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Online Mindfulness-Based Cancer Recovery Program for People Living with Cancer in Alberta: A Randomized Wait-List Controlled Trial

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Online Mindfulness-Based Cancer Recovery Program for People Living with Cancer in
Alberta: A Randomized Wait-List Controlled Trial

by

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A DISSERTATION

SUBMITTED TO THE FACULTY OF GRADUATE STUDIES
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Abstract

Objective

Through a randomized treatment-as-usual (TAU) wait-list controlled trial, the current studies examined the feasibility and impact of an online “real-time” synchronous Mindfulness-Based Cancer Recovery (MBCR) group program for distressed people diagnosed with cancer, who did not have access to in-person MBCR. Sub-analyses combined both the immediate and TAU wait-list groups to evaluate potential medical and physical demographic effects on participant mindfulness facets and symptom subscale scores to determine which participants improved most after the online MBCR intervention.

Methods

Sixty-two men and women exhibiting moderate-to-high distress were randomized to either immediate online MBCR or to wait for the next available program. Intent-to-treat mixed-model analyses for repeated measures were conducted. Subsequent, pre-post linear mixed model analysis was conducted on all participants who completed MBCR, and standardized change scores were calculated for subscales of mood and stress symptom measures.

Results

Feasibility targets for recruitment and retention were achieved. Participants were satisfied and would recommend online MBCR to other cancer survivors. Completion rates were comparable to in-person MBCR. Improvements and moderate effect sizes were reported in the online MBCR group relative to a TAU wait-list following MBCR for total scores of mood disturbance, stress symptoms, spirituality, and mindfully acting with awareness.

Significant main effects of time were observed for posttraumatic growth and remaining mindfulness facets. Sub-analyses revealed younger participants had greater reductions in stress symptoms, increases in spirituality, and non-reactivity to experience over time. Over time, men experienced significantly greater posttraumatic growth than women. Subscale analyses of mood disturbance and symptoms of stress revealed greatest relative improvements in the subscales of Vigor, Fatigue, and Sympathetic Nervous System Arousal.

Conclusions

Results provided evidence for the feasibility and efficacy of an online adaptation of MBCR, facilitating reduction of mood disturbance and stress symptoms, and increasing participant-reported spirituality and mindfully acting with awareness. Online MBCR also reduced the negative physical impact of distress by improving energy levels and inducing relaxation. Future study is warranted using larger active control RCT designs. Programs utilizing similar technology could potentially improve access to other specialized psychosocial programs.

Preface

While conducting the eCALM Trial for this dissertation, the following two manuscripts were published, and the third manuscript is in preparation for submission to a peer-reviewed journal. For each of the manuscripts, the first author conducted the data analysis, interpretation, and writing of the manuscripts. Overseeing, guiding, and directing throughout this process were Dr. Campbell and Dr. Carlson. All authors reviewed the published manuscripts. Chapters two and three contain the published articles that are reproduced in their entirety and are included as chapters within this dissertation with permission from the publishers. Chapter four includes the manuscript in preparation for submission.

Zernicke, K., Campbell, T., Speca, M., McCabe-Ruff, K., Flowers, S., Dirkse, D., & Carlson, L. (2013). The eCALM Trial-eTherapy for Cancer AppLYing Mindfulness: Online mindfulness-based cancer recovery program for underserved individuals living with cancer in Alberta: Protocol development for a randomized wait-list controlled clinical trial. *BMC Complementary and Alternative Medicine, 13*(1), 34.

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Zernicke, K., Campbell, T., Speca, M., McCabe-Ruff, K., Flowers, S., Tamagawa, R., & Carlson, L. Exploratory analyses of the associations between online mindfulness-based cancer recovery participation and changes in mood, stress symptoms, mindfulness, posttraumatic growth and spirituality. *(In preparation for submission)*

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To my parents and to my husband – words do not fully express my gratitude.

This work is dedicated to you.

May you be safe and secure

May you be happy and healthy

May you feel love, warmth, and affection

May you feel alive, engaged, and joyful

May you experience peace

May you live with ease

Table of Contents

Abstract	ii
Preface	iv
Acknowledgements.....	v
Dedicaton	vi
Table of Contents	vii
List of Tables	ix
List of Figures	x
List of Symbols, Abbreviations, and Nomenclature.....	xi
CHAPTER ONE: Introduction	1
Overall Prevalence of Cancer in Canada	2
Cancer Related Distress	2
Perceived Positive Changes from a Cancer Diagnosis	4
Defining and Measuring Mindfulness	6
MBSR Program Description	10
Mindfulness-Based Interventions (MBIs).....	13
Mindfulness-Based Cancer Recovery –TBCC Program.....	14
Evidence for Efficacy of MBIs Clinical and Medical Populations....	15
Evidence for the Efficacy of MBIs in Cancer.....	20
Internet Use, Therapy, and Online Interventions.....	26
Asynchronous Internet Interventions.....	28
CBT-Based Interventions in Non-Oncology Populations.....	28
MBIs for Non-Oncology Populations.....	30
Non-Mindfulness Interventions in Oncology	35
MBIs in Oncology.....	36
Synchronous Internet Interventions	36
Non-Mindfulness Interventions in Oncology	36
MBIs in Non-Oncology Populations	39
Rationale for Online Synchronous MBCR for a Cancer Population .	43
CHAPTER TWO: The eCALM Trial-eTherapy for Cancer AppLying Mindfulness: Online Mindfulness-Based Cancer Recovery Program for Underserved Individuals Living with Cancer in Alberta: Protocol Development for a Randomized Wait-List Controlled Clinical Trial	45
Abstract	46
Background.....	48
Methods.....	52
Analytic Strategy	65
Discussion	67
Competing Interests	69
Author’s Contributions	69

CHAPTER THREE: A Randomized Wait-List Controlled Trial of Feasibility and Efficacy of an Online Mindfulness-Based Cancer Recovery Program: The eTherapy for Cancer AppLying Mindfulness Trial	70
Preface.....	71
Abstract.....	72
Introduction.....	74
Methods.....	78
Results.....	85
Discussion.....	88
 CHAPTER FOUR: Exploratory analyses of the associations between online mindfulness-based cancer recovery participation and changes in mood, stress symptoms, mindfulness, posttraumatic growth and spirituality.	104
Abstract.....	105
Background.....	107
Methods.....	112
Results.....	118
Discussion.....	120
 CHAPTER FIVE: DISCUSSION.....	131
Summary of Chapters	132
Strengths of Current Work.....	137
Challenges and Limitations of the Current Work.....	141
Directions for Future Research	147
Conclusions.....	154
 REFERENCES	156
 APPENDICIES	189

List of Tables

Table		
2.1:	Measures for the Online MBSR and Wait-List Group Participants ..	61
3.1:	Participants Demographics	95
3.2:	Statistical Details of Linear Mixed Model Analyses Assessing Psychological Outcome Total Scale Scores for Intent to Treat (ITT) Sample (MBCR n = 30; TAU Control n=32)	96
3.3:	Unadjusted Means and Standard Deviations and Standardized Mean Difference Between Treatment and Control Group Effect Sizes for Outcome Total Scores for MBCR and TAU Groups.....	97
4.1:	Baseline Demographic Characteristics	127
4.2:	Statistical Details of Linear Mixed Model Analyses Assessing Psychological Outcome Total Scale Scores (N=62).....	128

List of Figures

Figure		
2.1:	Overall Trial Design and Participant Flow Diagram	54
3.1:	eCALM CONSORT Flow Diagram.....	99
3.2:	Impact of Online MBCR on the Profile of Mood States Total Mood Disturbance Score	100
3.3:	Impact of Online MBCR on the Calgary Symptoms of Stress Total Score	101
3.4:	Impact of Online MBCR on the Functional Assessment of Chronic Illness Therapy – Spiritual Well-being Total Score	102
3.5:	Impact of Online MBCR on the Five Facet Mindfulness Questionnaire Acting with Awareness Total Score	103
4.1:	Standardized change scores from pre to post intervention of a) POMS and b) CSOSI	129
4.2:	Standardized Time x Age Interaction Effects for a) CSOSI, b) FACIT-Sp, c) FFMQ Nonreact, Time x Sex Interaction Effect for d) PTGI	130

List of Symbols, Abbreviations, and Nomenclature

Acronym	Definition
AHSCT	Allogeneic Hematopoietic Stem Cell Transplant
AIDS	Acquired Immune Deficiency Syndrome
ANOVA	Analysis of Variance
BSI	Brief Symptom Inventory
CBT	Cognitive Behavioural Therapy
CD	Compact Disk
CHREB	Conjoint Health Research Ethics Board
CSOSI	Calgary Symptoms of Stress Inventory
DT	Distress Thermometer
DVD	Digital Versatile Disc
eCALM	eTherapy for Cancer Applying Mindfulness
EMA	Ecological Momentary Assessment
eMBCT	Electronic Mindfulness-Based Cognitive Therapy
F2F	Face-to-Face
FFMQ	Five Facet Mindfulness Questionnaire
FFMQ-awa	Five Facet Mindfulness Questionnaire Acting with Awareness total scale score
FFMQ-obs	Five Facet Mindfulness Questionnaire Observe total scale score
FFMQ-des	Five Facet Mindfulness Questionnaire Describe total scale score
FFMQ-nrea	Five Facet Mindfulness Questionnaire Nonreact total scale score

FFMQ-njud	Five Facet Mindfulness Questionnaire Nonjudge total scale score
FACIT-Sp	Functional Assessment of Chronic Illness Therapy – Spiritual Well-Being
HADS	Hospital Anxiety Depression Scale
HEP	Health Enhancement Program
HIV	Human Immunodeficiency Virus
IBS	Irritable Bowel Syndrome
IT	Internet Therapy
ITT	Intent-to-Treat
LMM	Linear Mixed Models
MBCR	Mindfulness-Based Cancer Recovery
MBCT	Mindfulness-Based Cognitive Therapy
MBCPM	Mindfulness-Based Chronic Pain Management
MBI(s)	Mindfulness-Based Interventions
MBSR	Mindfulness-Based Stress Reduction
MID	Minimally Important Difference
NCCN	National Comprehensive Cancer Network
NEP	Nutrition Education Program
OSG	Online Support Group
PE	Prolonged Exposure
PI	Principal Investigator
POMS	Profile of Mood States

PROs	Patient-Reported Outcomes
PTG	Posttraumatic Growth
PTGI	Posttraumatic Growth Inventory
RCT	Randomized Control Trial
RDS	Residual Depressive Symptoms
RM-ANOVA	Repeated Measures Analysis of Variance
SET	Supportive Expressive Therapy
SOSI	Symptoms of Stress Inventory
SPSS	Statistical Package for the Social Sciences
TAU	Treatment as Usual
TBCC	Tom Baker Cancer Centre
TMD	Total Mood Disturbance

CHAPTER 1: INTRODUCTION

Overall Prevalence of Cancer in Canada

According to the Canadian Cancer Society's 2014 annual statistics, the leading cause of death in Canada is cancer (Canadian Cancer Society's Advisory Committee on Cancer Statistics, 2014). As the number of individuals diagnosed with cancer in Canada continues to grow and survival rates increase, corresponding prevalence rates rise. Canadian statistics estimate at the beginning of 2009, there were 810,045 people living with cancer diagnosed sometime in the previous 10 years (Canadian Cancer Society's Advisory Committee on Cancer Statistics, 2014). The five-year relative survival rate for all cancers combined was reported to be 56% from 1992-1994, and this increased to a current estimate of 63% (Canadian Cancer Society's Advisory Committee on Cancer Statistics, 2014). Increasing survival rates, combined with improved cancer detection methods and treatments result in more Canadians living with, and surviving a cancer diagnosis. For individuals who receive a diagnosis of cancer and undergo cancer treatment, however, the experience continues to be a significant stressor that may impact multiple aspects of a person's life.

Cancer-Related Distress

A diagnosis of cancer is often characterized by challenges such as adjustment to diagnosis and treatment, disruption of one's current life situation, re-evaluation of life directions, and tolerance of constant uncertainty (Brennan, 2001). Not unexpectedly, the diagnosis and treatment of cancer is associated with high levels of emotional distress (Zabora, Brintzenhofesoc, Curbow, Hooker, & Piantadosi, 2001; Carlson, Angen, Cullum, Goodey, Koopmans et al., 2004), which may be considered a normal response to the existential threat that cancer symbolizes, rather than the result of a pathological

process (Anand, Srivastava, & Dalal, 2001). The National Comprehensive Cancer Network guidelines for distress management (2015) define distress as “a multifactorial unpleasant emotional experience of a psychological (i.e. cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness, and fears, to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis” (National Comprehensive Cancer Network, 2015).

