., Waadt, S., Duran, G., Engst-Hastreiter, U., Henrich, G., ...Dinkel, A. (2010). Group psychotherapy of dysfunctional fear of progression in patients with chronic arthritis or cancer. *Psychotherapy and Psychosomatics*, *79*(1), 31-38. doi: 10.1159/000254903
- Horowitz, M., Wilner, N., & Alvarez, W. (1979). Impact of events scale: a measure of subjective stress. *Psychosomatic Medicine*, *41*(3), 209-218. doi: 10.1192/bjp.180.3.205
- Humphris, G. & Ozakinci, G. (2008). The AFTER intervention: a structured psychological approach to reduce fears of recurrence in patients with head and neck cancer. *British Journal of Health Psychology* *13*, 223-230. doi: 10.1348/135910708X283751
- Kim, Y., Carver, C. S., Spillers, R. L., Love-Ghaffari, M., & Kaw, C. K. (2012). Dyadic effects of fear of recurrence on the quality of life of cancer survivors and their caregivers. *Quality of Life Research*, *21*(3), 517-525.

- Kissane, D. W., Bloch S., Miach, P., Smith, G. C., Seddon, A., & Keks, N. (2003). Cognitive-existential group psychotherapy for women with primary breast cancer: A randomised controlled trial. *Psycho-Oncology*, *12*(6), 532-546. doi: 10.1002/pon.1280
- Ladouceur, R., Dugas, M. J., Freeston, M. H., Léger E., Gagnon F., & Thibodeau N. (2000). Efficacy of a cognitive-behavioral treatment for generalized anxiety disorder: Evaluation in a controlled clinical trial. *Journal of Consulting and Clinical Psychology*, *68*(6), 957-964. doi: 0.1037/0022-006X.68.6.957
- Langlois, F., Ladouceur, R., Patrick, G., & Freeston, M. H. (2004). Characteristics of illness intrusions in a non-clinical sample. *Behavior Research and Therapy*, *42*, 683-696. doi: 10.1016/S0005-7967(03)00191-8
- Lebel, S., Beattie, S., Ares, I., & Bielajew, C. (2013). Young and worried: age and fear of recurrence among breast cancer survivors. *Health Psychology*, *32*(6), 695-705. doi: 10.1037/a0030186
- Lebel, S. & Maheu, C. (2009). *Development of a cognitive-existential intervention to address fear of cancer recurrence in women with cancer*. Unpublished manuscript, Department of Psychology, University of Ottawa, Ottawa, Canada.
- Lebel, S., Maheu, C., Lefebvre, M., Secord, S., Courbasson, C., Singh, M., . . . Catton, P. (2014). Addressing fear of cancer recurrence among women with cancer: A feasibility and preliminary outcome study. *Journal of Cancer Survivorship*, *8*, 485-496. doi: 10.1007/s11764-014-0357-3
- Lebel, S., Ozakinci, G., Humphris, G., Thewes, B., Prins, J., Dinkel, A., . . . Butow, P. (2016). Current state and future prospects of research on fear of cancer recurrence. *Psycho-Oncology*. doi: 10.1002/pon.4103

- Lebel, S., Rosberger, Z., Edgar, L., & Devins, G. M. (2007). Comparison of four common stressors across the breast cancer trajectory. *Journal of Psychosomatic Research, 63*, 225-232. doi: 10.1016/j.jpsychores.2007.02.002
- Lebel, S., Tomei, C., Feldstain, A., Beattie, S., & McCallum, M. (2013). Does fear of cancer recurrence predict cancer survivors' health care use? *Supportive Care in Cancer, 21*(3), 901-906. doi: 10.1007/s00520-012-1685-3
- Lee-Jones, C., Humphris, G., Dixon, R., & Hatcher, M. B. (1997). Fear of cancer recurrence – A literature review and proposed cognitive formulation to explain exacerbation of recurrence fears. *Psycho-Oncology, 6*(2), 95-105. Retrieved from: [http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1099-1611](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1099-1611)
- Leventhal, H., Diefenbach, M., & Leventhal, E. A. (1992). Illness cognition: using common sense to understand treatment adherence and affect cognition interactions. *Cognitive Therapy and Research, 16*(2), 143-163. doi: 10.1007/BF01173486
- Llewellyn, C. D., Weinman, J., McGurk, M., & Humphris, G. (2008). Can we predict which head and neck cancer survivors develop fears of recurrence? *Journal of Psychosomatic Research, 65*, 525-532. doi: <http://dx.doi.org/10.1016/j.jpsychores.2008.03.014>
- Mishel, M. H. (1981). The measurement of uncertainty in illness. *Nursing Research, 30*(5), 258-63. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/6912987>
- Mishel, M. H. (1988). Uncertainty in illness. *Journal of Nursing Scholarship, 20*, 225-231. doi: 10.1111/j.1547-5069.1988.tb00082.

- Mutsaers, B., Jones, G., Rutkowski, N., Tomei, C., Leclair, C. S., Petricone-Westwood, D., ... & Lebel, S. (2016). When fear of cancer recurrence becomes a clinical issue: a qualitative analysis of features associated with clinical fear of cancer recurrence. *Supportive Care in Cancer*, 24(10), 4207-4218. doi: 10.1007/s00520-016-3248-5
- Muzzin, L. J., Anderson, N. J., Figueredo, A. T., & Gudelis, S. O. (1994). The experience of cancer. *Social Science and Medicine*, 38, 1201–1208. doi: 10.1016/0277-9536(94)901856
- Northouse, L. L. (1981). Mastectomy patients and the fear of cancer recurrence. *Cancer Nursing*, 4(3), 213-220. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/6909039>
- Osborn, R. L., Demoncada, A. C., & Feuerstein, M. (2006). Psychosocial interventions for depression, anxiety, and quality of life in cancer survivors: meta-analyses. *The International Journal of Psychiatry in Medicine*, 36(1), 13-34. doi: 10.2190/EUFN-RV1K-Y3TR-FK0L
- Pelletier, O., Gosselin, P., Langlois, F., & Ladouceur, R. (2001). Study of psychometric properties of two new questionnaires assessing beliefs in hypochondriasis in a non-clinical population. *L'Encephale*, 28(4), 298-309.
- Peugh, J. L. (2010). A practical guide to multilevel modeling. *Journal of School Psychology*, 48(1), 85-112.
- Roberts, B., Browne, J., Ocaka, K. F., Oyok, T., & Sondorp, E. (2008). The reliability and validity of the SF-8 with a conflict-affected population in northern Uganda. *Health and Quality of Life Outcomes*, 6(1), 108. doi: 10.1186/1477-7525-6-108
- Savard, J., & Ivers, H. (2013). The evolution of fear of cancer recurrence during the cancer care trajectory and its relationship with cancer characteristics. *Journal of Psychosomatic Research*, 74, 354-360. doi: <http://dx.doi.org/10.1016/j.jpsychores.2012.12.013>

- Sheehan, D., & Lecrubier, Y. (2006). Mini-international neuropsychiatric interview (M.I.N.I.).5.0.0.c. Swedish version.
- Sexton, K. A., & Dugas, M. J. (2008). The Cognitive Avoidance Questionnaire: Validation of the English translation. *Journal of Anxiety Disorders, 22*, 355-370. doi: 10.1016/j.bbr.2011.03.031
- Sidani, S., & Braden, C. J. (2011). *Design, evaluation, and translation of nursing interventions*. John Wiley & Sons.
- Simard, S., Thewes, B., Humphris, G., Dixon, M., Hayden, C., Mireskandari, S., & Ozakinci, G. (2013). Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *Journal of Cancer Survivorship, 7*(3), 300-22. doi: 10.1007/s11764-013-0272-z.
- Simard, S., & Savard, J. (2009). Fear of cancer recurrence inventory: Development and initial validation of a multidimensional measure of fear of recurrence. *Supportive Care in Cancer, 17*(3), 241-251. doi: 10.1007/s00520-008-0444-y
- Singer, J. D. (1998). Using SAS PROC MIXED to fit multilevel models, hierarchical models, and individual growth models. *Journal of Educational and Behavioral Statistics, 23*(4), 323-355.
- Speckens, A. E. M., Spinhoven, P., Van Hemert, A. M., & Bolk, J. H. (2000). The reassurance questionnaire (RQ): Psychometric properties of a self-report questionnaire to assess reassurability. *Psychological Medicine, 30*, 841-847. Retrieved from: <http://www.ncbi.nlm.nih.gov/pubmed/11037092>
- Spielberger, C. D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A. (1983). *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press.

- Thewes, B., Brebach, R., Dzikowska, M., Rhodes, P., Sharpe, L. & Butow, P. (2014). Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. *Psycho-Oncology*, *23*, 390-396. doi: 10.1002/pon.3423
- Thewes, B., Butow, P., Bell, M. L., Beith, J., Stuart-Harris, R., Grossi, M., . . . Dalley, D. (2012). Fear of cancer recurrence in young women with a history of early-stage breast cancer: A cross-sectional study of prevalence and association with health behaviours. *Supportive Care in Cancer*, *20*, 2651-2659. doi: 10.1007/s00520-011-1371-x
- Thewes, B., Butow, P., Zachariae, R., Christensen, S., Simard, S., & Gotay, C. (2012). Fear of cancer recurrence: A systematic literature review of self-report measures. *Psycho-Oncology*, *21*(6), 571-587. doi: 10.1002/pon.2070
- Urbaniak, G. C., & Plous, S. (2007). Research randomizer. Retrieved from <http://www.randomizer.org>
- Ware, J. E., Kosinski, M., Dewey, J. E., & Gandek, B. (2001). How to score and interpret single-item health status measures: a manual for users of the SF-8 health survey. *Lincoln, RI: QualityMetric*
- Wu, S. M., Brothers, B. M., Farrar, W., & Andersen, B. L. (2014). Individual counseling is the preferred treatment for depression in breast cancer survivors. *Journal of Psychosocial Oncology*, *32*(6), 637-646. doi: 10.1080/07347332.2014.955239



CONSORT

TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram

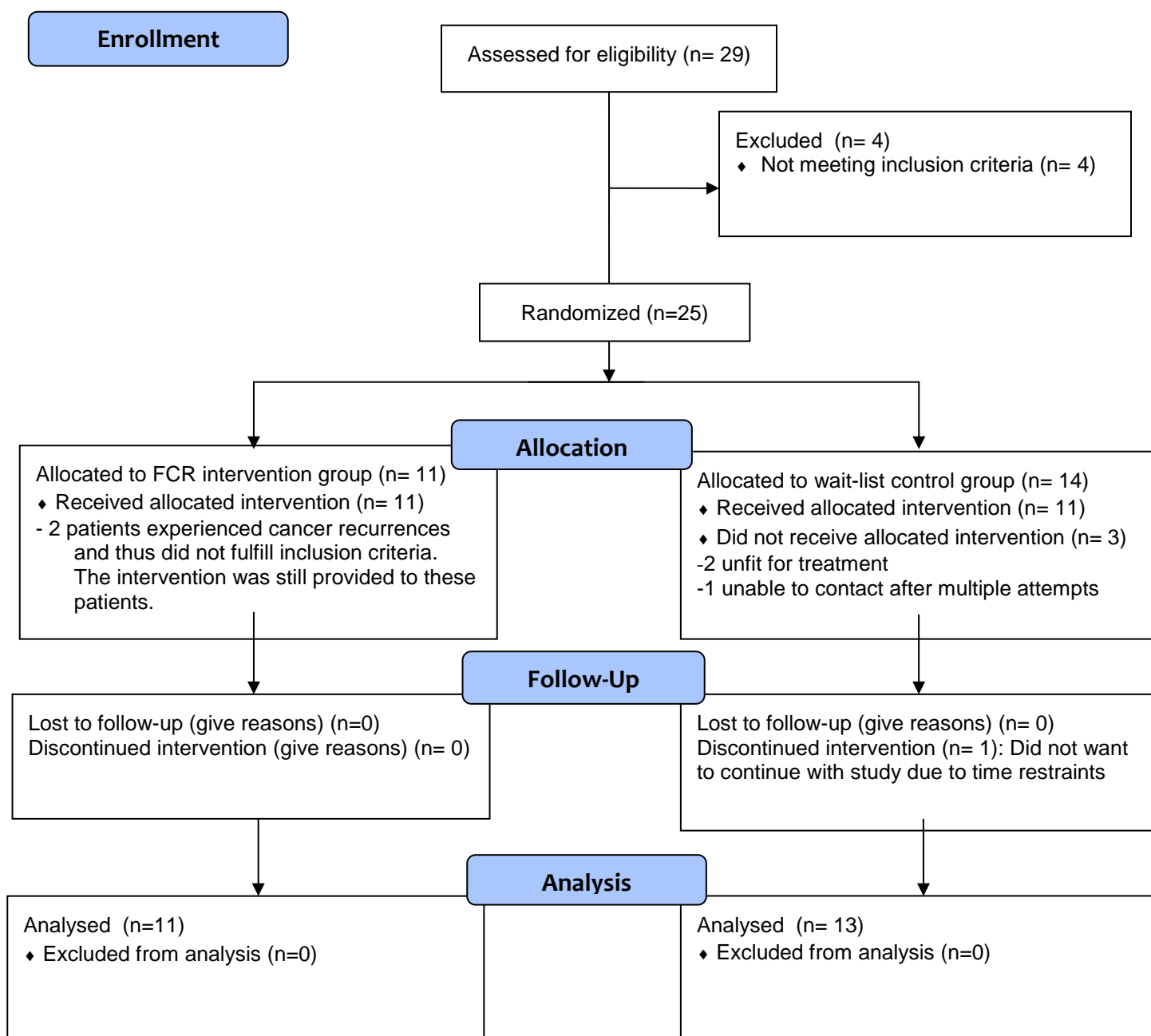


Figure 1. CONSORT flow diagram.

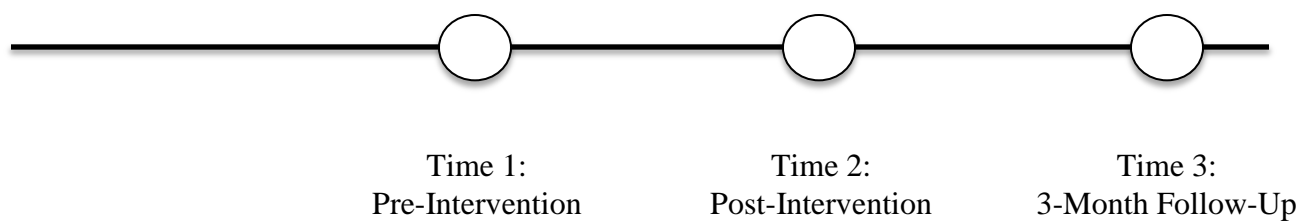
Experimental Group: 3 Time Points**Wait-list Control Group: 4 Time Points**

Figure 2. Summary of time points across experimental group and wait-list control group.

Table 1

Participant Characteristics, N=24

Variable	<i>M</i>	<i>SD</i>
Age (years)	55.0	10.76
Time since diagnosis (years)	1.54	1.53
	<i>n</i>	<i>%</i>
Primary ethnic background		
Caucasian	23	95.8
Asian	1	4.2
Civil status		
Married/Cohabiting	19	79.2
Divorced/separated	2	8.3
Widowed	3	12.5
Education		
High school or less	3	12.5
College or more	21	87.5
Occupation		
Employed full-time	10	41.7
Employed part-time	2	8.4
Unemployed	1	4.2
Unemployed due to illness	5	20.8
Retired	6	25.0
Income		
0 – 20,000	3	12.5
21 – 40,000	2	8.3
41 – 60,000	1	4.2
61 – 80,000	4	16.7
81 – 100,000	5	20.8
Over 100,000	9	37.5
Cancer stage		
Stage I	9	37.5
Stage II	2	8.3
Stage III	10	41.7
Not aware/missing	3	12.5
Primary cancer site		
Breast	18	75.0
Gynecological	5	20.8
Other (Ocular Melanoma)	1	4.2
Treatment regimen		
Surgery	4	16.7
Chemotherapy	1	4.2
Radiation therapy	1	4.2
Chemotherapy & Radiation	1	4.2
Chemotherapy & Surgery	2	8.3
Radiation & Surgery	4	16.7
Chemotherapy, Radiation & Surgery	11	45.8

Table 2

Mixed between-within ANOVA analyses comparing the experimental group's T1 (pre-intervention) and T2 (post-intervention) with the wait-list control groups T0 (baseline period) and T1 (pre-intervention)

Outcome Variable	Main Effect for Group	Main Effect for Time	Interaction Effect (RCT group x Time)	Simple Main Effects	Estimated Marginal Means
	<i>F</i> values, <i>p</i> values, and <i>r</i> ² values	<i>F</i> values, <i>p</i> values, and <i>r</i> ² values	<i>F</i> values, <i>p</i> values, and <i>r</i> ² values	<i>p</i> values	Time
FCRI (Range: 0-168)	<i>F</i> (1, 21.50) = .027, <i>p</i> = .871, <i>r</i> ² = 0.92	<i>F</i> (1, 15.18) = 8.04, <i>p</i> = .012*, <i>r</i> ² = 0.12	<i>F</i> (1, 15.18) = 4.57, <i>p</i> = .049*, <i>r</i> ² = 0.12	<i>p</i> = .003*	Experimental group: T1 (116), T2 (91) Wait-list control group: T0 (104), T1 (100)
IES (Range: 0-75)	<i>F</i> (1, 20.96) = 20.96 <i>p</i> = .332, <i>r</i> ² = 0.03	<i>F</i> (1, 14.63) = 3.33, <i>p</i> = .089, <i>r</i> ² = 0.01	<i>F</i> (1, 14.63) = 6.05, <i>p</i> = .027*, <i>r</i> ² = 0.03	<i>p</i> = .016*	Experimental group: T1 (41), T2 (30) Wait-list control group: T0 (40), T1 (42)
SF-8: Physical Health (Range: 9-69)	<i>F</i> (1, 22.47) = 3.30, <i>p</i> = .082	<i>F</i> (1, 14.61) = .380, <i>p</i> = .547	<i>F</i> (1, 14.61) = 2.13, <i>p</i> = .166	--	Experimental group: T1 (42), T2 (40) Wait-list control group: T0: (46), T1 (50)
SF-8: Mental Health (Range: 5-72)	<i>F</i> (1, 21.16) = .139, <i>p</i> = .713	<i>F</i> (1, 17.02) = 1.31, <i>p</i> = .268	<i>F</i> (1, 17.02) = 2.63, <i>p</i> = .123	--	Experimental group: T1 (34), T2 (41) Wait-list control group: T0: (37), T1 (36)
MUIS (Range: 1-165)	<i>F</i> (1, 22.50) = 1.50, <i>p</i> = .234, <i>r</i> ² = 0.03	<i>F</i> (1, 13.71) = 6.38, <i>p</i> = .025*, <i>r</i> ² = 0.04	<i>F</i> (1, 13.71) = 14.91, <i>p</i> = .002*, <i>r</i> ² = 0.08	<i>p</i> = .001*	Experimental group: T1 (93), T2 (80) Wait-list control group: T0: (91), T1 (94)
IUS (Range: 1-135)	<i>F</i> (1, 20.82) = .030, <i>p</i> = .864	<i>F</i> (1, 11.49) = .910, <i>p</i> = .360	<i>F</i> (1, 11.49) = .736, <i>p</i> = .409	--	Experimental group: T1 (86), T2 (79) Wait-list control group: T0: (84), T1 (84)
WW-H (Range: 1-65)	<i>F</i> (1, 20.76) = .494, <i>p</i> = .490	<i>F</i> (1, 16.81) = 1.21, <i>p</i> = .288	<i>F</i> (1, 16.81) = .159, <i>p</i> = .695	--	Experimental group: T1 (27), T2 (26) Wait-list control group: T0: (26), T1 (24)
CAQ (Range: 1-125)	<i>F</i> (1, 18.70) = .000, <i>p</i> = .997	<i>F</i> (1, 12.24) = 1.92, <i>p</i> = .191	<i>F</i> (1, 12.24) = .401, <i>p</i> = .538	--	Experimental group: T1 (72), T2 (63) Wait-list control group: T0: (69), T1 (66)
RQ (Range: 1-40)	<i>F</i> (1, 18.87) = .029, <i>p</i> = .867	<i>F</i> (1, 13.74) = .108, <i>p</i> = .747	<i>F</i> (1, 13.74) = .103, <i>p</i> = .753	--	Experimental group: T1 (26), T2 (26) Wait-list control group: T0: (25), T1 (26)
BRIEF COPE: Positive Reinterpretation (Range: 1-8)	<i>F</i> (1, 22.08) = 2.12, <i>p</i> = .159	<i>F</i> (1, 19.09) = .016, <i>p</i> = .899	<i>F</i> (1, 19.09) = 2.65, <i>p</i> = .120	--	Experimental group: T1 (5), T2 (6) Wait-list control group: T0: (5), T1 (4)
BRIEF COPE: Use of Emotional Support (Range: 1-8)	<i>F</i> (1, 20.82) = .001, <i>p</i> = .981	<i>F</i> (1, 20.69) = .298, <i>p</i> = .591	<i>F</i> (1, 20.69) = 1.74, <i>p</i> = .201	--	Experimental group: T1 (5), T2 (6) Wait-list control group: T0: (6), T1 (5)
BRIEF COPE: Acceptance (Range: 1-8)	<i>F</i> (1, 19.89) = 12.08 <i>p</i> = .002*, <i>r</i> ² = 0.29	<i>F</i> (1, 17.62) = .206, <i>p</i> = .655	<i>F</i> (1, 17.62) = 4.58, <i>p</i> = .507	--	Experimental group: T1 (7), T2 (6) Wait-list control group: T0: (5), T1 (5)

NB: * = Indicates significant differences at $p < 0.05$.

NB: r^2 values were calculated for variables that yielded significant findings.

Table 3

Repeated Measures ANOVA analyses examining psychological outcomes at baseline (T1), post-intervention (T2), and 3-month follow-up (T3): means, standard deviations, and effect size

Outcome Variable	Mean (SD)			N	F and p values	r ² values
	T1	T2	T3		Time	
FCRI (Range: 0-168)	108.68 (4.94)a	90.37 (5.24)b	82.03 (5.35)b	19	$F(2, 27.87)=15.82, p<0.001^*$	0.28
IES (Range: 0-75)	41.36 (3.09)a	28.91 (3.31)b	26.98 (3.31)b	20	$F(2, 28.68)=10.58, p<0.001^*$	0.21
SF-8: Physical Health (Range: 9-69)	47.45 (2.29)a	46.77 (2.61)a	46.89 (2.56)a	20	$F(2,27.93)=.052, p=.950$	NA
SF-8: Mental Health (Range: 5-72)	35.63 (1.95)a	43.94 (2.32)b	43.78 (2.26)b	20	$F(2, 28.72)=8.24, p<0.001^*$	0.18
MUIS (Range: 1-165)	93.048 (2.29)a	84.31 (2.58)b	76.65 (2.58)c	21	$F(2, 30.24)=21.46, p<0.001^*$	0.34
IUS (Range: 1-135)	83.93 (5.88)a	79.38 (6.05)ab	71.84 (5.99)b	20	$F(2,24.71)=5.43, p=.011^*$	0.04
WW-H (Range: 1-65)	25.45 (1.55)a	24.24 (1.67)a	23.30 (1.67)a	20	$F(2,31.34)=1.02, p=.371$	NA
CAQ (Range: 1-125)	67.86 (4.22)a	59.30 (4.54)ab	53.63 (4.54)b	20	$F(2, 29.01)=6.22, p=.006^*$	0.10
RQ (Range: 1-40)	26.49 (1.04)a	26.48 (1.12)a	23.57 (1.12)a	20	$F(2, 29.63)=3.92, p=.031^*$	0.10
BRIEF COPE: Positive Reinterpretation (Range: 1-8)	4.71 (.342)a	6.28 (.376)b	5.79 (.369)b	21	$F(2,32.71)=9.93, p<0.001^*$	0.17
BRIEF COPE: Use of Emotional Support (Range: 1-8)	5.29 (.354)a	6.13 (.398)a	5.60 (.388)a	21	$F(2, 32.92)=1.82, p=.178$	NA
BRIEF COPE: Acceptance (Range: 1-8)	5.86 (.304)a	6.47 (.338)ab	6.90 (.330)b	21	$F(2,33.66)=4.75, p=.015^*$	0.09

NB: * = Indicates significant differences at $p<0.05$.

NB: Within a row, values with different lowercase letters indicate significant differences at $p<0.05$.

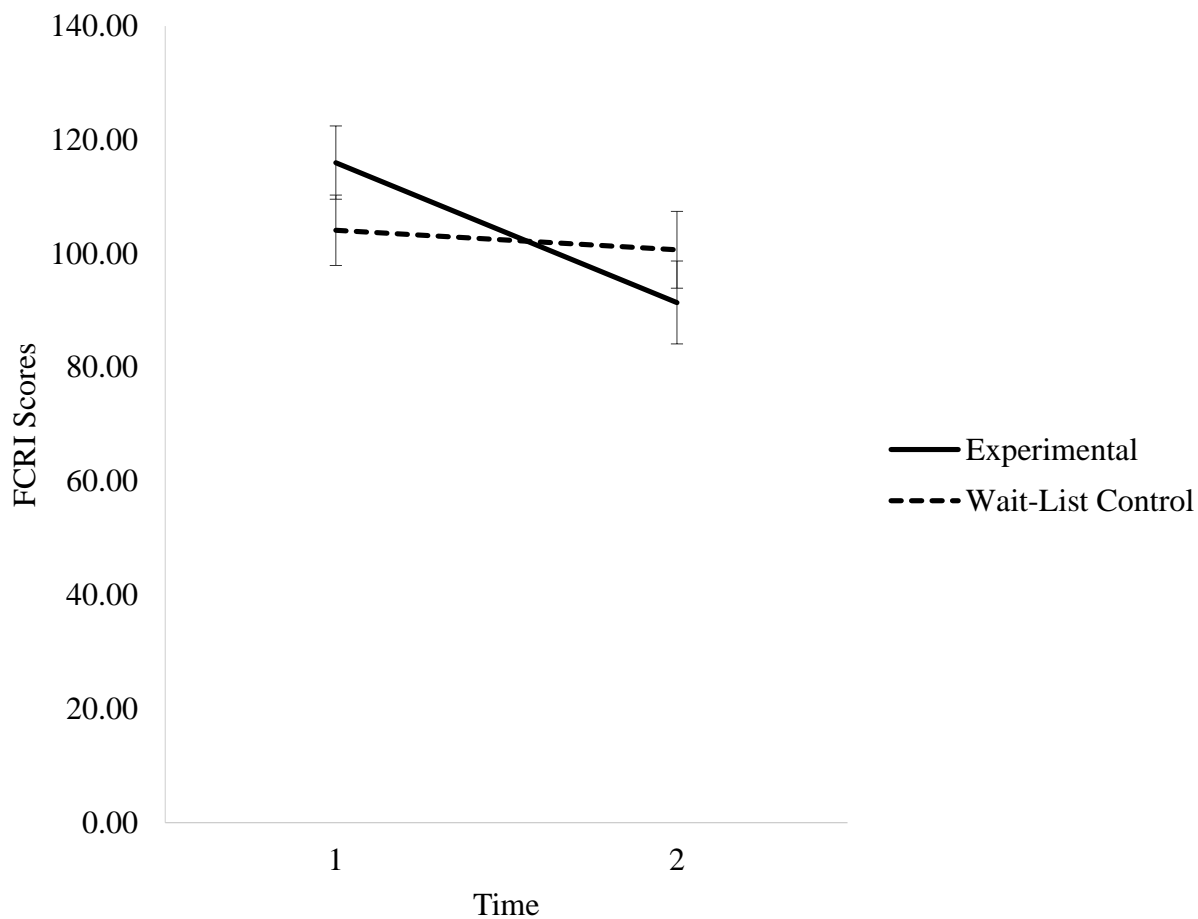


Figure 3. Between-within ANOVA findings for fear of cancer recurrence (FCRI) scores across therapy groups over time (Experimental group Time 1: Pre-intervention and Time 2: Post-intervention. Wait-list control group Time 1: Baseline 2-6 week waiting period and Time 2: pre-intervention).

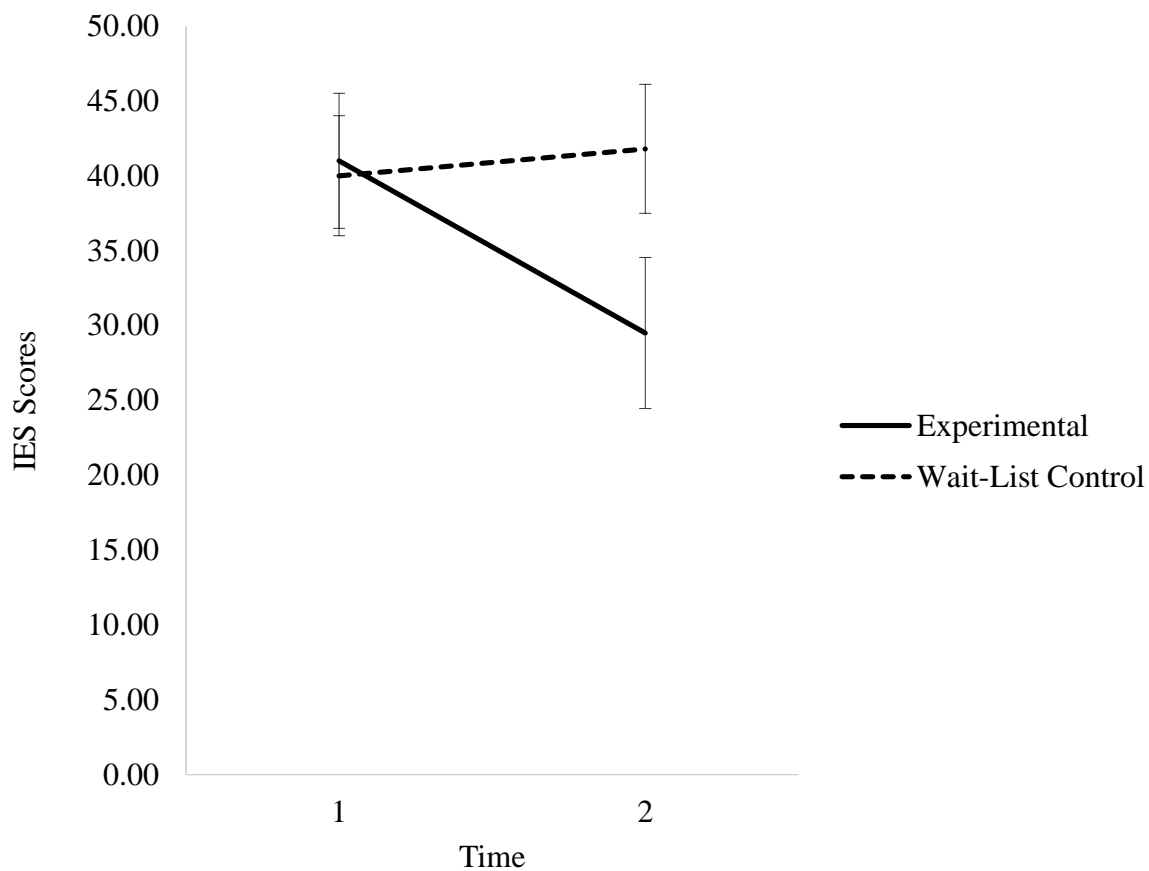


Figure 4. Between-within ANOVA findings for cancer-specific distress (IES) scores across therapy groups over time (Experimental group Time 1: Pre-intervention and Time 2: Post-intervention. Wait-list control group Time 1: Baseline 2-6 week waiting period and Time 2: pre-intervention).

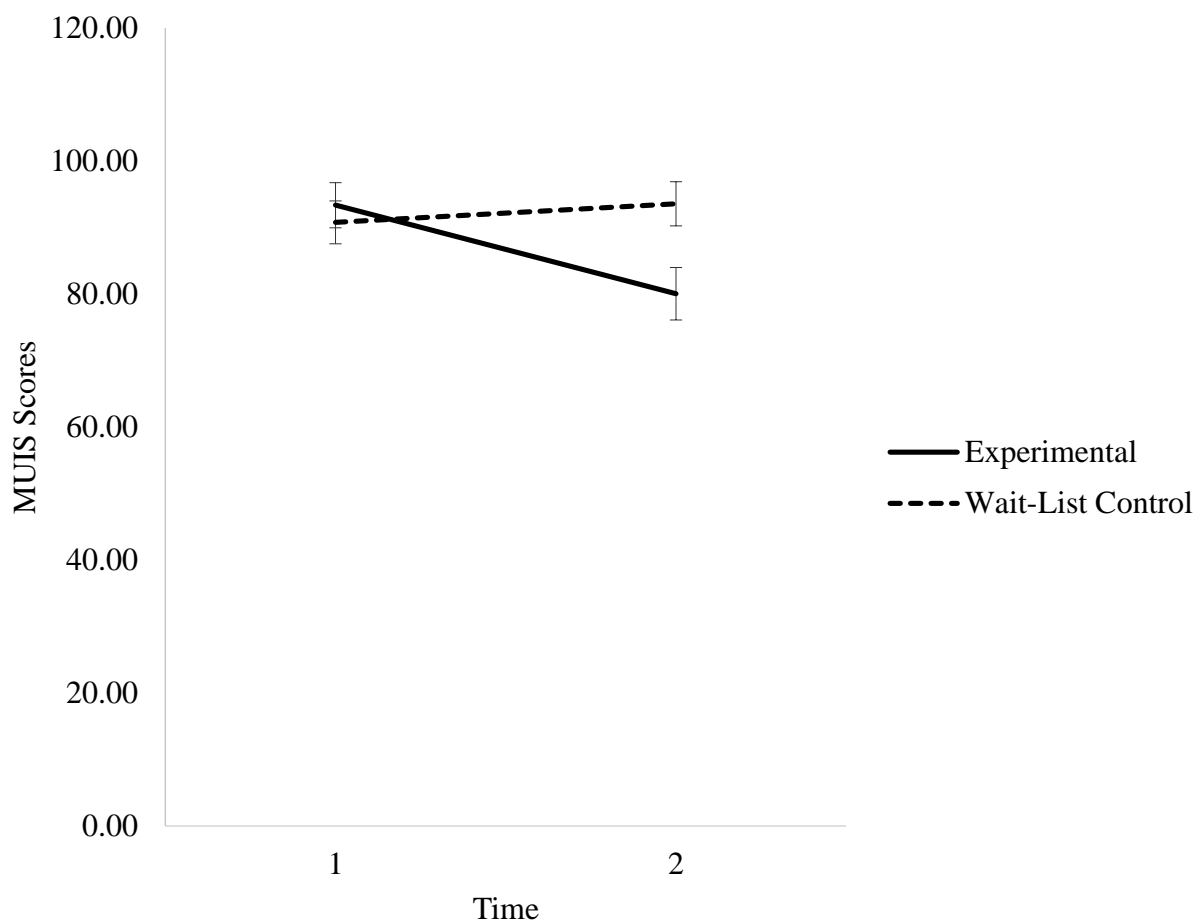


Figure 5. Between-within ANOVA findings for uncertainty in illness (MUIS) scores across therapy groups over time (Experimental group Time 1: Pre-intervention and Time 2: Post-intervention. Wait-list control group Time 1: Baseline 2-6 week waiting period and Time 2: pre-intervention).