Higher levels of distress have been related to reduced survival, satisfaction with care, and quality of life (Bidstrup, Johansen, & Mitchell, 2011). Following completion of primary cancer treatments, many people diagnosed with cancer continue to have high levels of distress requiring psychosocial care (Carlson et al., 2004), which can persist for months or even years post-treatment (Carlson et al., 2004; Carlson, Waller, Groff, Giese-Davis & Bultz, 2013; Ploos van Amstel, van den Berg, van Laarhoven, Gielissen, Prins et al., 2013; Lam, Soong, Yau, Wong, Tsang et al., 2013).

The prevalence of clinical levels of distress has been estimated to be one third of all individuals diagnosed with cancer (Carlson et al., 2004; Carlson & Bultz, 2003; Sellick & Edwardson, 2007; Zabora et al., 2001; Carlson et al., 2013; Dominick, Natarajan, Pierce, Madanat, Madlensky, 2014). For these distressed individuals, anxiety and mood disorders are common presentations across cancer type and severity (Bultz & Carlson, 2006; Carlson et al., 2004; Kangas, Henry, & Bryant, 2005; Kissane, Grabsch, Love, Clarke, Bloch et al., 2004). Sleep problems (Fortner, Stepanski, Wang,

Kasprowicz, & Durrence, 2002) pain and fatigue (Carlson et al., 2004; Carlson et al., 2013) are also frequently associated symptoms that represent serious challenges to quality of life, and may require behavioural or psychosocial intervention to manage.

Receiving a diagnosis of cancer may require an individual to adapt on multiple levels to cope with increased perceived stress from being confronted with a potentially life threatening disease, that subsequently may affect quality of life, psychological functioning, and experienced severity of cancer symptoms (e.g., Walker, Zona, & Fisher, 2006; Roscoe, Morrow, Hickok, Bushunow, Matteson et al., 2002). As levels of distress influence the subjective experience of symptoms, and subsequently influence functioning, psychosocial interventions intended to improve coping with perceived stress, mood disturbance, and quality of life are of high priority for those impacted by cancer (Carlson, Labelle, Garland, Hutchins & Birnie, 2009).

Perceived Positive Changes from a Cancer Diagnosis

Researchers within psycho-oncology have understandably prioritized reduction of negative psychological reactions consequent to a cancer diagnosis. However, possible benefits related to the cancer experience are gaining attention. Research suggests that despite the struggle to adjust to life with cancer, a subset of people diagnosed with cancer identify perceived positive changes post diagnosis and treatment, including more positive perceptions of relationships with important people in their life, increased personal growth, spirituality, and appreciation for life (Cordova, Cunningham, Carlson, & Andrykowski, 2001; Stanton, Bower & Low, 2006). In response, researchers have begun to investigate programs that may encourage a spectrum of perceived positive changes that potentially develop after a diagnosis of cancer.

Two constructs have received research attention related to perceived positive change—spirituality and posttraumatic growth—following a cancer diagnosis. Broadly defined, spirituality refers to the experiences and feelings associated with the search for connection to a transcendent power and the subjective sense that an individual's life has purpose, value, and meaning (Peterman, Fitchett, Brady, Hernandez, & Cella, 2002; Lechner, Stoelb & Antoni, 2008; Visser, Garssen & Vingerhoets, 2009). PTG generally refers to benefits perceived following a cancer diagnosis that exceed pre-cancer adjustment, and it is hypothesized that PTG arises from the emotional and cognitive struggle as individuals attempt to master a traumatic event (Linley & Joseph, 2004; Tedeschi & Calhoun, 2004). Spirituality and PTG have been associated with other positive outcomes, such as increased positive affect and psychological adjustment, as well as decreased physical discomfort and dysfunction following a diagnosis of cancer (Carver & Antoni, 2004; Henech & Danielson, 2009; Morrill, Brewer, O'Neill, Lillie, Dees, et al., 2008; Krupski, Kwan, Fink, Sonn, Malinski et al., 2006; Whitford & Olver, 2012; Tallman, Altmaier & Garcia, 2007).

Psychosocial interventions that increase perceived benefits for individuals living with cancer may support the adaptation, adjustment, and coping with the sequelae of living with cancer and longer-term survivorship. Thus, there is a need to concentrate on reducing negative symptoms associated with the cancer experience, while simultaneously working to investigate the potential positive effects of the disease experience such as increased personal growth and spirituality. Mindfulness-Based Stress Reduction (MBSR), and the cancer-specific adaptation, Mindfulness-Based Cancer Recovery (MBCR) provide a forum to facilitate both of these components in individuals living with cancer.

Defining and Measuring Mindfulness

How mindfulness is conceptualized, operationalized, and measured is a theme of vigorous discussion within the field of mindfulness science (e.g., Grossman, 2011; Baer, 2011; Brown, Ryan & Creswell, 2007; Brown, Ryan, Loverich, Biegel & West, 2011; Quaglia, Brown, Lindsay, Creswell, & Goodman; 2015). Conceptualizations of mindfulness within the scientific literature are subject to debate and refinement as different conceptual underpinnings result in varying operational definitions, subsequently resulting in different scale development and measurement (Quaglia et al., 2015). Mindfulness has been proposed to represent a trait (dispositional characteristic), a state to be developed through training, a practice, and an intervention (Davidson, 2010). Consensus regarding how to define “mindfulness” has not been achieved, but commonalities exist among several definitions (Coffey, Hartman, & Fredrickson, 2010; Davidson, 2010; Quaglia et al., 2015). An early working definition commonly cited in contemporary psychological literature is from Jon Kabat-Zinn, asserting that mindfulness can be defined as “paying attention in a particular way, on purpose, in the present moment, nonjudgmentally.” (Kabat-Zinn, 1994, page 4). Following that definition from Kabat-Zinn, Bishop and colleagues (2004) proposed an operational definition composed of a two-component model. The first proposed component refers to self-regulation of attention, referring to the ability to focus on present moment experience, allowing for increased awareness of internal sensations, thoughts, and emotions in the moment (Bishop, Lau, Shapiro, Carlson, Anderson, et al., 2004). The authors proposed mindfulness is a meta-cognitive process due to the requisite cognitive mechanisms of sustained attention, inhibition of elaborative processing, and attentional switching

(Bishop et al., 2004). The second component of mindfulness refers to the specific attitudes of curiosity, openness, and non-judgment and acceptance adopted toward present moment experiences. This conceptual orientation proposes “allowing” or “letting go” of present moment cognitions, sensations, and emotions rather than struggling to change current experience. Brown and Ryan (2004) agree with previously proposed scientific definitions that nonjudgment is part of mindfulness, but contend that nonjudgmental attitude is inherent in receptive attention, rather than a separate attitude (Brown & Ryan, 2004; Quaglia et al., 2015)

Shapiro, Carlson, Astin, and Freedman, in 2006, expanded Bishop and colleagues’ 2004 two-component model, offering a model of mindfulness to begin to clarify potential mechanisms of MBIs (Shapiro, Carlson, Astin & Freedman, 2006). The authors proposed three core “axioms” in this expanded model: 1) intention, 2) attention, and 3) attitude, as well as a meta-mechanism of action termed “reperceiving”. Intention is viewed as dynamic and pertains to an individual’s purpose brought to the specific mindfulness practice. The second and third axioms (i.e., attention and attitude) are analogous to Bishop’s earlier model. Shapiro and colleagues posit that paying attention, on purpose, with an attitude of open non-judgment and acceptance, can lead to a perspective or meta-cognitive shift termed “reperceiving”. That shift is proposed to facilitate “stepping back” and of curious observation, rather than struggling or being caught up in cognitions, feelings, and emotions (Shapiro et al., 2006). Mindful awareness in this expanded model is theorized to be cultivated through intentionally attending in an accepting, open way to the arising current moment, creating the meta-cognitive perspective shift of reperceiving (Shapiro & Carlson, 2009).

Given the diversity in definitions due to differences in conceptualization, the measurement of mindfulness mirrors such heterogeneity. Experts in mindfulness science continue to debate how to define and measure mindfulness as a practice, trait, state, and the effects of mindfulness (Brown, Ryan, Loverich, Biegel, & West, 2011; Baer, 2011; Grossman, 2011). Multiple self-report questionnaires have been developed to measure mindfulness in adult populations, with some mindfulness questionnaires measuring states (State Mindful Attention Awareness Scale: Brown & Ryan, 2003; State Toronto Mindfulness Scale: Lau, Bishop & Segal, 2006) or traits (Cognitive and Affective Mindfulness Scale – Revised: Feldman, Hayes, Kumar, Greeson & Laurenceau, 2007; Five Facet Mindfulness Scale: Baer, Smith, Hopkins, Krietemeyer & Toney, 2006; Frieberg Mindfulness Inventory: Walach, Buchheld, Buttenmuller, Kleinknecht & Schmidt, 2006; Kentucky Inventory of Mindfulness Skills: Baer, Smith & Allen, 2004; Mindful Attention and Awareness Scale: Brown & Ryan, 2003; Philadelphia Mindfulness Scale: Cardaciotto, Herbert, Forman, Moitra & Farrow, 2008).

Data from factor analysis procedures support the hypothesis that the construct of mindfulness—as it is defined in the context of mindfulness-based interventions, which include both attentional and attitudinal components—may be multifaceted (Baer et al., 2004; Baer et al., 2006). Based on differing conceptualizations and the above-listed mindfulness scales, the number of measured mindfulness facets or scores range from a single score to five. Baer and colleagues attempted to explore the factor structure of the mindfulness construct, by combing data from multiple mindfulness scales into one data set. Utilizing results from 613 undergraduate students, the authors identified a five facet structure, determining incremental validity of each facet in predicting psychological

symptoms, creating a Five Facet Mindfulness Questionnaire (FFMQ) that includes Observing, Describing, Acting with Awareness, Nonjudging of Inner Experience, and Nonreactivity to Inner Experience (Baer et al., 2006).

To add to the complexity of quantifying mindfulness, the measurement of mindfulness may be impacted based on the target population, including an individual's level of mindfulness training. Some scales were developed to assess dispositional or naturally occurring mindfulness (e.g., Mindful Awareness and Attention Scale - MAAS), while others were intended to be used within the training contexts of Mindfulness-Based Intervention (MBI) (e.g., Five Facet Mindfulness Questionnaire - FFMQ). Critics contend that mindfulness scale items may have different meanings for trained vs. untrained meditators, and that could impact the validity of these measures. Both the FFMQ and the MAAS, however, have demonstrated validity and reliability in non-trainee and trainee populations, as well as showing sensitivity to mindfulness training with scale scores changing in expected directions (Quaglia et al., 2015).

Although mindfulness science research may be limited by a lack of clear operationalization and measurement of mindfulness (e.g., Grossman & Van Dam, 2011), continuing to evaluate developed models and measures of mindfulness moves mindfulness science forward in an iterative process of refinement of operationalization and measurement of mindfulness. Developed measures allow for research into statistical models of mediation, a tool to help clarify whether the proposed definitions of mindfulness lead to the changes seen in MBIs (Baer et al., 2006; Brown & Ryan, 2003; Coffey et al., 2010; Shapiro et al., 2006).

MBSR Program Description

Mindfulness-Based Stress Reduction (MBSR) is a group intervention initially developed by Kabat-Zinn and colleagues at the University of Massachusetts Medical Center to help manage chronic pain outpatient populations (Kabat-Zinn, 2003; Labelle, Campbell & Carlson, 2010; Carlson & Speca, 2010; Carlson et al., 2009). Mindfulness, as defined by the MBSR program, is the practice of cultivating present moment awareness of internal and external experience (including cognitions, emotions and somatic sensations) in a non-reactive and non-judgmental, open manner to facilitate self-regulation of emotions and reactions to stress (Kabat-Zinn, 1990). Mindfulness is hypothesized to help trainees develop awareness and acceptance of internal and external experience, without judgment or attempting to change their experience, which allows an individual to behave in more adaptive ways to minimize impulsive, habitual, or “auto-pilot” reactions that may lead to increased psychological or physiological distress (Baer, 2003; Brown et al., 2007).

Underlying mindfulness practice is the premise that experiencing non-judgmental and open awareness of the present moment can effectively mitigate effects of stressors by decreasing excessive orientation toward the past or future where individuals can become mired in rumination and worry, potentially increasing depression and anxiety symptomatology (e.g., Kabat-Zinn, 2003). The multi-component MBSR program includes didactic teaching about the rationale for the development of stress, including ways of thinking that can maintain or exacerbate stress (e.g., rumination and worry) and the physical impact of stress on the body, highlighting the mind-body connection. Specific attitudes of mindfulness are explained and encouraged as alternative ways to

interact with daily life, including suspending judgment, patience, curiosity of beginner's mind, trust, non-striving, acceptance, and letting go (Carlson & Speca, 2010). Early in the program, participants are guided through a beginner's mind exercise involving mindful eating of a piece of food (often a raisin) with all five senses to encourage participants to shift out of habitual ways of experiencing and begin to notice details of their experience. These mindful attitudes are practiced and reinforced throughout the MBSR course to encourage development of these attitudes both during meditation practice and within daily activities.

In addition to didactic content, a variety of meditation techniques intended to facilitate and strengthen mindful presence are explored, including: breath awareness; body scan; sitting and walking meditations, imagery practice (such as lake and mountain meditations), self-compassion and loving-kindness (metta) meditation and "mindful movement" such as gentle Hatha yoga. Breath awareness and diaphragmatic breathing are introduced first to anchor attention and practice the relaxation response. The first formal meditation technique introduced is the body scan. Breath awareness begins the body scan practice, and then attention is focused sequentially on each part of the body, moving awareness through the body while emphasizing noting sensations without self-judgment.

Following the body scan, participants are introduced to sitting meditation. Again the practice begins with breath awareness, and gradually participants are encouraged to open their awareness to present moment awareness of internal and external experience (including cognitions, emotions, and somatic sensations) in a non-reactive and non-judgmental, open manner. Walking meditation and yoga practice facilitate coordination

of breath and movement and are intended as mindful movement exercises, rather than striving for particular positions or exercise. While formal meditation is practiced within the course, informal practice is encouraged through introduction of “mini” breathing exercises and eating exercises to begin to transfer mindful presence to everyday activities. Mindfulness exercises taught within the program share the common goal of cultivating the capacity to maintain a nonjudgmental awareness to whatever experience one is having in the present moment and with continued practice, transfer the situational technique to the development of a mindfulness approach to life experiences and situations (Baer, 2003).

Throughout the group intervention, emphasis is placed on group support and shared experience—through group members and course facilitators—to enhance skill development, as well as to problem solve and persevere with mindfulness practice (Carlson & Speca, 2010).

Variability exists in procedures and protocols for MBSR programs depending on the population targeted. In the original standard format, MBSR is an 8-week program, with weekly 2.5 hour classes as well as a full day 6-hour retreat between the sixth and seventh class totaling 26 hours of instruction. Adaptations to program length range from 6 to 10 weeks, and class time can vary from one to three hours with some adaptations of the program excluding the all-day or half-day retreat (Carmody & Baer, 2009). Carmody and Baer reviewed differences in MBSR class contact hours and effect sizes for psychological distress, and did not find evidence that shortened versions were less effective (Carmody & Baer, 2009). Variability in programs is expected, as the MBSR program was not intended to be strictly “franchised.” Kabat-Zinn reasoned that the

“optimal form of its delivery will depend critically on local factors and on the level of experience and understanding of the people undertaking the teaching” (Kabat-Zinn, 1996, page 165).

To balance flexible delivery with treatment fidelity of structured mindfulness interventions requires careful consideration of core required elements of MBSR as to ensure adaptations maintain key components and are delivered to participants (Dobkin, Hickman, Monshat, 2014). Key elements recently summarized by Dobkin and colleagues include core meditation practices, teaching modules provided through the formal training curriculum at the University of Massachusetts Centre for Mindfulness, and daily formal mindfulness practice, all while encouraging participants to craft a different relationship with life stress, integrate mindfulness practice into their daily lives, and cultivate self-compassion and care with the hope to relieve suffering (Dobkin et al., 2014). For many medical populations, adaptation is particularly salient as many individuals experience limitations or challenges with health that exclude them from participating in more intensive interventions, and by defining foundational components these elements can be maintained in such adaptations.

Mindfulness-Based Interventions (MBIs)

Secular structured mindfulness training programs within Western medical environments have been collectively termed Mindfulness-Based Interventions (MBIs) to acknowledge the multitude of adaptations the MBSR program has produced (Carlson, 2012). Mindfulness-Based Cognitive Therapy (MBCT) as well as the cancer-specific adaptation MBCR (that will be reviewed more in-depth below and in chapter two of this document), are two programs that have maintained the core elements of MBSR, while

modifying for specific populations (recurrent depression and cancer respectively). MBCT is an 8-week (2-hour weekly) group program adapted for people with a history of depressive episodes, and incorporates elements of cognitive therapy (Segal, Teasdale, & Williams, 2004). Emphasis during the program is focused on teaching participants to decenter, or de-identify with negative emotions, cognitions, and bodily sensations, and consider them as passing events. Skills are taught to facilitate disengagement from dysfunctional cognitive routines such as depression-related ruminative thinking patterns to minimize risk of depression symptom recurrence (Segal et al., 2004).

Mindfulness-Based Cancer Recovery - Tom Baker Cancer Centre (TBCC) Program

As initially described by Speca, Carlson, Goodey, and Angen (2000), and more recently outlined in 2010 by Carlson and Speca, the face-to-face (F2F) MBSR program offered at TBCC provides an opportunity to gain insight and awareness of one's personal responses to stress, and to learn techniques that foster healthier stress responses, as well as the opportunity to practice these skills in a group environment with other individuals living with cancer. The TBCC's F2F MBCR group intervention is based on the MBSR program previously described above and includes the same didactic, meditation, mindful movement, and group process components. A key adaptation of the F2F MBCR group program compared to the traditional MBSR program is that the 8-week intervention is provided in 90-minute sessions, which was an attempt to decrease the burden on participants with community parking issues and travel to the cancer centre. A 6-hour intensive session on a Saturday between weeks six and seven is also provided to participants to allow for an extended mindfulness practice session (Carlson & Speca,

2010). Participants are encouraged to practice 45 minutes per day, and are provided CDs and written materials to aid in meditation home practice.

Evidence for the Efficacy of MBIs in Clinical and Medical Populations

MBI participation is associated with positive effects in multiple clinical and medical populations. In general, treatment effects of a half standard deviation ($d = 0.5$, also described by Cohen as a medium effect size), are considered to represent clinically meaningful improvements in symptomatology – a proxy to assess how meaningful a change is to the individual participant’s life and functioning (Cohen, 1992; Norman, Sloan, Wyrwich, & Norman, 2003). In the first meta-analysis of the health benefits of MBSR, Grossman and colleagues (2004) identified 20 studies that met criteria of acceptable quality or relevance to be included in their analyses. Half of the 20 studies utilized randomized controlled designs, while six investigations employed forms of active control interventions to account for general or nonspecific effects of treatment. Overall, both controlled and uncontrolled studies assessing mental and/or physical health variables in medical populations of chronic pain, fibromyalgia, cancer, coronary artery disease, as well as prisoners, students, and volunteers, showed similar Cohen’s d effect sizes of approximately 0.5, indicating a medium effect of mindfulness interventions on improving physical symptoms (e.g., chronic pain), and ability to cope with a spectrum of issues from everyday distress and disability to clinical levels of stress and disorders (Grossman, Niemann, Schmidt, & Walach, 2004). The authors concluded that although, as a whole, the quality of evidence for the efficacy of MBIs on physical correlates of disease suffered from serious methodological flaws at that time, including a lack of randomized controlled

trials; results were generally supportive that mindfulness training has beneficial effects on psychological and physical well-being (Grossman et al., 2004).

Following Grossman and colleagues meta-analysis, many other conceptual, empirical, and meta-analytic reviews of the MBI literature have been independently conducted within mixed clinical and general medical populations (Baer, 2003; Bishop, 2002; Proulx, 2003; Shigaki, Glass & Schopp, 2006; Toneatto, & Nguyen, 2007; Ludwig & Kabat-Zinn, 2008; Praissman, 2008; Bohlmeijer, Prenger, Taal & Cuijpers, 2010; Hofmann, Sawyer, Witt & Oh, 2010; Carlson, 2012; De Vibe, Bjorndal, Tipton, Hammerstrom, & Kowalski, 2012; Khoury, Lecomte, Fortin, Masse, Therien, Bouchard, et al., 2013; Goyal, Singh, Sibinga, Gould, Rowland-Seymour et al., 2014; Gotink, Chu, Busschbach, Benson, Fricchione et al., 2015). Due to the volume of reviews, examples of reviews that highlight the importance of accounting for baseline distress levels, recent systematic or meta-analytic reviews conducted in specific illness populations, as well as the most recent large meta-analytic reviews are described below.

The MBI meta-analysis by Bohlmeijer and colleagues (2010) examined the effectiveness of MBIs on anxiety, depression, and psychological distress within a varied chronic somatic disease population. Eight randomized controlled trials were included in the review including two within an oncology population (MBCR: Speca et al., 2000; Mindfulness-Based Art Therapy: Monti, Peterson, Kunkel, Hauck, Pequignot et al., 2006). The authors calculated Cohen's *d* effect sizes of 0.26 and 0.47 for depression and anxiety symptoms respectively (Bohlmeijer et al., 2010). The authors explored whether study quality moderated effect sizes and concluded that when controlling for study quality, MBSR had small effects on depression, anxiety, and psychological distress in

people with chronic somatic diseases. Nevertheless, authors called for further research due to the limited number of studies included in this evaluation, and hypothesized that potential ceiling effects for low baseline anxiety/depression scores could impact the small effect sizes observed (Bohlmeijer et al., 2010).

Hofmann, Sawyer, Witt and Oh conducted a meta-analysis evaluating the impact of MBIs (MBSR or MBCT) on anxiety and depressive symptoms, and conducted separate analyses to compare the impact of controlling for baseline symptom severity in an attempt to mitigate such ceiling and floor effects. Thirty-nine studies (16 controlled, 23 uncontrolled) and 1,140 people diagnosed with a psychological or medical disorder were included (Hofmann et al., 2010). Authors report medium effect sizes in uncontrolled studies for anxiety (Hedges' $g = .63$) and depression (Hedges' $g = .59$) symptom reduction. Effect sizes were reduced when limiting inclusion to the 16 active treatment controlled studies for anxiety (Hedges' $g = .41$) and depression (Hedges' $g = .33$) symptom reduction. Authors' analyses of baseline symptom severity for anxiety and depression included uncontrolled and controlled studies. Results suggest that MBIs have similar impact across a range of anxiety and depression severity with medium effect sizes reported for both elevated (Hedges' $g = .67$) and non-elevated (Hedges' $g = .53$) baseline anxiety symptoms, as well as elevated (Hedges' $g = .53$) and non-elevated (Hedges' $g = .50$) baseline depression symptoms. Authors highlight the need to conduct additional randomized trials that include active control arms within well-defined symptom profiles (Hofmann et al., 2010).

With such high variability and inherent issues in diverse heterogeneity, specific medical populations have been subject to more focused systematic and meta-analytic

reviews, including pain intensity (systematic review: Reiner, Tibi, & Lipsitz, 2013); mental health improvements in a chronic pain population (systematic review and meta-analysis: Veehof, Oskam, Schreurs, & Bohlmeijer, 2011; systematic review: Rajguru, Kolber, Garcia, Smith, Patel et al., 2014); quality of life and pain improvements for individuals diagnosed with Fibromyalgia (systematic review and meta-analysis: Lauche, Cramer, Dobos, Langhorst, & Schmidt, 2013); chronic somatic diseases such as chronic fatigue and irritable bowel syndrome (meta-analysis: Bohlmeijer et al., 2010; systematic review and meta-analysis: Lakhan, & Schofield, 2013), multiple sclerosis (systematic review: Simpson, Booth, Lawrence, Byrne, Mair et al., 2014); reduction of stress, anxiety and depressive symptoms resulting from vascular disease (systematic review and meta-analysis: Abbott, Whear, Rodgers, Bethel, Coon et al., 2014), transient ischemic attack and stroke (systematic review: Lawrence, Booth, Mercer, & Crawford, 2013); and emotional distress resulting from HIV/AIDS (systematic review: Riley, & Kalichman, 2014). While some variability exists, findings from the substantial majority of systematic and meta-analytic reviews above support the hypothesis that structured group mindfulness training has beneficial effects on psychological (emotional distress, anxiety, and depressive symptoms) and physical well-being (pain and condition-specific symptoms associated with fibromyalgia and IBS), when faced with a wide variety of medical disorders. Overwhelmingly, authors call for continued well-controlled study designs to build available evidence quality, particularly randomization and active control comparisons.