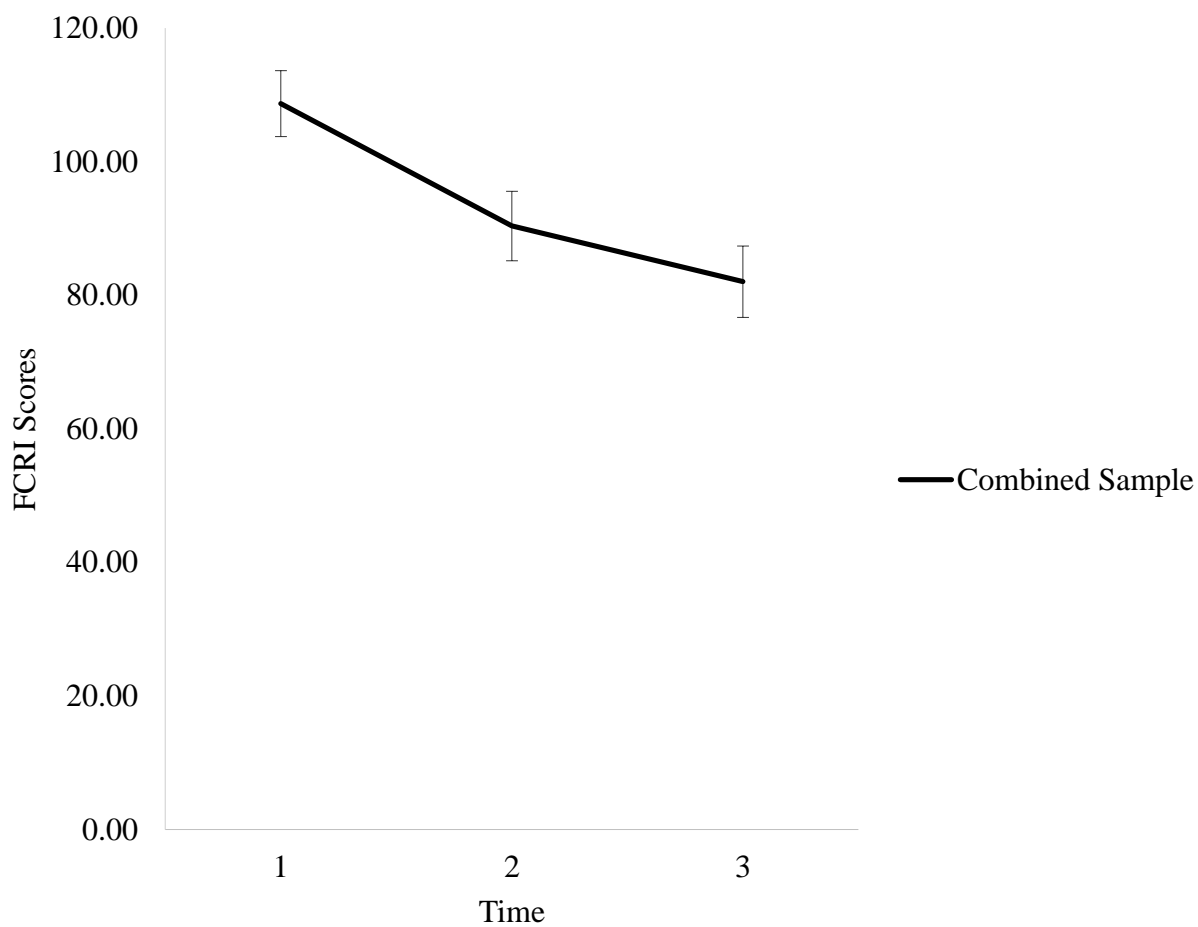


Figure 6. Repeated Measures ANOVA findings for fear of cancer recurrence (FCRI) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

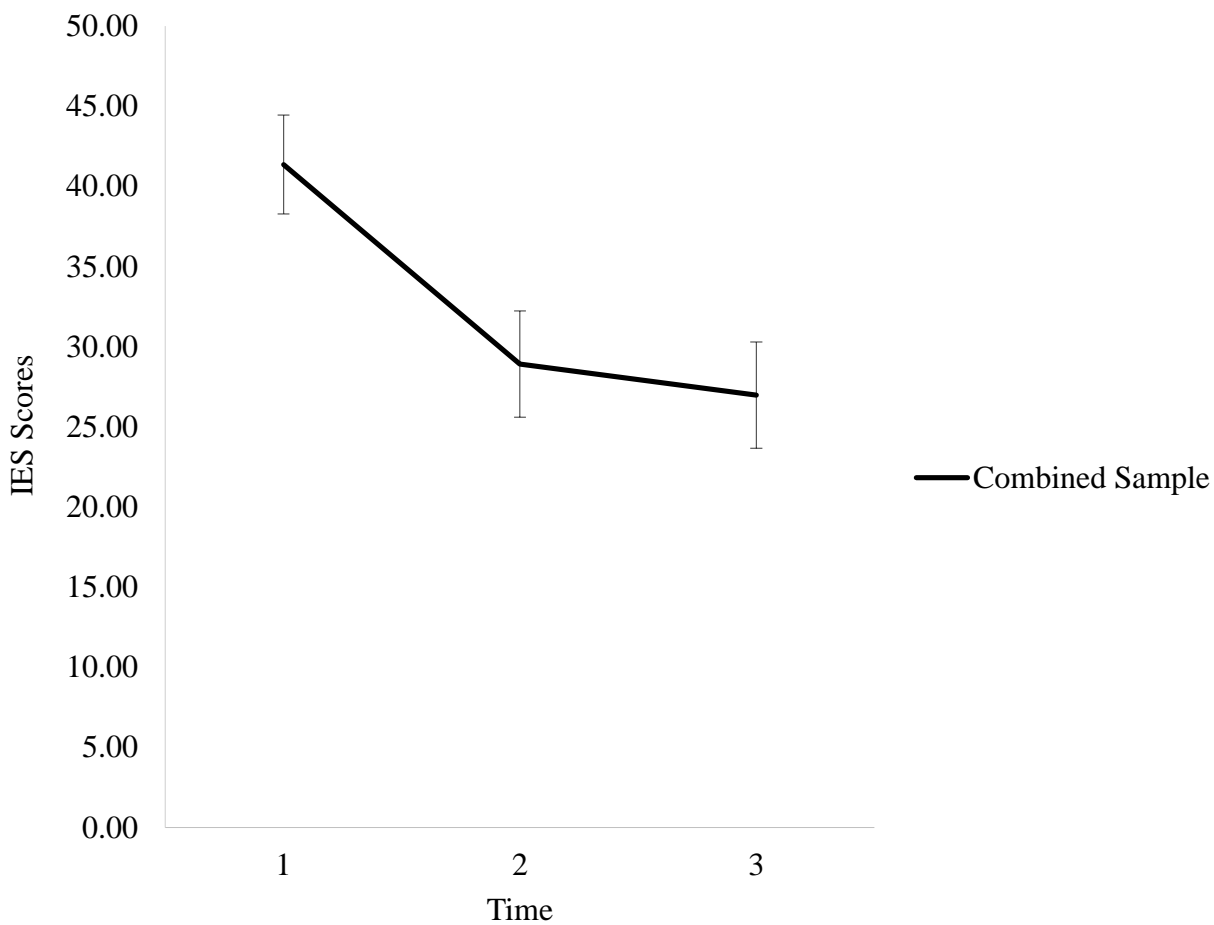


Figure 7. Repeated Measures ANOVA findings for cancer-specific distress (IES) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

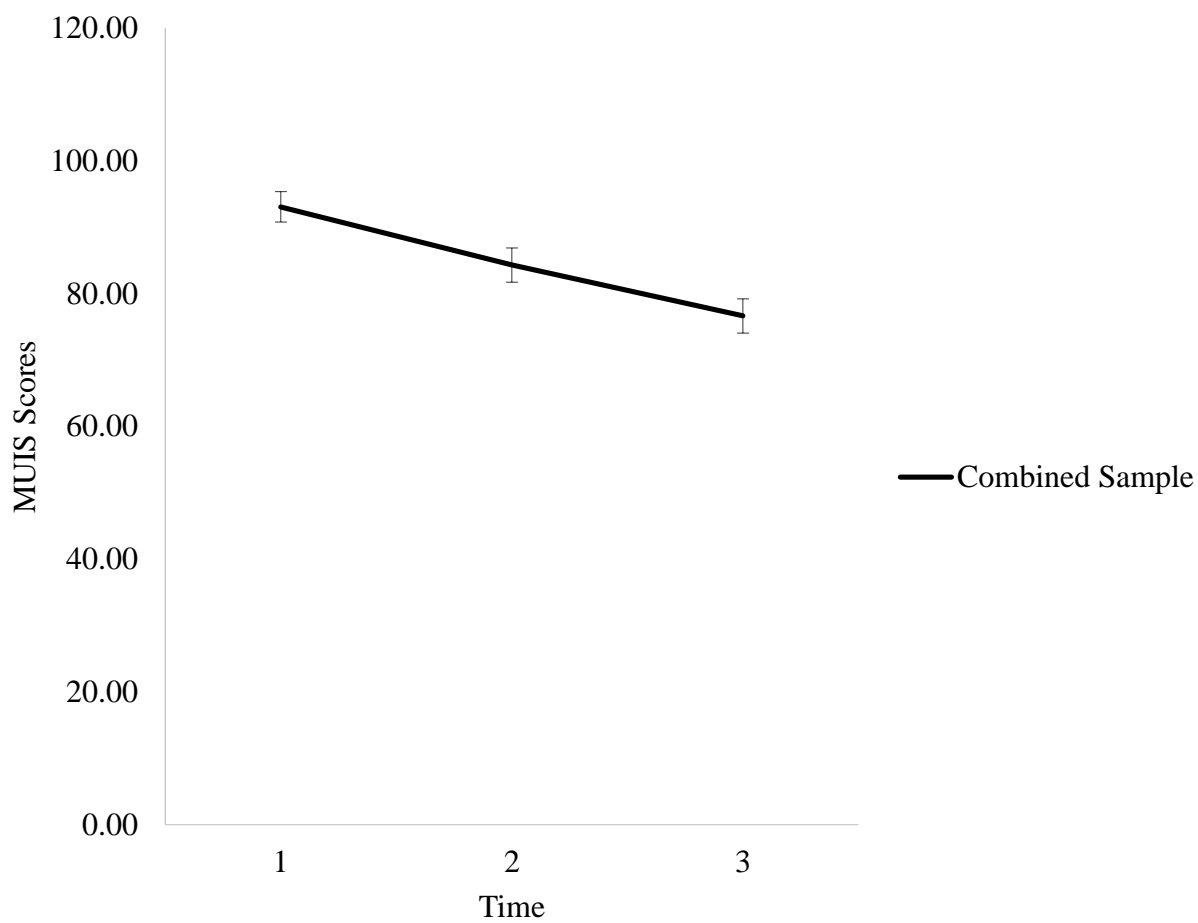


Figure 8. Repeated Measures ANOVA findings for uncertainty in illness (MUIS) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

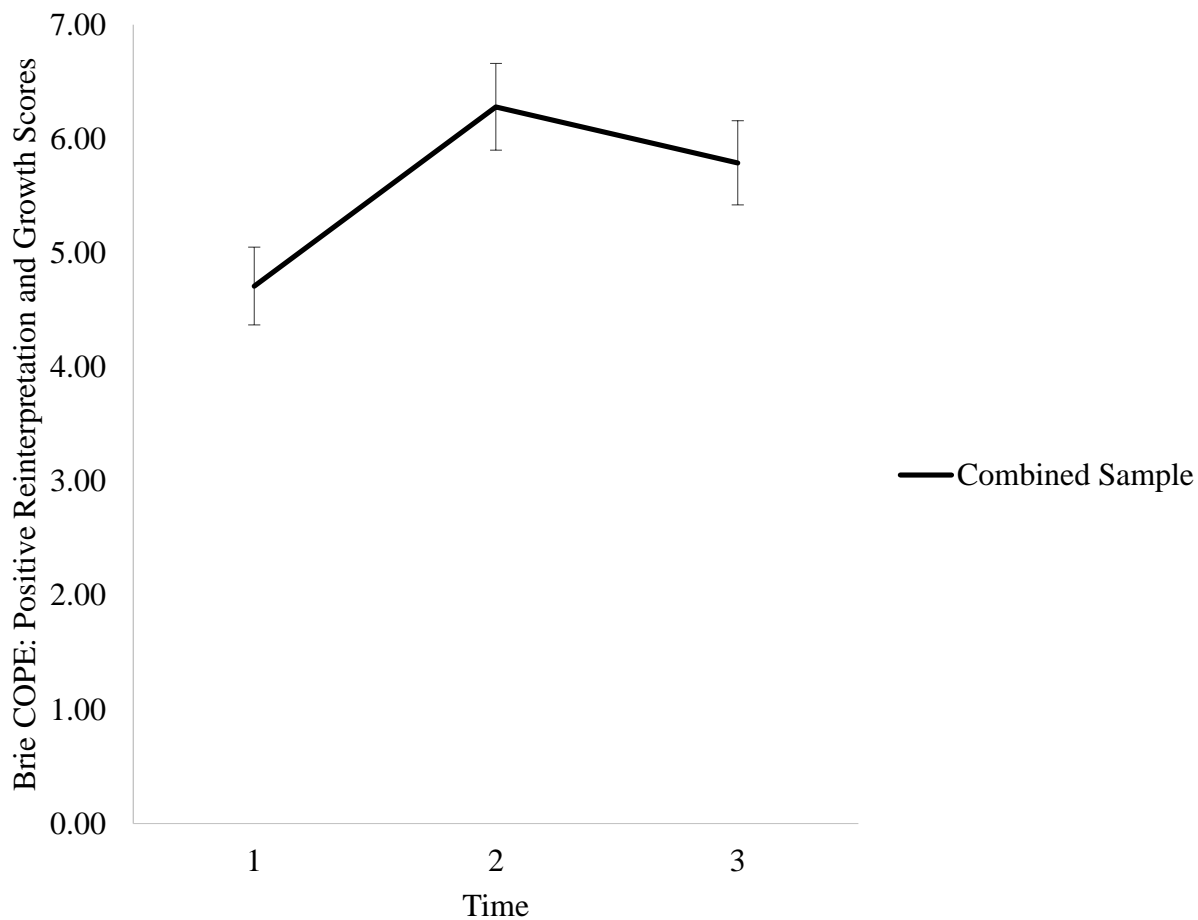


Figure 9. Repeated Measures ANOVA findings for positive reinterpretation and growth (BRIEF COPE subscale) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

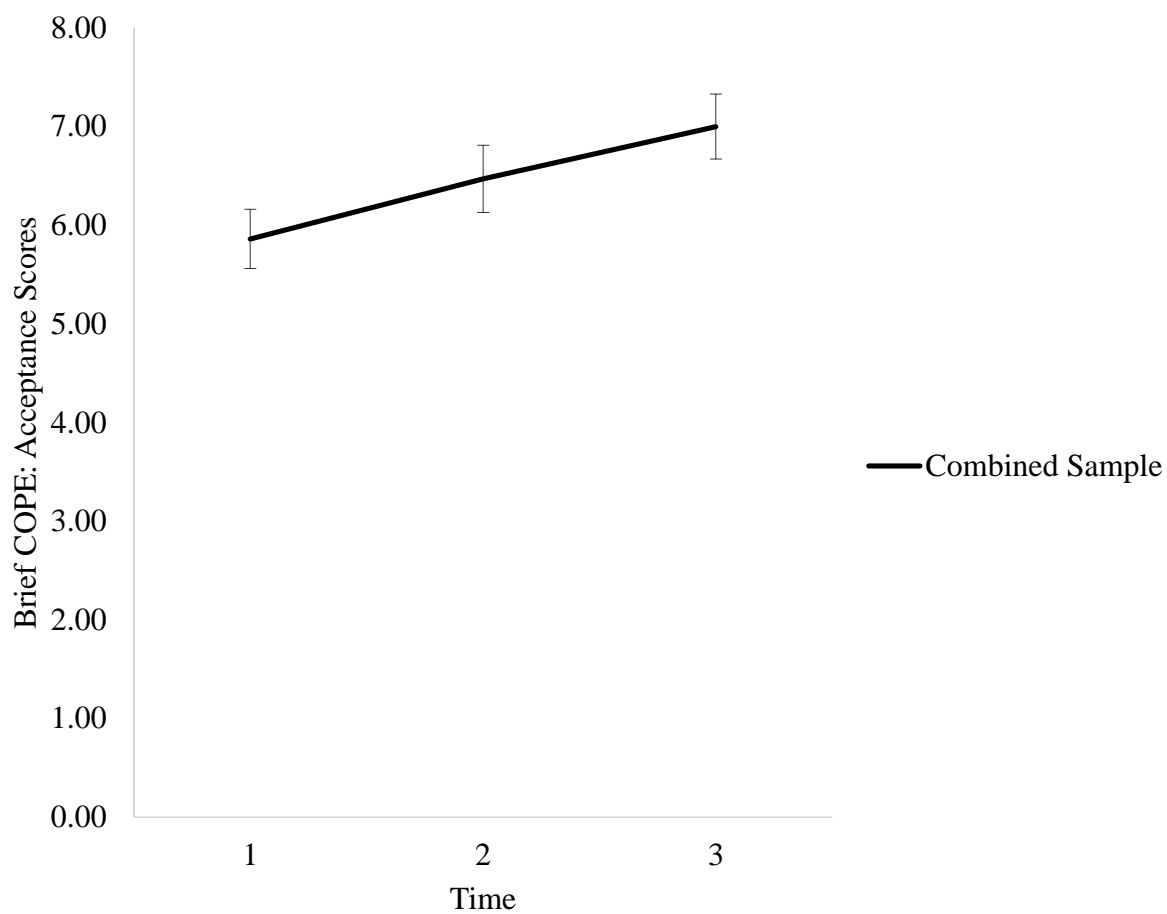


Figure 10. Repeated Measures ANOVA findings for acceptance (BRIEF COPE subscale) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

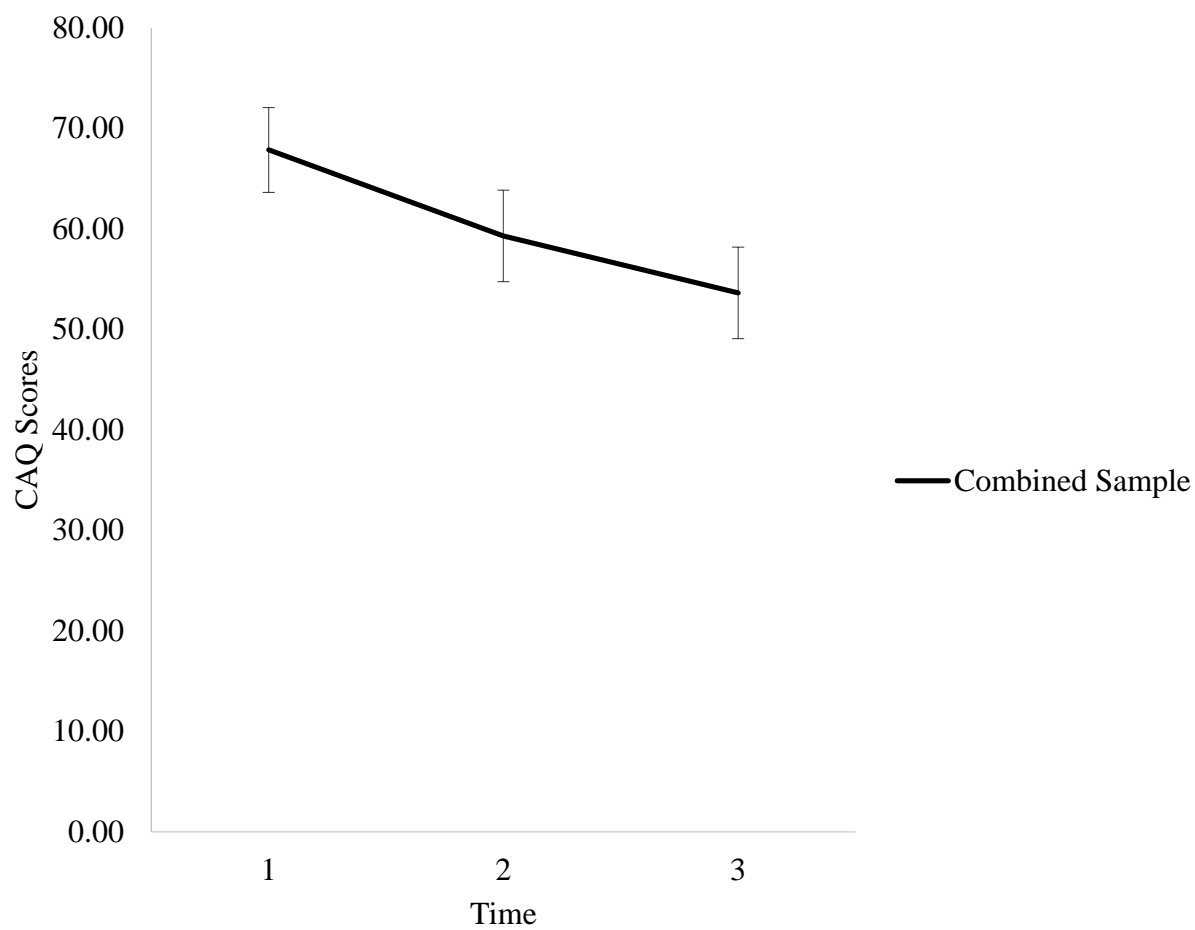


Figure 11. Repeated Measures ANOVA findings for cognitive avoidance (CAQ) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

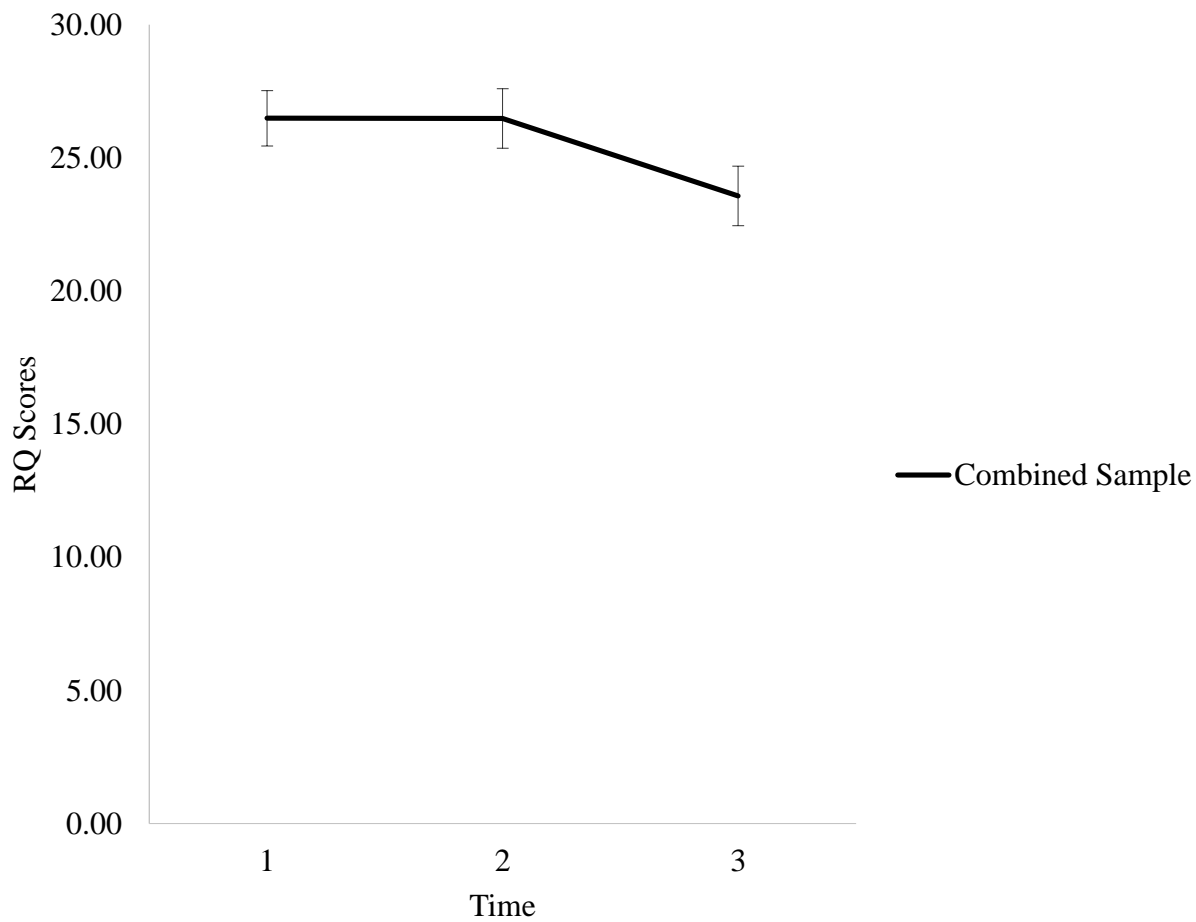


Figure 12. Repeated Measures ANOVA findings for reassurance seeking (RQ) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

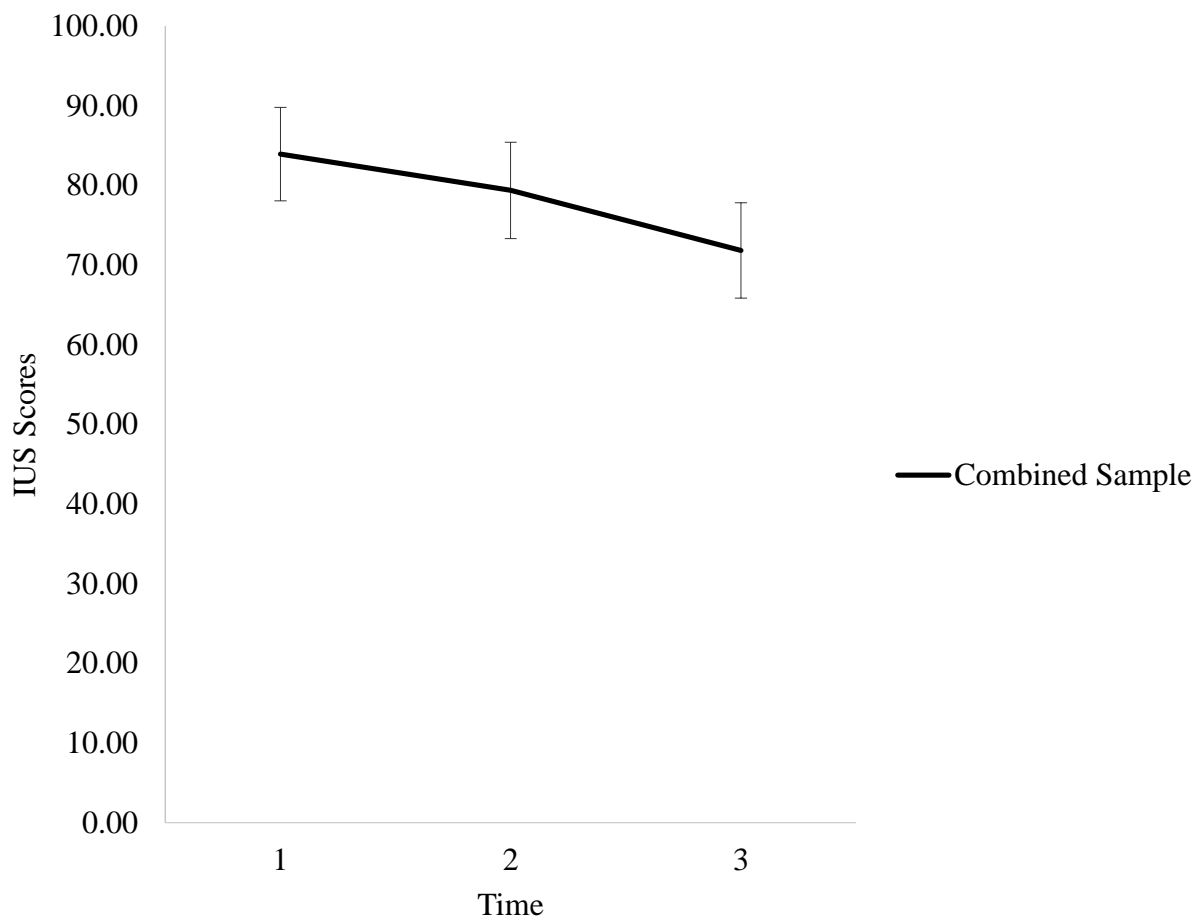


Figure 13. Repeated Measures ANOVA findings for intolerance of uncertainty (IUS) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

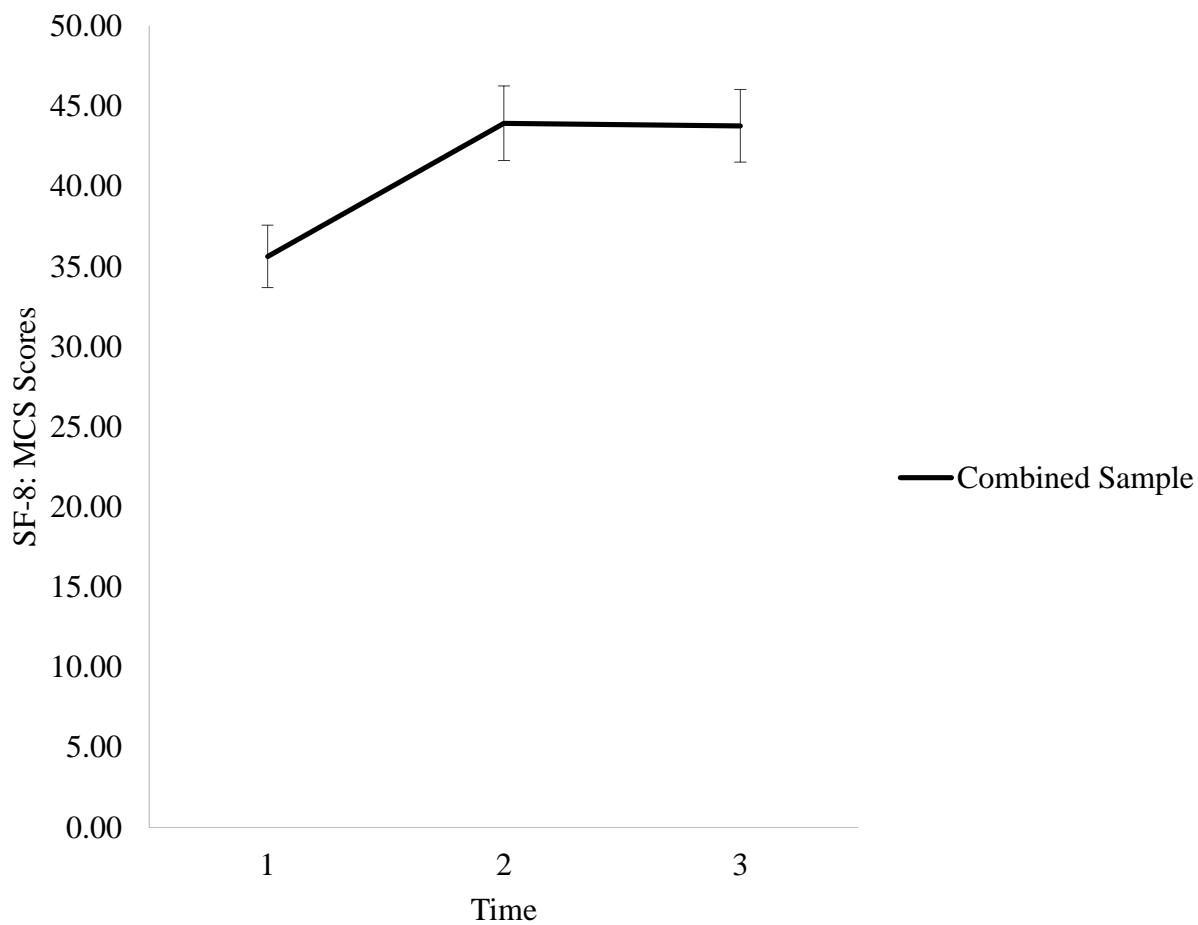


Figure 14. Repeated Measures ANOVA findings for quality of life: mental health (SF-8: MCS) scores across study participants over time (pre-intervention, post-intervention, and 3-month follow-up).

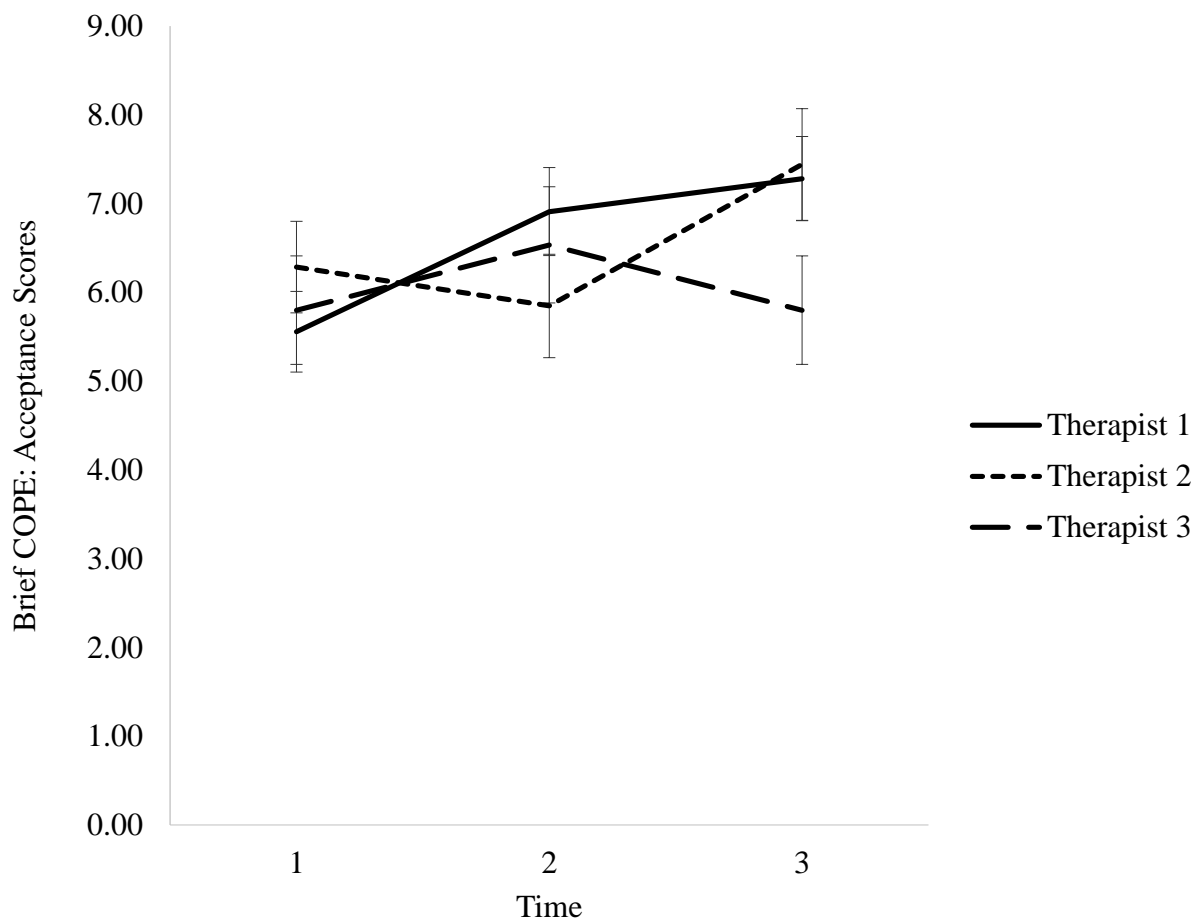


Figure 15. Between-Within ANOVA findings for acceptance (BRIEF COPE subscale) scores across therapists over time (T1: pre-intervention, T2: post-intervention, and T3: 3-month follow-up).