To attempt to synthesize the growing review literature focused on psychological health, a large meta-analysis conducted by Goyal and colleagues included 41 randomized

controlled trials (2,993 participants) that included various forms of meditation, and included only active control conditions evaluating a wide variety of health and psychological outcomes (Goyal et al., 2014). Fifteen studies focused on psychiatric populations (anxiety, depression, chronic worry, and insomnia), 16 trials focused on diverse medication populations (e.g., heart disease, lung disease, breast cancer, diabetes, hypertension, HIV), five studies evaluated substance abuse (e.g., tobacco, alcohol), and five trials evaluated chronic pain populations. Length of intervention and follow-up period ranged from four weeks to nine years. MBSR programs typically provided 20–27.5 hours of training over 8-weeks, while other mindfulness meditation trials reported approximately half the number of hours of training. Transcendental Meditation trials averaged between 16-39 hours, while other mantra meditation programs provided approximately half this amount.

Anxiety effect sizes (Cohen's *d*) ranged from 0.40 at 8 weeks to 0.22 at the three to six month follow-up, while depression was significant but slightly lower at 8 weeks (0.32) and comparable to anxiety at three to six month follow-up (0.33). Authors concluded that in particular, mindfulness programs reduced multiple negative dimensions of psychological stress including anxiety and depressive symptoms. However, caution is needed interpreting results, as limitations to the meta-analysis included significant clinical heterogeneity, variability in the types of controls, and significant heterogeneity in the type of meditation practice, dose, frequency, and duration of the interventions pooled. Authors echoed previous review recommendations for stronger study designs (Goyal et al., 2014).

Most recently in 2015, Gotink and colleagues conducted an overview of 23 systematic reviews (13 included meta-analyses) for MBSR and MBCT interventions utilizing wait-list, TAU or active control conditions for a variety of mental and physical health outcomes in cancer, chronic pain, cardiovascular disease, chronic somatic diseases, depression and anxiety populations (Gotink et al., 2015). Cancer-specific results will be reviewed separately in an upcoming section in this chapter. Overall results suggest that compared to wait-list or TAU, the mindfulness interventions significantly improved depressive symptoms (based on five reviews and 2814 people, $d = 0.37$), anxiety symptoms (four reviews and 2525 people, $d = 0.49$), stress symptoms (two reviews and 1570 people, $d = 0.51$), quality of life (two reviews and 511 people, $d = 0.39$) and physical functioning (three reviews and 1015 people, $d = 0.27$), but there was a relative lack of active control conditions to assess. Authors cite limitations of heterogeneity within patient categories, risk of publication bias and limited follow-up reported by many reviews (Gotink et al., 2015). Overall, conclusions support the use of structured MBIs for the adjunct treatment of diverse chronic illnesses.

Evidence for the Efficacy of MBIs in Cancer

MBSR is increasingly being offered in oncology settings due to the growing body of evidence investigating the efficacy of mindfulness-based interventions to reduce the psychological distress associated with a cancer diagnosis (Shennan, Payne, & Fenlon, 2011; Carlson, 2012). In the year 2000, Speca and colleagues published the first randomized controlled trial of MBSR in an oncology population, employing a wait-list design. Results indicated improvements in stress symptoms and mood disturbance

relative to controls (Speca et al., 2000), with improvements maintained at 6-month follow-up (Carlson, Ursuliak, Goodey, Angen, & Speca, 2001).

Following the first published RCT, a large influx of mindfulness research in oncology has occurred, with researchers conducting multiple qualitative, comprehensive, and meta analytic reviews of the literature (Ott, Norris, & Bauer-Wu, 2006; Smith, Richardson, Hoffman, & Pilkington, 2005; Mackenzie, Carlson & Speca, 2005; Matchim & Armer, 2007; Lamanque & Daneault, 2006; Ledesma & Kumano, 2009; Shennan et al., 2011; Musial, Bussing, Heusser, Choi, & Ostermann, 2011; Matchim, Armer, & Stewart, 2011; Piet, Wurtzen, & Zachariae, 2012, Greene, Philip, Poppito, & Schnur, 2012; Cramer, Lauche, Paul, & Dobos, 2012; Zainal, Booth, Huppert, 2013; Huang, He, Wang, & Zhou, 2015).

Based on these reviews of the literature, MBIs have shifted from a potential intervention for individuals diagnosed with cancer, to an evidence-based intervention for improving psychological, functional, and quality of life outcomes in oncology – with the majority of evidence focused in breast cancer (Matchim et al., 2011; Carlson, 2012; Piet et al., 2012). Recent comprehensive and meta-analytic reviews beginning with the first cancer-specific meta-analysis are reviewed, as well as key original research that has recently advanced the field by implementation of active control comparisons and rigorous or novel experimental designs.

The first meta-analytic review exclusively within oncology was conducted by Ledesma and Kumano in 2009, and investigated the mental and physical health impact of MBIs on individuals diagnosed with various types of cancer (including breast, ovarian, prostate, lung, ear, rectal, endometrial, and melanoma). While there was a broad range of

cancer types included, the majority of studies included were conducted with individuals suffering from breast and prostate cancer. A total of 10 studies met inclusion criteria (cancer patients who participated in a MBI program between 6-15 weeks in length and at least one quantitative outcome published by 2007). Outcome measures were divided into physical and mental health factors. The physical health factors included immune function, hormonal indices, and dietary fat, while the mental health factors included anxiety, depression, and daily stress (Ledesma & Kumano, 2009).

Overall effect sizes of $d = 0.48$ for mental health factors and $d = 0.18$ for physical health factors were observed, indicating a medium effect of mindfulness interventions on improving mental health factors, but much weaker for the specific physical health factors assessed (Ledesma & Kumano, 2009). This conclusion regarding physical health factors is limited because the study outcomes included in this category were immune function, hormones, and dietary fat, none of which are actual measures of physical health status or outcome.

Ledesma & Kumano suggest these results indicate MBIs may be helpful in supporting individuals with cancer in the psychosocial adjustment associated with the disease, while echoing the caution of previous reviews and calling for replication of randomized controlled trials that include active control groups and long-term follow-up (2009).

Musial and colleagues reviewed the literature to the end of 2010, including 19 studies, and reported comparable effect sizes to Ledesma and Kumano's 2009 review for distress (Cohen's $d = 0.48$) and mood ($d = 0.42$), however they did not investigate physical or biological health outcomes (Musial et al., 2011). The following year, Piet,

Wurtzen, and Zachariae (2012) conducted another meta-analysis of MBIs on symptoms of anxiety and depression in adults diagnosed with cancer. The review included 22 studies with 1403 participants, and the authors conducted separate analyses for randomized or non-randomized trials for effect size comparison. For the non-randomized trials, Hedges' g effect sizes for pre-to-post mindfulness intervention ranged from 0.42 to 0.60 for depression and anxiety, respectively. In the randomized trial analysis, Hedges' g effect sizes for pre-to-post mindfulness intervention for depression symptoms was 0.44, and 0.37 for anxiety symptoms. The authors also analyzed mindfulness skills in the RCT sample, indicating a small-to-medium improvement in mindfulness ($g = 0.39$), with this mindfulness total score estimate created from 11 different studies' data gathered from four different mindfulness questionnaires, including the MAAS (Brown & Ryan, 2003), FFMQ (Baer et al., 2006), the Freiburg Mindfulness Inventory (Walach et al., 2006), or the Kentucky Inventory of Mindfulness Skills (Baer et al., 2004). The subgroup analyses added evidence that when restricted to controlled trials, individuals diagnosed with cancer benefited from MBIs through reducing mood disturbance and anxiety symptoms, as well as overall improved self-reported mindfulness skills (Piet et al., 2012).

Recently, the earlier described meta-analysis by Gotink and colleagues included a review of MBIs for cancer (Gotink et al., 2015). Their cancer-specific search included six systematic reviews combining 16 RCTs with 1668 people diagnosed with cancer (Ledesma and Kumano, 2009; Piet et al., 2012; Cramer et al., 2012; Ott et al., 2006; Smith et al., 2005; Shennan et al., 2011). Echoing results of previous reviews, significant improvements were reported for mental health, including symptoms of depression, anxiety, stress, and quality of life, but not physical health such as sleep quality, body

mass or fat consumption (Gotink et al., 2015). Their review did report a dose response relationship with the number of minutes spent meditating and improved mood disturbance, as well for the number of classes attended and stress reduction (Gotink et al., 2015). Taken together, the majority of controlled and quasi-controlled review research supports the use of MBIs as effective treatment for improving the psychological well-being in people living with cancer. A repetitive theme from the above reviews is a request for improvement in methodological rigor and design of MBI trials. The following original research described below has reported active control condition comparisons and more rigorous designs to further the field.

A large study of MBSR included women with stage I or II breast cancer ($N = 172$) randomly assigned to one of three treatment arms: MBSR, nutrition education (active control) or a usual care group (Henderson, Clemow, Massion, Hurley, Druker et al., 2012). The nutrition education program (NEP) was designed to be equivalent to MBSR in terms of non-specific aspects of attention, contact time, credibility, and group support. Assessments were completed before the intervention, four months, one and two years post-intervention. Compared to both the active and/or usual care conditions, MBSR reduced psychological distress, enhanced acceptance of emotional states, improved active coping strategies, and facilitated a sense of meaning and spirituality. Increases in spirituality (Functional Assessment of Chronic Illness Therapy - Spirituality) and acceptance of emotional states (Courtauld Emotional Control Scale), both of which are issues specifically targeted by MBSR, appeared to endure over the 2-year follow-up, while initial improvements in distress were not maintained at 2-year follow-up. Authors

note baseline levels of distress were below clinical cutoffs for depression and anxiety, possibly creating a floor effect (Henderson et al., 2012).

A large multisite, randomized controlled trial screened women diagnosed with breast cancer for baseline distress levels, assigning 271 women to MBCR, Supportive Expressive Therapy (SET) or a one-day stress management control condition (Carlson, Doll, Stephen, Faris, Tamagawa et al., 2013). Both MBCR and SET active interventions were matched with 18 hours of professional contact and support. This trial assessed psychological and biological outcomes pre, post, and at 12-month follow-up. Regarding psychological outcomes, intent-to-treat (ITT) analyses indicated women in the MBCR program improved more over time on stress symptoms (as measured by the Calgary Symptoms of Stress Inventory) compared with women in both the SET ($p = .009$) and control ($p = .024$) groups. Analyses of individuals who completed the interventions showed greater improvements in the MBCR group in quality of life compared with the control group ($p = .005$) and in social support compared with the SET group ($p = .012$). Regarding biological outcomes, both SET and MBCR resulted in more normative (maintaining steeper slope) diurnal cortisol profiles than the control condition (flatter slope). This two active treatment and control comparison design of distressed women diagnosed with breast cancer strengthens the evidence that MBCR improves both psychological and biological outcomes up to a one year follow-up assessment (Carlson et al., 2013).

Examining sleep outcomes in people diagnosed with insomnia, MBCR was compared to Cognitive Behavioural Therapy (CBT) for the treatment of insomnia within a cancer population, in a randomized noninferiority designed trial (Garland, Carlson,

Stephens, Antle, Samuels et al., 2014). Assessments were conducted pre- and post-interventions (MBCR; $n = 47$ or CBT; $n = 64$) and at 3-month follow-up. Results revealed MBCR was not inferior to CBT (an established intervention for insomnia) in an oncology population. Insomnia severity immediately following the interventions indicated CBT was superior to MBCR, however, at 3-month follow-up differences were non-significant. Several strengths of the study, including 3-month follow-up, active control comparisons, as well as use of actigraphy to supplement self-report questionnaire data are noteworthy. Evaluating treatments such as MBCR against already established interventions for insomnia facilitate the development of options for individuals diagnosed with cancer—patient choice—based on preference and interest, potentially improving satisfaction and engagement with treatment.

Internet Use, Therapy, and Online Interventions

The use of the Internet is expanding, becoming a common social, personal, and professional communication tool (Barak & Suler, 2008; Bargh & McKenna, 2004; Madden, 2010). As of June 30, 2014, it is estimated that 42.3% of the world's population has access to the Internet, and specifically in North America it is estimated to be 87.8% (Internet World Stats, 2014). In a published review, Statistics Canada reported that 72% of Canadians living in smaller towns or rural areas use the Internet, and 84% of Albertans from any location within the province report using the Internet (Statistics Canada, 2010). With such high accessibility and interest, people are accessing the Internet for daily life activities, health information, and support, and individuals living with cancer are no exception.

With the increase in Internet capabilities and usage, psychosocial interventions are being offered online (Madden, 2010; Leykin, Thekdi, Shumay, Munoz, Riba, & Dunn, 2012). Internet-supported therapeutic interventions have flourished, and several factors, such as increasing acceptability of the Internet as a social tool, improvement of computer hardware and software (especially in relation to ease of use, privacy protection, and online communication capabilities) have broadened and increased the use of online interventions (Taylor & Luce, 2003; Barak et al., 2008; Leykin et al., 2012).

The term Internet Therapy (IT) or Internet-supported therapeutic interventions describe multiple ways to deliver treatment over the Internet. IT has been defined as therapeutic interaction that uses the Internet to bring together professionals in the mental health fields and their patients (Roehlen, Zack, & Speyer, 2004). Several terms for IT have been cited in the literature and are often used interchangeably, such as interapy, etherapy, cyber-counselling, online therapy, and Internet-based treatment (Lange, Schrieken, van de Ven, Bredeweg, Emmelkamp et al., 2000). The use of IT is increasing and is considered a powerful tool when used in addition to, or adequately integrated with, the presence of a therapist, or in situations where there is limited access to face-to-face (F2F) psychological services (Barak, Hen, Boniel-Nissim, & Shapira, 2008).

ITs range in both the amount and type of therapist or instructor contact, and can be divided into synchronous “real time” or delayed asynchronous interactions with participants (Andersson & Titov, 2014). The majority of online therapy takes place via e-mail (Stofle, 2001, Madden, 2010). E-mail is categorized as “asynchronous,” meaning that communication does not take place in “real time,” but rather whenever individuals have a chance to respond to one another. Less common is the practice of “synchronous”

online therapy that takes place in real time, often using chat-based interfaces (e.g., instant messaging platforms) or telephone or video conferencing. In synchronous communication, the participant and instructor or therapist are able to sit at their computers at the same time and interact with each other in that moment. Fast broadband connection allows auditory and video exchanges that simulate the speed of F2F conversations, and as high-speed Internet connections become more common, an increasing number of professionals are offering multimedia capabilities and videoconference sessions through a broad range of available software and programs (Bargh & McKenna, 2004; Barak et al., 2008).

Asynchronous Internet Interventions

CBT-Based Interventions in Non-Oncology Populations

Asynchronous Internet programs have been implemented as intervention modalities for the treatment of anxiety and mood disorders, with the majority to date utilizing cognitive behavioral orientations. Cognitive behavioural internet interventions have been found to be an effective treatment for a range of psychiatric conditions and health problems, and content, amount, and format of therapist assistance varies from self-help (none) to extensive contact over chat, email/text or telephone (Barak, Klein & Proudfoot, 2009). Such cognitive behavioral oriented web-based interventions have shown similar effect sizes as F2F interventions (Barak et al., 2008) and internet-delivered psychosocial interventions have gained increasing acceptability as adjunct options to existing F2F interventions (Andersson & Titov, 2014; Cuijpers, van Straten, & Andersson, 2008; Everts, van der Lee, & de Jager Meezenbroek, 2015).

German researchers (Meyer, Berger, Caspar, Beevers, Andersson et al., 2009) examined a 9-week web-based asynchronous intervention (Deprexis) for community adults recruited from online depression forums, with no other inclusion/exclusion criteria specified. Deprexis contained 10 modules representing different psychotherapy approaches (and also one introductory and one summary module). The program involves interactive components such as flash animations, and required participants to select response options that subsequently tailored feedback (Meyer et al., 2009). ITT analyses revealed a small effect size for improvements in depression symptoms as measured by the Beck Depression Inventory (Cohen's $d = .30$) and improvements were maintained at 6-month follow-up. The attrition rate for this study was high, as approximately half of the participants dropped out of the program before the 9-week assessment, however, the authors observed that even participants who attended only four sessions or less reported improvements in mood (Meyer et al., 2009).

Perini, Titov, and Andrews conducted a pilot study in 2008, and a randomized wait-list controlled trial in 2009 examining an online clinician-assisted computerized cognitive behavioral treatment intervention for depression. The treatment program (The Sadness Program) included four asynchronous components: six online lessons, homework assignments, an online discussion forum, and regular email contact with a mental health professional (Perini, Titov, & Andrews, 2008; Perini, Titov & Andrews, 2009). Participants in the treatment condition showed improvements on measures of depression with Cohen's d effect sizes of 0.76 to 0.98. The authors conclude asynchronous online programs for depression, combined with clinician support, can result in clinically significant improvements in mood (Perini et al., 2009).

Significant increase in randomized controlled trials evaluating internet-based guided/unguided cognitive behavioral interventions for mood and anxiety disorders has resulted in multiple meta-analyses for depressive symptoms, social anxiety disorder, generalized anxiety disorder and panic disorder (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Boettcher, Carlbring, Renneberg, & Berger, 2013; Cuijpers, Marks, van Straten, Cavanagh, Gega et al., 2009; Reger & Gahm, 2009; Spek, Cuijpers, Nyklícek, Riper, Keyzer, et al., 2007).

A large systematic review and meta-analysis was conducted that included three main Internet-delivered therapeutic approaches, including CBT, psychoeducation, and behavioural therapy studies up until March 2006. Barak, Hen, Boniel-Nissim & Shapira (2008) collected 64 research articles containing 92 studies utilizing 746 dependent measures (Barak et al., 2008). Nine categories of problems were included in the review: posttraumatic stress disorder, panic and anxiety, smoking cessation, drinking, body image, depression, physiological issues, weight loss and an “other” category. Within this compiled literature, 14 studies compared directly the effectiveness of F2F psychological interventions to Internet versions for the same problem, and overall revealed no differences in measured outcomes emphasizing similar improvements through F2F and Internet-based formats (Barak et al., 2008).

MBIs for Non-Oncology Populations

With cognitive behavioral Internet-based interventions for mood and anxiety disorders proceeding, Internet-based mindfulness and acceptance interventions followed, and to date published trials have largely been self-help based or unguided (Cavanagh, Strauss, Forder, & Jones, 2014). In a recent systematic review and meta-analysis of

online self-help mindfulness and acceptance-based interventions, 15 unguided mindfulness interventions with varying levels of follow-up e-mail or telephone support were included (Cavanagh et al., 2014). Six of the studies targeted non-clinical populations (e.g., Gluck & Maercher, 2011; Krusche, Cyhlarova, King, & Williams, 2012; Morledge, Alexandre, Fox, Fu, Higashi, et al., 2013).

Morledge and colleagues conducted a large, completely automated (video and MP3 – compressed sound format file) mindfulness-based intervention for broad public access, not limited to specific chronic diseases or conditions (Morledge et al., 2013). This ambitious 3-arm trial recruited to a mindfulness-based stress management program ($n = 183$), a mindfulness program plus a message board ($n = 184$), or a control group ($n = 184$), however only 35% of participants in the mindfulness program completed more than half of the 8-week program. Both the active treatment conditions, compared to the control condition, demonstrated reduction in perceived stress, increased mindfulness (MAAS), transcendence (Adult Self-Transcendence Inventory) and self-acceptance post intervention and 4-week follow-up. Authors reported some qualitative evidence that suggested the interactive message board improved participants' therapeutic experience, suggesting that greater benefits and potentially lower dropout-rate may be achieved with a more expansive and integrated social media component (Morledge et al., 2013).

Similarly in a clinical anxiety population, Boettcher and colleagues evaluated an online mindfulness program where participants practiced mindfulness without any contact or support from clinicians or fellow participants, and participants completed on average only half of the treatment protocol (Boettcher, Astrom, Pahlsson, Schenstrom, Andersson et al., 2014). The results of these two studies suggest that to ensure

compliance, and help participants complete full mindfulness training, extra support from program staff might be required.

A Swedish group of researchers had evaluated through a series of intervention studies an online asynchronous adapted version of an acceptance, exposure, and mindfulness-based intervention for IBS. The intervention was provided in self-help manual format, with five steps to sequentially complete before having the ability to move to the next section. Step One provided psychoeducation regarding the role of symptom-related behaviours and vigilance, as well as two mindfulness exercise to practice daily. Step Two involved explanation of the psychological model of IBS as well as the effect of anxiety on gut functioning, including how it specifically increases the awareness of IBS-related symptoms. Step Three reviewed the role of negative cognitions in exacerbating IBS-related anxiety, encouraging a mindful and accepting stance rather than struggling to control thoughts and emotions. Participants are encouraged to set value-based behavioural change goals related to meaningful activities to shift life focus off of minimization of IBS symptoms. Step Four introduced the concept of gradual systematic exposure and desensitization, including reducing avoidance (e.g., stressful situations, eating foods or physical activity) as well as minimizing safety behaviours. Step Five included a relapse prevention module, summation of learning and future goals (Ljotsson, Hesser, Andersson, Lackner, El Alaoui, et al. 2014). Online closed-group discussion forums were offered to participants in addition to contact with a therapist through an asynchronous messaging system, who provided support and additional clarification/psychoeducation as needed to participants.

These studies had generally produced large treatment effects on IBS-specific symptoms, quality of life, and psychological outcomes compared to a wait-list (Ljotsson, Falk, Vesterlund, Hedman, Lindfors et al., 2010), as well as long-term societal cost savings (Ljotsson, Andersson, Andersson, Hedman, Lindfors, et al. 2011a), maintenance of benefits over 12 – 18 months (Ljotsson, Hedman, Lindfors, Hursti, Lindefors et al., 2011c), and show advantage over an active treatment control condition (Ljotsson, Hedman, Andersson, Hesser, Lindfors, et al., 2011b).

This research group evaluated the online asynchronous mindfulness intervention compared to an online stress management program with 195 randomized participants (Ljotsson et al., 2011b). At post-intervention and 6-month follow-up, the participants in the MBI improved more than those in stress management on IBS-specific symptom severity, quality of life, and visceral sensitivity (Ljotsson et al., 2011b). Both treatment conditions improved similarly on stress, anxiety, and depression subscales, and did not report difference between intervention credibility or working alliance. Most recently, the authors conducted a large ($N = 309$) component-controlled randomized trial to investigate if systematic exposure had specific beneficial effects in a psychological treatment for IBS (Ljotsson et al. 2014). The authors randomized participants to two versions of the previously validated online asynchronous mindfulness program, with and without the systematic exposure component. The between-group effect size (Cohen's d) on an IBS-specific version of a gastrointestinal symptom rating scale was in favor of the intervention package including exposure ($d = 0.47$ immediately post-treatment, and 0.48 at 6-month follow-up). This well designed study concluded that systematic exposure included in the online program had incremental effects over the other components, and

provided utility of exposure exercises online in the treatment of IBS (Ljotsson et al., 2014). Taken together, this line of research has demonstrated consistent and beneficial effects on IBS symptoms of an asynchronous internet-delivered treatment, emphasizing the active component of exposure (Ljotsson et al., 2014).

In a non-randomized trial, an asynchronous web-based version of MBCT was evaluated in 100 recurrently depressed individuals and analyses were conducted on the full sample, as well as separately with people experiencing residual depressive symptoms (RDS) (Dimidjian, Beck, Felder, Boggs, Gallop et al., 2014). The authors used a quasi-experimental comparison between their program called “Mindful Mood Balance” and propensity matched (recurrently depressed or RDS controls receiving usual depression care at the same clinic) to evaluate depression symptom severity, rumination, mindful awareness, and program engagement. In Mindful Mood Balance, participants learn traditional skills of in-person MBCT by listening to guided instruction from a website with a downloadable audio file, watching a video interaction between the instructor and participant related to the skill being taught, and then have the opportunity to ask questions from facilitators in an asynchronous message format. Results indicate depression severity, as compared to the propensity matched control group, was reduced and maintained at 6-month follow-up in both the full sample and RDS sample analysis. Similar improvements on measures of rumination were also observed. Mindfulness, measured by the FFMQ total score pre- to post-intervention increased in the full sample compared to controls ($p < 0.02$), but did not in the RDS. Authors note limitations with non-randomization as well low retention rate (approximately 50%), however this

preliminary investigation supports the web-based delivery of MBCT compared to usual care for depression in a primary care setting (Dimidjian et al., 2014).

Non-Mindfulness Interventions in Oncology

Two asynchronous non-mindfulness online interventions have been evaluated specifically within a cancer population. A Norwegian research group evaluated the effects of an Internet support system through randomizing 325 individuals diagnosed with breast or prostate cancer to either “WebChoice” or a control condition that received information about publically available cancer websites. WebChoice was created to be an interactive health communication application. The purpose of the intervention was to monitor symptoms, tailor health information, allow interactive e-communication with nurses, and provide an e-forum for group discussion with other participants (Ruland, Andersen, Jeneson, Moore, Grimsbo, et al., 2013). This one-year trial revealed group ITT differences on a global symptom measure of distress, however physical and psychological distress, self-efficacy, quality of life, depression, and social support measures did not show group differences. A significant limitation to the trial was that 23% of participants randomized to WebChoice never logged into the platform, and only 64% logged on more than once in a full year, which brings into question dose of intervention received as well as acceptability of intervention for participants (Ruland et al., 2013). For interventions to be successful they have to be appealing enough to motivate individuals to participate, especially when participation is largely self-initiated and maintained.