General Discussion

Thesis Rationale

These manuscripts report on the findings of two pilot studies examining an individualized therapeutic intervention for the treatment of fear of cancer recurrence (FCR). As previously mentioned, the first study was a pilot study with $n=3$ cases, where the authors adapted the original FCR group intervention to an individual version, with the goal of examining the feasibility, acceptability, and overall satisfaction of this individual intervention. The second study was a pilot randomized controlled trial (RCT) with $n=25$ female cancer survivors, with the goal of testing the efficacy of the same individual FCR intervention as compared to a wait-list control group. These research studies were conducted in collaboration with a team of researchers and clinicians at the Psychosocial Oncology Program (PSOP) and the Psychology Department at The Ottawa Hospital (TOH) in Ottawa, Ontario, Canada.

A review of the literature on psychosocial interventions for cancer patients revealed that cognitive-behavioural therapy (CBT) interventions can be greatly beneficial, with studies demonstrating reductions in depression and anxiety (Edelman, Bell, & Kidman, 1999; Greer et al., 1992; Herschbach et al., 2010;), and increases in quality of life and coping (Breitbart et al., 2012; Kissane et al., 2003; Lee, Lim, Yoo, & Kim, 2011; Penedo et al., 2006; Simpson, Carlson, & Trew, 2001). However, this review of the literature revealed that there is a paucity of published interventions for the psychological treatment of FCR, which is the highest reported concern among cancer survivors (Simard & Savard, 2009; Simard et al., 2013; Thewes et al., 2014). Fortunately, intervention research in the area of FCR is emerging, with a number of ongoing RCTs that are aimed at targeting this important psychological construct (Butow et al., 2013; Lewis et al., 2013; van de Wal et al., 2015).

The adaptation, standardization, and subsequent pilot testing of this individual FCR intervention served to address a number of concerns. Primarily, it appears that limited published psychotherapeutic interventions exist for the treatment of FCR. Furthermore, it appears that very few *individual* therapeutic interventions exist that specifically address FCR. Moreover, there are limited FCR interventions that exist for both men *and* women living with this concern. Therefore, the present studies aimed to address the gaps in the literature by adapting the aforementioned FCR group intervention to an individual format, and to offer this individual intervention to both men and women. This general discussion will report on the findings of these two studies, integrate these findings in accordance to relevant theoretical models, and detail the studies' limitations, strengths, clinical implications, and future research directions.

Study 1: Review of Objectives and Hypotheses

To review, the objectives of the first study were to: 1) Adapt and standardize Lebel and Maheu's (2009) cognitive-existential (CE) FCR group intervention to an individual format; and 2) Pilot-test the feasibility, acceptability, and satisfaction with the individual FCR intervention. The authors hypothesized the following: 1) Participants would find the intervention feasible, acceptable, and satisfactory; 2) Participants would show a reduction in their FCR and cancer-specific distress immediately after completing the intervention.

Study 1: Main Pilot Findings

Consistent with the proposed hypotheses, results from this study revealed that all hypotheses were supported.

It was feasible to recruit male and female patients of mixed cancer sites within the respective study timeline, and was feasible for participants to complete their questionnaire packages once a week for 10 weeks. While the study's acceptability was challenged due to

attrition in the earlier stages of the intervention, participants who completed the therapy indicated that they found the intervention to be helpful, fair, and reasonable. Furthermore, the session attendance rate was 100% across all 3 participants, suggesting further acceptability of the intervention. While participants showed downward trends in FCR and cancer-specific distress, as indicated in our hypothesis, participants remained in the recommended clinical range for FCR at discharge, and one participant remained in the recommended clinical range for cancer-specific distress at discharge. One potential reason for this finding is that a validated clinical cut-off score for FCR has yet to be firmly established. While certain FCR inventories may suggest cut-off scores to identify high levels of FCR, to date, there is an absence of an agreed-upon definition of clinical FCR, of a validated clinical interview, and an accompanying validated cut-off score for FCR in the literature. For example, the recommended clinical cut-off score of ≥ 13 on the Fear of Cancer Recurrence Inventory-Short Form (FCRI-SF; Simard & Savard, 2009), which corresponds to the severity subscale of the FCRI, is currently being debated (Costa, Smith, & Fardell, 2016). This clinical cut-off was established using the purpose-designed face-to-face Structured Interview for Fear of Cancer Recurrence (SIFCR) as a gold-standard measure (Simard & Savard, 2009; Simard & Savard, 2015), although data supporting this recommended cut-off score are preliminary. For example, the authors of the FCRI-SF initially proposed a cut-off score of ≥ 13 for maximizing sensitivity, and a cut-off score of ≥ 16 for maximizing specificity (Simard & Savard, 2015). Furthermore, a study conducted by Fardell et al. (2016) found that a cut-off score of ≥ 22 provided optimal specificity and sensitivity for identifying cancer survivors with clinically significant levels of FCR. These findings illustrate the challenge of reliably identifying survivors experiencing clinical FCR (Fardell et al., 2016). Future studies should strive to develop

a gold-standard clinical interview with a validated clinical cut-off score, in order to accurately determine what constitutes as high FCR.

The post-session feedback questionnaires and exit interviews revealed that participants found the intervention to be helpful, and were grateful and appreciative for the overall experience. Participants reported that the aspects of the intervention they appreciated most were cognitive restructuring techniques, relaxation exercises, calming self-talk, and planning for the future. Participants also reported that the least appreciated aspects of the intervention were fairly minimal, including pacing of exercises on the relaxation CD. Participants identified specific mechanisms of change from the intervention, such as addressing their worst-case scenario and fostering a safe therapeutic relationship. Lastly, all participants reported experiencing improvements in their FCR upon completion of the intervention. Overall findings from this pilot study tentatively suggest that this individual intervention was helpful in decreasing participants' FCR and cancer-specific distress.

Study 2: Review of Objectives and Hypotheses

The objective of the second study was to examine the efficacy of the individual FCR intervention via a small-scale randomized controlled clinical trial. The authors hypothesized the following: 1) Participants in the experimental group would have lower scores on the primary outcome measure of FCR after treatment than would participants in the wait-list control group; 2a) Participants in the experimental group would have lower scores on secondary outcome measures of cancer-specific distress, intolerance of uncertainty, uncertainty in illness, cognitive avoidance, reassurance-seeking and faulty beliefs about worrying than would participants in the wait-list control group; 2b) Participants in the experimental group would demonstrate enhanced coping skills in positive reinterpretation and growth, acceptance, and use of emotional support,

and report better mental and physical quality of life after treatment, than would participants in the wait-list control group; 3) When grouped together, all participants (both experimental group and wait-list control group) would have lower scores on the primary outcome measure of FCR after treatment, and these effects would be maintained at 3-month follow-up; 4a) When grouped together, all participants (both experimental group and wait-list control group) would have lower scores on the secondary outcome measures of cancer-specific distress, intolerance of uncertainty, uncertainty in illness, cognitive avoidance, reassurance-seeking and faulty beliefs about worrying, and these effects would be maintained at 3-month follow-up; 4b) When grouped together, all participants (both experimental group and wait-list control group) would demonstrate enhanced coping skills in positive reinterpretation and growth, acceptance, and use of emotional support, and report better quality of life after treatment, and these effects would be maintained at 3-month follow-up.

Study 2: Main Pilot Findings

Consistent with the first study hypothesis, participants in the experimental group had lower scores on the primary outcome measure of FCR after treatment, as compared to the wait-list control group. In regards to hypothesis 2a, participants in the experimental group also had lower scores on cancer-specific distress and uncertainty in illness as compared to the wait-list control group, but did not show improvements on the remaining secondary outcome variables (i.e., cognitive avoidance, reassurance-seeking, worry, and intolerance of uncertainty).

Hypothesis 2b was not supported, as participants in the experimental group did not show improvements on coping skills in positive reinterpretation and growth, acceptance, and use of emotional support, or quality of life (physical health and mental health), as compared to participants in the wait-list control group. Consistent with hypothesis 3, when all participants

were grouped together, they had lower scores on the primary outcome measure of FCR after treatment, which was maintained at 3-month follow-up. In regards to hypothesis 4a, when all participants were grouped together, they had lower scores on cancer-specific distress, uncertainty in illness, cognitive avoidance, intolerance of uncertainty and reassurance-seeking, but not for worry. In regards to hypothesis 4b, when all participants were grouped together, participants showed improvements on mental health quality of life, and coping subscales of positive reinterpretation and growth and acceptance, but not for quality of life (physical health) or use of emotional support. Of these changes in secondary outcomes, all were either maintained or improved at 3-month follow-up. The remaining secondary outcome variables (i.e., worry, physical health quality of life, and use of emotional support) did not improve over time.

Analyses were also conducted to identify any individual therapist differences across outcome measures over time. With the exception of the acceptance coping subscale on the BRIEF COPE (Carver, 1997), no significant individual therapist effects emerged on any of the outcome measures. These findings suggest that the therapists were applying the same treatment protocol across participants (i.e., regardless of the therapist, the treatment was effective, and the treatment effects were maintained). Overall, results from this pilot RCT revealed the preliminary efficacy of this individualized intervention for the treatment of FCR.

Integration of Findings within Theoretical Models

As previously mentioned, the FCR intervention is theoretically guided by the Common Sense Model (CSM; Lee-Jones, Humphris, Dixon & Hatcher, 1997; Leventhal, Diefenbach & Leventhal, 1992); Mishel's (1988) Uncertainty in Illness theory, and cognitive models of worry (Dugas, Gagnon, Ladouceur & Freeston, 1998; Ladouceur et al., 2000; Langlois, Ladouceur, Patrick, & Freeston, 2004). The overarching theme that emerged across both studies is that FCR

is a multifaceted, complex experience that does not fit perfectly within one specific theoretical model. The findings from these studies showed support for all three of the aforementioned models.

The Common Sense Model. To review, the CSM (Leventhal et al., 1992) posits that FCR is a multidimensional construct. As previously noted, the CSM was initially proposed to explain adherence to medical regimens, and was further expanded by Lee-Jones et al. (1997) in the most exhaustive and comprehensive theoretical formulation of FCR to date (Fardell et al., 2016). The model maintains that internal and external triggers increase one's belief that they are at risk of recurrence, which in turn heightens FCR. Once the perception of being at risk for recurrence is activated, survivors are primed to focus on their physical sensations (e.g., previously benign symptoms), interpreting these sensations as further evidence of a recurrence. In cases of clinically high FCR, this can result in anxious preoccupation, personal checking behaviours, and reassurance-seeking (Lee-Jones et al., 1997). These suboptimal coping strategies only offer temporary relief from FCR by providing immediate feedback. However, this relief is often short-lived, and ultimately increases FCR in the long-term (Lee-Jones et al., 1997).

In line with the CSM, one of the goals of the intervention was to teach participants to think about their triggers differently, and less catastrophically. In session 1, participants were asked to identify their triggers, and identify which maladaptive coping behaviours they engaged in most. By teaching participants to recognize their triggers, and helping them realize that benign symptoms are not necessarily indicative of cancer, they learned to perceive their triggers and their risk of recurrence differently. Through the use of cognitive restructuring techniques and the provision of information in the intervention, therapists were able to help participants break the cycle between triggers and perceived risk of recurrence, and ultimately help reduce their FCR, as

evidenced by clinically significant reductions on the FCRI (Simard & Savard, 2009) over time in study 2. Increasing participants' awareness of their triggers and daily living with FCR also served to promote the inclusion of more adaptive coping strategies, such as cognitive reframing and relaxation exercises. Thus, while participants still encountered triggers as they normally would, they were able to reframe their perspectives by virtue of the strategies they learned (e.g., "I am sad to hear my neighbour has cancer, but this news does not mean that I will have a cancer recurrence").

The CSM (Lee-Jones et al., 1997; Leventhal et al., 1992) also discusses maladaptive coping behaviours. Survivors living with high FCR have been shown to manage their FCR by extensively using problematic or suppressive coping strategies, such as reassurance-seeking and body checking (Lebel & Maheu, 2009; Simard & Savard, 2009; Simard, Savard & Ivers, 2010). In study 2, coping was measured via 3 of the 14 BRIEF COPE subscales (i.e., positive reinterpretation and growth, acceptance, and use of emotional support; Carver, 1997), as improvements were found on these three subscales in Lebel et al.'s (2014) study. Significant results were found for positive reinterpretation and growth and acceptance, but use of emotional support was non-significant. It is possible that another outcome measure may have better captured the concept of emotional support, as the measure used in study 2 was a subscale (as opposed to an entire measure assessing emotional coping). Future research could examine if other validated psychological instruments are more appropriate in assessing emotional coping. Another possibility for the non-significant findings in use of emotional support could be a function of the FCR group vs. individual intervention modality. In Lebel et al.'s (2014) study, women of the same cancer type received the FCR intervention via group therapy. It is possible that these women in the group setting may have experienced an increase in emotional support as

a function of the validation received from other group members, who could often relate to the same FCR-related experiences. In the individual intervention, participants occasionally lamented that family, friends, physicians, and/or therapists could not truly understand their cancer experience unless they had been diagnosed themselves. This may lend further credence as to why the emotional support subscale was non-significant in study 2.

There appears to be a common theme in emotional coping across FCR-related studies. For example, in Lebel et al.'s (2014) study, use of emotional support decreased at 3-month follow-up, and was no longer significantly different from pre-intervention levels. These results may suggest that while participants felt emotionally supported by group members throughout the intervention, these effects were not maintained upon completion of the intervention, when participants no longer drew support from one another on a weekly basis. Furthermore, in Mutsaers et al.'s (2016) study, qualitative analyses revealed that patients with clinical levels of FCR reported feeling alone, despite being supported by loved ones and their healthcare team. Participants also reported how others found it difficult to truly understand their FCR, which further exacerbated their loneliness (Mutsaers et al., 2016). These findings highlight the observed difficulties in emotional coping across patients living with FCR. Future interventions could address how patients can obtain further emotional support, and focus on incorporating additional emotional coping strategies. Having access to supplemental emotional coping tools may help patients feel considerably less alone in their cancer journey.

Overall, the findings from these studies are congruent with the CSM. From a clinical perspective, it appears that the sequence of proposed events outlined in the CSM occurred throughout the therapy sessions. Specifically, participants learned to view their triggers differently, which led to a reduction in perceived risk of recurrence, and ultimately reduced their

overall FCR. Furthermore, participants replaced existing maladaptive coping strategies with adaptive coping strategies, such as cognitive reframing tools and behavioural techniques. Lastly, the significant findings on the positive reinterpretation and growth and acceptance subscales on the BRIEF COPE in study 2 are further evidence of participants' increased coping skills, and demonstrate further support for this theoretical model.

Uncertainty in Illness Theory. To review, according to Mishel's (1988) Uncertainty in Illness theory, uncertainty occurs when illness-related components are inconsistent, unpredictable, random, and complex. This model maintains that providing patients with accurate information about symptoms of a cancer recurrence should decrease uncertainty, and thus, decrease FCR. Illness uncertainty is also compounded by the possibility that the cancer could recur at any time, and that triggers or reminders of the cancer experience are often unpredictable. Furthermore, the model outlines that while uncertainty can never be completely eliminated from patients' lives, patients can learn adaptive cognitive and behavioural coping strategies to target and manage their uncertainty (Mishel, 1988).

Uncertainty was addressed with participants in sessions 2 and 3 of the FCR intervention. Participants were taught that while uncertainty could not be completely eradicated, they could learn to tolerate uncertainty, and subsequently increase their sense of mastery. In-session exercises included identifying triggers, completing thought records, cognitive reframing exercises, practicing relaxation techniques, and preparing questions for oncologists at upcoming medical visits. Preparing questions served to elicit patient-provider communication, to provide information about signs and symptoms of a recurrence, and to further help manage uncertainty about a possible recurrence. In study 2, results indicated that there were significant reductions in

illness uncertainty, as measured by Mishel's (1988) Uncertainty in Illness scale. These findings lend support to Mishel's (1988) Uncertainty in Illness theory.

While the findings from study 2 demonstrated clinically significant reductions in both FCR and illness uncertainty, the relationship between change in FCR and illness uncertainty has not been explicitly tested. Therefore, it is unclear whether the reduction in illness uncertainty contributed to the reported reduction in FCR (Fardell et al., 2016). Moreover, it is unclear how illness uncertainty necessarily leads to fears about a recurrence, or whether FCR precedes illness uncertainty, as researchers have previously suggested (Mast, 1998). One possible explanation may be varying degrees of intolerance of uncertainty across individuals (Eisenberg et al., 2015) – those who are more tolerant of the uncertainty associated with a recurrence are less likely to develop FCR, whereas individuals who are intolerant of uncertainty are more likely to develop FCR (Fardell et al., 2016).

While the data from this thesis suggest that participants' illness uncertainty was successfully targeted over time, and thus provides support for the Uncertainty in Illness theory (Mishel, 1988), what remains unknown is how patients specifically cope with uncertainty in illness. Therefore, further testing of the relationship between illness uncertainty and FCR is necessary, and future research should explore the specific mechanisms of the FCR intervention that target illness uncertainty (e.g., the provision of information, learning about signs and symptoms of a recurrence, reductions in checking behaviours, etc.).

Cognitive models of worry. As previously mentioned, cognitive models of worry (Dugas, et al., 1998; Ladouceur et al., 2000; Langlois et al., 2004) suggest that one of the functions of worry is to avoid feared outcomes through emotional interference. Similarly to Mishel's (1988) Uncertainty in Illness theory, uncertainty can cause great discomfort, and

subsequently result in higher levels of worry. In many cases, worry actually increases uncertainty and raises anxiety levels. Cognitive models of worry suggest that worriers tend to hold faulty beliefs about the benefit of worry (e.g., “If I don’t worry about my health, then I am likely to miss an early sign of recurrence and therefore likely to get a more aggressive cancer”; Lebel & Maheu, 2009). Cognitive models of worry also maintain that worriers have lower tolerance of uncertainty than non-worriers (Ladouceur et al., 2000).

Dugas et al.’s (1998) conceptual model of Generalized Anxiety Disorder (GAD) maintains that intolerance of uncertainty, faulty beliefs about the benefit of worry, poor problem orientation, and cognitive avoidance are key components in the maintenance of GAD. Many of the characteristics of GAD are similar to those of FCR (e.g., intrusive thoughts, persistent worry about health, and faulty beliefs about the benefit of worry; Simard et al., 2010). While FCR has been found to be different than GAD, there are shared underlying mechanisms between these constructs (Simard et al. 2015). Relative to erroneous beliefs about the benefit of worry, individuals living with FCR may feel that worry promotes a sense of preparedness, and that worry may potentially minimize the negative impact of a possible cancer recurrence. Previous studies have found that high subjective risk of recurrence is associated with higher FCR, and general worry about cancer (Llewellyn et al., 2008; Simard et al., 2013).

Much like the core features of Dugas et al.’s (1998) model, the FCR intervention includes specific targeted exercises to address these components, such as challenging faulty beliefs about the benefit of worry, increasing tolerance for uncertainty by discussing acceptable levels of worry, and challenging tendencies to avoid or suppress negative thoughts or images. Worry-based strategies include listing advantages and disadvantages to worry, and discussing counterproductive levels of worry (e.g., illustrating to participants how they often overestimate

the benefits of worrying and underestimate its costs). Strategies to increase participants' tolerance for uncertainty included the provision of information and calming self-talk. Similarly, the provision of information on symptoms of recurrence appears to be a common exercise across other FCR interventions (Butow et al., 2013; Smith et al., 2015). Further strategies to target intolerance of uncertainty included reminding participants of their previous coping strategies (i.e., how they successfully coped in the past with unexpected or uncertain events), and examining areas in participants' lives within their responsibility and control. Strategies aimed at reducing cognitive avoidance included exposure to participants' worst-case scenario, and exploration of their thoughts and feelings surrounding this scenario.

In study 2, outcomes of worry, intolerance of uncertainty, and cognitive avoidance were measured. Our results indicated that there were significant reductions in intolerance of uncertainty, as measured by the Intolerance of Uncertainty scale (IUS; Buhr & Dugas, 2002), which lends support to the aforementioned model proposed by Dugas et al. (1998). Also consistent with Dugas et al.'s (1998) model, results from study 2 demonstrated significant reductions in cognitive avoidance, as measured by the Cognitive Avoidance Questionnaire (CAQ; Sexton & Dugas, 2008). These findings suggest that the intolerance of uncertainty and cognitive avoidance strategies incorporated in the intervention were helpful to participants over time.

Contrary to our hypothesis in study 2a, worry did not significantly decrease over time, as evidenced by results on the Why do people Worry about Health? questionnaire (WW-H; Pelletier, Gosselin, Langlois & Ladouceur, 2002). While worry is an important construct to target, it has not been examined at length in FCR-related intervention studies. This was the first time that worry was measured upon pilot-testing this FCR intervention, and there are a number

of reasons that may explain the non-significant worry findings. Primarily, it is possible that another outcome measure may have captured the core features of worry better than our selected measure. Another consideration is the possibility of one's predisposition to worry and anxiety. Given that all of the participants initially scored in the clinically high range for FCR (i.e., a form of anxiety), it is possible that these individuals may have a more anxious predisposition as compared to individuals who have low levels of FCR. Research has shown that GAD was significantly associated with FCR (Roth et al., 2006), and Lipkus, Klein, Skinner and Rimer (2005) found that pre-existing levels of worry exacerbated pessimistic judgments or biases, and led to increased perceived risk of developing cancer. Thus, it is possible that participants' tendency to worry may have been pre-existing, and thus, fairly elevated prior to the onset of the intervention.

While two sessions of the FCR intervention were devoted to psychoeducation, in-session exercises, and coping strategies for managing worry, this amount may have not been adequate for a clinically significant reduction. Future intervention studies could focus on incorporating additional worry-based strategies, such as operationalizing the concept of worry to patients (i.e., further elucidating the differences between adaptive versus maladaptive worry), explaining the applicability of worry-based strategies to all life domains, and increasing worry-targeted techniques (e.g., scheduling "worry time" while applying CBT principles, such as cognitive restructuring). However, it should be noted that if FCR is conceptualized in terms of worry, clinically significant reductions were found.

One nascent consideration is the impact of Meta-cognitive Therapy (MCT) on FCR and worry. MCT is well suited for cancer survivors, as it teaches patients more effective ways to respond to the presence of fears associated with a recurrence at a meta-cognitive level. This

includes meta-awareness of cognitions and learning to be an objective observer of the content of one's thoughts, without the need for reaction or evaluation of these thoughts (Butow et al., 2013). Fardell et al. (2016) recently proposed a theoretical framework of FCR that includes elements of MCT. The model incorporates the importance of metacognitions - that certain beliefs about the nature and importance of worry can underlie a particular style of coping with worry that is problematic (e.g., "If I worry about cancer coming back, I will be prepared for it"), including rumination, attending to threat-related information, attempts to control, and avoidance or suppression of thoughts about recurrence (Fardell et al., 2016). Given that metacognitions and beliefs about cancer vulnerability are associated with FCR (Lee-Jones et al., 1997; Llewellyn et al., 2008), this may suggest the importance of incorporating MCT techniques for anxious cancer survivors. Indeed, MCT is also one of the guiding frameworks for Butow et al.'s (2013) Conquer Fear Intervention, although these mechanisms have yet to be tested.

The findings that emerged across study 1 and study 2 show support for the CSM (Lee-Jones et al., 1997; Leventhal et al. 1992), Mishel's (1988) Uncertainty in Illness Theory, and cognitive models of worry (Dugas et al., 1998; Ladouceur et al., 2000; Langlois et al., 2004). As evidenced by improvements in adaptive coping strategies, reductions in maladaptive cognitive and behavioural strategies, reductions in intolerance of uncertainty, and ultimately, reductions in FCR, findings from these studies support aspects of the CSM. When the model was presented to participants in session, they would often verbalize the relevance of this theoretical framework within their own personal lives (e.g., identifying specific internal and external triggers, maintaining beliefs in the benefit of worry, and identifying personal maladaptive coping strategies). Findings also support the Uncertainty in Illness Theory (Mishel, 1988), as indicated by the significant findings in illness uncertainty over time. Strategies included in the intervention

to target uncertainty, such as the provision of accurate information and the utilization of adaptive coping strategies, are consistent within Mishel's (1988) model. Additionally, findings from these studies support aspects of the aforementioned cognitive models of worry. Consistent with the theoretical underpinnings of Dugas et al.'s (1998) model, reductions in intolerance of uncertainty and cognitive avoidance were found over time. However, despite efforts to reduce worry throughout the intervention, belief structures about the benefit of worry were maintained across participants. As indicated above, future research endeavours could focus on incorporating meta-cognitive strategies in the FCR intervention, in order to address the construct of worry more effectively.

Overall, results from these studies suggest that FCR is a multifaceted experience that does not fit perfectly within one specific theoretical model. A research priority would be to identify the common elements of FCR models and begin empirically validating their proposed relationship with FCR (Lebel et al., 2016). The novel findings presented in this thesis certainly demonstrate the efficacy of an individualized FCR intervention that is grounded within three relevant theoretical frameworks. However, these results also speak to the necessity for an integrated, comprehensive model of FCR that pulls from these respective findings. From a clinical perspective, it may not be feasible for clinicians to seamlessly utilize all aspects of three theoretical models when treating patients. Therefore, the development of an integrated model of FCR would allow clinicians to consolidate information and incorporate pertinent aspects of FCR for the treatment of their patients. Future research could strive to develop an integrated model as such, and efforts should be made to determine what components of the proposed model are most helpful, or have the greatest influence, on changes in FCR. Once this integrated model is developed, further research should strive to test the validity of the proposed framework.

Thesis Limitations

It is important to note some limitations of the aforementioned studies. Both study 1 and 2 had relatively small sample sizes ($n=3$ and $n=25$, respectively), which limits the generalizability of the findings. Furthermore, a convenience sampling method was used, which again may limit whether the findings are applicable to a broader population. Therefore, results from both studies should be interpreted with caution.

For study 1, the preliminary findings of downward trends may in part be explained by the selection of participants with clinically high levels of FCR and cancer-specific distress. Likewise, for study 2, the efficacy of this intervention may be partially explained by participants living with high levels of FCR and cancer-specific distress. Additionally, the results from these studies are only representative of the participants under investigation, and may not represent the opinions of future participants who partake in this intervention.

As previously noted, for study 1, recruitment of colorectal cancer patients was challenging. Despite exhaustive efforts to recruit this patient population, the study was subsequently opened to patients of all cancer sites, in order to adhere to established study timelines. While it was not possible to recruit the specific cancer population as originally intended, successful efforts were made to recruit and retain one male and two females in our sample. For study 2, the original study timeline was significantly reduced due to unanticipated job restructuring at TOH. As a result of this change, the original 6-week waitlist for the control group was reduced to a 2-6 week waitlist, therefore compromising the initial study design. While this unanticipated change affected certain aspects of this study, efforts were made to ensure that participants assigned to the control group waited as long as possible before receiving the intervention. Of the participants assigned to the control group, $n=5$ waited 6 weeks, $n=2$ waited 5

weeks, $n=1$ waited 4 weeks, and $n=2$ waited 2 weeks. Thus, half of the control group participants were assigned to the originally intended 6-week waitlist.

Additionally, while we initially intended to recruit $n=10$ males for study 2, it was not feasible to do so. This may be because more females were referred to the study compared to males, or more females expressed interest in participation as a whole. In total, only three males were referred to both studies. One male participated in study 1, another male participated in study 1 but subsequently dropped out, and another male expressed interest in study 2, but did not meet eligibility criteria. As a result, this intervention was only tested on two male participants in study 1, limiting the applicability of the findings.

The current media and its portrayal of men's health may partially explain the absence of male survivors in our studies. Previous research demonstrated that Canadian newspaper outlets portrayed stereotypical ideologies of dominant masculine health behaviours and reactions to prostate cancer (e.g., a stoic attitude towards personal health, competition, and emphasis on courageousness, etc.; Halpin, Phillips & Oliffe, 2008). Interestingly, any discussion on the negative effects of treatment was conspicuously absent (Halpin et al., 2008). The results from this study reinforce the implicit beliefs about hegemonic masculinity and stereotypical behaviours for coping with cancer. If these beliefs are perpetuated across Canadian media outlets, it may lead male cancer survivors to avoid, or even refuse, psychological services. Given that print media are an important health resource for cancer patients (Carlsson, 2000), perhaps these studies need to be advertised differently for men. It is possible that the cancer promotional advertisements used in these studies (e.g., study posters and flyers) were more appealing to women than men. Future research could examine alternative promotional materials that may draw the attention of male cancer survivors.

Despite our best efforts to encourage questionnaire completion amongst our participants in study 2 (via phone calls and email reminders), our response rate was not ideal. It is possible that participants found the 20-page questionnaire package to be somewhat cumbersome to complete, and were reluctant to complete the same packages over three or four time points. Therefore, since some participants did not complete their follow-up questionnaires, the results may not be entirely representative of all individuals who participated in this study. However, in an attempt to maximize as many usable data points as possible, the recommended statistical practice of Linear Mixed Models (LMM) was used. Lastly, in study 2, a small sample of therapists ($n=3$) delivered the intervention to participants, which limits the ability to truly detect therapist effects. In order to obtain more conclusive data, future studies should include a larger number of therapists, who can then deliver the intervention across a larger sample of participants.

Thesis Strengths

This individual FCR intervention poses an original contribution to research. The findings in both study 1 and study 2 bring awareness to this previously understudied topic of FCR, and illustrate how pervasive this concern is for cancer survivors. Given the absence of published psychological interventions in the literature that strive to target FCR, this individual intervention not only addresses the gaps in the literature, but also provides a service for survivors who are consumed with fear. Overall findings from these studies suggest that this brief intervention may be successful in reducing FCR among men and women with cancer. In study 2, improvements in FCR were also maintained at the 3-month follow-up. Results as such are very promising, given that when left untreated, FCR usually does not decrease over time (Koch, Jansen, Brenner & Arndt, 2012; Simard et al., 2013).

A noteworthy strength of this intervention is that it is grounded in theory, and highlights specific, concretized tools and strategies for the management of FCR. This manualized, standardized treatment may serve as a helpful asset for clinicians working with highly anxious cancer survivors. Another strength of the intervention is that the tools and strategies have wide applicability across cancer types and other illnesses, as these techniques are rooted in cognitive-behavioural and existential frameworks.

Clinical Implications

This is one of the first individual psychotherapy interventions to directly address FCR. Results from these studies illustrate the importance of offering one-on-one intervention services for patients, especially since individuals who receive their preferred treatment modality report better therapeutic outcomes by the end of treatment (Carlson et al., 2014). As previously noted, the individual intervention also provides therapeutic services for patients who are less comfortable in group therapy settings, provides opportunities for psychological services when comprising a group may not be feasible, and allows for greater flexibility in scheduling.

This individual intervention responds to a growing clinical need for cancer survivors to have access to psychological services that can help improve their quality of life and mental health. Currently, there is limited evidence suggesting that medical management is addressing FCR for cancer survivors. It is apparent that targeted FCR-related psychotherapy interventions are effective, but screening tools and techniques need to be further validated, and then incorporated, into oncological-medical practice. It is hoped that health care providers will have access to guidelines for developing screening strategies that identify patients with FCR. There is also a great necessity to increase psychotherapy referrals for patients living with FCR, given the aforementioned difficulties associated with this concern. One possibility would be to offer

psychotherapy services for patients at the onset of diagnosis. Having access to psychological services at the forefront can allow patients to address their emotions and concerns surrounding their diagnosis, and may help reduce the likelihood of developing clinically high FCR.

Furthermore, it is imperative that FCR services are more readily available to a wider population, in order to reach patients from different settings who may be affected by these worries. Indeed, providing access to care across metropolitan and rural areas will serve to enhance functioning across a multitude of survivors.

Future Directions

As noted earlier, this is the first FCR-related intervention to be validated in more than one therapeutic modality. As both group and individual modalities appear to be effective (Lebel et al., 2014; Tomei, Lebel Maheu & Mutsaers, 2016), this should encourage research offering both types of FCR-related interventions. Future research should also continue investigating the therapeutic ingredients that are most effective for the psychological treatment of FCR. An exploratory study by Moran, Tomei, Lefebvre, Harris, Maheu and Lebel (2016) began identifying the mechanisms of therapeutic change in the FCR intervention by examining the worst-case scenario exercise. Results from this study suggested that participants who had more exposure to their worst-case scenario (via higher homework adherence scores) also had lower levels of FCR post-intervention. These findings are consistent with the aforementioned results in study 1, where one of the largest mechanisms of change for participants was through exposure to their worst-case scenario. These interrelated findings suggest that the worst-case scenario may be an essential therapeutic ingredient in the treatment of FCR, and also further confirms the benefit of exposure-based treatments for related forms of anxiety.

Treatment flexibility in the FCR intervention may be another possible research endeavour. Given the unpredictable course of events from date of diagnosis until the end of cancer treatment, flexible therapeutic options should be available for patients. For example, for patients who are dealing with the ramifications of cancer treatments (e.g., fatigue, neuropathy, pain, nausea, etc.), offering telephone sessions or home visits may be a viable alternative. Furthermore, it may be useful to offer booster sessions post-intervention, to assess patient functioning and reinforce therapeutic gains. Future research efforts may also consider lengthening the FCR intervention (e.g., 8-12 sessions). As evidenced by participants in study 1 remaining in the clinical range for FCR, it is possible that additional sessions addressing FCR over several weeks may provide more help to participants, and continue to decrease their fears and cancer-specific distress. Supplementary sessions could be devoted to further processing of the worst-case scenario, or increasing worry-related strategies and exercises. Future research directions could also include testing the intervention on cancer survivors living with low FCR. While results from these studies show the efficacy of the intervention for patients living with high FCR, efforts should be made to assess the impact of the intervention as compared to patients with low FCR.

In the interest of increasing social support for survivors, this intervention could be broadened to include caregivers, spouses and children, given that the effects of cancer often extend beyond the diagnosed individual (E. Romano, personal communication). The inclusion of topics such as addressing the tyranny of positive thinking, prevention of caregiver burnout, accessing emotional needs, and the importance of resilience and self-care strategies may be helpful for loved ones affected by cancer. Additionally, the intervention could be modified to include a component on re-building social skills, given the time-consuming and deleterious

effects of cancer on the individual. Strategies such as psychoeducation on the benefits of social support, role-playing scenarios, and modelling effective communication could be added to the intervention, to help survivors improve their relationships and enhance their support network.

Larger-scale RCTs are required to further establish the efficacy of this FCR intervention. Replicating these research studies in areas other than a large metropolitan region, such as smaller, rural areas, would not only provide essential access to supportive care, but also increase the generalizability of the findings. Furthermore, it is imperative that this intervention be tested on wider populations, such as patients of mixed cancer sites, to further assess the intervention's applicability. For example, future research could test the intervention on male cancer survivors, to assess for any gender differences or similarities. Furthermore, it would be prudent for future research endeavours to include a broader range of ages (e.g., relatively younger and older age ranges), and a broader range of ethnicities, for purposes of inclusivity and also generalizability to the population at large.

Another future research direction would be to broaden this intervention to other chronic illnesses, such as Multiple Sclerosis, diabetes, Parkinson's disease, and/or cardiac illnesses. A valuable research endeavour would be to adapt and offer this intervention to patients with chronic illnesses, as there is often an underlying fear experienced by patients that manifests across these illnesses (e.g., fear of disease progression, fear of hypoglycaemia, fear of falling, and fear of cardiac-related stimuli and sensations). Given that the FCR intervention is grounded in evidence-based cognitive-behavioural frameworks, research efforts could further test the intervention across different populations. Another imperative research direction would be to broaden this intervention to caregivers of cancer patients. Given patients' needs for emotional coping and support, efforts could be made to tailor the intervention to caregivers. In addition to

the existing core strategies, the intervention could be adapted to include aspects for caregivers, such as fostering effective communication skills, addressing the tyranny of positive thinking, accessing emotional needs, and encouraging self-care strategies. Therefore, both patients and caregivers afflicted by cancer could utilize therapeutic services for FCR.

Overall, the results from these studies demonstrate that this FCR intervention can be helpful for cancer survivors living with moderate to high FCR. It is hoped that future intervention efforts will build on these results and continue to enhance patients' mental health, and ultimately improve and restore their quality of life.

References

- Breitbart, W., Poppito, S., Rosenfeld, B., Vickers, A. J., Li, Y., Abbey, J., . . . Cassileth, B. R. (2012). Pilot randomized controlled trial of individual meaning-centered psychotherapy for patients with advanced cancer. *Journal of Clinical Oncology*, *30*(12), 1304-1309. doi: 10.1200/JCO.2011.36.2517
- Buhr, K., & Dugas, M. J. (2002). The intolerance of uncertainty scale: psychometric properties of the English version. *Behaviour Research and Therapy*, *40*, 931-945. doi:10.1016/S0005-7967(01)00092-4.
- Butow, P. N., Bell, M. L., Smith, A. B., Fardell, J. E., Thewes, B., Turner, J., . . . Mihalopoulos, C. (2013). Conquer fear: protocol of a randomized controlled trial of a psychological intervention to reduce fear of cancer recurrence. *BMC Cancer*, *13*, 201. doi: 10.1186/1471-2407-13-201
- Carlson, L. E., Tamagawa, R., Stephen, J., Doll, R., Faris, P., Dirkse, D., & Speca, M. (2014). Tailoring mind-body therapies to individual needs: patients' program preference and psychological traits as moderators of the effects of mindfulness-based cancer recovery and supportive-expressive therapy in distressed breast cancer survivors. *Journal of the National Cancer Institute Monographs*, *50*, 308-314. doi: 10.1093/jncimonographs/lgu034.
- Carlsson, M. (2000). Cancer patients seeking information from sources outside the health care system. *Supportive Care in Cancer*, *8*, 453-7. doi: 10.1007/s005200000166
- Carver, C. S. (1997). You want to measure coping but your protocol's too long: Consider the BRIEF COPE. *International Journal of Behavioral Medicine*, *4*(1), 92-100. doi: 10.1207/s15327558ijbm0401_6

- Costa, D. S. J., Smith, A. B., & Fardell, J. (2016). The sum of all fears: Conceptual challenges with measuring fear of cancer recurrence. *Supportive Care in Cancer*, *24*(1), 1-3. doi: 10.1007/s00520-015-2943-y
- Dugas, M. J., Gagnon, F., Ladouceur, R., & Freeston, M. H. (1998). Generalized anxiety disorder: A preliminary test of a conceptual model. *Behaviour Research and Therapy*, *36*(2), 215-226. Retrieved from www.ncbi.nlm.nih.gov/pubmed/9613027
- Edelman, S., Bell, D. R., & Kidman, A. D. (1999). A group cognitive behaviour therapy programme with metastatic breast cancer patients. *Psycho-Oncology*, *8*, 295-305. doi: 10.1002/(SICI)1099-1611(199907/08)8:4<295::AID-PON386>3.0.CO;2-Y
- Eisenberg, S. A., Kurita, K., Taylor- Ford, M., Agus, D. B., Gross, M. E., & Meyerowitz, B. E. (2015). Intolerance of uncertainty, cognitive complaints, and cancer- related distress in prostate cancer survivors. *Psycho- Oncology*, *24*(2), 228-235. doi: 10.1002/pon.3590
- Fardell, J. E., Jones, G., Smith, A. B., Lebel, S., Thewes, B., Costa, D., . . . Butow, P. (2016). *Screening for clinical fear of cancer recurrence using the Fear of Cancer Recurrence Inventory-Severity Scale*. Manuscript in preparation.
- Fardell, J. E., Thewes, B., Turner, J., Gilchrist, J., Sharpe, L., Smith, A. B., . . . Butow, P. (2016). Fear of cancer recurrence: a theoretical review and novel cognitive processing formulation. *Journal of Cancer Survivorship*, *10*, 663-673. doi: 10.1007/s11764-015-0512-5
- Greer, S., Moorey, S., Baruch, J. D., Watson, M., Robertson, B. M., Mason, A., . . . Bliss, J. M. (1992). Adjuvant psychological therapy for patients with cancer: A prospective randomised trial. *British Medical Journal*, *304*(6828), 675-680. doi: <http://dx.doi.org/10.1136/bmj.304.6828.675>

- Halpin, M., Phillips, M., & Oliffe, J. L. (2009). Prostate cancer stories in the Canadian print media: representations of illness, disease and masculinities. *Sociology of Health & Illness*, 31(2), 155-169. doi: 10.1111/j.1467-9566.2008.01122
- Herschbach, P., Berg, P., Waadt, S., Duran, G., Engst-Hastreiter, U., Henrich, G., . . . Dinkel, A. (2010). Group psychotherapy of dysfunctional fear of progression in patients with chronic arthritis or cancer. *Psychotherapy and Psychosomatics*, 79(1), 31-38. doi: 10.1159/000254903
- Kissane, D. W., Bloch S., Miach, P., Smith, G. C., Seddon, A., & Keks, N. (2003). Cognitive-existential group psychotherapy for women with primary breast cancer: A randomised controlled trial. *Psycho-Oncology*, 12(6), 532-546. doi: 10.1002/pon.1280
- Koch, L., Jansen, L., Brenner, H., & Arndt, V. (2013). Fear of recurrence and disease progression in long-term (≥ 5 years) cancer survivors-a systematic review of quantitative studies. *Psycho-Oncology*, 22, 1-11. doi: 10.1002/pon.3022
- Ladouceur, R., Dugas, M. J., Freeston, M. H., Léger E., Gagnon F., & Thibodeau N. (2000). Efficacy of a cognitive-behavioral treatment for generalized anxiety disorder: Evaluation in a controlled clinical trial. *Journal of Consulting and Clinical Psychology*, 68(6), 957-964. doi: 0.1037/0022-006X.68.6.957
- Langlois, F., Ladouceur, R., Patrick, G., & Freeston, M. H. (2004). Characteristics of illness intrusions in a non-clinical sample. *Behavior Research and Therapy*, 42, 683-696. doi: 10.1016/S0005-7967(03)00191-8
- Lebel, S. & Maheu. C. (2009). *Development of a cognitive-existential intervention to address fear of cancer recurrence in women with cancer*. Unpublished manuscript, Department of Psychology, University of Ottawa, Ottawa ON Canada.

- Lebel, S., Maheu, C., Lefebvre, M., Secord, S., Courbasson, C., Singh, M., . . . Catton, P. (2014). Addressing fear of cancer recurrence among women with cancer: A feasibility and preliminary outcome study. *Journal of Cancer Survivorship*, 8, 485-496. doi: 10.1007/s11764-014-0357-3
- Lebel, S., Ozakinci, G., Humphris, G., Thewes, B., Prins, J., Dinkel, A., . . . Butow, P. (2016). Current state and future prospects of research on fear of cancer recurrence. *Psycho-Oncology*. doi: 10.1002/pon.4103
- Lee, H., Lim, Y., Yoo, M. S., & Kim, Y. (2011). Effects of a nurse-led cognitive-behaviour therapy on fatigue and quality of life of patients with breast cancer undergoing radiotherapy. *Cancer Nursing*, 34(6), 22-30. doi: 10.1097/NCC.0b013e31820d1734
- Lee-Jones, C., Humphris, G., Dixon, R., & Hatcher, M. B. (1997). Fear of cancer recurrence – A literature review and proposed cognitive formulation to explain exacerbation of recurrence fears. *Psycho-Oncology*, 6(2), 95-105. doi: 10.1002/(SICI)1099-1611(199706)6:2<95::AID-PON250>3.0.CO;2-B
- Lewis, F., Merckaert, I., Caillier, M., Delevallez, F., Libert, Y., Lienard, A., . . . Razavi, D. (2013). Reducing breast cancer patients' psychological distress related to fear of recurrence: A randomized study comparing the efficacy of a therapy group and a support group [Abstract]. *Psycho-Oncology*, 22, 74.
- Leventhal, H., Diefenbach, M., & Leventhal, E. A. (1992). Illness cognition: using common sense to understand treatment adherence and affect cognition interactions. *Cognitive Therapy and Research*, 16(2), 143-163. doi: 10.1007/BF01173486

- Lipkus, I. M., Klein, W. M., Skinner, C. S., & Rimer, B. K. (2005). Breast cancer risk perceptions and breast cancer worry: What predicts what? *Journal of Risk Research*, 8(5), 439-452. doi: <http://dx.doi.org/10.1080/1366987042000311018>
- Llewellyn, C. D., Weinman, J., McGurk, M., & Humphris, G. (2008). Can we predict which head and neck cancer survivors develop fears of recurrence? *Journal of Psychosomatic Research*, 65, 525-532. doi:10.1016/j.jpsychores.2008.03.014
- Mast, M. E. (1998). Survivors of breast cancer: illness uncertainty, positive reappraisal, and emotional distress. *Oncology Nursing Forum* 25(3), 555-562. Retrieved from www.ncbi.nlm.nih.gov/pubmed/9568610.
- Moran, C., Tomei, C., Lefebvre, M., Harris, C., Maheu, C., & Lebel, S. (2016). *An exploratory study of the worst-case scenario exercise as an exposure treatment for fear of cancer recurrence*. Manuscript submitted for publication.
- Mishel, M. H. (1988). Uncertainty in illness. *Journal of Nursing Scholarship*, 20, 225-231. doi: 10.1111/j.1547-5069.1988.tb00082.
- Mutsaers, B., Jones, G., Rutkowski, N., Tomei, C., Leclair, C. S., Petricone-Westwood, D., . . . Lebel, S. (2016). When fear of cancer recurrence becomes a clinical issue: a qualitative analysis of features associated with clinical fear of cancer recurrence. *Supportive Care in Cancer*, 1-12. doi: 10.1007/s00520-016-3248-5.
- Pelletier, O., Gosselin, P., Langlois, F., & Ladouceur, R. (2001). Study of psychometric properties of two new questionnaires assessing beliefs in hypochondriasis in a non-clinical population. *L'Encephale*, 28(4), 298-309. Retrieved from www.ncbi.nlm.nih.gov/pubmed/12232539.

- Penedo, F. J., Molton, I., Dahn, J. R., Shen, B. J., Kinsinger, D., Traeger, L., . . . Antoni, M. (2006). A randomized clinical trial of group-based cognitive-behavioral stress management in localized prostate cancer: development of stress-management skills to improve quality of life and benefit finding. *Annals of Behavioral Medicine, 31*(3), 261-270. doi: 10.1207/s15324796abm3103_8
- Roth, A., Nelson, C. J., Rosenfeld, B., Warshowski, A., O'shea, N., Scher, H., . . . Breitbart, W. (2006). Assessing anxiety in men with prostate cancer: further data on the reliability and validity of the Memorial Anxiety Scale for Prostate Cancer (MAX-PC). *Psychosomatics, 47*(4), 340-347. doi: 10.1176/appi.psy.47.4.340
- Simard, S. & Savard, J. (2009). Fear of cancer recurrence inventory: Development and initial validation of a multidimensional measure of fear of recurrence. *Supportive Care in Cancer, 17*(3), 241-251. doi: 10.1007/s00520-008-0444-y
- Simard, S., Savard, J., & Ivers, H. (2010). Fear of cancer recurrence: specific profiles and nature of intrusive thoughts. *Journal of Cancer Survivorship, 4*(4), 361-71. doi: 10.1007/s11764-010-0136-8.
- Simard, S., & Savard, J. (2015). Screening and comorbidity of clinical levels of fear of cancer recurrence. *Journal of Cancer Survivorship, 9*(3), 481-491. doi: 10.1007/s11764-015-0424-4
- Simard, S., Thewes, B., Humphris, G., Dixon, M., Hayden, C., Mireskandari, S., & Ozakinci, G. (2013). Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *Journal of Cancer Survivorship, 7*(3), 300-22. doi: 10.1007/s11764-013-0272-z.

- Simpson, J. S., Carlson, L. E., & Trew, M. E. (2001). Effect of group therapy for breast cancer on healthcare utilization. *Cancer Practice*, *9*(1), 19-26. doi: 10.1111/j.1523-5394.2001.91005.pp.x
- Smith, A. B., Thewes, B., Turner, J., Gilchrist, J., Fardell, J., Sharpe, L., . . . Clutton, S. (2015). Pilot of a theoretically grounded psychologist- delivered intervention for fear of cancer recurrence (Conquer Fear). *Psycho-Oncology*, *24*(8), 967-970. doi: 10.1002/pon.3775
- Thewes, B., Brebach, R., Dzikowska, M., Rhodes, P., Sharpe, L & Butow, P. (2014). Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. *Psycho-Oncology*, *23*, 390-396. doi: 10.1002/pon.3423
- Tomei, C., Lebel, S., Maheu, C., & Mutsaers, B. (2016). Addressing fear of recurrence: improving psychological care in cancer survivors. *Supportive Care in Cancer*, 1-4. doi: 10.1007/s00520-016-3103-8
- van de Wal, M. A., Gielissen, M. F. M., Servaes, P., Knoop, H., Speckens, A. E. M., & Prins, J. B. (2015). Study protocol of the SWORD-study: a randomised controlled trial comparing combined online and face-to-face cognitive behaviour therapy versus treatment as usual in managing fear of cancer recurrence. *BMC Psychology*, *3*(12). doi: 10.1186/s40359-015-0068-1.

Appendix A

Telephone Screening and Eligibility Script, Study 1

Telephone Script to Call Interested Participants

Date: _____ Research Assistant: _____ Participant ID: _____

Hello, my name is Christina Tomei. I am a Ph.D. student in Clinical Psychology at the University of Ottawa. Thank you for your interest in the fear of cancer recurrence study. This study is part of my doctoral dissertation research. I will be looking to see if a new form of therapy for fear of cancer recurrence works. There will be therapy sessions for 1-1.5 hours a week, over the course of 6 weeks. We will meet once a week for the therapy sessions at The Ottawa Hospital Cancer Centre, Psychosocial Oncology Program. You will receive a copy of the intervention manual and learn a variety of coping exercises to help manage your fear of cancer recurrence, along with completing some in-between session exercises. All the sessions are videotaped to allow for quality checks. If you choose to participate, you will be asked to complete a series of online questionnaires before and after the therapy, to help us see if the therapy worked. You will receive reminder emails throughout to complete the questionnaires. We will protect your confidentiality: your name will not be associated with any of the questionnaires. If you are interested in participating in the study, we would start by assessing your eligibility to participate. In order to do this, I will ask you some questions over the phone. Should you meet eligibility criteria, we would then set up a meeting to get to know each other and go over some finer details about the therapy.

“Do you have any questions?”

If no, continue with the next question.

If yes, answer the questions to the best of your knowledge.

“Are you interested in participating in this study?”

If no: “Thank you for your time. For statistical purposes, may I ask you for your age, cancer diagnosis, and the reason for non-participation?”

If participant says ‘no’, please add: “Once again, thank you for your interest in this study. Have nice day.”

If patient says 'yes', please complete the following:

Refusal

Age: _____

Reason for declining participation: _____

If yes: “Thank you for your interest! I will ask you some questions to see if you are eligible to participate in the study. This should take about 10 minutes of your time.”

ELIGIBILITY CRITERIA

	Yes	No
1.a) Is this your first diagnosis of cancer?	_____	_____
1.b) Have you had a recurrence of your cancer?	_____	_____
1.c) What is the stage of your cancer?	Stages I-III	Stage IV
1.d) Have you completed your cancer treatments?	_____	_____
1.e) Are you 18 years of age or older?	_____	_____
1.f) What is your year of birth?	_____	_____
1.g) Can you speak, read, and write English?	_____	_____
1.h) Are you currently enrolled in individual or group psychotherapy for cancer issues?	_____	_____

***If participant answers No to questions 1 a, d, e, or g, he/she is not eligible for the study.*

***If participant indicates having a stage IV cancer (**question 1b**) or is enrolled in psychotherapy for cancer issues (**question 1h**), he/she is not eligible for the study.*

If the participant is not eligible:

“Thank you for answering my questions. Unfortunately, you are not eligible to take part in the study. Would you like us to discuss other psychological resources that may be appropriate for you?”

If participant is eligible so far, administer the following two measures:

“Most people who have been diagnosed with cancer are worried, to varying degrees, that there might be a recurrence of the cancer. By **recurrence**, we mean the possibility that the cancer could **return** or **progress** in the same place or in another part of the body. This questionnaire aims to better understand the experience of worries about cancer recurrence. I am going to read you several statements. I need you to let me know to what degree it applied to you **DURING THE PAST MONTH**.

1. How long have you been thinking about the possibility of cancer recurrence?				
0 I don't think about it	1 A few weeks	2 A few months	3 A few years	4 Several years
2. How much time <u>per day</u> do you spend thinking about the possibility of cancer recurrence?				
0 I don't think about it	1 A few seconds	2 A few minutes	3 A few hours	4 Several hours
3. How often do you think about the possibility of cancer recurrence?				
0 Never	1 A few times a month	2 A few times a week	3 A few times a day	4 Several times a day
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
4. In your opinion, what is your risk of having a cancer recurrence?				0 1 2 3 4
5. I am afraid of a cancer recurrence				0 1 2 3 4
6. I am worried or anxious about the possibility of cancer recurrence				0 1 2 3 4
7. I believe that I am cured and the cancer will not come back				0 1 2 3 4
8. I believe it is normal to be worried or anxious about the possibility of cancer recurrence				0 1 2 3 4
9. When I think about the possibility of a recurrence, other unpleasant thoughts or images come to mind (death, suffering, consequences for my family)				0 1 2 3 4

TOTAL: _____

ELIGIBLE (13 OR MORE) _____

“I’m going to read you a list of comments made by people about their cancer experience. Please tell me how frequently each item was true for you DURING THE PAST 7 DAYS. **You can say not at all, rarely, sometimes, often.** Again you can write these words down if you think it will help with your answer.”

	Not at All	Rarely	Sometimes	Often
1. I thought about my cancer experience when I didn’t mean to.	0	1	3	5
2. I avoided letting myself get upset when I thought about my cancer experience or I was reminded of it.	0	1	3	5
3. I tried to remove my cancer experience from my memory.	0	1	3	5
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about my cancer experience that came into my mind.	0	1	3	5
5. I had waves of strong feelings about my cancer experience.	0	1	3	5
6. I had dreams about my cancer experience.	0	1	3	5
7. I stayed away from reminders of my cancer experience.	0	1	3	5
8. I felt as if my cancer experience had not happened or was not real.	0	1	3	5
9. I tried not to talk about my cancer experience.	0	1	3	5
10. Pictures about my cancer experience popped into my mind.	0	1	3	5
11. Other things kept making me think of my cancer experience.	0	1	3	5
12. I was aware that I still had a lot of feelings about my cancer experience, but I didn’t deal with them.	0	1	3	5
13. I tried not to think about my cancer experience.	0	1	3	5
14. Any reminder brought back feeling about my cancer experience.	0	1	3	5
15. My feelings about my cancer experience were kind of numb.	0	1	3	5

TOTAL: _____

ELIGIBLE (24 OR MORE): _____

If the participant is not eligible:

“Thank you for answering my questions. Unfortunately, you are not eligible to take part in the study. Would you like us to discuss other psychological resources that may be appropriate for you?”

If the participant is eligible:

“Thank you for answering my questions. You are eligible to participate in the study! The next step is for you and I to set up a meeting. During this meeting, we will complete some additional measures, determine if this therapy is a good fit for your needs, and sign the consent forms. We will meet at The Ottawa Hospital’s Psychosocial Oncology Program.

“What are your availabilities for the meeting?”

Date : _____

Time : _____

“Thank you very much for your time. I look forward to meeting with you.”

Appendix B

Consent Form, Study 1



PARTICIPANT INFORMED CONSENT FORM

Title of Study: Adapting a Cognitive-Existential Group Intervention for Fear of Cancer Recurrence to an Individual Therapy

Local Site Principal Investigator (PI): Dr. Cheryl Harris, Ph.D., C.Psych

Sponsor: None

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

Why am I being given this form?

You are being asked to participate in this research study because we would like to examine how to help cancer patients address questions and concerns they may have with living with a past cancer diagnosis, such as fear of cancer recurrence. We will look at the usefulness of using an individual psychotherapy intervention as a way to approach understanding and dealing with issues that one may have following a cancer diagnosis. The goal is to see if whether the individual therapy is a good way to address issues and questions that relate to living with a cancer diagnosis.

Why is this study being done?

The purpose of this pilot study is to develop and test a new form of psychotherapy to decrease fear of cancer recurrence for women and men with cancer and its treatment, and thereby enhance psychological functioning throughout survivorship. We estimate that 4 participants will be enrolled in the study.

How is the study designed?

In order to test this new form of psychotherapy, we will be using questionnaires and interviews. Upon determining if you are eligible for participation in this study, you will be assigned a participant number and asked to complete a series of online questionnaires before, during, and after the intervention. You will be asked to wait a period of 4 weeks prior to beginning the therapy. After each therapy session, you will be asked to complete the online questionnaire package. You will also be asked to complete an exit interview upon completion of the intervention. Once all participants have completed psychotherapy, we will put together the results of the questionnaires and interviews to see if this therapy appears to work Christina

Tomei, a Ph.D. student in Clinical Psychology at the University of Ottawa and one of the study co-investigators, will conduct the therapy sessions. This study is in partial fulfillment of Christina Tomei's doctoral thesis requirements.

What is expected of me?

You will receive a weekly form of psychotherapy of 60 minutes for 6 weeks at the Ottawa Hospital Cancer Centre - Psychosocial Oncology Program (PSOP). All of the treatment you will receive is part of the study. You will also receive instructions on how to practice relaxation techniques, and you will be asked to practice these techniques at home. Prior to the therapy, you will meet with a member of the research team at PSOP to determine eligibility and to prepare you for the therapy.

You will be asked to complete 10 online questionnaire packages. You will be asked to complete these online questionnaires during the four-week wait period, and after each therapy session, for a total of 10 times. You will be assigned a participant number and given a link to access the online questionnaires. The questionnaires are to assess your fear of cancer recurrence and the psychological impact of cancer, and the package includes a demographic information form. During the intervention phase, each questionnaire package will also include a post-session feedback questionnaire, which will ask about your opinion of each therapy session. The questionnaires will take approximately 20 minutes to complete. You may skip any questions that make you uncomfortable or that you do not wish to answer.

You will meet with Christina Tomei once a week for 6 weeks to receive the individual therapy. Prior to beginning the therapy, confidentiality will be explained to you. You will be provided with a manual with coping strategies and techniques to guide you through the intervention. All therapy sessions will be video recorded using the video camera at the PSOP. The videos are immediately stored in secured files on the hospital hard drive. The video recordings will not be associated with any identifying information. Only members of the research team will have access to the videos.

You will be asked to participate in 1 exit interview, at the end of the therapy intervention. The exit interview is conducted to discuss your opinions on the intervention, and to determine your level of satisfaction. The exit interview will be approximately 30 minutes long. You may skip any questions that make you uncomfortable or that you do not wish to answer. The exit interview will be audio recorded and conducted by a member of the research team who will be blind to your experience with the intervention. The audio recordings will not be associated with any identifying information. Only members of the research team will have access to the audio recordings. As this is a research study, video and audio recording is a necessary component for participation in the intervention. The recordings are necessary for both research and clinical supervision purposes. Therefore, you will not be able to participate in the study should you choose to opt out of the recordings.

How long will I be involved in the study?

The entire study will last approximately 4 months. Your participation in the study will last approximately 10 weeks. Over this time, you will be required to visit the Psychosocial Oncology Program at the Ottawa Hospital Cancer Centre for 7 visits.

What are the potential risks I may experience?

You will be asked to reflect about your personal experiences with cancer and issues revolving around fear of cancer recurrence. There is very little risk associated with this study. Some patients find they get emotional when talking about their cancer experience. If you experience any discomfort that we feel requires one on one psychological support, we can suggest a reference to the PSOP at the Ottawa Hospital Cancer Centre. This option is available to you at any time.

Questionnaires and Interviews:

You might find the questionnaires and interviews to be lengthy. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

Can I expect to benefit from participating in this research study?

You may not receive any direct benefit from your participation in this study. Your participation may allow the researchers to understand what therapeutic techniques are helpful for survivors living with fear of cancer recurrence. This may benefit future patients and may contribute to the development of effective interventions for women and men who have been treated for cancer at the hospital.

Do I have to participate? What alternatives do I have? If I agree now, can I change my mind and withdraw later?

Your participation in this study is voluntary. The alternative to this study is not to participate.

You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting your medical care or other services to which you are entitled or are presently receiving at this institution.

If you withdraw your consent, the study team will no longer collect your identifying information for research purposes. All questionnaires are anonymous and assigned by participant number, so there is no link between the participant and their questionnaire.

Will I be paid for my participation or will there be any additional costs to me?

You will be reimbursed the cost of public transportation or parking fees (with proof of receipt) for each visit that you make for the study. This will include one pre-therapy meeting as well as

the 6 therapy sessions, for a total of 7 visits.

How is my personal information being protected?

- All information collected during your participation in this study will be identified with a unique study number, and will not contain information that identifies you, such as your name, address, etc.
- The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave this site.
- Any documents or samples leaving The Ottawa Hospital will contain only your unique study number. This includes publications or presentations resulting from this study.
- Information that identifies you will be released only if it is required by law.
- For audit purposes only, your original study records may be reviewed under the supervision of Dr. Cheryl Harris' staff by representatives from:
 - The Ottawa Health Science Network Research Ethics Board (OHSN-REB),
 - The Ottawa Hospital
 - The University of Ottawa School of Psychology
- Research records will be kept for 10 years, after this time they will be destroyed.

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

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

Who do I contact if I have any further questions?

If you have any questions about this study, please contact the primary investigator, Dr. Cheryl Harris, or the co-investigators, Christina Tomei, and Dr. Sophie Lebel.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at the Ottawa Hospital. If you have any questions about your rights as a study participant, you may contact the Chairperson.



Adapting a Cognitive-Existential Group Intervention for Fear of Cancer Recurrence to an Individual Therapy

Consent to Participate in Research

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

Participant's Printed Name

Participant's Signature

Date

Investigator or Delegate Statement

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

Investigator/Delegate's Printed Name

Investigator/Delegate's Signature

Date

Appendix C
Fidelity Checklist, Study 1 & 2

Fidelity Checklist CE Individual Intervention

Date:

Therapist:

Rater:

SESSION 1

	Skill/activity	Frequency or done yes(1)/no(0)	Rating 0, 1, 2	Comments
	SPECIFIC CONTENT AND TASKS			
1.	Therapist asked to obtain level of FCR on a post-it (enter data)			
2.	Therapist reviewed CBT Triangle/ABC Model			
3.	Therapist reviewed FCR model			
4.	Session 1: Exercise 1: Therapist defined triggers and asked patient to identify some of their triggers.			
5.	Therapist explained the emotional process when experiencing a trigger			
6.	Therapist explained the physical process when experiencing a trigger			
7.	Therapist reviewed how patient feels when experiencing a trigger			
8.	Therapist introduces and explains cognitive restructuring to patient			
9.	Session 1: Exercise 2 completed (thought record)			
10.	Session 1: Exercise 3– Patient identified a more realistic response			
11.	Session 1: Exercise 3 - Therapist read the progressive muscular relaxation text			
12.	Therapist reviewed how the patient felt during the PMR			
13.	Therapist concluded on session objective to understand effect of FCR on patient			
14.	Therapist reviewed homework for next session			
15.	Session ended with grounding exercise			
	INTERVENTION-SPECIFIC SKILLS			
	Therapist refers back to theoretical framework (i.e. inappropriate use of avoidance, worry, extensive info seeking)			
	Therapist refers back to specific tools and skills taught in the intervention			
	NON-SPECIFIC SKILLS			
	Therapist initiated problem solving skills (i.e. what would you do if you were facing a similar problem)			
	Therapist used here and now technique (i.e. what is it like to say that out loud?)			
	Therapist demonstrated empathy towards patient			

	Therapist processed difficult emotions in depth			
	Therapist had adequate time management (i.e. spent enough time on each exercise and finished on time)			

Final adherence rating for session 1: specific content and tasks (/15) + intervention-specific skills (/4) + non-specific skills (/10) = /29 = /100

SESSION 2				
	Skill/activity	Frequency or done yes(1)/no(0)	Rating 0, 1, 2	Comments
	SPECIFIC CONTENT AND TASKS			
1.	Therapist describes aim of session 2 to reduce uncertainty			
2.	Therapist checks in with patient for any questions/concerns			
3.	Therapist asked to obtain level of FCR on a post-it (enter data)			
4.	Therapist reviewed last session homework			
5.	Therapist explained that increase in information decreases uncertainty			
6.	Session 2: Exercise 1: Therapist explained notion of unpredictable aspects of life, but that we can control our reactions and have managed to cope to date			
7.	Session 2: Exercise 1: Therapist went through the patient responses to the questions posted in patient manual			
8.	Session 2: Exercise 3: Regaining control. Therapist provided time to do and review the pie exercise from the Patient manual			
9.	Therapist processes items 3 and 4 with patient from the pie exercise			
10.	Session 2: Exercise 4: Calming self-talk exercise was done			
11.	Therapist helps patient formulate at least one calming-self talk			
12.	Therapist concluded on session objective to deal with uncertain future, how to prioritize what is within our control and use of calming self-talk			
13.	Therapist reviewed homework for next session			
14.	Session ended with grounding exercise			
	INTERVENTION-SPECIFIC SKILLS			
15.	Therapist refers back to theoretical framework (i.e. inappropriate use of avoidance, worry, extensive info seeking)			
16.	Therapist refers back to specific tools and skills taught in the intervention			
	NON-SPECIFIC SKILLS			
17.	Therapist initiated problem solving skills (i.e. what would you do if you were facing a similar problem)			
18.	Therapist used here and now technique (i.e. what is it like to say that out loud?)			
19.	Therapist demonstrated empathy towards patient			

20.	Therapist processed difficult emotions in depth			
21.	Therapist had adequate time management (i.e. spent enough time on each exercise and finished on time)			

Final adherence rating for session 2: specific content and tasks (/14) + intervention-specific skills (/4) + non-specific skills (/10) = /28 = /100

SESSION 3				
	Skill/activity	Frequency or done yes(1)/no(0)	Rating 0, 1, 2	Comments
	SPECIFIC CONTENT AND TASKS			
1.	Therapist describes aim of session 3 to demystify faulty belief of worry			
2.	Therapist checks in with patient for any questions/concerns			
3.	Therapist asked to obtain level of FCR on a post-it (enter data)			
4.	Therapist reviewed last session homework			
5.	Therapist explained notion of faulty beliefs of worry			
6.	Session 3: Exercise 1: Therapist asked patient to identify two advantages and disadvantages of worry			
7.	Therapist processed the worry questionnaire			
8.	Therapist explained Figure 1 Avoidance			
9.	Therapist explained Figure 2 Exposition			
10.	Session 3: Exercise 3: Therapist asks patient to list triggers			
11.	Session 3: Exercise 3 part 2: Therapist processed consequence of maladaptive coping strategies using the table/model			
12.	Session 3: Exercise 3 part 2: Therapist asked patient to list and share considered adaptive coping behaviors to anxiety situation			
13.	Session 3: Exercise 4: Guided imagery (explain exercise)			
14.	Therapist dimmed light			
15.	Therapist read the guided imagery script			
16.	Therapist processed the experience of guided imagery			
17.	Therapist concluded on aim of session			
18.	Therapist reviewed homework for next session			
19.	Session ended with a grounding exercise			
	INTERVENTION-SPECIFIC SKILLS			
20.	Therapist refers back to theoretical framework (i.e. inappropriate use of avoidance, worry, extensive info seeking)			
21.	Therapist refers back to specific tools and skills taught in the intervention			
	NON-SPECIFIC SKILLS			
22.	Therapist initiated problem solving skills (i.e. what would you do if you were facing a similar problem)			
23.	Therapist used here and now technique (i.e. what is it like to say that out loud?)			