MBIs in Oncology

More recently, an asynchronous Internet intervention for an oncology population evaluated cancer related fatigue through individual MBCT (eMBCT) in the Netherlands (Everts et al., 2015). This non-randomized pilot trial of a 9-week therapist guided (through email correspondence) individual eMBCT program reported fatigue severity and distress decreased pre- to post-eMBCT, with approximately 35% of participants reporting a clinically significant decrease in fatigue—no longer reporting fatigue complaints. Limitations of this trial included no control comparison, and of the 257 eligible participants who started the eMBCT intervention, approximately 40% did not complete at least 70% of the online course. One of the recommendations elicited from participants to improve the intervention was to provide additional F2F contact or telephone contact (Everts et al., 2015).

Synchronous Internet Interventions

Non-Mindfulness Interventions in Oncology

In the cancer literature, online support groups designed and moderated by health care professionals are limited, however, of note, there have been a few professionally facilitated synchronous online support groups (OSG) that involve real time “chatting” or typing between participants (Lieberman, Golant, Giese-Davis, Winzlenberg, Benjamin, et al., 2003; Stephen, Rojubally, MacGregor, McLeod, Speca, et al., 2013; Stephen, Collie, McLeod, Rojubally, Fergus, et al., 2014). The first published professionally-facilitated online text-based support group involved a 16-week single-group design clinical trial (Lieberman et al., 2003). Sixty seven women diagnosed with breast cancer were enrolled in the trial, however only 32 participants started the intervention, and outcome measures

were administered pre- and post-OSG with no control comparison. The authors reported that the OSG significantly reduced depression ($t = 5.1, p < .001$) and negative reactions to pain ($t = 4.4, p < .001$), and while not significant, there was a trend toward improvements in posttraumatic growth (Lieberman et al., 2003). This work is limited by the lack of a control or comparison group, so changes could be due to a number of reasons outside of group participation.

More recently, Stephen and colleagues developed and tested a platform for real-time text-based (i.e. typing rather than talking) professionally-led support groups through the “CancerChatCanada” website. They reported qualitative content analyses of 102 interviews with participants diagnosed with cancer and their caregivers who participated in a synchronous live 10-week therapist-led text-based chat group (Stephen et al., 2013). This publication of the CancerChatCanada platform revealed high levels of satisfaction, with 89% of participants reporting experiences that were better than expected, and professional facilitators were viewed as vital to have helped participants benefit emotionally from the discussions.

In 2014, this research group followed up their content analyses with more in-depth theme analyses relating to the intervention’s benefits and challenges. Benefits included cancer survivors feeling comfort with the ease of accessing support from their own home to allow for accommodation of competing demands on their time, privacy within the groups allowing discussion regarding important matters such as death, and the groups providing a forum for expressing difficult emotions. Benefits of “talking with text” included being able to cry and “talk” simultaneously, as well as the emotional bond that developed with the groups, but challenges were difficulty following fast-paced

conversations (Stephen et al., 2014). This research supports the notion that in a Canadian context, people diagnosed with cancer are interested in synchronous online interventions, and can benefit from text-based professionally facilitated support.

Several groups have developed and tested synchronous interventions involving audio or visual capabilities in addition to text-based chat in cancer populations. Shepherd and colleagues conducted a pilot study in 2006 to examine whether individual videoconferencing would improve rural cancer patients' anxiety and depression levels and quality of life (Shepherd, Goldstein, Whitford, Thewes, Brummell et al., 2006). Psychological intervention via videoconferencing consisted of approximately one-hour individual sessions held weekly or biweekly for between one and six sessions ($M < 3.04$, $SD = 1.54$). Twenty-five individuals diagnosed with cancer attended an average of three sessions with a clinical psychologist who provided brief cognitive behavioural therapy (including problem solving skills, activity scheduling and controlled breathing). Assessment using the Hospital Anxiety and Depression Scale and the Functional Assessment of Cancer Therapy-General scale were completed pre, post, and at one-month follow-up. Participant anxiety decreased ($p = 0.01$) over the intervention period, with improvement sustained over the one-month follow-up period. Depression levels also decreased ($p = 0.38$) and overall quality of life improved ($p = 0.04$) (Shepherd et al., 2006). While this preliminary study is promising, because it was a simple pre-post study with a small sample size, further research is needed to test rigorously the therapeutic potential of videoconferencing in a cancer population.

In a similar vein, Lounsberry, MacRae, Angen, Hoeber, and Carlson conducted a feasibility study of a telehealth-delivered psycho-educational support group for

allogeneic hematopoietic stem cell transplant (AHSCT) patients (2009). The facilitator-led support and didactic groups were set up through videoconferencing equipment located at various community health centres across three Canadian provinces. While participants did not demonstrate any significant improvements in quality of life, spirituality, distress, or positive growth, 100% stated they were satisfied with the program, and 74% attended five or more of the six sessions (Lounsberry et al., 2009). The authors concluded psycho-educational support groups via videoconferencing may provide a viable alternative for those with limited access to psychosocial support (Lounsberry et al., 2009).

MBIs in Non-Oncology Populations

While not within an oncology population but within a clinical pain context, Gardner-Nix and colleagues evaluated a controlled but non-randomized 10-week Mindfulness-Based Chronic Pain Management (MBCPM) intervention in the Toronto, Canada area. The MBCPM program was based on the MBSR intervention, but additional emphasis was placed on learning to observe emotions associated with pain and general health education components, which include topics such as nutrition, exercise, sleep medication, and visualization techniques to manage pain (Gardner-Nix, Backman, Barbati & Grummitt, 2008). Participants received the intervention via traditional F2F teaching ($n = 99$), via real-time videoconferencing ($n = 57$) at their local hospital site, or were wait-listed ($n = 59$). Baseline and post-intervention outcome measures of quality of life, pain catastrophizing, and pain intensity ratings were collected and analyzed.

The quality of life measure the authors included in their analysis, the SF-36, yields a physical component score (composed of physical functioning, physical role,

bodily pain, and general health domains) and a mental component score (composed of vitality, emotional role, social functioning, and mental health domains). The Pain Catastrophizing Scale is a 13-item scale measuring domains of rumination (persisting negative thoughts), magnification (fear-driven pain exacerbations) and helplessness (no control) (Gardner-Nix et al., 2008).

Participants in the F2F and videoconferencing groups achieved similar gains in mental health ($p < 0.01$) and pain catastrophizing levels ($p < 0.01$) relative to controls. However, the F2F group obtained higher scores on the physical dimension of quality of life ($p = 0.01$) and lower pain intensity ratings ($p = 0.05$) than the videoconferencing group. The authors speculated that the F2F and videoconferencing participants may have been inherently different in nature, since the study was not randomized. The F2F and videoconferencing groups differed prior to the initiation of the intervention on their physical component scores, which were lower at baseline for videoconferencing participants compared to the F2F group. The authors speculated this difference may be due to the greater travel and parking difficulties required to attend the F2F groups, causing those with greater physical disability to either choose the online version initially or drop out of the F2F version once enrolled (Gardner-Nix et al., 2008). Overall, attrition rates were higher for F2F participants compared to the videoconferencing or wait-list groups, supporting this contention. The authors concluded that videoconferencing was an effective mode of delivery for a MBI (Gardner-Nix et al., 2008), particularly for those with greater functional impairment who may have difficulties attending groups in-person.

In an epilepsy population, an MBCT program for depression was designed and evaluated for group delivery via the Internet or telephone, so that individuals could

receive treatment while staying in their homes (Thompson, Walker, Obolensky, Winning, Barmon, et al., 2010). This randomized wait-list controlled trial ($N = 40$) utilized teleconferencing technology which was synchronous and provided eight one-hour sessions. However, the Internet-based version was developed as an asynchronous “course” that could be accessed at any time with written materials, videos, and discussion posting forums. Depressive symptoms decreased in both the asynchronous Internet and the synchronous telephone intervention groups compared to a wait-list control. The Beck Depression Inventory scores decreased in the telephone group by 68%, the Internet group by 59% and the wait-list by 15%, with no significant difference between the Internet and telephone groups. No effects were reported for other investigated outcomes of knowledge/skills, self-efficacy, or quality of life (Thompson et al., 2010).

Two different mind-body interventions, one yoga-based and one mindfulness-based, in two different formats (in-person and online) were evaluated in a randomized controlled trial of 239 non-clinical workplace employees (Wolever, Bobinet, McCabe, Mackenzie, Fekete, et al., 2012). Employees were differentially randomized from two different US states. Connecticut participants were randomized to 5 conditions: F2F “Mindfulness at Work” class, online Mindfulness at Work, a control condition provided resource information, Viniyoga with and without a DVD component. California participants were randomized to three conditions: online mindfulness, Viniyoga without the DVD component and control. Preliminary analysis revealed no differences between Viniyoga with/without the DVD and were combined for analysis. The 12-week (12 hour) Viniyoga program includes asanas (physical postures), breathing techniques and guided relaxation, as well as emphasized home practice. The Mindfulness at Work online

synchronous and F2F programs were a 12-week (14 hour) stress management program utilizing mindfulness meditation to target work-related stress, work-life balance and self-care through brief (5-15 minute) mindfulness exercises designed to be used at work. The online program was provided in a synchronous online classroom format. The in-person Mindfulness at Work intervention consisted of 12 weekly hour-long classes at the worksite, with a 2-hour mindfulness extended practice at week 10 (Wolever et al., 2012).

Of the 205 participants that completed the study, attrition levels did not differ between groups, however within the mindfulness program, higher attrition occurred in the in-person (27.3%) vs. online groups (3.8%). All mind-body programs and versions indicated a similar reduction in perceived stress and sleep difficulties compared to control, with no significant effects for depression measures, heart rate variability, blood pressure or work productivity. The heart rhythm coherence ratio (a proposed measure of autonomic balance), improved in the online mindfulness group compared to the F2F mindfulness group, although authors contend attrition differences may have influenced this result. This study provides support for similar improvements but less attrition from an online vs. in-person format of a mindfulness intervention in a non-clinical sample.

Most recently, and most similar to our study, a full MBSR program was adapted to a live synchronous internet protocol for individuals suffering with mental fatigue following an acquired brain injury including traumatic brain injury or stroke (Johansson, Bjuhr, Karlsson, Karlsson, & Ronnbock, 2015). Thirty-eight participants were recruited for the study and divided into three groups: F2F MBSR, Internet-delivered live MBSR, and an in-person walking control group. Due to difficulty with recruitment to Internet MBSR within the city, and differing patient preferences, groups were not randomized,

and therefore could not be directly compared. Consequently analysis was limited to a non-randomized pre-post design with 10 of the 13 participants completing the intervention. The Internet group significantly reduced mental fatigue symptoms. Limitations of the trial include small sample size and non-randomization, however preliminary evidence suggests that individuals with acquired brain injury can reduce mental fatigue symptoms through a live, interactive online MBSR program (Johansson et al., 2015), providing support for feasibility of online synchronous adaptations of MBSR in clinical populations.

Rationale for Online Synchronous MBCR for a Cancer Population – eCALM Trial

It has been reported that F2F MBCR programs can reduce mood disturbance, decrease symptoms of stress, and improve quality of life in individuals living with cancer (Ledesma & Kumano, 2009; Piet et al., 2012). However, practical barriers to participation (e.g., geographical distance, transportation issues, cancer-related illness, limited mobility) may impede access to F2F programs. Previous studies have shown people with functional impairment may prefer at-home internet based programs to in-person groups (Gardner-Nix et al., 2008; Thompson et al., 2010). Hence, the Internet represents a promising method of delivering empirically supported psychosocial interventions such as MBCR to an underserved oncology population. Synchronous online therapy is available to anyone with a computer that has sufficient Internet capabilities, and can potentially reach people in the comfort of their own homes. By allowing individuals to participate in evidence-based group interventions without leaving their own homes, common reasons for difficulty attending or prematurely discontinuing F2F groups may be reduced.