24.	Therapist demonstrated empathy towards patient			
25.	Therapist processed difficult emotions in depth			
26.	Therapist had adequate time management (i.e. spent enough time on each exercise and finished on time)			

Final adherence rating for session 3: specific content and tasks (/19) + intervention-specific skills (/4) + non-specific skills (/10) = /33= /100

SESSION 4

	Skill/Activity	Frequency or done yes(1)/no(0)	Rating 0, 1, 2	Comments
	SPECIFIC CONTENT AND TASKS			
1.	Therapist describes aim of session 4 to face their worst fear			
2.	Therapist checks in with patient for any questions/concerns			
3.	Therapist asked to obtain level of FCR on a post-it (enter data)			
4.	Therapist reviewed last session homework			
5.	Session 4: Exercise 1: Therapist asked to view pink elephant picture			
6.	Therapist explained rationale of exposure and consequences of using avoidance			
7.	Therapist explained the procedural outcome when we avoid fears			
8.	Session 4: Exercise 2: Therapist asked patient to list fears associated with return of cancer			
9.	Therapist read script example of what may happens when you explore your fears			
10.	Therapist processes at least one specific fear listed from patient from exercise 2.			
11.	Session 4: Exercise 3: Most challenging feared scenario. Therapist asked patient to complete Exercise 3			
12.	Therapist reviewed patient's most challenging scenario			
13.	Therapist processes patient's most challenging scenario into a more realistic outcome scenario			
14.	Therapist helps patient build a more realistic outcome scenario			
15.	Session 4: Exercise 4: Therapist read and did body scan exercise			
16.	Therapist processed the experience of body scan by checking in on patient's emotional state			
17.	GL concluded on aim of session			
18.	GL reviewed homework for next session			
19.	Session ended with grounding exercise			
	INTERVENTION-SPECIFIC SKILLS			
20.	Therapist refers back to theoretical framework (i.e. inappropriate use of avoidance, worry, extensive info seeking)			
21.	Therapist refers back to specific tools and skills taught in the intervention			
	NON-SPECIFIC SKILLS			

22.	Therapist initiated problem solving skills (i.e. what would you do if you were facing a similar problem)			
23.	Therapist used here and now technique (i.e. what is it like to say that out loud?)			
24.	Therapist demonstrated empathy towards patient			
25.	Therapist processed difficult emotions in depth			
26.	Therapist had adequate time management (i.e. spent enough time on each exercise and finished on time)			

Final adherence rating for session 4: specific content and tasks (/19) + intervention-specific skills (/4)
+ non-specific skills (/10) = /33 = /100

SESSION 5				
	Skill/Activity	Frequency or done yes(1)/no(0)	Rating 0, 1, 2	Comments
	SPECIFIC CONTENT AND TASKS			
1.	Therapist describes aim of session 5 to move beyond specific fears and building more realistic outcome			
2.	Therapist checks in with patient for any questions/concerns			
3.	Therapist asked to obtain level of FCR on a post-it (enter data)			
4.	Therapist reviewed last session homework			
5.	Session 5: Exercise 1: Completed exercise on coping strategies listed in Patient workbook			
6.	Therapist teaches how to problem solve by looking at situation in alternate ways			
7.	Session 5: Exercise 2: moving beyond fears. Therapist invites patient to reflect on the 2 questions (and challenges catastrophic thinking with prompts, if necessary)			
8.	Session 5: Exercise 3: Therapist did the mindfulness exercise			
9.	Therapist process the experience of mindfulness exercise and checks in on patient's emotional state			
10.	Therapist concluded on aim of session			
11.	Therapist reviewed homework for next session			
12.	Session ended with grounding exercise			
	INTERVENTION-SPECIFIC SKILLS			
13.	Therapist refers back to theoretical framework (i.e. inappropriate use of avoidance, worry, extensive info seeking)			
14.	Therapist refers back to specific tools and skills taught in the intervention			
	NON-SPECIFIC SKILLS			
15.	Therapist initiated problem solving skills (i.e. what would you do if you were facing a similar problem)			
16.	Therapist used here and now technique (i.e. what is it like to say that out loud?)			
17.	Therapist demonstrated empathy towards patient			
18.	Therapist processed difficult emotions in depth			
19.	Therapist had adequate time management (i.e. spent enough time on each exercise and finished on time)			

Final adherence rating for session 5: specific content and tasks (/12) + intervention-specific skills (/4) + non-specific skills (/10) = /26 = /100

SESSION 6				
	Skill/Activity	Frequency or done yes(1)/no(0)	Rating 0, 1, 2	Comments
SPECIFIC CONTENT AND TASKS				
1.	Therapist describes aim of session 6 to review content covered and to provide closure to the therapy intervention			
2.	Therapist checks in with patient for any questions/concerns			
3.	Therapist asked to obtain level of FCR on a post-it (enter data)			
4.	Therapist reviewed last session homework			
5.	Therapist helped patient bring closure by reflecting on the end of the intervention and their feelings towards it			
6.	Therapist concluded on aim of session			
7.	Session ended with grounding exercise			
INTERVENTION-SPECIFIC SKILLS				
8.	Therapist refers back to theoretical framework (i.e. inappropriate use of avoidance, worry, extensive info seeking)			
9.	Therapist refers back to specific tools and skills taught in the intervention			
NON-SPECIFIC SKILLS				
10.	Therapist initiated problem solving skills (i.e. what would you do if you were facing a similar problem)			
11.	Therapist used here and now technique (i.e. what is it like to say that out loud?)			
12.	Therapist demonstrated empathy towards patient			
13.	Therapist processed difficult emotions in depth			
14.	Therapist had adequate time management (i.e. spent enough time on each exercise and finished on time)			

Final adherence rating for session 6: specific content and tasks (/7) + intervention-specific skills (/4) + non-specific skills (/10) = /21 = /100

Appendix D
Questionnaire Package, Study 1

Today's Date: _____

Study ID#: _____

Demographic Information

Please check the statement that best reflects your circumstances by placing an "X" on the line beside your chosen statement. Also, please provide your specific answer to question 6.

1. Current Marital Status:

- | | |
|--|--|
| <input type="checkbox"/> (1) single, never married | <input type="checkbox"/> (3) separated, divorced |
| <input type="checkbox"/> (2) married/common-law | <input type="checkbox"/> (4) widowed |

2. Highest Education Level Achieved:

- | | |
|--|---|
| <input type="checkbox"/> (1) elementary school | <input type="checkbox"/> (4) part of university/college |
| <input type="checkbox"/> (2) part of high school | <input type="checkbox"/> (5) university/college |
| <input type="checkbox"/> (3) high school | <input type="checkbox"/> (6) graduate school |

3. Current Occupational Status: (select the best response)

- | | |
|--|---|
| <input type="checkbox"/> (1) employed full-time | <input type="checkbox"/> (5) unemployed |
| <input type="checkbox"/> (2) employed part time by choice | <input type="checkbox"/> (6) retired |
| <input type="checkbox"/> (3) employed part-time due to illness | <input type="checkbox"/> (7) homemaker |
| <input type="checkbox"/> (4) unemployed due to illness | <input type="checkbox"/> (8) student |

4. Please describe your ethnic background:

- | | |
|---|---------------------------------------|
| <input type="checkbox"/> (1) Caucasian | <input type="checkbox"/> (3) Asian |
| <input type="checkbox"/> (2) African-Canadian | <input type="checkbox"/> (4) Hispanic |
| <input type="checkbox"/> (5) Other | |

5. Annual Income Level: (household)

___ (1) \$00,000 – \$20,000

___ (4) \$61,000 - \$80,000

___ (2) \$21,000 - \$40,000

___ (5) \$81,000 - \$ 100,000

___ (3) \$41,000 - \$60,000

___ (6) greater than \$100,000

6. Age: _____

Medical History

Please check the answer that best reflects your circumstances by placing an “X” on the box beside your chosen response. Also, please provide your specific answers to the additional questions if checking yes.

1. Have you ever been diagnosed with cancer?

Yes Please indicate when: _____

No

2. If you are aware, please indicate the stage of your cancer at diagnosis:

a. Stage: _____

3. Please list your current medications and dosages:

4. Please circle the treatments you have received:

Surgery

Chemotherapy

Radiation

Other _____

Please indicate your **end of treatment** date: _____

Use of additional support services:

3. Are you currently receiving the services of a mental health professional for your feelings towards cancer?

Yes Please indicate: _____

No

4. Are you currently attending a support group to help you deal with your feelings towards cancer?

Yes Please indicate: _____

No

Fear of Cancer Recurrence Inventory

Most people who have been diagnosed with cancer are worried, to varying degrees, that there might be a recurrence of the cancer. **By recurrence, we mean the possibility that the cancer could return or progress in the same place or in another part of the body.** This questionnaire aims to better understand the experience of worries about cancer recurrence. Please read each statement and indicate to what degree it applied to you **DURING THE PAST MONTH** by circling the appropriate number.

0	1	2	3	4
Never	Rarely	Sometimes	Most of the time	All the time

The following situations make me think about the possibility of cancer recurrence:

- | | | | | | |
|---|---|---|---|---|---|
| 1. Television shows or newspaper articles about cancer or illness
..... | 0 | 1 | 2 | 3 | 4 |
| 2. An appointment with my doctor or other health professional
..... | 0 | 1 | 2 | 3 | 4 |
| 3. Medical examinations (e.g. annual check-up, blood tests, X-rays)
..... | 0 | 1 | 2 | 3 | 4 |
| 4. Conversations about cancer or illness in general
..... | 0 | 1 | 2 | 3 | 4 |
| 5. Seeing or hearing about someone who is ill
..... | 0 | 1 | 2 | 3 | 4 |
| 6. Going to a funeral or reading the obituary section of the paper
..... | 0 | 1 | 2 | 3 | 4 |
| 7. When I feel unwell physically or when I am sick
..... | 0 | 1 | 2 | 3 | 4 |
| 8. Generally, I avoid situations or things that make me think about the possibility of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |

0	1	2	3	4
Not at all	A little	Somewhat	A lot	A great deal

- | | | | | | |
|--|---|---|---|---|---|
| 9. I am worried or anxious about the possibility of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |
| 10. I am afraid of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |
| 11. I believe it is normal to be worried or anxious about the possibility of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |
| 12. When I think about the possibility of cancer recurrence, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family)
..... | 0 | 1 | 2 | 3 | 4 |
| 13. I believe that I am cured and that the cancer will not come back | 0 | 1 | 2 | 3 | 4 |

.....
 14. In your opinion, are you at risk of having a cancer recurrence?

0	1	2	3	4
Not at all at risk	A little at risk	Somewhat at risk	A lot at risk	A great deal at risk

15. How often do you think about the possibility of cancer recurrence?

0	1	2	3	4
Never	A few times a month	A few times a week	A few times a day	Several times a day

16. How much time per day do you spend thinking about the possibility of cancer recurrence?

0	1	2	3	4
I don't think about it	A few seconds	A few minutes	A few hours	Several hours

17. How long have you been thinking about the possibility of cancer recurrence?

0	1	2	3	4
I don't think about it	A few weeks	A few months	A few years	Several years

0	1	2	3	4
Not at all	A little	Somewhat	A lot	A great deal

When I think about the possibility of cancer recurrence, I feel:

- | | | | | | |
|--|---|---|---|---|---|
| 18. Worry, fear or anxiety
..... | 0 | 1 | 2 | 3 | 4 |
| 19. Sadness, discouragement or disappointment
..... | 0 | 1 | 2 | 3 | 4 |
| 20. Frustration, anger or outrage
..... | 0 | 1 | 2 | 3 | 4 |
| 21. Helplessness or resignation
..... | 0 | 1 | 2 | 3 | 4 |

My thoughts or fears about the possibility of cancer recurrence disrupt:

- | | | | | | |
|--|---|---|---|---|---|
| 22. My social or leisure activities (e.g. outings, sports, travel)
..... | 0 | 1 | 2 | 3 | 4 |
| 23. My work or everyday activities
..... | 0 | 1 | 2 | 3 | 4 |
| 24. My relationships with my partner, my family, or those close to me
..... | 0 | 1 | 2 | 3 | 4 |
| 25. My ability to make future plans or set life goals
..... | 0 | 1 | 2 | 3 | 4 |
| 26. My state of mind or my mood
..... | 0 | 1 | 2 | 3 | 4 |
| 27. My quality of life in general
..... | 0 | 1 | 2 | 3 | 4 |

	0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
28. I feel that I worry excessively about the possibility of cancer recurrence	0	1	2	3	4
29. Other people think that I worry excessively about the possibility of cancer recurrence	0	1	2	3	4
30. I think that I worry more about the possibility of cancer recurrence than other people who have been diagnosed with cancer	0	1	2	3	4

	0 Never	1 Rarely	2 Sometimes	3 Most of the time	4 All the time
--	-------------------	--------------------	-----------------------	------------------------------	--------------------------

When I think about the possibility of cancer recurrence, I use the following strategies to reassure myself:

31. I call my doctor or other health professional	0	1	2	3	4
32. I go to the hospital or clinic for an examination	0	1	2	3	4
33. I examine myself to see if I have any physical signs of cancer	0	1	2	3	4
34. I try to distract myself (e.g. do various activities, watch television, read, work)	0	1	2	3	4
35. I try not to think about it, to get the idea out of my mind	0	1	2	3	4
36. I pray, meditate or do relaxation	0	1	2	3	4
37. I try to convince myself that everything will be fine or I think positively	0	1	2	3	4
38. I talk to someone about it	0	1	2	3	4
39. I try to understand what is happening and deal with it	0	1	2	3	4
40. I try to find a solution	0	1	2	3	4
41. I try to replace this thought with a more pleasant one	0	1	2	3	4
42. I tell myself "stop it"	0	1	2	3	4
Do you feel reassured when you use these strategies?	0	1	2	3	4

IMPACT OF EVENT SCALE

EVENT: CANCER EXPERIENCE

Directions: Below is a list of comments made by people about stressful life events and the context surrounding them. Please read each item and decide how frequently each item was true for you DURING THE PAST 7 DAYS. Please place an “X” on the box below the frequency you want to indicate for each statement.

		Not at All	Rarely	Sometimes	Often
1.	I thought about my cancer experience when I didn't mean to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	I avoided letting myself get upset when I thought about my cancer experience or I was reminded of it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	I tried to remove my cancer experience from my memory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.	I had trouble falling asleep or staying asleep because of pictures or thoughts about my cancer experience that came into my mind.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.	I had waves of strong feelings about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.	I had dreams about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.	I stayed away from reminders of my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	I felt as if my cancer experience had not happened or was not real.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	I tried not to talk about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Pictures about my cancer experience popped into my mind.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Other things kept making me think of my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	I was aware that I still had a lot of feelings about my cancer experience, but I didn't deal with them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13.	I tried not to think about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Any reminder brought back feeling about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	My feelings about my cancer experience were kind of numb.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix E
Post-Session Feedback Questionnaires, Study 1

Questionnaire – Session 1

For the following questions, please answer honestly. There are no right or wrong answers.

Please rate each of the following statements on a scale from 1 to 5:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

I found the exercise of writing down my triggers in session helpful

1 2 3 4 5

I found the exercise of completing a thought record in session helpful

1 2 3 4 5

I enjoyed completing the thought record

1 2 3 4 5

I found writing down my fears was helpful

1 2 3 4 5

I found the progressive muscular relaxation exercise useful

1 2 3 4 5

I found writing down my questions about recurrence to be helpful

1 2 3 4 5

My mind wandered during the Relaxation CD at home

1 2 3 4 5

I had difficulty concentrating and staying focused during the Relaxation CD at home

1 2 3 4 5

I enjoyed listening to the Relaxation CD at home

1 2 3 4 5

For the following questions, please answer either “Yes” or “No”, and select the appropriate number that corresponds with your experience.

Have you filled out the thought record over the course of the week? Yes No

How many DAYS during the past week have you filled out the thought record?

0 1 2 3 4 5 6 7

How many TIMES during the past week have you filled out the thought record?

0 1 2 3 4 5 6 7

Have you used the Relaxation CD during the past week? Yes No

How many DAYS during the past week did you use the Relaxation CD?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you use the Relaxation CD?

0 1 2 3 4 5 6 7

Please provide feedback for the following questions:

What was most helpful for you this session?

What was most helpful of the homework exercises?

What did you take from this session?

Questionnaire – Session 2

For the following questions, please answer honestly. There are no right or wrong answers.

Please rate each of the following statements on a scale from 1 to 5:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

I found the exercise of discussing my questions about a cancer recurrence in session to be helpful

1 2 3 4 5

It is likely that I will ask my oncologist the questions I prepared

1 2 3 4 5

I found it helpful to talk about my uncertainty about my future this session

1 2 3 4 5

I was able to identify areas of my life where I am in control

1 2 3 4 5

I enjoyed completing the pie chart exercise in session

1 2 3 4 5

Selecting calming self-talk phrases was a useful exercise for me

1 2 3 4 5

I found it helpful to identify specific triggers and apply relevant calming self-talk phrases

1 2 3 4 5

I had difficulty concentrating and staying focused during the Relaxation CD at home

1 2 3 4 5

I enjoyed listening to the Relaxation CD at home

1 2 3 4 5

For the following questions, please answer either “Yes” or “No”, and select the appropriate number that corresponds with your experience.

Were you able to listen to your relaxation CD and incorporate two of your favourite calming self-talk phrases this week? Yes No

How many DAYS during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

Were you able to fill out the thought record this week? Yes No

How many DAYS during the past week have you filled out the thought record?

0 1 2 3 4 5 6 7

How many TIMES during the past week have you filled out the thought record?

0 1 2 3 4 5 6 7

Were you able to engage in progressive muscle relaxation (PMR) this week? Yes No

How many DAYS during the past week did you engage in PMR?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you engage in PMR?

0 1 2 3 4 5 6 7

Please provide feedback for the following questions:

What was most helpful for you this session?

What was most helpful of the homework exercises?

What did you take from this session?

Questionnaire – Session 3

For the following questions, please answer honestly. There are no right or wrong answers.

Please rate each of the following statements on a scale from 1 to 5:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

I found this session helpful in increasing my tolerance for uncertainty

1 2 3 4 5

It was useful to identify the advantages and disadvantages of worrying about FCR

1 2 3 4 5

I found the explanation of avoidance and anxiety level to be helpful

1 2 3 4 5

It was useful to identify triggers that could lead me to use maladaptive coping strategies

1 2 3 4 5

I enjoyed the guided imagery exercise in session

1 2 3 4 5

For the following questions, please answer either “Yes” or “No”, and select the appropriate number that corresponds with your experience.

Was it useful to challenge your need to worry, and identify alternative ways of thinking (e.g., identifying a more realistic/helpful point of view) ? Yes No

Were you able to identify your automatic thoughts and write down the facts/evidence that supports these thoughts? Yes No

How many DAYS during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

Were you able to engage in the guided imagery exercise this week? Yes No

How many DAYS during the past week did you engage in the guided imagery exercise?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you engage in the guided imagery exercise?

0 1 2 3 4 5 6 7

Please provide feedback for the following questions:

What was most helpful for you this session?

What was most helpful of the homework exercises?

What did you take from this session?

Questionnaire – Session 4

For the following questions, please answer honestly. There are no right or wrong answers.

Please rate each of the following statements on a scale from 1 to 5:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

Listing my specific fears about my cancer returning was a useful exercise

1 2 3 4 5

Writing down my worst case scenario was a helpful exercise

1 2 3 4 5

This is the first time I have written down my worst case scenario

1 2 3 4 5

I found the body scan exercise helpful in session

1 2 3 4 5

For the following questions, please answer either “Yes” or “No”, and select the appropriate number that corresponds with your experience.

Were you able to complete the homework exercise of writing down your worst-case scenario, and reading it once a day? Yes No

Were you able to write down your feelings before and after you read your worst-case scenario?

Yes No

How many DAYS during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

Were you able to engage in the body scan exercise this week? Yes No

How many DAYS during the past week did you engage in the body scan exercise?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you engage in the body scan exercise?

0 1 2 3 4 5 6 7

Please provide feedback for the following questions:

What was most helpful for you this session?

What was most helpful of the homework exercises?

What did you take from this session?

Questionnaire – Session 5

For the following questions, please answer honestly. There are no right or wrong answers.

Please rate each of the following statements on a scale from 1 to 5:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

Writing down coping strategies to manage my worst fears was a useful exercise

1 2 3 4 5

Identifying what my future means to me was helpful

1 2 3 4 5

I am learning to identify alternative/helpful ways of thinking about my worst fear

1 2 3 4 5

I found the mindfulness exercise (eating meditation) helpful in this session

1 2 3 4 5

For the following questions, please answer either “Yes” or “No”, and select the appropriate number that corresponds with your experience.

Were you able to write down some goals and priorities for the future? Yes No

If yes, did you find writing down goals/priorities to be helpful? Yes No

If yes, were you able to write down a tentative plan to achieve those goals and priorities?

Yes No

How many DAYS during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

Were you able to engage in the mindfulness exercise this week? Yes No

How many DAYS during the past week did you engage in the mindfulness exercise?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you engage in the mindfulness exercise?

0 1 2 3 4 5 6 7

Please provide feedback for the following questions:

What was most helpful for you this session?

What was most helpful of the homework exercises?

What did you take from this session?

Questionnaire – Session 6

For the following questions, please answer honestly. There are no right or wrong answers.

Please rate each of the following statements on a scale from 1 to 5:

1 = Strongly Disagree

2 = Disagree

3 = Neutral

4 = Agree

5 = Strongly Agree

I found it helpful to debrief in the final session about my experience in the FCR intervention

1 2 3 4 5

This intervention has helped me think about my cancer in a different way

1 2 3 4 5

By practicing the mindfulness exercises, I notice that I am more relaxed

1 2 3 4 5

For the following questions, please answer either “Yes” or “No”, and select the appropriate number that corresponds with your experience:

How many DAYS during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

How many TIMES during the past week did you listen to your relaxation CD?

0 1 2 3 4 5 6 7

Please provide feedback for the following questions:

Which session was most helpful for you? Please identify which session and explain why.

Which session was least helpful for you? Please identify which session and explain why.

Of all the homework exercises, which was most useful? Please explain.

Which session did you take the most from? Please identify which session and explain why.

Appendix F
Qualitative Exit Interview Guide, Study 1

Qualitative Exit Interview Guide

Hello, my name is _____. To begin, I would like to request your permission to tape our telephone conversation for quality monitoring only. So you know, any identifiers such as your name will be removed from both the tape and typed versions of the interviews. We will also keep all tapes in a password-protected file on a desktop computer situated in locked area at The Ottawa Hospital until data analysis is complete, when we will destroy the tapes. Only the main investigators will have access to this information. Do you agree to have this interview audiotape?

Yes No

Also, we encourage you to be honest when answering. There are no right or wrong answers.

1. What was your experience like in participating in this study?

2. What is your experience with FCR like, now that you have completed the sessions?

If change for the better:

- How is your FCR better?
- Why is your FCR better?
- What do you attribute being better to?

If unchanged:

- What is that like for you that it's unchanged?
- What are your feelings about this?
- What do you attribute being unchanged to?

If change for worse:

- How is your FCR worse?
- Why is your FCR worse?
- What do you attribute it being worse to?

3. What were the most important moments for you throughout the therapy?
 - What was your experience of that moment?
 - How did it impact you then?
 - How does it impact you today?

4. What was most helpful with dealing with your fear of cancer recurrence in this study?
5. What was least helpful with your fear of cancer recurrence in this study?
6. A lot of material was covered in session and also outside/in between sessions.
 - What did you think of this combination of in session and between session material referencing?
 - How helpful was the in-session material?
 - How helpful was the in-between session material?
 - Which exercise (either in or out of session) did you find most helpful?
7. What exercises did you like best?
8. What exercises you did not like?
9. How did you feel about the homework assignments?
10. If you could do this therapy again, what would you change?
11. If you could do this therapy again, what would you keep the same?
12. What do you think about the format of the intervention, such as the number of sessions and the length of each session?
 - Would you change something about the number/length of sessions?
 - How did you find the pace of the sessions?
13. Would you recommend this intervention for patients in similar circumstances?
14. This wraps up the questions I wanted to ask. Do you have any additional comments or questions?

Thank you very much for your time. If you have any further questions or comments, you can contact Dr. Sophie Lebel.

Appendix G
Telephone Screening and Eligibility Script, Study 2

TELEPHONE SCRIPT

Date: _____ **Research assistant:** _____ **Participant ID #:** _____

GOALS OF THE STUDY:

Hello, my name is _____ and I am involved in the study on fear of cancer recurrence here at The Ottawa Hospital Cancer Centre.

First, I would like to thank you for your interest in this study. This study is about helping men and women deal with fear of cancer recurrence. Specifically, our intent is to help individuals manage their fear of cancer recurrence. If you decide that you want to participate, you will be randomly assigned by chance to receive either the individual psychotherapy intervention, or you will be placed on 6-week wait list to receive the intervention. The decision will be made by chance. If you choose to participate, you will have to complete a series of questionnaires before and after the therapy to help us see if it worked for the participants. Please note that all intervention sessions will be video-recorded and reviewed by members of the research team to make sure the therapy is given to you as intended. We will protect your confidentiality: your name will not be associated with any of the questionnaires or the videos. If you choose not to participate but still feel you need some help, that is OK and we will try to guide you towards an appropriate resource for you.

“Are you interested to hear more about the study?”

If no, continue with the next question.

If yes, Ask if they have questions and try to answer the questions to the best of your knowledge.

If no: “Thank you for your time. May I ask you for your age, cancer diagnosis, and the reason for non-participation for statistical purposes?”

If participant says ‘no’ please add: “Once again, thank you for your interest in this study. Have a nice day. Good bye.”

If patient says 'yes', please complete the following:

Refusal

Cancer diagnosis: _____

Age: _____

Reason for declining participation : _____

If patient says 'yes', please complete the following:

If yes: “Thank you for your interest! I will ask you some questions to see if you are eligible to participate in the study. This should take about 5-10 minutes of your time.”

ELIGIBILITY CRITERIA

	Yes	No
1.a) Is this your first diagnosis of cancer?	_____	_____
1.b) Have you had a recurrence of your cancer?	_____	_____
1.c) What is the stage of your cancer?	Stages I-III _____	Stage IV _____
1.d) Have you completed your treatments (with the exception of adjuvant chemotherapy or hormonal therapy)	_____	_____
1.e) Are you 18 years of age or older?	_____	_____
1.f) What is your year of birth?	_____	
1.g) Can you speak, read, and write English?	_____	_____
1.h) Are you currently enrolled in individual or group psychotherapy for cancer issues?	_____	_____

1.i) Are you a current or previous patient of TOH?

Yes

No

***If participant answers No to questions **1 a, d, e, g or i**, he/she is not eligible for the study.*

***If participant indicates having a stage IV cancer (**question 1b**) or is enrolled in psychotherapy for cancer issues (**question 1h**), he/she is not eligible for the study.*

If the participant is not eligible:

“Thank you for answering my questions. Unfortunately, you are not eligible to take part in the study. Would you like us to discuss other psychological resources that may be appropriate for you?”

If participant is eligible so far, administer the following two measures:

Fear of Cancer Recurrence Inventory (FCRI): Severity Subscale

Most people who have been diagnosed with cancer are worried, to varying degrees, that there might be a recurrence of the cancer. **By recurrence, we mean the possibility that the cancer could return or progress in the same place or in another part of the body.** This questionnaire aims to better understand the experience of worries about cancer recurrence. **I am going to read you several statements. I need you to let me know how to what degree it applied to you DURING THE PAST MONTH.**

1. How long have you been thinking about the possibility of cancer recurrence?				
0 I don't think about it	1 A few weeks	2 A few months	3 A few years	4 Several years
2. How much time <u>per day</u> do you spend thinking about the possibility of cancer recurrence?				
0 I don't think about it	1 A few seconds	2 A few minutes	3 A few hours	4 Several hours
3. How often do you think about the possibility of cancer recurrence?				
0 Never	1 A few times a month	2 A few times a week	3 A few times a day	4 Several times a day
0 Not at all	1 A little	2 Somewhat	3 A lot	4 A great deal
4. In your opinion, what is your risk of having a cancer recurrence?				0 1 2 3 4
5. I am afraid of a cancer recurrence				0 1 2 3 4
6. I am worried or anxious about the possibility of cancer recurrence				0 1 2 3 4
7. I believe that I am cured and the cancer will not come back				0 1 2 3 4

8. I believe it is normal to be worried or anxious about the possibility of cancer recurrence	0 1 2 3 4
9. When I think about the possibility of a recurrence, other unpleasant thoughts or images come to mind (death, suffering, consequences for my family)	0 1 2 3 4

TOTAL: _____

ELIGIBLE (13 OR MORE) _____

IMPACT OF EVENT SCALE

I'm going to read you a list of comments made by people about their cancer experience. Please tell me how frequently each item was true for you DURING THE PAST 7 DAYS. **You can say not at all, rarely, sometimes, often.** Again you can write these words down if you think it will help with your answer.

	Not at All	Rarely	Sometimes	Often
1. I thought about my cancer experience when I didn't mean to.	0	1	3	5
2. I avoided letting myself get upset when I thought about my cancer experience or I was reminded of it.	0	1	3	5
3. I tried to remove my cancer experience from my memory.	0	1	3	5
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about my cancer experience that came into my mind.	0	1	3	5
5. I had waves of strong feelings about my cancer experience.	0	1	3	5
6. I had dreams about my cancer experience.	0	1	3	5
7. I stayed away from reminders of my cancer experience.	0	1	3	5
8. I felt as if my cancer experience had not happened or was not real.	0	1	3	5
9. I tried not to talk about my cancer experience.	0	1	3	5
10. Pictures about my cancer experience popped into my mind.	0	1	3	5
11. Other things kept making me think of my cancer experience.	0	1	3	5
12. I was aware that I still had a lot of feelings about my cancer experience, but I didn't deal with them.	0	1	3	5
13. I tried not to think about my cancer experience.	0	1	3	5
14. Any reminder brought back feeling about my cancer experience.	0	1	3	5
15. My feelings about my cancer experience were kind of numb.	0	1	3	5

Score: _____ x 5 = _____

_____ x 3 = _____

_____ x 1 = _____

_____ x 0 = _____

Total _____

Eligible (24 or more) _____

If the participant is not eligible:

“Thank you for answering my questions. Unfortunately, you are not eligible to take part in the study. Would you like us to discuss other psychological resources that may be appropriate for you?”

If the participant is eligible:

“Thank you for answering my questions. You are eligible to participate in the study! The next step is to set up a meeting. During this meeting, you and your therapist will complete some additional measures, determine if this therapy is a good fit for your needs, and sign the consent forms. You will meet at the Ottawa Hospital’s Psychosocial Oncology Program.

“What are your availabilities for the meeting?”

Date : _____

Time : _____

“Thank you very much for your time. A member of the research team will be in touch with you shortly.”

Appendix H
MINI Screener, Study 2

ASAIS ID: _____	LAST NAME: _____	FIRST NAME: _____	MI: _____
-----------------	------------------	-------------------	-----------

MINI SCREEN 6.0.0

If YES, go to the corresponding M.I.N.I. module

- | | | |
|--|--|------------|
| ➤ Have you been depressed or down, most of the day, nearly every day , for the past two weeks? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → A |
| ➤ In the past two weeks, have you been much less interested in most things or much less able to enjoy the things you used to enjoy most of the time ? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → A |
| ➤ In the past month did you think that you would be better off dead or wish you were dead? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → B |
| ➤ In the past month have you thought about killing yourself? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → B |
| ➤ Have you ever had a period of time when you were feeling 'up' or 'high' or 'hyper' or so full of energy or full of yourself that you got into trouble, or that other people thought you were not your usual self? (Do not consider times when you were intoxicated on drugs or alcohol.) | <input type="checkbox"/> NO <input type="checkbox"/> YES | → C |
| ➤ Have you ever been persistently irritable, for several days, so that you had arguments or verbal or physical fights, or shouted at people outside your family? Have you or others noticed that you have been more irritable or over reacted, compared to other people, even in situations that you felt were justified? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → C |
| ➤ Have you, on more than one occasion, had spells or attacks when you suddenly felt anxious, frightened, uncomfortable or uneasy, even in situations where most people would not feel that way? Did the spells surge to a peak, within 10 minutes of starting?
CODE YES ONLY IF THE SPELLS PEAK WITHIN 10 MINUTES. | <input type="checkbox"/> NO <input type="checkbox"/> YES | → D |
| ➤ Did any of those spells or attacks come on unexpectedly or occur in an unpredictable or unprovoked manner? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → D |
| ➤ Do you feel anxious or uneasy in places or situations where help might not be available or escape might be difficult: like being in a crowd, standing in a line (queue), when you are away from home or alone at home, or when crossing a bridge, traveling in a bus, train or car? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → E |
| ➤ In the past month did you have persistent fear and significant anxiety at being watched, being the focus of attention, or of being humiliated or embarrassed? This includes things like speaking in public, eating in public or with others, writing while someone watches, or being in social situations. | <input type="checkbox"/> NO <input type="checkbox"/> YES | → F |
| ➤ In the past month have you been bothered by recurrent thoughts, impulses, or images that were unwanted, distasteful, inappropriate, intrusive, or distressing? (e.g., the idea that you were dirty, contaminated or had germs, or fear of contaminating others, or fear of harming someone even though you didn't want to, or fearing you would act on some impulse, or fear or superstitions that you would be responsible for things going wrong, or obsessions with sexual thoughts, images or impulses, or hoarding, collecting, or religious obsessions.) | <input type="checkbox"/> NO <input type="checkbox"/> YES | → G |
| ➤ In the past month , did you do something repeatedly without being able to resist doing it, like washing or cleaning excessively, counting or checking things over and over, or repeating, collecting, or arranging things, or other superstitious rituals? | <input type="checkbox"/> NO <input type="checkbox"/> YES | → H |

ASAS ID: _____ LAST NAME: _____ FIRST NAME: _____ MI: _____

IF YES, GO TO THE CORRESPONDING M.I.N.I. MODULE

- Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury to you or someone else? EXAMPLES OF TRAUMATIC EVENTS INCLUDE SERIOUS ACCIDENTS, SEXUAL OR PHYSICAL ASSAULT, A TERRORIST ATTACK, BEING HELD HOSTAGE, KIDNAPPING, FIRE, DISCOVERING A BODY, SUDDEN DEATH OF SOMEONE CLOSE TO YOU, WAR, OR NATURAL DISASTER. NO YES
- Did you respond to the trauma with intense fear, helplessness, or horror? → H
- During the past month, have you re-experienced the event in a distressing way (such as, dreams, intense recollections, flashbacks or physical reactions)? → H
- In the past **12 months**, have you had 3 or more alcoholic drinks within a 3 hour period on 3 or more occasions? NO YES → I
- Now I am going to show you a list (OR READ THE LIST BELOW) of street drugs or medicines.* In the past **12 months**, did you take any of these drugs more than once, to get high, to feel elated, to get a buzz, or to change your mood? NO YES → J

amphetamines	speed, crystal meth	Dexedrine®, Ritalin®	diet pills, rush	THC, marijuana, cannabis, hashish
Cocaine, crack	steroids, GHB	Valium®, Xanax®	Ativan	barbiturates
heroin	morphine, methadone	opium, Demerol®	codeine	Percodan®, OxyContin®, Vicodin®
LSD, mescaline	PCP, angel dust, ecstasy	MDA, MDMA	ketamine	inhalants glue, ether
- Have you ever believed that people were spying on you or that someone was plotting against you or trying to hurt you? NO YES
- Have you ever heard things other people couldn't hear such as voices? NO YES
- Have you ever had visions when you were awake or have you ever seen things other people couldn't see? NO YES
- How tall are you?
|_|_|_| inches
- What was your lowest weight in the past 3 months?
|_|_|_| lbs
- IS PATIENT'S WEIGHT LOWER THAN THE THRESHOLD CORRESPONDING TO HIS/HER HEIGHT? NO YES → M

Height (ft in)	4'9	4'10	4'11	5'0	5'1	5'2	5'3	5'4	5'5	5'6	5'7
Weight (lbs)	81	84	87	89	92	96	99	102	105	108	112
Height (ft in)	5'8	5'9	5'10	5'11	6'0	6'1	6'2	6'3			
Weight (lbs)	115	118	122	125	129	132	136	140			
- In the past **three months**, did you have eating binges or times when you ate a very large amount of food within a **2-hour** period? NO YES → N
- In the last **3 months**, did you have eating binges as often as twice a week? NO YES → N
- Were you **excessively** anxious or worried about several routine things over the past 6 months? NO YES → O

* ALL BRANDS LISTED ARE TRADEMARKS OF THEIR RESPECTIVE OWNERS

Appendix I
Consent Form, Study 2



PARTICIPANT INFORMED CONSENT FORM

Title of Study: A Therapy Intervention to Address Fear of Recurrence in Men and Women with Cancer

Local Site Principal Investigator (PI): Dr. Monique Lefebvre, Ph.D., C.Psych

Sponsor: None

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

Why am I being given this form?

You are being asked to participate in this research study because we would like to examine how to help cancer patients address questions and concerns they may have with living with a past cancer diagnosis, such as fear of cancer recurrence. You are being asked to participate in this study because you have indicated that fear of cancer recurrence was distressing to you. We will look at the usefulness of using an individual psychotherapy intervention as a way to approach understanding and dealing with issues that one may have following a cancer diagnosis. The goal is to see if whether the individual therapy is a good way to address issues and questions that relate to living with a cancer diagnosis.

Why is this study being done?

The purpose of this study is to test a new form of psychotherapy to decrease fear of cancer recurrence for women and men with cancer, and thereby enhance psychological functioning throughout survivorship. This study is in partial fulfillment of Christina Tomei's doctoral thesis requirements.

We estimate that 20 participants will be enrolled in the study.

How is the study designed?

The proposed study is a randomized controlled trial, designed to examine a psychotherapy intervention in men and women with cancer who have completed treatment. Upon determining that you are eligible to participate, you will be randomly assigned by chance to receive either the individual psychotherapy intervention, or you will be placed on 6-week wait list, after which you

will the option to receive the intervention. Each participant will have an equal chance of being selected for the intervention (50:50).

What is expected of me?

Upon determining if you are eligible for participation in this study, you will meet with a member of the research team to prepare you for the therapy.

If you are randomized to the psychotherapy group, you will participate in a six-week, 1-hour therapy session where you will receive instructions and strategies to help change how you cope and your outlook on the future. The treatment will take place at the Ottawa Hospital Cancer Centre Psychosocial Oncology Program (PSOP). You will be asked to complete questionnaires during your pre-therapy meeting, one week after the end of the six week intervention, and three months following completion of the intervention

If you are randomized to the control group, you will be asked to wait 6 weeks prior to receiving the intervention. As part of your participation in this study, you will be asked to complete a series of questionnaires. You will be asked to complete questionnaires during your pre-therapy meeting, before the start of the intervention, one week after the end of the six week intervention, and three months following completion of the intervention.

Regardless of which group you are in, you will be assigned a participant number and given a link to access the online questionnaires. The questionnaires assess your fear of cancer recurrence, the psychological impact of cancer, uncertainty, coping, and quality of life. The questionnaire package will take you approximately 20-30 minutes to complete. You may skip any questions that make you uncomfortable or that you do not wish to answer. You may have a copy of the study results upon your request.

Prior to beginning the therapy, confidentiality will be explained to you. You will be provided with a manual with coping strategies and techniques to guide you through the intervention. All therapy sessions will be video recorded using the video camera at the PSOP. The videos are immediately stored in secured files on the hospital hard drive. The video recordings will not be associated with any identifying information. Only members of the research team will have access to the videos. As this is a research study, video recording is a necessary component for participation in the intervention. The recordings are necessary for both research and clinical supervision purposes. Therefore, you will not be able to participate in the study should you choose to opt out of the recordings.

How long will I be involved in the study?

The entire study will last approximately 5 months. Your participation in the study will last approximately 20-26 weeks (this includes the 3-month follow-up). Over this time, you will be required to visit the Psychosocial Oncology Program at the Ottawa Hospital Cancer Centre for 7 visits, regardless of which group you are randomized to.

Your participation in the study may be stopped for any of the following reasons:

- The study team feels it is in your best interest.
- You have been unable to follow the study team's instructions.

What are the potential risks I may experience?

You will be asked to reflect about your personal experiences with cancer and issues revolving around fear of cancer recurrence. There is very little risk associated with this study. Some people find they might get emotional when talking about their cancer experience. If you experience any discomfort that we feel requires one on one psychological support, we can suggest a reference to the Ottawa Hospital Cancer Centre. This option is available to you at any time.

Questionnaires

You might find the questionnaires to be lengthy. You might not like all of the questions that you are asked. You do not have to answer any questions that make you uncomfortable.

Can I expect to benefit from participating in this research study?

You may not receive any direct benefit from your participation in this study. Your participation may allow the researchers to understand what therapeutic techniques are helpful for survivors living with fear of cancer recurrence. This may benefit future patients and may contribute to the development of effective interventions for women and men who have been treated for cancer at the hospital.

Do I have to participate? What alternatives do I have? If I agree now, can I change my mind and withdraw later?

Your participation in this study is voluntary. The alternative to this study is not to participate. You may decide not to be in this study, or to be in the study now, and then change your mind later without affecting your medical care or other services to which you are entitled or are presently receiving at this institution.

If you withdraw your consent, the information collected to date will be used in the study.

Will I be paid for my participation or will there be any additional costs to me?

You will be reimbursed the cost of public transportation or parking fees (with proof of receipt) for each visit that you make for the study. This will include one pre-therapy meeting as well as the 6 therapy sessions, for a total of 7 visits.

How is my personal information being protected?

- All information collected during your participation in this study will be identified with a unique study number, and will not contain information that identifies you, such as your name, address, etc.

- The link between your unique study number and your name and contact information will be stored securely and separate from your study records, and will not leave this site.
- Any documents or samples leaving The Ottawa Hospital will contain only your unique study number. This includes publications or presentations resulting from this study.
- Information that identifies you will be released only if it is required by law.
- For audit purposes only, your original study records may be reviewed under the supervision of Dr. Monique Lefebvre's staff by representatives from:
 - The Ottawa Health Science Network Research Ethics Board (OHSN-REB),
 - The Ottawa Hospital Research Institute
 - The University of Ottawa School of Psychology Research Ethics Board
- Research records will be kept for 10 years, after this time they will be destroyed.

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

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

Who do I contact if I have any further questions?

If you have any questions about this study, please contact the primary investigator, Dr. Monique Lefebvre, or the co-investigators, Christina Tomei, and Dr. Sophie Lebel.

The Ottawa Health Science Network Research Ethics Board (OHSN-REB) has reviewed the plans for this research study. The Board considers the ethical aspects of all research studies involving human participants at the Ottawa Hospital. If you have any questions about your rights as a study participant, you may contact the Chairperson.



A Therapy Intervention to Address Fear of Recurrence in Men and Women with Cancer

Consent to Participate in Research

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

 Participant's Printed Name

 Participant's Signature

 Date

Investigator or Delegate Statement

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

 Investigator/Delegate's Printed Name

 Investigator/Delegate's Signature

 Date

Appendix J
Questionnaire Package, Study 2

Measurement Time point: _____

Participant ID #: _____

Today's Date: _____Demographic Information

Please check the statement that best reflects your circumstances by placing an "X" on the line beside your chosen statement. Also, please provide your specific answer to question 6.

1. Current Marital Status:

- | | |
|--|--|
| <input type="checkbox"/> (1) single, never married | <input type="checkbox"/> (3) separated, divorced |
| <input type="checkbox"/> (2) married/common-law | <input type="checkbox"/> (4) widowed |

2. Highest Education Level Achieved:

- | | |
|--|---|
| <input type="checkbox"/> (1) elementary school | <input type="checkbox"/> (4) part of university/college |
| <input type="checkbox"/> (2) part of high school | <input type="checkbox"/> (5) university/college |
| <input type="checkbox"/> (3) high school | <input type="checkbox"/> (6) graduate school |

3. Current Occupational Status: (select the best response)

- | | |
|--|---|
| <input type="checkbox"/> (1) employed full-time | <input type="checkbox"/> (5) unemployed |
| <input type="checkbox"/> (2) employed part time by choice | <input type="checkbox"/> (6) retired |
| <input type="checkbox"/> (3) employed part-time due to illness | <input type="checkbox"/> (7) homemaker |
| <input type="checkbox"/> (4) unemployed due to illness | <input type="checkbox"/> (8) student |

4. Please describe your ethnic background:

- | | |
|---|---------------------------------------|
| <input type="checkbox"/> (1) Caucasian | <input type="checkbox"/> (3) Asian |
| <input type="checkbox"/> (2) African-Canadian | <input type="checkbox"/> (4) Hispanic |
| <input type="checkbox"/> (5) Other | |

5. Annual Income Level: (household)

___ (1) \$00,000 – \$20,000

___ (4) \$61,000 - \$80,000

___ (2) \$21,000 - \$40,000

___ (5) \$81,000 - \$ 100,000

___ (3) \$41,000 - \$60,000

___ (6) greater than \$100,000

7. Age: _____

Medical History

Please check the answer that best reflects your circumstances by placing an “X” on the box beside your chosen response. Also, please provide your specific answers to the additional questions if checking yes.

5. Have you ever been diagnosed with cancer?

Yes Please indicate what type of cancer: _____

Please indicate when you were diagnosed: _____

No

6. If you are aware, please indicate the stage of your cancer at diagnosis:

b. Stage: _____

3. Please list your current medications and dosages:

4. Please circle the treatments you have received:

Surgery

Chemotherapy

Radiation

Other _____

Please indicate your **end of treatment** date: _____

Use of additional support services:

7. Are you currently receiving the services of a mental health professional for your feelings towards cancer?

Yes Please indicate: _____

No

8. Are you currently attending a support group to help you deal with your feelings towards cancer?

Yes Please indicate: _____

No

Fear of Cancer Recurrence Inventory (FCRI)

Most people who have been diagnosed with cancer are worried, to varying degrees, that there might be a recurrence of the cancer. **By recurrence, we mean the possibility that the cancer could return or progress in the same place or in another part of the body.** This questionnaire aims to better understand the experience of worries about cancer recurrence. Please read each statement and indicate to what degree it applied to you **DURING THE PAST MONTH** by circling the appropriate number.

0	1	2	3	4
Never	Rarely	Sometimes	Most of the time	All the time

The following situations make me think about the possibility of cancer recurrence:

- | | | | | | |
|---|---|---|---|---|---|
| 1. Television shows or newspaper articles about cancer or illness
..... | 0 | 1 | 2 | 3 | 4 |
| 2. An appointment with my doctor or other health professional
..... | 0 | 1 | 2 | 3 | 4 |
| 3. Medical examinations (e.g. annual check-up, blood tests, X-rays)
..... | 0 | 1 | 2 | 3 | 4 |
| 4. Conversations about cancer or illness in general
..... | 0 | 1 | 2 | 3 | 4 |
| 5. Seeing or hearing about someone who is ill
..... | 0 | 1 | 2 | 3 | 4 |
| 6. Going to a funeral or reading the obituary section of the paper
..... | 0 | 1 | 2 | 3 | 4 |
| 7. When I feel unwell physically or when I am sick
..... | 0 | 1 | 2 | 3 | 4 |
| 8. Generally, I avoid situations or things that make me think about the possibility of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |

0	1	2	3	4
Not at all	A little	Somewhat	A lot	A great deal

- | | | | | | |
|--|---|---|---|---|---|
| 9. I am worried or anxious about the possibility of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |
| 10. I am afraid of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |
| 11. I believe it is normal to be worried or anxious about the possibility of cancer recurrence
..... | 0 | 1 | 2 | 3 | 4 |
| 12. When I think about the possibility of cancer recurrence, this triggers other unpleasant thoughts or images (such as death, suffering, the consequences for my family)
..... | 0 | 1 | 2 | 3 | 4 |
| 13. I believe that I am cured and that the cancer will not come back | 0 | 1 | 2 | 3 | 4 |

14. In your opinion, are you at risk of having a cancer recurrence?

- | | | | | |
|--------------------|------------------|------------------|---------------|----------------------|
| 0 | 1 | 2 | 3 | 4 |
| Not at all at risk | A little at risk | Somewhat at risk | A lot at risk | A great deal at risk |

15. How often do you think about the possibility of cancer recurrence?

- | | | | | |
|----------|---------------------|--------------------|-------------------|---------------------|
| 0 | 1 | 2 | 3 | 4 |
| Never | A few times a month | A few times a week | A few times a day | Several times a day |

16. How much time per day do you spend thinking about the possibility of cancer recurrence?

- | | | | | |
|------------------------|---------------|---------------|-------------|---------------|
| 0 | 1 | 2 | 3 | 4 |
| I don't think about it | A few seconds | A few minutes | A few hours | Several hours |

17. How long have you been thinking about the possibility of cancer recurrence?

- | | | | | |
|------------------------|-------------|--------------|-------------|---------------|
| 0 | 1 | 2 | 3 | 4 |
| I don't think about it | A few weeks | A few months | A few years | Several years |

0	1	2	3	4
Not at all	A little	Somewhat	A lot	A great deal

When I think about the possibility of cancer recurrence, I feel:

- | | | | | | |
|--|---|---|---|---|---|
| 18. Worry, fear or anxiety
..... | 0 | 1 | 2 | 3 | 4 |
| 19. Sadness, discouragement or disappointment
..... | 0 | 1 | 2 | 3 | 4 |
| 20. Frustration, anger or outrage
..... | 0 | 1 | 2 | 3 | 4 |
| 21. Helplessness or resignation
..... | 0 | 1 | 2 | 3 | 4 |

My thoughts or fears about the possibility of cancer recurrence disrupt:

- | | | | | | |
|--|---|---|---|---|---|
| 22. My social or leisure activities (e.g. outings, sports, travel)
..... | 0 | 1 | 2 | 3 | 4 |
| 23. My work or everyday activities
..... | 0 | 1 | 2 | 3 | 4 |
| 24. My relationships with my partner, my family, or those close to me
..... | 0 | 1 | 2 | 3 | 4 |
| 25. My ability to make future plans or set life goals
..... | 0 | 1 | 2 | 3 | 4 |
| 26. My state of mind or my mood
..... | 0 | 1 | 2 | 3 | 4 |
| 27. My quality of life in general | 0 | 1 | 2 | 3 | 4 |

	0	1	2	3	4
	Not at all	A little	Somewhat	A lot	A great deal
28. I feel that I worry excessively about the possibility of cancer recurrence	0	1	2	3	4
29. Other people think that I worry excessively about the possibility of cancer recurrence	0	1	2	3	4
30. I think that I worry more about the possibility of cancer recurrence than other people who have been diagnosed with cancer	0	1	2	3	4

0	1	2	3	4
Never	Rarely	Sometimes	Most of the time	All the time

When I think about the possibility of cancer recurrence, I use the following strategies to reassure myself:

31. I call my doctor or other health professional	0	1	2	3	4
32. I go to the hospital or clinic for an examination	0	1	2	3	4
33. I examine myself to see if I have any physical signs of cancer	0	1	2	3	4
34. I try to distract myself (e.g. do various activities, watch television, read, work)	0	1	2	3	4
35. I try not to think about it, to get the idea out of my mind	0	1	2	3	4
36. I pray, meditate or do relaxation	0	1	2	3	4
37. I try to convince myself that everything will be fine or I think positively	0	1	2	3	4
38. I talk to someone about it	0	1	2	3	4
39. I try to understand what is happening and deal with it	0	1	2	3	4
40. I try to find a solution	0	1	2	3	4
41. I try to replace this thought with a more pleasant one	0	1	2	3	4
42. I tell myself "stop it"	0	1	2	3	4
43. Do you feel reassured when you use these strategies?	0	1	2	3	4

EVENT: CANCER EXPERIENCE (IES)

Directions: Below is a list of comments made by people about stressful life events and the context surrounding them. Please read each item and decide how frequently each item was true for you DURING THE PAST 7 DAYS. Please place an "X" on the box below the frequency you want to indicate for each statement.

	Not at All	Rarely	Sometimes	Often
1. I thought about my cancer experience when I didn't mean to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I avoided letting myself get upset when I thought about my cancer experience or was reminded of it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I tried to remove my cancer experience from my memory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I had trouble falling asleep or staying asleep because of pictures or thoughts about my cancer experience that came into my mind.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I had waves of strong feelings about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I had dreams about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I stayed away from reminders of my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt as if my cancer experience had not happened or was not real.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I tried not to talk about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Pictures about my cancer experience popped into my mind.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Other things kept making me think of my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I was aware that I still had a lot of feelings about my cancer experience, but I didn't deal with them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I tried not to think about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Any reminder brought back feeling about my cancer experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. My feelings about my cancer experience were kind of numb.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Quality of Life SF-8™ Health Survey Scoring Demonstration

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

For each of the following questions, please mark an [x] in the one box that best describes your answer.

1. Overall, how would you rate your health during the **past 4 weeks?**

Excellent	Very good	Good	Fair	Poor	Very poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. During the **past 4 weeks**, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?

Not at all	Very little	Somewhat	Quite a lot	Could not do physical activities
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. During the **past 4 weeks**, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

None at all	A little bit	Some	Quite a lot	Could not do daily work
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. How much **bodily** pain have you had during the **past 4 weeks?**

None	Very mild	Mild	Moderate	Severe	Very severe
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. During the **past 4 weeks**, how much energy did you have?

Very much	Quite a lot	Some	A little	None
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

6. During the **past 4 weeks**, how much did your physical health or emotional problems limit your usual social activities with family or friends?

Not at all	Very little	Somewhat	Quite a lot	Could not do social activities
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

-
7. During the **past 4 weeks**, how much have you been bothered by **emotional problems** (such as feeling anxious, depressed or irritable)?

Not at all	Very little	Somewhat	Quite a lot	Could not do social activities
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

-
8. During the **past 4 weeks**, how much did personal or emotional problems keep you from doing your usual work, school or other daily activities?

Not at all	Very little	Somewhat	Quite a lot	Could not do daily activities
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

THE IUS SCALE (Intolerance of Uncertainty)

Direction: Please indicate how you tolerate uncertainty.

Questions:	Not at all characteristic of me	Rarely characteristic of me	Sometimes characteristic of me	Entirely characteristic of me
1. Uncertainty stops me from having a strong opinion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Being uncertain means that a person is disorganized.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Uncertainty makes life intolerable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. It's unfair having no guarantees in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. My mind can't be relaxed if I don't know what will happen tomorrow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Uncertainty makes me uneasy, anxious, or stressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Unforeseen events upset me greatly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It frustrates me not having all the information I need.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Uncertainty keeps me from living a full life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. One should always look ahead so as to avoid surprises.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. A small unforeseen event can spoil everything, even with the best planning.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. When it's time to act, uncertainty paralyzes me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Being uncertain means that I am not first rate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. When I am uncertain, I can't go forward.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. When I am uncertain, I can't function very well.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Questions:	Not at all characteristic of me	Rarely characteristic of me	Sometimes characteristic of me	Entirely characteristic of me
16. Unlike me, others seem to know where they are going with their lives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Uncertainty makes me vulnerable, unhappy, or sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. I always want to know what the future has in store for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I can't stand being taken by surprise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. The smallest doubt can stop me from acting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. I should be able to organize everything in advance.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Being uncertain means that I lack confidence.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I think it's unfair that other people seem to be sure about their future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Uncertainty keeps me from sleeping soundly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. I must get away from all uncertain situations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. The ambiguities in life stress me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. I can't stand being undecided about my future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Mishel Uncertainty in Illness Scale (Uncertainty)

INSTRUCTIONS:

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. If you agree with a statement, then you would mark under either “Strongly Agree” or “Agree.” If you disagree with a statement, then mark under either “Strongly Disagree” or “Disagree.” If you are undecided about how you feel, then mark under “Undecided” for that statement. Please respond to every statement.

1. I don't know what is wrong with me.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

2. I have a lot of questions without answers.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

3. I am unsure if my illness is getting better or worse.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

4. It is unclear how bad my pain will be.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

5. The explanations they gave me about my condition seem hazy to me.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

6. The purpose of each treatment is clear to me.

Strongly Disagree (1) Disagree (2) Undecided (3) Agree (4) Strongly Agree (5)

7. When I have pain, I know what this means about my condition.

Strongly Disagree (1) Disagree (2) Undecided (3) Agree (4) Strongly Agree (5)

8. I do not know when to expect things will be done to me.

Strongly Disagree (1) Disagree (2) Undecided (3) Agree (4) Strongly Agree (5)

9. My symptoms continue to change unpredictably.

Strongly Disagree (1) Disagree (2) Undecided (3) Agree (4) Strongly Agree (5)

10. I understand everything explained to me.

Strongly Disagree (1) Disagree (2) Undecided (3) Agree (4) Strongly Agree (5)

11. The doctors say things to me that could have many meanings.

Strongly Disagree (1) Disagree (2) Undecided (3) Agree (4) Strongly Agree (5)

12. I can predict how long my illness will last.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

13. My treatment is too complex to figure out.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

14. It is difficult to know if the treatments or medications I am getting are helping.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

15. There are so many different types of staff, it's unclear who is responsible for what.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

16. Because of the unpredictability of my illness, I cannot plan for the future.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

17. The course of my illness keeps changing. I have good and bad days.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

18. It's vague to me how I will manage my care now that I have completed my treatments.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

19. I have been given many different opinions about what is wrong with me.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

20. It is not clear what is going to happen to me.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

21. I usually know if I am going to have a good or bad day.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

22. The results of my tests are inconsistent.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

23. The effectiveness of the treatment is undetermined.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

24. It is difficult to determine how long it will be before I can be my independent self again.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

25. I can generally predict the course of my illness.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

26. Because of my treatment, what I can do and cannot do keeps changing.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

27. I'm certain they will not find anything else wrong with me.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

28. The treatment I am receiving has a known probability of success.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

29. They have not given me a specific diagnosis.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
--------------------------	-----------------	------------------	--------------	-----------------------

30. My physical distress is predictable; I know when it is going to get better or worse.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

31. I can depend on the nurses to be there when I need them.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

32. The seriousness of my illness has been determined.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

33. The doctors and nurses use everyday language so I can understand what they are saying.

Strongly Disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly Agree (5)
_____	_____	_____	_____	_____

Why do People Worry About Health? Questionnaire

Everyone worries from time to time. You will find below a series of statements that can relate to worrying. Please use the measuring scale below to express how each point reflects how you feel (write the number that corresponds in front of each statements).

	1	2	3	4	5
	Not at all true	A little bit true	Somewhat true	Mostly true	Completely true
___	1.	By worrying, I can better prevent illness.			
___	2.	The fact that I worry motivates me to consult a doctor sooner.			
___	3.	I would be better prepared to accept the illness if it occurs because I have already worried about it.			
___	4.	The act of worrying keeps away the illness and prevents it from occurring in my surroundings.			
___	5.	If I worry about an illness, I have a better chance of finding the best treatment.			
___	6.	The act of worrying helps me to reduce the risk of becoming ill.			
___	7.	The fact that I worry motivates me to be more adherent to treatment.			
___	8.	The fact that I worry shows that I take responsibility for my health.			
___	9.	The fact that I worry now will assure that I will be less sad if I do become ill.			
___	10.	The act of worrying prevents me from becoming ill. .			
___	11.	The fact that I worry motivates me to consult my doctor and therefore have better medical follow-up.			
___	12.	The fact that I worry allows me to detect symptoms of illness more quickly and therefore prevents illnesses.			
___	13.	The fact that I worry about my health proves that I do everything I can to stay healthy.			

Cognitive Avoidance Questionnaire

People react differently to certain types of thoughts. Using the following scale, please indicate to what extent each of the following statements is typical of the way that you respond to certain thoughts. **Please circle the appropriate number (1 to 5).**

	Not at all typical	A little typical	Somewhat typical	Very typical	Completely typical
1. There are things that I would rather not think about.	1	2	3	4	5
2. I avoid certain situations that lead me to pay attention to things I don't want to think about.	1	2	3	4	5
3. I replace threatening mental images with things I say to myself in my mind.	1	2	3	4	5
4. I think about things that concern me as if they were occurring to someone else.	1	2	3	4	5
5. I have thoughts that I try to avoid.	1	2	3	4	5
6. I try not to think about the most upsetting aspects of some situations so as not to be too afraid.	1	2	3	4	5
7. I sometimes avoid objects that can trigger upsetting thoughts.	1	2	3	4	5
8. I distract myself to avoid thinking about certain disturbing subjects.	1	2	3	4	5
9. I would avoid people who make me think about things I do not want to think about.	1	2	3	4	5
10. I often do things to distract myself from my thoughts.	1	2	3	4	5
11. I think about trivial details so as not to think about important subjects that worry me.	1	2	3	4	5
12. Sometimes I throw myself into an activity so as not to think about certain things	1	2	3	4	5
13. To avoid thinking about subjects that upset me, I force myself to think about something else.	1	2	3	4	5
14. There are things I try not to think about.	1	2	3	4	5

	Not at all typical	A little typical	Somewhat typical	Very typical	Completely typical
15. I keep saying things to myself in my head to avoid visualizing scenarios (a series of mental images) that frighten me.	1	2	3	4	5
16. Sometimes I avoid places that make me think about things I would prefer not to think about.	1	2	3	4	5
17. I think about past events so as not to think about future events that make me feel insecure.	1	2	3	4	5
18. I avoid actions that remind me of things I do not want to think about.	1	2	3	4	5
19. When I have mental images that are upsetting, I say things to myself in my head to replace the images.	1	2	3	4	5
20. I think about many little things so as not to think about more important matters.	1	2	3	4	5
21. Sometimes I keep myself occupied just to prevent thoughts from popping up in my mind.	1	2	3	4	5
22. I avoid situations that involve people who make me think about unpleasant things.	1	2	3	4	5
23. Rather than having images of upsetting events form in my mind, I try to describe the events using an internal monologue (things that I say to myself in my head).	1	2	3	4	5
24. I push away the mental images related to a threatening situation by trying to describe the situation using an internal monologue.	1	2	3	4	5
25. I think about things that are worrying other people rather than thinking about my own worries.	1	2	3	4	5

Reassurance Questionnaire (Coping 3)

Please check the answer that BEST reflects YOUR RESPONSE to each statement by placing an “X” in the box that best represents your chosen answer.

	Not at All	Rarely	Sometimes	Most of the time
1. Does your physician take your symptoms not seriously enough?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Do you feel reassured by a visit to your physician if you are worrying about your health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. If you initially feel reassured by a visit to your physician, does your anxiety return later on?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you keep worrying as long as it is not possible to rule out a serious illness?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you keep worrying as long as you do not know the origin of your symptoms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you think the diagnosis made by your physician is incorrect?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Do you ask for a referral to a consultant, even if your physician does not think this is necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Do you think your physician is keeping something from you?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Do you think that your physician has not examined you properly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Do you think that your symptoms should be investigated more extensively (laboratory tests, X-rays, etc.)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Brief COPE (Coping 4)

We are interested in how people respond when they confront difficult or stressful events in their lives. There are lots of ways to try to deal with stress. This questionnaire asks you to indicate what you generally do and feel, when you experience stressful events. Obviously, different events bring out somewhat different responses, but think about what you usually do when you are under a lot of stress. Then respond to each of the following items by blackening one number on your answer sheet for each, using the response choices listed just below. Please try to respond to each item separately in your mind from each other item. **Choose your answers thoughtfully, and make your answers as true FOR YOU as you can.** Please answer every item. There are no "right" or "wrong" answers, so choose the most accurate answer for YOU--not what you think "most people" would say or do. Indicate what YOU usually do when YOU experience a stressful event.

Questions:	I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot
I look for something good in what is happening.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been trying to see it in a different light, to make it seem more positive.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been getting emotional support from others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been getting comfort and understanding from someone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been accepting the reality of the fact that it has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been learning to live with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

THANK YOU FOR YOUR PARTICIPATION!

Appendix K
Accepted Commentary Article, Study 1

*Addressing fear of recurrence: improving
psychological care in cancer survivors*

**Christina Tomei, Sophie Lebel, Christine
Maheu & Brittany Mutsaers**

Supportive Care in Cancer

ISSN 0941-4355

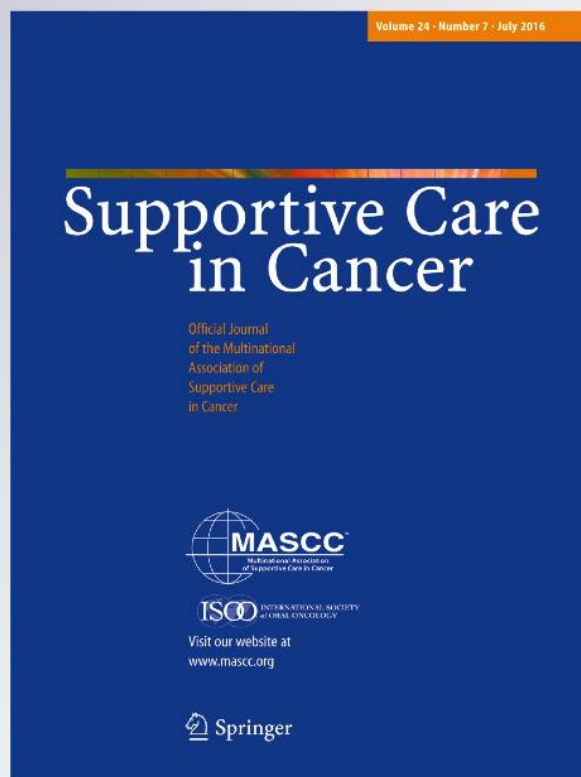
Volume 24

Number 7

Support Care Cancer (2016)

24:2815-2818

DOI 10.1007/s00520-016-3103-8



Your article is protected by copyright and all rights are held exclusively by Springer-Verlag Berlin Heidelberg. This e-offprint is for personal use only and shall not be self-archived in electronic repositories. If you wish to self-archive your article, please use the accepted manuscript version for posting on your own website. You may further deposit the accepted manuscript version in any repository, provided it is only made publicly available 12 months after official publication or later and provided acknowledgement is given to the original source of publication and a link is inserted to the published article on Springer's website. The link must be accompanied by the following text: "The final publication is available at link.springer.com".



COMMENTARY

Addressing fear of recurrence: improving psychological care in cancer survivors

Christina Tomei¹ & Sophie Lebel¹ & Christine Maheu² & Brittany Mutsaers¹Received: 22 December 2015 / Accepted: 24 January 2016 / Published online: 2 February 2016
Springer-Verlag Berlin Heidelberg 2016

Abstract

Purpose Fear of cancer recurrence (FCR) is defined as the fear or worry that the cancer will return or progress in the same area or another part of the body. FCR is associated with impaired functioning and lower quality of life in cancer patients. A cognitive-existential (CE) manualized group intervention for women with FCR showed a moderate effect size in reducing FCR, cancer-specific distress, and maladaptive coping. However, it appears that no individual intervention for FCR exists for both men and women. Therefore, the group intervention was adapted to an individual format.

Methods This study was conducted to determine the feasibility, acceptability, and satisfaction of the individual intervention. The intervention was pilot-tested on $n=3$ cancer survivors. The 6-week sessions included cognitive restructuring, structured exercises, and relaxation techniques. Participants completed questionnaire packages during a 4-week baseline period and throughout the 6-week intervention. Participants completed exit interviews following the intervention.

Results General trends in baseline and intervention stages were compared. Based on the line graphs, the individual intervention appears to help survivors lower their elevated FCR and cancer-specific distress. Qualitative exit interviews conducted with the study participants demonstrated that the intervention was acceptable and satisfactory.

Conclusions This clinical intervention allows researchers to systematically focus on evidence-based treatments for managing FCR, and displays the availability of treatment options in different therapeutic modalities. However, further research is needed to identify the active therapeutic ingredients and mechanisms of change in the intervention. Overall, intervention studies suggest it is possible to help cancer survivors manage their FCR.

Keywords Cancer · Fear of cancer recurrence · Psychosocial interventions · Coping · Psychosocial oncology

This manuscript seeks to inform future research and practice in the area of psychosocial oncology, namely, fear of cancer recurrence.

Fear of cancer recurrence (FCR) is defined as the fear or worry that the cancer will return or progress in the same area or another part of the body [1]. FCR can result in psychological distress, impaired functioning, and lower quality of life [1–4]. A recent literature review estimated about 50 % of cancer survivors experience moderate-to-high levels of FCR [2], which is often characterized by frequent rumination, excessive monitoring for potential recurrences, and avoidance of reminders (e.g., anniversary of diagnosis) [3, 5]. FCR can have deleterious effects on patients' mental health and overall quality of life.

Despite a growing interest in FCR, there are few published psychological interventions that specifically address FCR [4–8]. In order to address the mental health needs of individuals living with FCR, Lebel et al. [5] developed and pilot-tested a manualized, 6-week cognitive-existential (CE) group intervention for women with breast or gynecological cancers. The intervention demonstrated significant improvement in

* Christina Tomei
ctome085@uottawa.ca

¹ School of Psychology, University of Ottawa, 136 Jean-Jacques Lussier Private, Room 4016, Ottawa, ON K1N 6N5, Canada

² Ingram School of Nursing, McGill University, 3506 University Street, Room 401-A, Wilson Hall, Montreal, QC H3A 2A7, Canada

Author's personal copy

2816

Support Care Cancer (2016) 24:2815–2818

FCR (effect size 0.73), immediately post-therapy and at a 3-month follow-up [5].