Despite the demonstrated effectiveness of MBCR, its effectiveness has yet to be tested using an Internet-based synchronous version of the program in a cancer population. The purpose of the dissertation was to examine an online synchronous adaptation of an MBCR intervention for an oncology population. Individuals with cancer were randomized to either an online MBCR condition or a wait-list control condition. This study will help determine whether additional, larger, treatment studies are needed to evaluate online MBCR.

**CHAPTER 2: THE ECALM TRIAL-ETHERAPY FOR CANCER
APPLYING MINDFULNESS: ONLINE MINDFULNESS-BASED
CANCER RECOVERY PROGRAM FOR UNDERSERVED
INDIVIDUALS LIVING WITH CANCER IN ALBERTA:
PROTOCOL DEVELOPMENT FOR A RANDOMIZED WAIT-LIST
CONTROLLED CLINICAL TRIAL**

Abstract

Background

Elevated stress can exacerbate cancer symptom severity, and after completion of primary cancer treatments, many individuals continue to have significant distress. Mindfulness-Based Cancer Recovery (MBCR) is an 8-week group psychosocial intervention consisting of training in mindfulness meditation and yoga designed to mitigate stress, pain, and chronic illness. Efficacy research shows face-to-face (F2F) MBCR programs have positive benefits for cancer patients; however barriers exist that impede participation in F2F groups. While online MBCR groups are available to the public, none have been evaluated. Primary objective: determine whether underserved patients are willing to participate in and complete an online MBCR program. Secondary objectives: determine whether online MBCR will mirror previous efficacy findings from F2F MBCR groups on patient-reported outcomes.

Method/Design

The study includes cancer patients in Alberta, exhibiting moderate distress, who do not have access to F2F MBCR. Participants will be randomized to either online MBCR, or waiting for the next available group. An anticipated sample size of 64 participants will complete measures online pre and post treatment or waiting period. Feasibility will be tracked through monitoring numbers eligible and participating through each stage of the protocol.

Discussion

Forty-seven have completed/completing the intervention. Data suggest it is possible to conduct a randomized TAU wait-list controlled trial of online MBCR to reach underserved cancer survivors.

Trial Registration

Clinical Trials.gov Identifier: NCT01476891

Background

Receiving a diagnosis of cancer can be highly stressful, requiring psychological and behavioral adjustments to cope effectively with increased levels of stress that subsequently may affect psychological functioning (Walker et al., 2006) and cancer symptom severity (Roscoe et al., 2002). The prevalence of clinical levels of distress in individuals with cancer is in the 35%–45% range (Carlson et al., 2004; Carlson & Bultz, 2003; Sellick & Edwardson, 2007; Zabora et al., 2001). Distress in these individuals most commonly presents as anxiety and mood disorders across stage and site of illness (Carlson et al., 2004; Bultz & Carlson, 2006; Kangas et al., 2005; Kissane et al., 2004). Therefore, the development and testing of accessible psychosocial interventions intended to reduce stress and improve mood and quality of life are important (Carlson et al., 2009).

Interest in the potential health benefits of mindfulness meditation within the Western medical system has increased with the development and proliferation of interventions modeled after the original Mindfulness-Based Stress Reduction (MBSR) program at the University of Massachusetts Medical Center, developed in the late 1970s by Jon Kabat-Zinn and colleagues (Carlson et al., 2009; Labelle, et al., 2010). Mindfulness meditation is the practice of cultivating moment-to-moment awareness of internal and external experience in an accepting and open manner (Kabat-Zinn, 1990). MBSR is an 8-week group intervention consisting of intensive training in mindfulness meditation and Hatha yoga that is designed to treat symptoms of stress, pain and chronic illness (Kabat-Zinn, 1990). Attitudes of open inquiry, patience, suspended judgment and compassion are encouraged and cultivated through the program during class and also through assigned daily homework. Individuals are taught to focus attention on sensations of the breath, body, and objects that enter awareness, such as thoughts and emotions, with the

intention to fully experience the present moment (Kabat-Zinn, 1990). One result of such focused attention in the present moment is reduction of rumination on the past or persistent worry about the future, as well as increased tolerance of uncomfortable emotional experiences (improved emotional regulation), which can result in decreases in symptomatology.

Research indicates F2F MBSR interventions are efficacious for treating a variety of symptoms associated with a range of chronic medical and psychiatric problems, including cancer (Carlson & Speca, 2007; Lamanque & Daneault, 2006; Mackenzie et al., 2005; Matchim & Armer, 2007; Ott et al., 2006; Smith et al., 2005; Shigaki et al., 2006; Ledesma & Kumano, 2009). Current literature, including the body of work from our research team on MBSR in oncology shows participation in F2F MBSR results in decreased stress symptoms, mood disturbance, anger, and fatigue, with concurrent increases in sleep quality, post-traumatic growth, spirituality and enhanced quality of life (Lamanque & Daneault, 2006; Ledesma & Kumano, 2009; Carlson et al, 2001; Carlson & Garland, 2005; Garland, Carlson, Cook, Lansdell & Speca, 2007; Shapiro, Bootzin, Figueredo, Lopez & Schwartz, 2003; Speca et al., 2000; Tacon, Caldera & Ronaghan, 2004; Tacon, 2006; Lengacher, Johnson-Mallard, Post-White, Moscoso, Jacobsen et al., 2009), as well as changes in several potentially important cancer biomarkers including immune function and stress hormones (Carlson, Speca, Faris & Patel, 2007; Carlson, Speca, Patel & Goodey, 2004). Meta-analytic and comprehensive reviews of the effects of F2F MBSR in cancer concluded that it is a clinically valuable evidence-based intervention for cancer patients (Matchim & Armer, 2007; Ott et al., 2006; Smith et al., 2005; Ledesma & Kumano, 2009) with average Cohen's *d* effect sizes for improving psychological and physical well-being of 0.48 and 0.18, respectively (Ledesma & Kumano, 2009).

Despite their proven efficacy, there may be practical and psychological barriers to participation in F2F MBSR programs, such as geographic distance, cancer-related illness, fatigue, limited mobility or disability, child care, transportation, time, and self-consciousness, to name but a few. The Internet represents a promising method of delivering psychosocial interventions such as MBSR to underserved cancer patients who are unable to attend F2F programs. With the increase in Internet use and capabilities, psychosocial interventions are beginning to be offered online (Madden, 2010), and the use of synchronous online therapy that takes place in “real-time” has increased. Fast broadband connection allows auditory and video exchanges that simulate the speed of F2F conversations, and videoconferencing using a broad range of software and programs is gaining greater use in therapy contexts (Bargh & McKenna, 2004; Barak et al., 2008). In a meta-analysis, Barak et al., in 2008, compared the effectiveness of F2F psychological interventions such as Cognitive Behavioral Therapy (CBT) or Prolonged Exposure (PE) to Internet versions, and overall revealed comparable results (Barak et al., 2008). Most similar to the proposed online MBSR study, Gardner-Nix and colleagues evaluated a non-randomized 10-week Mindfulness-Based Chronic Pain Management (MBCPM) intervention for chronic pain patients. The MBCPM program was based on the MBSR program, but additional emphasis was placed on learning to observe emotions associated with pain and general health education (Gardner-Nix et al., 2008). Patients received MBCPM via traditional F2F teaching, via videoconferencing at their local hospital, or were wait-listed. Baseline and post intervention measures showed patients in the F2F and videoconferencing groups achieved similar gains in mental health and pain catastrophizing relative to controls. However, the F2F group obtained significantly higher scores on the physical dimension of quality of life and lower pain intensity ratings than the videoconferencing group (Gardner-Nix et al., 2008). The authors concluded that

while Internet interventions show potential for treating chronic pain patients, results may be better in-person for some outcomes. While this study did use videoconferencing technology, advancements in sophisticated “real-time” technology since 2008 are significant and have potential to substantially enhance patient interaction and the overall patient experience. Our current study represents an advance over this methodology for several reasons: randomization of our participants, elimination of the need for patients to travel to treatment centres - increasing rural and remote individuals’ access despite geographic location, transportation issues, fatigue etc. We are also able to capitalize on the current technology for improved speed and quality of online communication in our trial.

The positive benefits of MBSR in individuals living with cancer have been well documented by our research team. However, practical and psychosocial barriers may impede participation and access to our popular F2F programs (Barak et al., 2008; Owen, Klapow, Roth, Shuster, Bellis et al., 2005). The Internet represents a promising method of delivering empirically supported psychosocial interventions such as MBSR to this underserved cancer population who are otherwise unable to participate, but it has never been evaluated in this context.

In this paper, we describe an ongoing trial to assess the efficacy of an online adaptation of an MBSR intervention for individuals diagnosed with cancer, online MBSR; the first of its kind. Participants are randomized to either an adapted online MBSR condition or a TAU wait-list control condition. This study will help set the direction for future treatment studies to further evaluate online MBSR.

Objectives. The eCALM Study’s primary objective is to determine feasibility – to examine whether moderately to highly distressed individuals diagnosed with cancer will be

willing to participate in online 8-week MBSR groups and complete the intervention. This feasibility objective will objectively be assessed through evaluation of recruitment, retention, attendance, adherence and participant satisfaction. The secondary objective is to examine the efficacy of the online synchronous adaptation of an MBSR intervention for individuals diagnosed with cancer compared to a treatment-as-usual (TAU) wait-list group on a range of previously studied patient-reported outcomes (PROs) including mood, symptoms of stress, post-traumatic growth, spirituality and mindfulness.

Hypotheses. 1) Participants will be willing to participate and complete an 8-week online MBSR intervention. Our estimated feasibility outcome proportions of 5% interested, 30% eligible, 85% consent, and 85% complete the intervention will be deemed feasible if within 5% of each target; 2) Participants in the online MBSR treatment condition will demonstrate greater decreases in symptoms of stress and mood disturbance over the course of the intervention, when compared to participants in the TAU wait-list control condition; 3) Participants in the online MBSR condition will demonstrate greater increases in mindfulness, spirituality and posttraumatic growth over the course of the intervention, when compared to participants in the TAU wait-list condition.

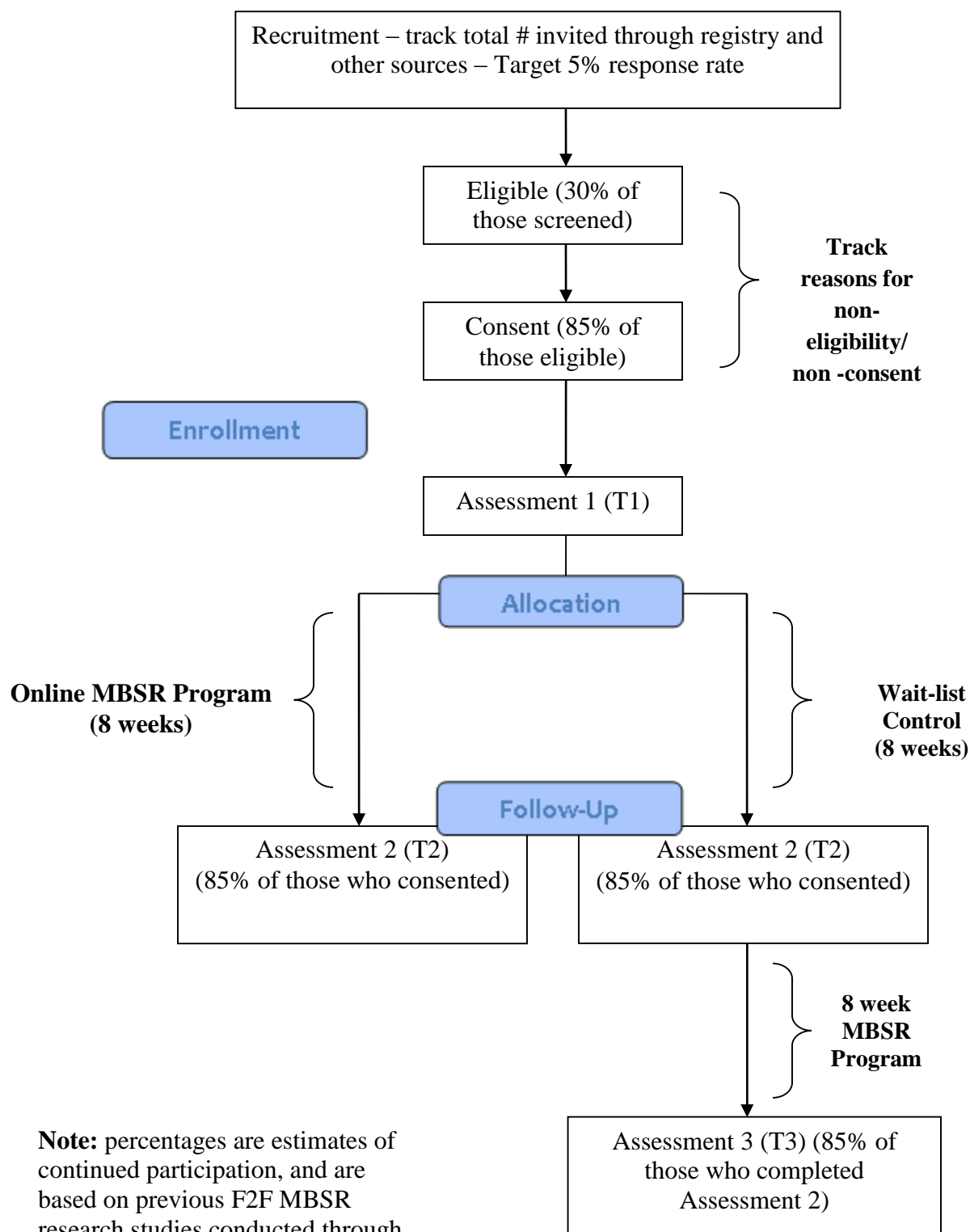
Methods

Study Design

Figure 2.1 illustrates the overall study design and participant flow for the trial. This study utilizes a randomized TAU wait-list controlled trial design with pre- and post-assessment. Ethics approval was obtained from the University of Calgary, Conjoint Health Research Ethics Board (CHREB). While the TAU wait-list trial design may limit potential long-term follow-up, preventing conclusions about efficacy of the treatment to maintain effects after this specified

time frame, recruitment with a no-treatment control may compromise our ability to accrue participants. Additionally, a TAU wait-list design can control for the influences of pre- and post-treatment assessment, symptom self-monitoring, natural recovery from cancer treatments and spontaneous remission or deterioration of symptoms.