With the success of the aforementioned pilot study, and evidence suggesting that patients who receive the treatment modality of their choice report better therapeutic outcomes by the end of treatment [9], an individual format of this intervention was developed. A pilot study of this individual version was conducted with $n = 3$ cancer survivors and addressed several gaps in the literature, including to provide FCR-specific services for male and female survivors; to provide therapy for individuals less comfortable in group therapy settings; to support survivors in underrepresented cancer populations (e.g., colorectal cancer); to improve coping and psychological

functioning; and to investigate mechanisms of change for reducing FCR. The overall goal of the study was to test the feasibility, acceptability, and satisfaction with the individual FCR intervention.

The first and second authors discussed the process for adapting the group intervention therapist and patient manuals (for more information on the intervention, please see [5]). Participants were recruited from The Ottawa Hospital Cancer Centre via study posters and referrals from health care professionals. Participants attended six weekly therapy sessions and completed weekly online questionnaires consisting of two psychological measures, the Fear of Cancer Recurrence Inventory (FCRI) [10] and the Impact of Events Scale (IES)

Table 1 Detailed description of the individual cognitive-existential intervention (modified from Lebel & Maheu, unpublished manuscript)

Session #	Session description
1	<ul style="list-style-type: none"> - Introduction of participant with a focus on their experience with FCR - Introduce FCR model - Identification of internal and external triggers - Introduce notion of cognitive restructuring and triggers, handout of thinking errors - Coping skills teaching: progressive muscular relaxation (PMR) - Homework: thought record, PMR record, prepare list of questions for oncologist
2	<ul style="list-style-type: none"> - Discuss questions list about signs of recurrence and follow-up care to ask oncologist at next visit - Discuss ways of regaining sense of control - Coping skills teaching: calming self-talk phrases and use of relaxation CD - Homework: thought record, PMR record, self-talk log
3	<ul style="list-style-type: none"> - Explore reasonable levels of worry - Complete B/Why Worry^ questionnaire - Challenge faulty beliefs about benefits of worry - Review maladaptive coping strategies like reassurance-seeking and avoidance - Coping skills teaching: guided imagery - Homework: challenge worries, examine evidence, guided imagery log
4	<ul style="list-style-type: none"> - Provide psycho-education about worry and the need for exposure to underlying fears, write down worst-case scenario - Promote emotional expression and confront specific fears that underlie participant's FCR - Coping skill teaching: mindfulness exercise (body scan) - Homework: review worst-case scenario daily, write down feelings before and after, body scan daily
5	<ul style="list-style-type: none"> - Review exposure to worst-case scenario - Discuss ways of coping with some of the feared outcomes - Encourage expression of feelings of demoralization - Encourage participants to become re-engaged with important life goals, people, or activities they may have given up - Discuss what the future and planning now means for each participant - Coping skills teaching: mindfulness (eating meditation) - Homework: write out plans for future, practice mindfulness
6	<ul style="list-style-type: none"> - Review all content covered to date - Discuss resource list - Discuss future goals - Set new priorities - Promote the expression of saying goodbye and provide closure

[11]. Table 1 provides a detailed description of the individual FCR intervention.

Based on line graphs and qualitative interviews, it appears that the individual intervention can help survivors living with elevated FCR. Line graphs were created using weekly total scores for the FCRI and the IES. Data points were visually inspected to examine whether decreases in FCR and cancer-specific distress occurred for each participant by the end of treatment. While participants remained in the clinical range for FCR at discharge, line graphs indicated downward trends in the expected direction for both FCR and cancer-specific distress, and this downward trend accelerated after session 4 (i.e., once the participants' worst-case scenario had been processed). Furthermore, two of the three participants were no longer in the clinical range for cancer-specific distress by the end of the intervention.

Following completion of the intervention, the fourth author conducted qualitative telephone exit interviews with the participants. Content and thematic analysis of these interviews revealed that all participants found the intervention useful and reported that the sessions had favorable pacing and length. Participants described the importance of developing a trusting therapeutic relationship, developing new patterns of thinking, facing their worst-case scenario, and planning for the future as important mechanisms of change. An extensive description of the study methods and results is available by request from the first author.

This clinical intervention allows researchers to systematically focus on evidence-based treatments for managing FCR, and displays the availability of treatment options that can be offered in different therapeutic modalities. Qualitative exit interviews conducted with participants demonstrated that the intervention content, dosage, and timeframe was acceptable and satisfactory. However, further research is needed to identify the active therapeutic ingredients and mechanisms of change in the intervention. In order to assess the mechanisms of change, an in-depth analysis of participants' worst-case scenario is presently underway. Additional qualitative analyses should be conducted in order to further determine the active therapeutic ingredients present in the intervention.

A recent study showed that despite the prevalence of FCR, oncology specialists refer just over 20 % of patients with clinical FCR for psychotherapy services [12]. This small percentage of referrals speaks to the growing need for access to treatment and services for patients living with FCR. Fortunately, several interventions targeting FCR are presently being tested in randomized controlled trials [7, 8], which can lead to the development of evidence-based guidelines on the management of FCR.

Additional discussion between researchers and clinicians is necessary to establish a consensual definition and cut-off score for clinical FCR (Lebel et al., submitted). While the aforementioned definition of FCR is often cited, agreement

on the definition of FCR and its diagnostic characteristics is lacking at the present time. Furthermore, while a score of 13 is the recommended clinical cut-off score for FCR on the FCRI's severity subscale [13], this score has been questioned and may not represent a true clinically significant decrease in FCR. Indeed, study participants reported experiencing less distress and were feeling better about their FCR upon completion of the intervention, despite their scores remaining above 13 on the severity subscale. Further research is required in order to accurately capture the core features of this phenomenon.

Intervention studies suggest it is possible to help cancer survivors deal with realistic FCR [4, 5]. This feasibility study is a first effort in offering the FCR intervention to patients with mixed cancer diagnoses. The results of this study have direct implications for clinical services for patients with cancer and may decrease the use of health care services by anxious individuals seeking reassurance. Furthermore, results show the potential to adapt a successful group therapy into an individual format, therefore promoting that this important therapeutic work can be done in a one-on-one setting. Overall, psychosocial interventions that target FCR can result in improved coping, enhanced psychological functioning, and ultimately improve and restore quality of life for cancer survivors.

Acknowledgments We extend our gratitude to the staff at The Ottawa Hospital Cancer Centre for their invaluable help with recruitment, and to our study participants for their dedication and courageousness.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

References

- Vickberg SM (2003) The Concerns About Recurrence Scale (CARS): a systematic measure of women's fears about the possibility of breast cancer recurrence. *Ann Behav Med* 25:16–24. doi:10.1207/S15324796ABM2501_03
- Simard S, Thewes B, Humphris G, Dixon M, Hayden C, Mireskandari S et al (2013) Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *J Cancer Surviv* 7:300–322. doi:10.1007/s11764-013-0272-z
- Lee-Jones C, Humphris G, Dixon R, Hatcher MB (1997) Fear of cancer recurrence—a literature review and proposed cognitive formulation to explain exacerbation of recurrence fears. *Psychooncology* 6:95–105

4. Herschbach P, Berg P, Waadt S, Duran G, Engst-Hastreiter U, Henrich G et al (2010) Group psychotherapy of dysfunctional fear of progression in patients with chronic arthritis or cancer. *Psychother Psychosom* 79:31–38. doi:[10.1159/000254903](https://doi.org/10.1159/000254903)
5. Lebel S, Maheu C, Lefebvre M, Secord S, Courbasson C, Singh M et al (2014) Addressing fear of cancer recurrence among women with cancer: a feasibility and preliminary outcome study. *J Cancer Surviv* 8:485–496. doi:[10.1007/s11764-014-0357-3](https://doi.org/10.1007/s11764-014-0357-3)
6. Thewes B, Bell M, Smith A, Fardell J, Turner J, Butow P, the PoCoG FCR Working Group (2012) Conquer fear: the development and pilot testing of a novel psychological treatment for fear of cancer recurrence. *Asia Pac J Clin Oncol* 8:207
7. Butow P, Bell ML, Smith A B, Fardell JE, Thewes B, Turner J, Gilchrist J, Béth J, Girgis A, Sharpe L, Shih S, Mihalopolous C, members of the Conquer Fear Authorship Group (2013) Conquer fear: protocol of a randomised controlled trial of a psychological intervention to reduce fear of cancer recurrence. *BMC Cancer*. doi:[10.1186/1471-2407-13-201](https://doi.org/10.1186/1471-2407-13-201)
8. van de Wal MA, Gidissen MFM, Servaes P, Knoop H, Speckens AEM, Prins JB (2015) Study protocol of the SWORD-study: a randomised controlled trial comparing combined online and face-to-face cognitive behaviour therapy versus treatment as usual in managing fear of cancer recurrence. *BMC Psychology*. doi:[10.1186/s40359-015-0068-1](https://doi.org/10.1186/s40359-015-0068-1)
9. Carlson L, Tamagawa R, Stephen J, Doll R, Faris P, Dirkse D et al (2014) Tailoring mind-body therapies to individual needs: patients' program preference and psychological traits as moderators of the effects of mindfulness-based cancer recovery and supportive-expressive therapy in distressed breast cancer survivors. *J Natl Cancer Inst Monogr* 50:308–314. doi:[10.1093/jncimonographs/igu034](https://doi.org/10.1093/jncimonographs/igu034)
10. Simard S, Savard J (2009) Fear of cancer recurrence inventory: development and initial validation of a multidimensional measure of fear of recurrence. *Support Care Cancer* 17:241–251. doi:[10.1007/s00520-008-0444-y](https://doi.org/10.1007/s00520-008-0444-y)
11. Horowitz M, Wilner N, Alvarez W (1979) Impact of events scale: a measure of subjective stress. *Psychosom Med* 41:209–218
12. Thewes B, Brebach R, Dzdowska M, Rhodes P, Sharpe L, Butow P (2014) Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. *Psychooncology* 23:390–396. doi:[10.1002/pon.3423](https://doi.org/10.1002/pon.3423)
13. Simard S, Savard J (2015) Screening and comorbidity of clinical levels of fear of cancer recurrence. *J Cancer Surviv* 9:481–491. doi:[10.1007/s11764-015-0424-4](https://doi.org/10.1007/s11764-015-0424-4)

Appendix L
Submitted Article, Study 2

Examining the Efficacy of an Intervention for Fear of Cancer Recurrence: A Randomized
Controlled Clinical Trial Pilot Study

Christina Tomei¹, Sophie Lebel¹, Christine Maheu², Monique Lefebvre³, & Cheryl Harris³

¹ *School of Psychology, University of Ottawa, Ottawa, ON, Canada*

² *Ingram School of Nursing, McGill University, Montreal, QC, Canada*

³ *Psychology Department, The Ottawa Hospital, Ottawa, ON, Canada*

Correspondence:

Christina Tomei, M.A.
University of Ottawa

Formatted for the *Journal of Supportive Care in Cancer*

Total number of written pages: 19

Number of tables: 3

Number of figures: 2

Acknowledgments

We are grateful to our study participants for their strength, courage, and resilience. Thank you all for trusting the therapeutic process.

Abstract (249/250 words)

Purpose: Fear of cancer recurrence (FCR) is the most frequently reported unmet need identified in cancer survivors. Despite this, there is limited research on psychosocial interventions that target FCR. To address this gap in the literature, an individual cognitive-existential psychotherapy intervention for FCR was pilot-tested via a small-scale randomized controlled trial (RCT).

Methods: Twenty-five female cancer survivors were randomized to an experimental group or a wait-list control group. Sessions included cognitive restructuring techniques, behavioural experiments, confronting existential distress, and relaxation exercises. Nineteen women completed the 6-week therapy intervention, and completed questionnaire packages at various time points.

Results: Between-within ANOVAs revealed significant interactions in the primary outcome measure of FCR, and secondary outcome measures of cancer-specific distress and uncertainty in illness for participants in the experimental group. Repeated measures ANOVAs revealed reductions in FCR, cancer-specific distress, uncertainty in illness, reassurance-seeking, cognitive avoidance, and intolerance of uncertainty, and improvements in positive reinterpretation and growth, emotional coping, quality of life (improved mental health) for participants in the experimental group, as compared to the wait-list control group. Most changes were maintained at follow-up.

Conclusions: Results from this study demonstrate promising results in addressing FCR in female cancer survivors through a cognitive-existential intervention. Future research should continue investigating the specific therapeutic ingredients that are most effective for the psychological treatment of FCR.

Implications for Cancer Survivors: This intervention responds to a need for the development of evidence-based clinical services to improve quality of life in cancer survivors. Additional research is needed to further test this intervention on patients of mixed cancer sites.

Keywords: Psychosocial oncology; fear of cancer recurrence; psychosocial interventions; coping; pilot study; randomized controlled clinical trial.

Background

Research in the realm of psychosocial oncology has consistently demonstrated that cancer survivors have a variety of unmet needs, with fear of cancer recurrence (FCR) being the most frequently reported unmet need [1, 2]. FCR is defined as “fear, worry or concern relating to the possibility that cancer will come back or progress” [3]. Nearly 50% of cancer survivors experience moderate-to-high FCR [4], and these individuals engage in maladaptive coping behaviours, such as excessive bodily checking, reassurance-seeking, and avoidance of feared outcomes [5, 6, 7, 8, 9]. Results from systematic reviews indicate that FCR tends to remain stable over time, and that high FCR at baseline is a strong predictor of higher long-term FCR [4, 8]. FCR is also consistently associated with psychological distress, anxiety, depression, lower quality of life, and stress-response symptoms [4, 10, 11]. Studies have shown that cancer patients who endorse high levels of FCR are more likely to refuse transfer from a cancer centre to follow-up by a primary care provider, and are more likely to seek readmission to a specialized cancer centre [12].

Despite evidence that cancer patients with higher FCR have poorer psychological adjustment and may utilize health care resources excessively [6], to date, there are a few published psychosocial interventions that address FCR. Of the few FCR interventions that are published, most are group therapies [5, 13, 14, 15, 16), are partially randomized [13], consist of pilot studies without a control group [14, 17], occurred in a different care context (i.e., inpatient services; [13]), or address FCR as a secondary outcome [15, 16, 18]. Thus, while intervention research on FCR is emerging [9], it appears that very few *individual* therapeutic interventions exist that specifically target FCR. This absence of one-on-one FCR interventions speaks to a growing need for such therapeutic services. Thus, the current study aimed to address the gaps in the literature by adapting an existing FCR group intervention to an individual therapy format.

Similarly, further interventions for the treatment of FCR have recently been developed, and these interventions are currently being tested in randomized controlled trials (RCTs; [19, 20]).

In an effort to address the needs of patients with moderate-to-high FCR, Lebel and colleagues [14] designed a cognitive-existential group intervention for the treatment of FCR. The intervention is theoretically guided by Leventhal's Common Sense Model [7], Mishel's Uncertainty in Illness [21], and by cognitive models of worry [22, 23]. Lebel et al. [14] adapted components of the cognitive-existential group intervention developed by Kissane and colleagues [24], which was designed to address some of the existential issues related to living with cancer. The intervention consists of six consecutive, 1.5-hour weekly group therapy sessions. Patients completed a variety of in-session tasks, including cognitive restructuring exercises, behavioural experiments, and relaxation techniques. Patients were also encouraged to access their emotions, to tolerate their existential distress in the here-and now, and to confront specific fears regarding their FCR. The authors piloted the group intervention with breast and ovarian cancer participants ($n=54$), and results of the study demonstrated significant patient improvement, with a moderate effect size in FCR (0.73), cancer-specific distress (0.38), quality of life (0.54), uncertainty (0.41), and coping strategies (0.16-0.27; Lebel et al., [14]). Almost all changes were sustained at 3-month follow-up. This intervention is currently being tested in a longitudinal, multi-site randomized controlled trial (RCT), designed to compare the CE group intervention to a structurally equivalent control group [25].

While the pilot findings from Lebel et al.'s [14] study illustrate the importance of psychotherapy outcome research in the area of FCR, as previously mentioned, most interventions for cancer patients are offered in a group therapy format. Relatedly, there is a need for targeted one-on-one psychotherapy interventions for the treatment of FCR, as it appears that very few

individual therapeutic interventions exist that specifically target this construct. Unfortunately, clinicians are currently not equipped to help cancer survivors experiencing these fears, as these concerns are not addressed in medical management [26]. To account for the paucity of one-on-one interventions addressing FCR, authors C. Tomei and S. Lebel adapted Lebel et al.'s [14] existing FCR group intervention to an individual format. Changes from the group format included reducing the sessions from 120 to 60-90 minutes, and included extended discussion of existential concerns and processing the participants' worst-case scenarios. The individual FCR intervention was initially tested on $n=3$ patients to assess feasibility, acceptability, and patient satisfaction [27]. Quantitative results tentatively illustrated that the individual intervention was helpful in decreasing cancer survivors' FCR and cancer-specific distress, and qualitative findings indicated that the study participants found the intervention to be acceptable and satisfactory. By offering this individual FCR intervention, we served to meet the therapeutic needs and preferences of cancer survivors, and to provide therapeutic services where group interventions are not feasible. Notably, it is also preferable for cancer survivors to receive the treatment modality of their choice, as research suggests that this results in better therapeutic outcomes by the end of treatment [28, 29]. Indeed, a meta-analysis revealed that individually-based interventions for cancer patients have been found to be more effective than group-based interventions [30], further suggesting the importance of developing individualized intervention protocols.

As a result of the promising findings from the initial pilot study, the authors conducted a small-scale pilot RCT on $n=25$ female cancer survivors, to further investigate the efficacy of the adapted individual intervention (based off of Lebel et al.'s [14] group intervention). To the

knowledge of the authors, this is one of the first one-on-one interventions addressing FCR, tested via a pilot RCT.

Method

Procedure

The pilot study consisted of a two-arm, small-scale RCT. Female patients of mixed cancer sites (breast, gynecological and ocular melanoma) were recruited from the Psychosocial Oncology Program and the Division of Gynecologic Oncology at The Ottawa Hospital (TOH) in Ottawa, Ontario, Canada. Approval was obtained from the Institutional Research Ethics Boards of all affiliated investigators. Furthermore, this RCT was registered on <http://www.clinicaltrials.gov> (Identifier: NCT02382315). To ensure the quality of this RCT, the authors utilized the CONSORT checklist and flow diagram, and ensured all elements of the checklist were met. In order to partake in the study, all of the following inclusion criteria were required for participation: a) women diagnosed with cancer (stages I-III), b) fluency in English, c) 18 years of age or older, d) clinical level of FCR as indicated by a score of 13 or greater on the severity subscale of the Fear of Cancer Recurrence Inventory (FCRI; [31]), e) clinical distress level as indicated by a score of 24 or greater on the Impact of Events Scale (IES; [32] and f) completion of cancer treatment (e.g., chemotherapy, radiation, and/or surgery). Exclusion criteria were as follows: a) refusal to provide informed consent; b) non-understanding of the English language, c) Stage IV cancer (as these women are facing end of life issues, are often too sick to complete treatment, and/or are dealing with active disease, as opposed to threat of recurrence), d) previous cancer recurrence, e) current enrollment in group or individual psychotherapy for cancer issues during the FCR treatment; and f) evidence of unmanaged mental health disorder

that may interfere with the psychological treatment for FCR (as indicated by questions endorsed by participants on the Mini International Neuropsychiatric Interview screener tool (MINI; [33]).

Sample size. G*Power 3.1.5 was used to calculate the necessary sample size for a repeated measures analysis of variance (ANOVA), between-within factors, with two groups (intervention group and wait-list control group), and three measurement time points (pre-, post-, and 3-month follow-up), using the effect size that was found in Lebel et al.'s [14] pilot study of 0.73 ($\phi=.80, p <.05$). To obtain this effect size, a sample of 14 participants was required. While 14 participants was the minimum number necessary to detect a difference between groups based on these parameters, a total of 25 participants were recruited, to safely account for any potential attrition.

Participants were recruited via study posters, referrals from TOH health care professionals, and via TOH's electronic patient database, using a tool that searches for patients who have consented to be contacted for research purposes. The authors placed a request to TOH health records, asking to compile a list of patients who had been diagnosed with breast or gynecological cancer in the past 5 years, stages I-III, with no evidence of recurrence. Once the list of patients was prepared and provided to the study team, patients were phoned for recruitment purposes. Those individuals who were interested in participating, expressed concerns with FCR, and met eligibility criteria were included in the study. Of potential participants meeting inclusion criteria, individuals were contacted consecutively. Over a recruitment time period of six months (January to July 2015), a total of $n=29$ individuals expressed interest in the intervention and were assessed for eligibility to participate in the study. Of this total, $n=4$ did not meet the aforementioned eligibility criteria, therefore, a total of $n=25$ individuals were enrolled in the intervention. Of the 25 participants who were randomized, $n=1$ was unable to be contacted

after multiple attempts, and $n=2$ were deemed to be unsuitable for participation in the intervention prior to the onset of therapy (for reasons surrounding substance dependence and interpersonal concerns), and were directed to other psychological services. During the course of the intervention, $n=1$ dropped out during the intervention due to time restraints, and $n=2$ experienced cancer recurrences. This resulted in a final sample of $n=19$ eligible participants who completed the intervention. In the interest of ethical practice, the FCR intervention was still provided to the individuals who experienced cancer recurrences. All useable questionnaire data was retained for statistical analyses. Please see CONSORT diagram for further detail in figure 1.

All enrolled participants were randomly assigned (50% likelihood) to one of two conditions, regardless of the outcome for the previous participant. Participants were randomly assigned to either the intervention arm ($n=11$), where they received the six-week FCR intervention immediately, or the control arm ($n=14$), where they received standard medical care at TOH and were waitlisted to receive the FCR intervention 6 weeks later. Due to study timeline restrictions, wait-list times for participants in the control group varied between 2-6 weeks. While the authors initially intended for all control group participants to wait a full 6 weeks before receiving the intervention, the original wait-list timeline was reduced as a result of unanticipated job restructuring. Thus, the timeline of the study was significantly reduced, resulting in shorter wait-list times. Random assignment of participants to each group was implemented via an online random number generator. An individual outside of the research team conducted the random assignment using this computerized procedure, and randomization outcomes were placed in individual sealed envelopes. During the pre-therapy meeting, the assigned therapist opened the sealed envelope in front of the participant, and revealed the group to which they were randomized.

A pre-therapy meeting was conducted with each study participant to document consent, explain expectations, assess for readiness to take part in FCR-related psychotherapy, and to assess for any major Axis I psychiatric concerns using the MINI [33]. Participants were assigned a unique study number for identification purposes. The therapists ($n=3$), including the first author, were Clinical Psychology doctoral students. All therapists received training via a one-day workshop. All therapy sessions were video-recorded, and S. Lebel reviewed random (pre-selected) sessions in order to assess treatment integrity and fidelity. Specifically, more than 20% of the videos were reviewed (2/6 sessions per therapist, per participant). A systematic fidelity checklist was created to ensure adherence to treatment protocol. Out of the 48 sessions that were viewed and rated, all sessions had an adherence rate above 80%, with the exception of 1 session. In that latter case, additional supervision was provided to the therapist prior to the next scheduled intervention session. The high adherence ratings suggest that the intervention was delivered systematically to all participants. S. Lebel and M. Lefebvre provided weekly clinical supervision for the therapy facilitators.

The FCR Intervention

C. Tomei and S. Lebel collaboratively discussed and adapted the intervention from the original group therapy format to a one-on-one approach. Changes from the group format included reducing the sessions from 120 to 60-90 minutes, to reflect the more typical hour-long individual psychotherapy session duration, and extended opportunity for discussion of existential concerns with processing of participants' worst-case scenarios during sessions 4 and 5 [27]. The intervention consisted of 6 weekly sessions, with in-session exercises and homework exercises assigned each week. Goals of the intervention included learning to distinguish worrisome symptoms from benign symptoms, utilizing new adaptive coping strategies (e.g., cognitive

restructuring techniques and relaxation exercises), decreasing existing maladaptive strategies, and increasing tolerance for uncertainty. For further details on the content of each therapy session, please see [27].

Outcome Measures

Participants in the experimental group were asked to complete a series of self-administered questionnaires before the onset of the intervention (T1), after completing the intervention (T2), and at 3-month follow-up (T3). Participants in the control group completed the same series of self-administered questionnaires, with the addition of one time point. These time-points included a baseline period (T0), before the onset of the intervention (T1), after completing the intervention (T2), and at 3-month follow-up (T3). Please see figure 2 for a visual representation of the study time points. All participants were given a demographic information form to complete at baseline (i.e., during the pre-therapy meeting). The demographic form included information about participants' current marital status, highest education level, current occupational status, ethnic background, age, annual income level, and medical history. The outcome measures below were selected based on the results from Lebel et al.'s [14] pilot study, as the majority of these measures demonstrated improvements.

Primary outcome measure. The primary outcome was FCR, which was measured using *The Fear of Cancer Recurrence Inventory* (FCRI; [31]). The FCRI is a 42-item instrument that has been used to examine FCR in previous studies [34, 35]. Subscales on the FCRI include Triggers, Severity, Psychological Distress, Coping Strategies, Functioning Impairment, Insight, and Reassurance. The total FCR score has demonstrated excellent internal consistency ($\alpha=0.95$; [31]) and temporal stability (test-retest=0.89; [35]). Based on a study of mixed cancer patients ($n=60$), a score of 13 or greater on the nine-item severity subscale (range 0–36) was found to

reliably identify respondents who experience a clinical level of FCR [36]. In the current study, Cronbach's alpha for the FCRI at T1 was 0.95.

Secondary outcome measures. *The Impact of Events Scale* (IES; [32]) was used to measure cancer-specific distress. The IES is a 15-item scale that measures the frequency of intrusive and avoidant thoughts associated with stressful life events over the past 7 days. Subscales on the IES include Intrusion and Avoidance. The total IES score was used in the present study (i.e., sum of all items). In the current study, Cronbach's alpha for the IES at T1 was 0.74. Quality of life was measured using the *SF-8* [37]. The SF-8 is an 8-item health-related quality of life measure that provides an assessment of general physical health (PCS) and mental health (MCS) components within a 4-week recall period. Higher summary PCS and MCS scores indicate better health. In the current study, Cronbach's alpha for the PCS summary score at T1 was 0.74, and 0.86 for the MCS summary score. Uncertainty was measured using Mishel's [21] ***Uncertainty in Illness Scale (MUIS-C;)*, a 23-item scale that includes** factors including ambiguity and unpredictability. In the current study, Cronbach's alpha for the MUIS-C at T1 was 0.76. **Uncertainty was also measured using the *Intolerance of Uncertainty Scale* (IUS; [38, 39], a 27-item self-report measure that assesses individuals' beliefs about uncertainty (e.g., uncertainty being stressful and upsetting, uncertainty being unfair).** In the current study, Cronbach's alpha for the IUS at T1 was 0.96. Perceived benefits of worrying was measured using the ***Why do people Worry about Health (WW-H)*** questionnaire [40], a 13-item questionnaire that assesses positive beliefs about worrying. In the current study, Cronbach's alpha for the WW-H at T1 was 0.81.

Coping was measured using the following three questionnaires: The ***Cognitive Avoidance Questionnaire*** (CAQ; [41]), a 25-item self-report measure that assesses the tendency

to employ cognitive avoidance strategies when encountering intrusive thoughts. Higher scores on the CAQ indicate a greater tendency to cognitively avoid threatening events. In the current study, Cronbach's alpha for the CAQ at T1 was 0.93. The *Reassurance Questionnaire* (RQ; [42]) is a 10-item self-report questionnaire that assesses the extent to which individuals feel reassured by their physician. In the current study, Cronbach's alpha for the RQ at T1 was 0.76. Coping was also measured using 3 subscales of the *Brief COPE questionnaire* [43]: (1) Positive reinterpretation and growth, (2) Use of emotional support, and (3) Acceptance, consisting of a total of 6 items. In the current study, Cronbach's alpha for the positive reinterpretation and growth subscale at T1 was 0.87. Cronbach's alpha for the use of emotional support subscale at T1 was 0.80. Lastly, Cronbach's alpha for the acceptance subscale at T1 was 0.78.

Statistical Analyses

Statistical analyses were performed using SPSS version 23. Demographic characteristics of the participants were generated (i.e., means, standard deviations) and are presented in Table 1. A mixed between-within subjects ANOVA and repeated measures ANOVAs were carried out within the linear mixed models (LMM) component of SPSS. The LMM approach was utilized to account for an unequal number of evaluations at each timepoint, and thus, preserved more values [44]. The between-within subjects ANOVA was conducted to compare the experimental group's T1 (pre-intervention) and T2 (post-intervention) with the wait-list control groups T0 (baseline period) and T1 (pre-intervention), and to assess for differences over time between both groups. Following this, repeated measures ANOVAs were carried out to assess changes in the means across all participants over time (T1 – pre-intervention; T2 – post-intervention; and T3 – 3 month follow-up). Lastly, within LMM, a mixed between-within subjects ANOVA design was also performed to identify any individual therapist differences across outcome measures over time.

Within LMM, there are many ways to model covariance across time. Of the different ways in which one could model covariance, Singer [45] suggested using simple covariance structures, such as unstructured, autoregressive, and compound symmetry. To determine which covariance structure best described this dataset; the authors employed the Akaike Information Criterion (AIC) in SPSS. The AIC assessed which mathematical model was the best fit for these analyses [45]. Following Singer's [45] suggestion, the authors used the lowest reported AIC value, as the lower the AIC value, the better that structure is in describing a particular dataset. For the between-within analyses, the autoregressive covariance structure yielded the lowest AIC values across the different DVs. For the repeated measures analyses and therapist differences analyses, the compound symmetry covariance structure yielded the lowest AIC values across the DVs. The statistical results below are based on the respective covariance structures mentioned above.

Results

Participants

A total of 25 women were enrolled in the study, and of these, $n=19$ were breast cancer survivors, $n=5$ were gynecological cancer survivors, and $n=1$ was an ocular melanoma cancer survivor. Of the 25 women enrolled in the study, data were collected on $n=24$ participants, and after accounting for attrition and ineligibility, $n=19$ women completed the intervention (13 breast, 5 gynecological, 1 ocular melanoma). The majority of participants were diagnosed with stage III breast cancer, and were diagnosed on average 1.5 years prior to participation. The average age of participants was 55 years old (range 34-74 years). The average participant was university educated, employed full-time, and married or cohabiting.

Changes in Outcome Measures

Significance. Given the exploratory nature of this research, a Bonferroni correction to the alpha level was not applied, in the interest of reducing the probability of Type II errors occurring.

Effect size. Using a technique described by Peugh [46], to obtain the variance accounted for in LMM, predicted values were calculated in SPSS, and those predicted values were correlated for our models against the dependent variables. This resulted in a correlation that when squared, provided the variance accounted for (r^2). Specifically, r^2 was used as our measure of effect size.

Mixed between-within subjects ANOVAs. Out of the 9 outcome measures in the between-within analyses, 3 variables showed significant interactions: FCRI (fear of cancer recurrence), IES (cancer-specific distress), and MUIS (uncertainty in illness). A LMM analysis (comparable to a mixed between-within subjects ANOVA) was conducted to assess the impact of RCT group (experimental group or wait-list control) on participants' scores on the FCRI across two time periods (experimental group: pre-intervention and post-intervention; wait-list control: baseline period (+/- 6 weeks) and pre-intervention). There was a main effect for time, $F(1, 15.18) = 8.04, p = .012, r^2 = 0.12$. There was no main effect for RCT group, $F(1, 21.50) = .027, p = .871, r^2 = 0.92$. The mean difference across time for the control group was not significant, $p = .638$. There was a significant interaction effect between RCT group and time, $F(1, 15.18) = 4.57, p = .049, r^2 = 0.12$. Tests of simple main effects revealed that the mean difference across time for the experimental group was significant at $p = .003$.

Scores on the IES revealed that the main effect for time was not significant, $F(1, 14.63) = 3.33, p = .089, r^2 = 0.01$. There was no main effect for RCT group, $F(1, 20.96) = 20.96, p = .332, r^2 = 0.03$. The mean difference across time for the control group was not significant, $p =$

611. There was a significant interaction effect between RCT group and time, $F(1, 14.63) = 6.05$, $p = .027$, $r^2 = 0.03$. Tests of simple main effects revealed that the mean difference across time for the experimental group was significant at $p = .016$.

Scores on the MUIS revealed there was a main effect for time, $F(1, 13.71) = 6.38$, $p = .025$, $r^2 = 0.04$. There was no main effect for RCT group, $F(1, 22.50) = 1.50$, $p = .234$, $r^2 = 0.03$. The mean difference across time for the control group was not significant, $p = .323$. There was a significant interaction effect between RCT group and time, $F(1, 13.71) = 14.91$, $p = .002$, $r^2 = 0.08$. Tests of simple main effects revealed that the mean difference across time for the experimental group was significant at $p = .001$. The effect sizes of the observed changes on the aforementioned outcome measures are considered to be small effects [47].

The aforementioned findings indicate that the experimental group reported a decrease on these three outcomes, while the control group did not report such a change. The between-within analyses results were not significant for the remaining outcome variables. Please see Table 2 for the results for all 9 outcome measures.

Repeated measures ANOVAs. For all study participants, the means and standard deviations of the primary and secondary outcome variables at baseline (T1), post-intervention (T2) and 3-month follow-up (T3) are displayed in Table 3. A LMM analysis (comparable to a repeated measures ANOVA) was conducted and revealed significant time effects for FCR, cancer-specific distress, uncertainty in illness, cognitive avoidance, reassurance-seeking, intolerance of uncertainty, quality of life (improved mental health), and the following coping subscales: positive reinterpretation and growth and acceptance. The repeated measures ANOVA results for all 9 outcome measures can be found in Table 3. The effect sizes of the observed changes ranged from 0.04-0.34 (small to medium effects; [47]).

Individual therapist differences. A LMM analysis (comparable to a mixed between-within subjects ANOVA design) was performed to evaluate any individual therapist differences across outcome measures over time (i.e., if there were any differences in outcome measures achieved by different therapists). There were no therapist effects detected, however, there was one interaction between therapist and time on the acceptance coping subscale of the BRIEF COPE, $F(4, 29.18) = 3.17, p = .028$. This interaction effect suggests that the patterns across therapists on the acceptance coping subscale changed as a function of time. Otherwise, no significant interactions between therapist and time emerged on the remaining outcome measures. These results suggest that as a whole, all three therapists were applying the same standard of treatment, and seeing the same effect. Please note that the individual therapist difference data is not shown, for purposes of brevity and space limitations.

Discussion

The goal of this study was to test the preliminary effects of this individualized, manualized FCR intervention. This is one of the first pilot intervention trials aimed at the treatment of FCR. Based on the results from this study, it appears that the intervention can be helpful in decreasing FCR in female cancer survivors, and may also improve secondary outcomes of cancer-specific distress, uncertainty in illness, cognitive avoidance, reassurance-seeking, intolerance of uncertainty, quality of life (improved mental health), and positive reinterpretation and growth and acceptance coping. Results indicate that improvements were maintained at the 3-month follow-up. Overall, these findings provide evidence that the observed changes are not just a result of the passage of time or other external events, but are indicative of the effects of the intervention, which appear to last at least up to 3 months post-completion.

Results from this study generally indicate consistency across the theoretical models that guided this intervention. In line with Leventhal's Common Sense Model [7], significant reductions were found in FCR and coping subscales of positive reinterpretation and acceptance. However, the emotional support coping subscale was found to be non-significant. This may be due to participants feeling alone in their cancer journey, as feeling alone has been found to be a potential clinical feature of FCR [48]. Future interventions could address these beliefs and help patients increase their social supports. Consistent with the Uncertainty in Illness theory [21], results indicated that there were significant reductions in illness uncertainty across participants over time. However, as the relationship between change in FCR and illness uncertainty was not formally measured, further testing of the relationship between these two constructs is necessary. Consistent with cognitive models of worry [22, 23], results showed significant reductions in intolerance of uncertainty and cognitive avoidance. Contrary to our expectations, worry did not significantly decrease over time. One consideration is the possibility of one's predisposition to worry and anxiety. Given that all of the participants initially scored in the clinically high range for FCR (i.e., a form of anxiety), it is possible that these individuals may have a more anxious predisposition as compared to individuals who have low levels of FCR. Future intervention studies could focus on incorporating additional worry-based strategies, such as operationalizing the concept of worry to patients and increasing worry-targeted techniques.

It appears that this intervention is feasible. Over the course of 6 months, we were able to successfully recruit our desired number of 25 study participants. As previously mentioned, of these 25 participants, a total of 19 participants successfully completed the intervention. Four of the 25 participants were deemed ineligible to continue participation (due to unsuitability or cancer recurrences), one participant could not be reached after enrollment, and one participant

dropped out very early in the intervention due to time restraints (after session 2), resulting in one true dropout. Therefore, based on the number of individuals who completed the intervention, we can infer that the intervention appealed to the majority of our participants.

Limitations

While this intervention poses a unique contribution to research, there are limitations to this study. Primarily, this is a pilot RCT with a small sample size, which limits the generalizability of the findings. More specifically, the results are only representative of the participants in this study, and may not represent the opinions of future participants. Furthermore, this intervention was only tested on female patients with specific cancers, further limiting the applicability of the findings. Larger RCTs are necessary to continue establishing the efficacy of this intervention, particularly using a broader oncology population that includes males, and patients with different forms of cancer. If these further studies replicate our findings, it will demonstrate broad intervention applicability.

As previously noted, the alpha level was not adjusted due to the exploratory nature of this study, indicating that these results should be interpreted with caution. Nonetheless, these interesting research findings may be suggestive of future investigation in larger studies.

The original study timeline was significantly reduced due to unanticipated job restructuring. As a result of this change, the original 6-week waitlist for the control group was reduced to a 2-6 week waitlist, therefore compromising the initial study design. While this unanticipated change affected certain aspects of this study, efforts were made to ensure that participants assigned to the control group waited as long as possible before receiving the intervention. Of the participants assigned to the control group, $n=5$ waited 6 weeks, $n=2$ waited 5 weeks, $n=1$ waited 4 weeks, and $n=2$ waited 2 weeks. Thus, half of the control group participants

were assigned to the originally intended 6-week waitlist.

Another limitation to the study is that some participants did not complete all timepoint evaluations. However, we retained data on all of the participants for our analyses, including participants who completed the intervention, who experienced recurrences, etc. Multiple efforts were made to follow-up with participants to request completion of questionnaires. Thus, future research must focus on an alternate strategy for successfully acquiring participant data.

Another noted limitation is the absence of a control group for the follow-up results at the 3-month time point. For ethical and practical reasons (i.e., retention of participations and completing the study in a timely manner), we limited the between comparisons to T1 and T2 only, and did not include T3.

The efficacy of this intervention may be partially explained by participants having had high levels of FCR and cancer-specific distress. At the present time, it is not known if the intervention would be appropriate, or as effective, in reducing FCR if individuals have lower levels of FCR and cancer-specific distress.

Future Directions

Results from this study suggest that it is possible to help individual cancer survivors manage their FCR. The steady recruitment rate and low dropout rate may also suggest participants' interest and motivation to complete the intervention. Interestingly, the recruitment and dropout rates for this study (the individual treatment modality) are different as compared to those found in Lebel et al.'s [14] pilot study (the group treatment modality). In Lebel et al.'s [14] study, recruitment of the 56 participants took 2 years (versus this study's recruitment rate of 6 months), and there was a 21% drop out rate (versus this study's dropout rate of 0.04%). This poses the question of whether the individual version of the intervention is perceived differently,

or, is perhaps considered to be more acceptable, or less threatening, by participants than the group version. Certainly, clinical experience suggests that female patients often decline group therapy for fear of being distressed by other patients' experiences and psychological anguish. Furthermore, one of the benefits of the individual therapy is the flexibility in scheduling sessions. While the group therapy occurred at a specific day and time each week, participants in the individual intervention were able to select their preferred time and day for each weekly session. It is possible that the differences in recruitment rates and attrition rates across the group and individual interventions may in part be due to scheduling factors, as half of the participants who were considered dropouts in Lebel et al.'s [14] study cited scheduling conflicts (i.e., needing to miss more than the one weekly session that the protocol allowed). A future study could compare the feasibility, acceptability and efficacy of the group intervention versus the individual intervention, to determine if the treatments are comparably effective, and for whom. Another approach would be to conceptualize the study by treatment preferences – to identify patient attributes that may influence engagement in treatment, adherence to treatment, and outcome achievement [49].

This is the first FCR-related intervention to be validated in more than one therapeutic modality. As both group and individual modalities appear to be effective, this should encourage further research offering both group and individual interventions targeting this phenomenon. Future research should also continue investigating the specific therapeutic ingredients that are most effective for the psychological treatment of FCR. Future studies could also examine whether cognitive techniques (e.g., targeting distorted thinking, cognitive restructuring), existential techniques (e.g., focusing on meaning, loss and identity, promoting the experience of emotional expression of specific fears, and processing one's worst-case scenario), and/or

relaxation techniques (e.g., progressive muscular relaxation, calming self-talk phrases) are most helpful in decreasing FCR.

Clinical Implications

This individualized intervention has direct clinical implications for survivors living with FCR. This intervention can help cancer survivors reduce FCR and psychological distress through gentle confrontation of fear, loss and meaning, and through the use of adaptive coping strategies, such as cognitive reframing and planning for the future. Furthermore, this intervention can help participants replace existing maladaptive coping behaviours, such as avoidance and reassurance-seeking, with authentic connection, as well as helpful and realistic tools moving forward, therefore enhancing quality of life.

The results from this pilot RCT may continue to inform intervention efforts targeting FCR. At the present time, several RCTs are underway to address FCR-related interventions, which may ultimately lead to evidence-based guidelines on how to manage FCR. Presently, it appears that oncology-related specialists refer only 21% of patients with high FCR for psychosocial services [26], despite the high prevalence of FCR-related suffering. This clearly illustrates how these psychological services can be helpful to a wider population. Furthermore, a standard method for screening patients with FCR would be a helpful addition to current assessments within onco-medical settings. Cost-efficacy studies should be conducted in the near future, as there is increasing evidence that these FCR interventions are effective and well received by patients. Lastly, these interventions have potential benefit to the healthcare system, as well as patients and loved ones.

Funding: This research was supported through a Young Researcher Award from the Faculty of Social Sciences of the University of Ottawa to Dr. Sophie Lebel.

Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent: Informed consent was obtained from all individual participants included in the study.

References

1. Baker F, Denniston M, Smith T, West MM. Adult cancer survivors: how are they faring? *Cancer*. 2005;104(S11):2565-76. doi:10.1002/cncr.21488.
2. Lebel S, Rosberger Z, Edgar L, Devins GM. Comparison of four common stressors across the breast cancer trajectory. *J Psychosom Res*. 2007;63(3):225-32. doi:10.1016/j.jpsychores.2007.02.002.
3. Lebel S, Ozakinci G, Humphris G, Mutsaers B, Thewes B, Prins, J et al. From normal response to clinical problem: definition and clinical features of fear of cancer recurrence. *Support Care Cancer*. 2016; 24: 3272-5. doi: 10.1007/s00520-016-3272-5.
4. Simard S, Thewes B, Humphris G, Dixon M, Hayden C, Mireskandari S et al. Fear of cancer recurrence in adult cancer survivors: a systematic review of quantitative studies. *J Cancer Surviv*. 2013;7(3):300-22. doi:10.1007/s11764-013-0272-z.
5. Humphris G, Ozakinci G. The AFTER intervention: a structured psychological approach to reduce fears of recurrence in patients with head and neck cancer. *Br J Health Psychol*. 2008;13(2):223-30. doi:10.1348/135910708X283751.
6. Lebel S, Tomei C, Feldstain A, Beattie S, McCallum M. Does fear of cancer recurrence predict cancer survivors' health care use? *Supportive Care in Cancer*. 2013;21(3):901-6. doi:10.1007/s00520-012-1685-3.
7. Lee-Jones C, Humphris G, Dixon R, Bebbington Hatcher M. Fear of cancer recurrence: a literature review and proposed cognitive formulation to explain exacerbation of recurrence fears. *Psycho-Oncology*. 1997;6(2):95-105. doi:10.1002/(SICI)1099-1611(199706)6:2<95::AID-PON250>3.0.CO;2-B.

8. Simard S, Savard J, Ivers H. Fear of cancer recurrence: specific profiles and nature of intrusive thoughts. *J Cancer Surviv.* 2010;4(4):361-71. doi:10.1007/s11764-010-0136-8.
9. Thewes B, Butow P, Bell ML, Beith J, Stuart-Harris R, Grossi M et al. Fear of cancer recurrence in young women with a history of early-stage breast cancer: a cross-sectional study of prevalence and association with health behaviours. *Support Care Cancer.* 2012;20(11):2651-9. doi:10.1007/s00520-011-1371-x.
10. Crist JV, Grunfeld EA. Factors reported to influence fear of recurrence in cancer patients: a systematic review. *Psycho-Oncology.* 2013;22(5):978-86. doi:10.1002/pon.3114.
11. Vickberg SMJ. The concerns about recurrence scale (CARS): a systematic measure of women's fears about the possibility of breast cancer recurrence. *Ann Behav Med.* 2003;25(1):16-24. doi:10.1207/S15324796ABM2501_03.
12. Glynne-Jones R, Chait I, Thomas SF. When and how to discharge cancer survivors in long term remission from follow-up: the effectiveness of a contract. *R Coll Radiol.* 1997;9(1):25-9. doi:10.1016/S0936-6555(97)80055-6.
13. Herschbach P, Berg P, Waadt S, Duran G, Engst-Hastreiter U, Henrich G et al. Group psychotherapy of dysfunctional fear of progression in patients with chronic arthritis or cancer. *Psychother Psychosom.* 2010;79(1):31-8. doi:10.1159/000254903.
14. Lebel S, Maheu C, Lefebvre M, Secord S, Courbasson C, Singh M et al. Addressing fear of cancer recurrence among women with cancer: a feasibility and preliminary outcome study. *J Cancer Surviv.* 2014;8(3):485-96. doi:10.1007/s11764-014-0357-3.
15. Lengacher CA, Johnson-Mallard V, Barta M, Fitzgerald S, Moscoso MS, Post-White J et al. Feasibility of a mindfulness-based stress reduction program for early-stage breast cancer survivors. *J Holist Nurs.* 2011:0898010110385938. doi:10.1177/0898010110385938.

16. Lengacher CA, Johnson-Mallard V, Post-White J, Moscoso MS, Jacobsen PB, Klein TW et al. Randomized controlled trial of mindfulness-based stress reduction (MBSR) for survivors of breast cancer. *Psycho-Oncology*. 2009;18(12):1261-72. doi:10.1002/pon.1529.
17. Smith AB, Thewes B, Turner J, Gilchrist J, Fardell J, Sharpe L, et al. Pilot of a theoretically grounded psychological intervention for fear of cancer recurrence (Conquer Fear). *Psycho-oncology*. 2015; 24(8):967-970. doi: 10.1002/pon.3775
18. Cameron LD, Booth RJ, Schlatter M, Ziginskas D, Harman JE. Changes in emotion regulation and psychological adjustment following use of a group psychosocial support program for women recently diagnosed with breast cancer. *Psycho-Oncology*. 2007;16(3):171-80. doi:10.1002/pon.1050.
19. Butow PN, Bell ML, Smith AB, Fardell JE, Thewes B, Turner J et al. Conquer fear: protocol of a randomised controlled trial of a psychological intervention to reduce fear of cancer recurrence. *BMC Cancer*. 2013;13:201. doi:10.1186/1471-2407-13-201.
20. Van de Wal MA, Gielissen MFM, Servaes P, Knoop H, Speckens AEM, Prins JB. Study protocol of the SWORD-study: a randomised controlled trial comparing combined online and face-to-face cognitive behaviour therapy versus treatment as usual in managing fear of cancer recurrence. *BMC Psychol*. 2015;3:12. doi:10.1186/s40359-015-0068-1.
21. Mishel MH. The measurement of uncertainty in illness. *Nurs Res*. 1981;30(5):258-63.
22. Ladouceur R, Dugas MJ, Freeston MH, Léger E, Gagnon F, Thibodeau N. Efficacy of a cognitive-behavioral treatment for generalized anxiety disorder: evaluation in a controlled clinical trial. *J Consult Clin Psychol*. 2000;68(6):957-64. doi:10.1037/0022-006X.68.6.957.
23. Langlois F, Ladouceur R, Patrick G, Freeston MH. Characteristics of illness intrusions in a non-clinical sample. *Behav Res Ther*. 2004;42(6):683-96. doi:10.1016/S0005-7967(03)00191-8.

24. Kissane DW, Bloch S, Miach P, Smith GC, Seddon A, Keks N. Cognitive-existential group therapy for patients with primary breast cancer: techniques and themes. *Psycho-Oncology*. 1997;6(1):25-33. doi:10.1002/(SICI)1099-1611(199703)6:1<25::AID-PON240>3.0.CO;2-N.
25. Maheu C, Lebel S, Courbasson C, Lefebvre M, Singh M, Bernstein LJ et al. Protocol of a randomized controlled trial of the fear of recurrence therapy (FORT) intervention for women with breast or gynecological cancer. *BMC Cancer*. 2016;16:291. doi:10.1186/s12885-016-2326-x.
26. Thewes B, Brebach R, Dzikowska M, Rhodes P, Sharpe L, Butow P. Current approaches to managing fear of cancer recurrence; a descriptive survey of psychosocial and clinical health professionals. *Psycho-Oncology*. 2014;23(4):390-6. doi:10.1002/pon.3423.
27. Tomei C, Lebel S, Maheu C, Mutsaers B. Addressing fear of recurrence: improving psychological care in cancer survivors. *Support Care Cancer*. 2016:1-4. doi:10.1007/s00520-016-3103-8.
28. Carlson LE, Tamagawa R, Stephen J, Doll R, Faris P et al. Tailoring mind-body therapies to individual needs: patients' program preference and psychological traits as moderators of the effects of mindfulness-based cancer recovery and supportive-expressive therapy in distressed breast cancer survivors. *Journal of the National Cancer Institute Monographs*. 2014; 50, 308-314. doi: 10.1093/jncimonographs/lgu034
29. Wu, S., Brothers, B.M., Farrar, W., Anderson, B.L. Individual counselling is the preferred treatment for depression in breast cancer survivors. *Journal of Psychosocial Oncology*. 2014; 32, 637-646. doi: 10.1080/07347332.2014.955239
30. Osborn, R.L., Demoncada, A. C., Feuerstein, M. Psychosocial interventions for depression, anxiety, and quality of life in cancer survivors: meta-analyses. *The International Journal of*

- Psychiatry in Medicine. 2006; 36(1), 13-34. doi: 10.2190/EUFN-RV1K-Y3TR-FK0L
31. Simard S, Savard J. Fear of Cancer Recurrence Inventory: development and initial validation of a multidimensional measure of fear of cancer recurrence. *Support Care Cancer*. 2009;17(3):241-51. doi:10.1007/s00520-008-0444-y.
 32. Horowitz MJ, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. *Psychosom Med*. 1979;41(3):209-18.
 33. Sheehan D, Lecrubier Y, Sheehan KH, Amorim P, Janavs J, Weiller E. Mini-international neuropsychiatric interview (MINI). 5.0. 0. c. Swedish version. 2006.
 34. Savard J, Ivers H. The evolution of fear of cancer recurrence during the cancer care trajectory and its relationship with cancer characteristics. *J Psychosom Res*. 2013;74(4):354-60. doi:10.1016/j.jpsychores.2012.12.013.
 35. Thewes B, Butow P, Zachariae R, Christensen S, Simard S, Gotay C. Fear of cancer recurrence: a systematic literature review of self-report measures. *Psycho-Oncology*. 2012;21(6):571-87. doi:10.1002/pon.2070.
 36. Simard S, Savard J. Screening and comorbidity of clinical levels of fear of cancer recurrence. *J Cancer Surviv*. 2015;9(3):481-91. doi:10.1007/s11764-015-0424-4.
 37. Ware JE, Kosinski M, Dewey JE, Gandek B. How to score and interpret single-item health status measures: a manual for users of the of the SF-8 health survey. Lincoln, RI; Boston, MA: QualityMetric, Inc.; 2001.
 38. Freeston MH, Rhéaume J, Letarte H, Dugas MJ, Ladouceur R. Why do people worry? *Pers Individ Diff*. 1994;17(6):791-802. doi:10.1016/0191-8869(94)90048-5.
 39. Buhr K, Dugas MJ. The intolerance of uncertainty scale: Psychometric properties of the English version. *Behav Res Ther*. 2002;40(8):931-45. doi:10.1016/S0005-7967(01)00092-4.

40. Pelletier O, Gosselin P, Langlois F, H M, Ladouceur R, J M. Le questionnaire d'évitement cognitif (QEC): développement et validation auprès d'adultes et d'adolescents. [The Cognitive Avoidance Questionnaire (CAQ): development and validation among adult and adolescent samples.]. *J Ther Comport Cogn.* 2002;12(1):24-37.
41. Sexton KA, Dugas MJ. The Cognitive Avoidance Questionnaire: Validation of the English translation. *J Anxiety Disord.* 2008;22(3):355-70. doi:10.1016/j.janxdis.2007.04.005.
42. Speckens AEM, Spinhoven P, Van Hemert AM, Bolk JH. The Reassurance Questionnaire (RQ): psychometric properties of a self-report questionnaire to assess reassurability. *Psychol Med.* 2000;30(04):841-7. doi:null.
43. Carver, CS. You want to measure coping but your protocol's too long: Consider the BRIEF COPE. *Int J Behav Med.* 1997; 4(1), 92-100. doi: 10.1207/s15327558ijbm0401_6
44. Garson GD. Hierarchical linear modeling: Guide and applications. Sage; 2012.
45. Singer JD. Using SAS PROC MIXED to Fit Multilevel Models, Hierarchical Models, and Individual Growth Models. *J Educ Behav Stat.* 1998;23(4):323-55. doi:10.3102/10769986023004323.
46. Peugh JL. A practical guide to multilevel modeling. *J Sch Psychol.* 2010;48(1): 85-112. doi:10.1016/j.jsp.2009.09.002
47. Cohen, J. A power primer. *Psychol Bull.* 1992; 112(1), 155-159.
48. Mutsaers B, Jones G, Rutkowski N, Tomei C, Seguin Leclair C, Petricone-Westwood D, et al. When fear of cancer recurrence becomes a clinical issue: a qualitative analysis of features associated with clinical fear of cancer recurrence. *Support Care Cancer.* 2016; 24(10), 4207-4218. doi: 10.1007/s00520-016-3248-5

49. Sidani, S, Braden, CJ. Design, evaluation, and translation of nursing interventions. West Sussex: Wiley-Blackwell; 2011.



CONSORT 2010 Flow Diagram

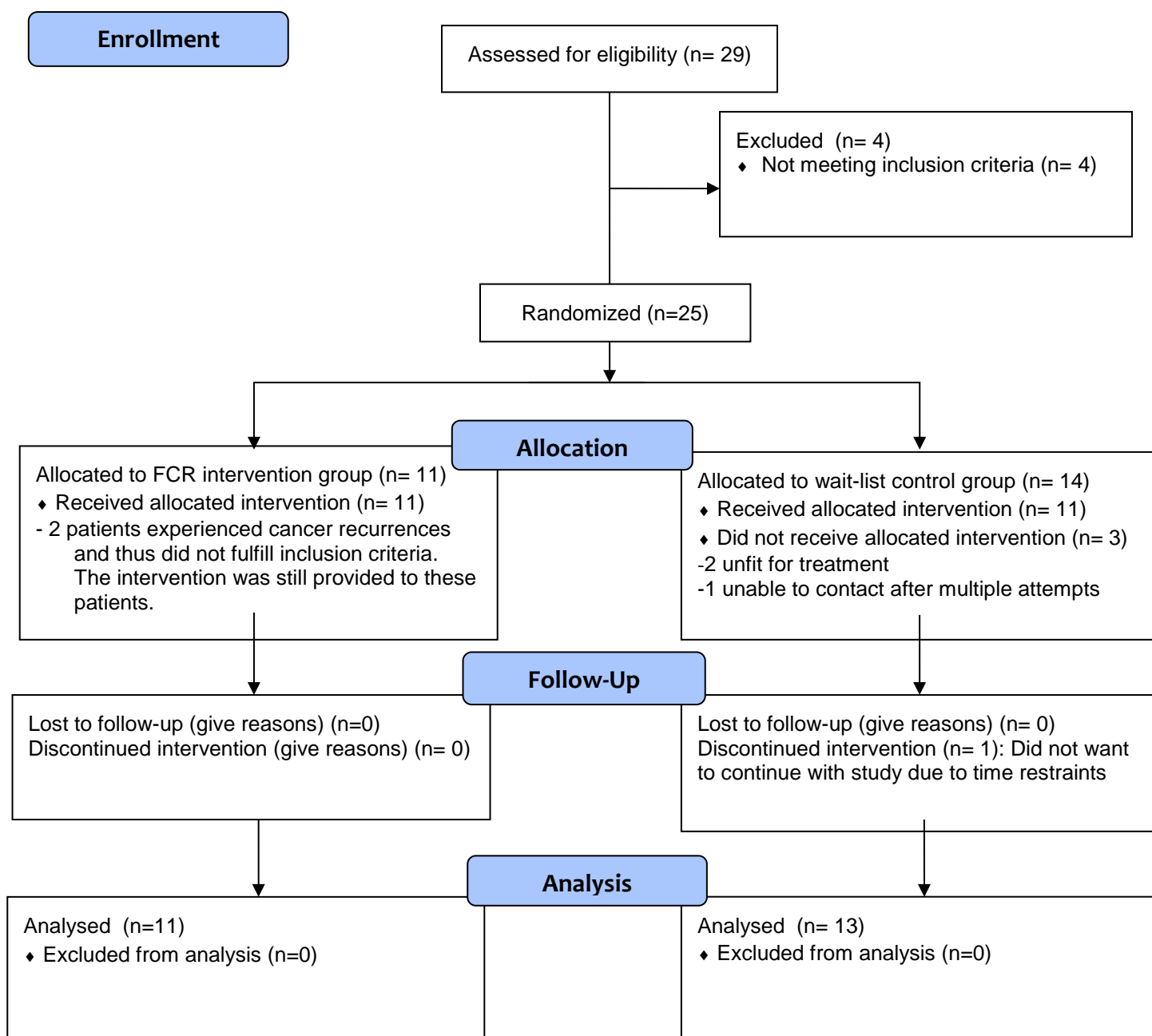


Figure 1. CONSORT flow diagram.

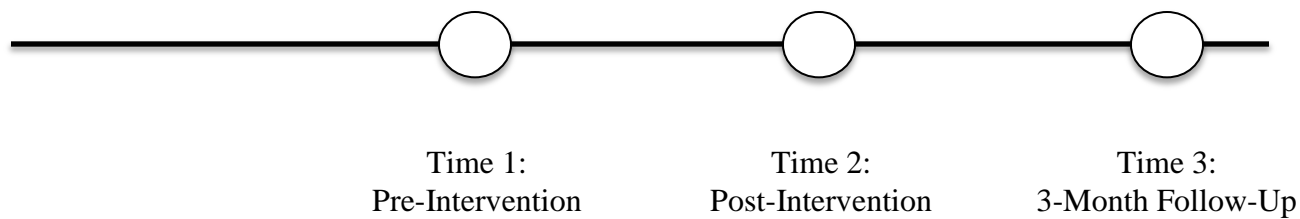
Experimental Group: 3 Time Points**Wait-list Control Group: 4 Time Points**

Figure 2. Summary of time points across experimental group and wait-list control group.

Table 1

Participant Characteristics, N=24

Variable	<i>M</i>	<i>SD</i>
Age (years)	55.0	10.76
Time since diagnosis (years)	1.54	1.53
	<i>n</i>	<i>%</i>
Primary ethnic background		
Caucasian	23	95.8
Asian	1	4.2
Civil status		
Married/Cohabiting	19	79.2
Divorced/separated	2	8.3
Widowed	3	12.5
Education		
High school or less	3	12.5
College or more	21	87.5
Occupation		
Employed full-time	10	41.7
Employed part-time	2	8.4
Unemployed	1	4.2
Unemployed due to illness	5	20.8
Retired	6	25.0
Income		
0 – 20,000	3	12.5
21 – 40,000	2	8.3
41 – 60,000	1	4.2
61 – 80,000	4	16.7
81 – 100,000	5	20.8
Over 100,000	9	37.5
Cancer stage		
Stage I	9	37.5
Stage II	2	8.3
Stage III	10	41.7
Not aware/missing	3	12.5
Primary cancer site		
Breast	18	75.0
Gynecological	5	20.8
Other (Ocular Melanoma)	1	4.2
Treatment regimen		
Surgery	4	16.7
Chemotherapy	1	4.2
Radiation therapy	1	4.2
Chemotherapy & Radiation	1	4.2
Chemotherapy & Surgery	2	8.3
Radiation & Surgery	4	16.7
Chemotherapy, Radiation & Surgery	11	45.8

Table 2
Mixed between-within ANOVA analyses comparing the experimental group's T1 (pre-intervention) and T2 (post-intervention) with the wait-list control groups T0 (baseline period) and T1 (pre-intervention)

Outcome Variable	Main Effect for Group	Main Effect for Time	Interaction Effect (RCT group x Time)	Simple Main Effects	Estimated Marginal Means
	<i>F</i> values, <i>p</i> values, and <i>r</i> ² values	<i>F</i> values, <i>p</i> values, and <i>r</i> ² values	<i>F</i> values, <i>p</i> values, and <i>r</i> ² values	<i>p</i> values	Time
FCRI (Range: 0-168)	<i>F</i> (1, 21.50) =.027, <i>p</i> = .871, <i>r</i> ² = 0.92	<i>F</i> (1, 15.18) = 8.04, <i>p</i> = .012*, <i>r</i> ² = 0.12	<i>F</i> (1, 15.18) = 4.57, <i>p</i> = .049*, <i>r</i> ² = 0.12	<i>p</i> = .003*	Experimental group: T1 (116), T2 (91) Wait-list control group: T0 (104), T1 (100)
IES (Range: 0-75)	<i>F</i> (1, 20.96) =20.96 <i>p</i> =.332, <i>r</i> ² = 0.03	<i>F</i> (1, 14.63) = 3.33, <i>p</i> = .089, <i>r</i> ² = 0.01	<i>F</i> (1, 14.63) = 6.05, <i>p</i> = .027*, <i>r</i> ² = 0.03	<i>p</i> = .016*	Experimental group: T1 (41), T2 (30) Wait-list control group: T0 (40), T1 (42)
SF-8: Physical Health (Range: 9-69)	<i>F</i> (1, 22.47) =3.30, <i>p</i> =.082	<i>F</i> (1, 14.61) =.380, <i>p</i> =.547	<i>F</i> (1, 14.61) =2.13, <i>p</i> =.166	--	Experimental group: T1 (42), T2 (40) Wait-list control group: T0: (46), T1 (50)
SF-8: Mental Health (Range: 5-72)	<i>F</i> (1, 21.16) = .139, <i>p</i> =.713	<i>F</i> (1, 17.02) = 1.31, <i>p</i> =.268	<i>F</i> (1, 17.02) = 2.63, <i>p</i> =.123	--	Experimental group: T1 (34), T2 (41) Wait-list control group: T0: (37), T1 (36)
MUIS (Range: 1-165)	<i>F</i> (1, 22.50) =1.50, <i>p</i> = .234, <i>r</i> ² = 0.03	<i>F</i> (1, 13.71) = 6.38, <i>p</i> = .025*, <i>r</i> ² = 0.04	<i>F</i> (1, 13.71) = 14.91, <i>p</i> = .002*, <i>r</i> ² = 0.08	<i>p</i> = .001*	Experimental group: T1 (93), T2 (80) Wait-list control group: T0: (91), T1 (94)
IUS (Range: 1-135)	<i>F</i> (1, 20.82) =.030, <i>p</i> =.864	<i>F</i> (1, 11.49) =.910, <i>p</i> =.360	<i>F</i> (1, 11.49) =.736, <i>p</i> =.409	--	Experimental group: T1 (86), T2 (79) Wait-list control group: T0: (84), T1 (84)
WW-H (Range: 1-65)	<i>F</i> (1, 20.76) =.494, <i>p</i> =.490	<i>F</i> (1, 16.81) =1.21, <i>p</i> =.288	<i>F</i> (1, 16.81) =.159, <i>p</i> =.695	--	Experimental group: T1 (27), T2 (26) Wait-list control group: T0:(26), T1 (24)
CAQ (Range: 1-125)	<i>F</i> (1, 18.70) =.000, <i>p</i> =.997	<i>F</i> (1, 12.24) =.1.92, <i>p</i> =.191	<i>F</i> (1, 12.24) =.401, <i>p</i> =.538	--	Experimental group: T1 (72), T2 (63) Wait-list control group: T0: (69), T1 (66)
RQ (Range: 1-40)	<i>F</i> (1, 18.87) =.029, <i>p</i> =.867	<i>F</i> (1, 13.74) =.108, <i>p</i> =.747	<i>F</i> (1, 13.74) =.103, <i>p</i> =.753	--	Experimental group: T1 (26), T2 (26) Wait-list control group: T0: (25), T1 (26)
BRIEF COPE: Positive Reinterpretation (Range: 1-8)	<i>F</i> (1, 22.08) =2.12, <i>p</i> = .159	<i>F</i> (1, 19.09) =.016, <i>p</i> = .899	<i>F</i> (1, 19.09) =2.65, <i>p</i> =.120	--	Experimental group: T1 (5), T2 (6) Wait-list control group: T0: (5), T1 (4)
BRIEF COPE: Use of Emotional Support (Range: 1-8)	<i>F</i> (1, 20.82) =.001, <i>p</i> = .981	<i>F</i> (1, 20.69) =.298, <i>p</i> = .591	<i>F</i> (1, 20.69) = 1.74, <i>p</i> =.201	--	Experimental group: T1 (5), T2 (6) Wait-list control group: T0: (6), T1 (5)
BRIEF COPE: Acceptance (Range: 1-8)	<i>F</i> (1, 19.89) =12.08 <i>p</i> = .002*, <i>r</i> ² = 0.29	<i>F</i> (1, 17.62) =.206, <i>p</i> = .655	<i>F</i> (1, 17.62) =.458, <i>p</i> = .507	--	Experimental group: T1 (7), T2 (6) Wait-list control group: T0: (5), T1 (5)

NB: * = Indicates significant differences at *p*<0.05.

NB: *r*² values were calculated for variables that yielded significant findings.

Table 3

Repeated Measures ANOVA analyses examining psychological outcomes at baseline (T1), post-intervention (T2), and 3-month follow-up (T3): means, standard deviations, and effect size

Outcome Variable	Mean (SD)				F and p values	r ² values
	T1	T2	T3	N	Time	
FCRI (Range: 0-168)	108.68 (4.94)a	90.37 (5.24)b	82.03 (5.35)b	19	$F(2, 27.87)=15.82, p<0.001^*$	0.28
IES (Range: 0-75)	41.36 (3.09)a	28.91 (3.31)b	26.98 (3.31)b	20	$F(2, 28.68)=10.58, p<0.001^*$	0.21
SF-8: Physical Health (Range: 9-69)	47.45 (2.29)a	46.77 (2.61)a	46.89 (2.56)a	20	$F(2,27.93)=.052, p=.950$	NA
SF-8: Mental Health (Range: 5-72)	35.63 (1.95)a	43.94 (2.32)b	43.78 (2.26)b	20	$F(2, 28.72)=8.24, p<0.001^*$	0.18
MUIS (Range: 1-165)	93.048 (2.29)a	84.31 (2.58)b	76.65 (2.58)c	21	$F(2, 30.24)=21.46, p<0.001^*$	0.34
IUS (Range: 1-135)	83.93 (5.88)a	79.38 (6.05)ab	71.84 (5.99)b	20	$F(2,24.71)=5.43, p=.011^*$	0.04
WW-H (Range: 1-65)	25.45 (1.55)a	24.24 (1.67)a	23.30 (1.67)a	20	$F(2,31.34)=1.02, p=.371$	NA
CAQ (Range: 1-125)	67.86 (4.22)a	59.30 (4.54)ab	53.63 (4.54)b	20	$F(2, 29.01)=6.22, p=.006^*$	0.10
RQ (Range: 1-40)	26.49 (1.04)a	26.48 (1.12)a	23.57 (1.12)a	20	$F(2, 29.63)=3.92, p=.031^*$	0.10
BRIEF COPE: Positive Reinterpretation (Range: 1-8)	4.71 (.342)a	6.28 (.376)b	5.79 (.369)b	21	$F(2,32.71)=9.93, p<0.001^*$	0.17
BRIEF COPE: Use of Emotional Support (Range: 1-8)	5.29 (.354)a	6.13 (.398)a	5.60 (.388)a	21	$F(2, 32.92)=1.82, p=.178$	NA
BRIEF COPE: Acceptance (Range: 1-8)	5.86 (.304)a	6.47 (.338)ab	6.90 (.330)b	21	$F(2,33.66)=4.75, p=.015^*$	0.09

NB: * = Indicates significant differences at $p<0.05$.

NB: Within a row, values with different lowercase letters indicate significant differences at $p<0.05$.