Figure 2.1. Overall Trial Design and Participant Flow Diagram



Eligibility

Inclusion criteria: 1) age 18 years or older; 2) speak and read English sufficiently to complete questionnaires; 3) women and men who have been diagnosed with of any type of cancer, at any time in the past with no restriction on tumor site; 4) before or currently receiving primary treatment, or completed primary treatment within the last 36 months. This time was chosen in order to assure a group of individuals who were fairly recently involved in diagnosis and treatment, thus also increasing the likelihood that the issues they are dealing with will be more similar, but also including individuals up to three years post primary cancer treatment who still feel significant distress; 5) exhibiting moderate distress as established by responses on the Distress Thermometer (DT) of 4 or greater out of 10. This is an important criterion as statistical problems with floor effects are common in volunteer samples who have relatively high levels of functioning prior to trial involvement; 6) willing to participate in the intervention requirements; able to participate in the intervention (two hours per week for eight weeks, and the full-day retreat), and agree to the randomization procedure; 7) Internet access; self-reported familiarity with computer usage and Internet access with an overall point 5 Megabyte capability and minimum download (2 Megabytes) and upload (500 Kilobytes) is necessary; and 8) residents in Alberta, who have limited access to existing F2F MBSR programs.

Exclusion criteria: 1) concurrent self-reported diagnosis of psychosis, bipolar disorder, substance abuse or suicidality. Individuals with depression, anxiety or adjustment disorders are not excluded; 2) individuals who have previously participated in an F2F MBSR group.

Recruitment

Potentially eligible participants in Alberta are identified through media outreach, promotional pamphlets, community based networks, and by cancer registry case records to mail

study invitation letters. In Alberta, only one major cancer centre has MBSR classes specifically for individuals diagnosed with cancer; therefore all individuals who are unable to attend these F2F classes would be eligible to participate. The Alberta Cancer Registry estimates as of September 2011, 25,000 individuals diagnosed with cancer are eligible to be contacted for the trial. According to research conducted by the PI, approximately 35-45% of these individuals will meet criteria of being distressed. Additionally, 77% of Albertans 16 years of age and older have Internet access and 429 communities throughout the province of Alberta have broadband Internet (www.albertacanada.com; www.albertasupernet.ca). This forms a potentially large cohort to identify individuals living with cancer who have Internet access for this study.

Procedures

The study, including its nature, outcomes, and extent of participant involvement, is discussed with all prospective participants. Consent is obtained, and participants are informed that they can refuse to answer any question and they can withdraw from the study at any time. On average the quantitative assessments take 30–45 minutes. Before and after the 8-week online MBSR intervention, participants complete an identical battery of questionnaires (T1 & T2). These assessments are completed online in a secure environment with reminder follow-up emails/phone calls placed to participants who fail to complete their questionnaires within two weeks of expected receipt. Two follow-up email reminders separated one week apart are sent and, if no response, a maximum of three attempts to remind patients via telephone at different times of the day are made, with messages left. Participants who are randomized to the control group complete an additional assessment (T3) following their participation in the MBSR program after waiting.

Screening, Consent and Enrollment

At first contact, interested participants are informed of the protocol and randomized design of the study. If interested, researchers ensure that individuals meet basic eligibility criteria. Potentially eligible participants complete the distress screen by phone conducted by the research coordinators. If interested and eligible, study procedures are explained in detail and consent obtained. Consent is also obtained to access medical records to confirm tumor location, stage and treatments received. Due to the lack of F2F contact during screening and consent, additional time is allocated to ensure fully informed consent by providing potential participants the opportunity to ask clarifying questions electronically or telephonically, and to require that the participant affirm that s/he has read the document, understands it, and has been presented with the opportunity to ask questions.

Researchers then provide a questionnaire package (including demographics and medical history, mood, stress, mindfulness, posttraumatic growth and spirituality measures) to complete online. Once a cohort is in place, participants are randomly allocated to one of two conditions using an online research randomization tool. All allocations are computer-based and not predictable. This process eliminates introduction of experimenter bias into participants' group assignment. Once randomized participants are informed of group assignment (i.e., the immediate MBSR or the TAU wait-list control condition) they are mailed a webcam, headset, and MBSR course materials before they begin the program. Technical staff guide participants through installation of the equipment and online classroom tools in an orientation session before the first MBSR class. Those participants randomized to the TAU wait-list condition are informed of their program start date and contacted closer to such date to send course materials.

Masking

The nature of the group assignment and intervention does not allow for masking of participants. Research tasks are assigned to separate members of the team in order to ensure that primary investigators remain blind to participant status, and all questionnaires are completed online, attenuating the influence of bias on the part of research assistants.

Intervention Group – Online MBSR for Cancer (Mindfulness-Based Cancer Recovery)

Components of the MBSR program include: didactic instruction, experiential practice, and group process. Didactically, specific topics covered within the two hour sessions and in the participant manual are: (a) concepts fundamental to mindful living and mindfulness meditation, (b) emotional, behavioural and cognitive patterns, and how such patterns can influence individual stress responses, and (c) the physical and psychological symptoms of stress and the influence of stress on physical and psychological health. Participants are instructed to apply principles taught didactically, through experiential practice of mindfulness meditation during group sessions and also as homework between formal classes. Guided meditation recordings and videos are distributed to support home practice. Participants are expected to practice 45 minutes of meditation and yoga postures daily. During class sessions the instructor guides participants through experiential activities including gentle Hatha yoga, qigong mindful movement, and various types of mindfulness meditation such as sitting and walking meditations. The instructor facilitates group discussions to encourage conversation around challenges experienced with meditation practice. Both fellow participants and the instructor offer support and feedback to assist in problem solving when difficulties are

encountered during meditation practice. The instructor encourages communication and support between group members to enhance the group process (Kabat-Zinn, 1990).

The online MBCR intervention was modeled after the F2F MBCR group intervention described above. The online format that most closely resembles F2F interaction (ability to see, hear and interact with group members in real-time) is a synchronous online intervention with video and audio capabilities. In collaboration with the online education company eMindful Inc. (www.emindful.com), participants are able to access eMindful's online virtual classroom and participate in real-time, online, synchronous, 2-hour MBSR classes for eight consecutive weeks. Participants are asked to engage in the interactive features of the eMindful virtual classroom during the online classes. This includes logging on to the virtual classroom website, watching and listening in "real-time" to streaming video and audio of the class instructor and other group participants on their computer screen, "chat" with the instructor and other group participants using a keyboard, and interactively participate using the headsets, webcams, and keyboards. Live images through the webcam facilitate interaction with the instructor and other participants.

The virtual classroom allows for multiple webcams to be viewed by all participants and instructor simultaneously. Online classroom access requires a password and the instructor ensures only approved participants are present in the class. Recorded versions of the classes are available through software that prevents download of the recording (provided through streaming video) as well as password access. This classroom feature allows the PI to monitor MBCR treatment fidelity throughout the trial. Class content and schedule follow the adapted F2F MBCR manual utilized by both PI and Co-I

(Drs. Carlson and Speca respectively) and course program published elsewhere (Carlson & Speca, 2010). Participants are able to access the manual online or receive a hard copy from research coordinators through post if preferred. The guided meditation recordings and videos are available for participants to download electronically. Participants are provided both orientation/instructions for set up of the new equipment and also an orientation session before the first class where headsets, webcams, website and classroom functionality are tested and reviewed. This orientation session is completed before the start of the first MBSR class. Each participant is emailed a summary of dates and orientation material before the start of session one. Technical support is continuously provided by eMindful during all online sessions to address any technical issues with the hardware and software, while study related questions are directed to the research team.

Treatment as Usual (TAU) Wait-list Control Condition

In parallel with the online MBCR program, the TAU wait-list condition completes pre (T1) and post (T2) assessment measures before and after their wait period. Additionally, following the wait period, the control group completes the online MBSR intervention and completes one additional assessment time point (T3).

Outcome Measures and Questionnaires

Table 2.1 contains the outcome measures and their administration timing for the online MBCR and TAU wait-list group participants. Medical history (i.e., type of cancer, dates of diagnosis and treatment, and types of treatment received) and demographic information (i.e., sex, age, ethnic background, education, marital status, and current employment status) is obtained at the first assessment and later verified in the

participant's medical chart, with consent. Participants are also asked to indicate how much experience with meditation and/or yoga they have had previously.

TABLE 2.1. Outcome Measures for the Online MBCR and Wait-List Group Participants

Construct	Measure	Administration
Primary Objective: Feasibility	See Figure 1 for estimates – study deemed feasible if within 5% of each target value	
Program Satisfaction	eCALM – Online MBCR Program Evaluation Form	<ul style="list-style-type: none"> • Post intervention only
Dose of intervention delivered and dose received	Delivered: Attendance log Received: Meditation Log	<ul style="list-style-type: none"> • Throughout intervention
Distress Screening	Score of 4 or higher on the Distress Thermometer (DT)	<ul style="list-style-type: none"> • Pre intervention only
Primary Measure of Secondary Objective: Mood	Profile of Mood States (POMS)	<ul style="list-style-type: none"> • Pre and Post MBSR or wait
Other Secondary Outcomes: Stress	Calgary Symptoms of Stress Inventory (CSOSI)	<ul style="list-style-type: none"> • Pre and Post MBSR or wait
Post-Traumatic Growth	Posttraumatic Growth Inventory (PTGI)	<ul style="list-style-type: none"> • Pre and Post MBSR or wait
Mindfulness	Five Facet Mindfulness Questionnaire (FFMQ)	<ul style="list-style-type: none"> • Pre and Post MBSR or wait
Spirituality	Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp)	<ul style="list-style-type: none"> • Pre and Post MBSR or wait

Meditation Log and Attendance: Information on minutes spent in home practice of meditation and yoga is collected from each participant each week and returned to the study coordinator, which is shared with the group instructor. As part of the online virtual classroom capabilities, a basic feature of conference archiving is utilized. This feature can track all the MBSR classes with a list of attendees, and what time the participants entered and exited the classroom for attendance tracking.

Screening Measures

Distress Thermometer. The Distress Thermometer (DT) is a 0 to 10 single visual analogue scale oriented as a vertical thermometer (National Comprehensive Cancer Network, 2013). The DT has been validated against clinical diagnosis of anxiety and mood disorders, the Brief Symptom Inventory (BSI), the Hospital Anxiety Depression Scale (HADS), and endorsed for use by the National Comprehensive Cancer Network (NCCN). A cut-off score ≥ 4 has been identified in the literature as optimal with regards to both sensitivity and specificity for labeling individuals diagnosed with cancer as having significant psychological distress (Jacobsen, Donovan, Trask, Fleishman, Zabora et al., 2005; Dolbeault, Mignot, Gauvain-Piquard, Mandereau, Asselain et al., 2003).

Primary Outcome Measure

Profile of Mood States (POMS). The POMS is an instrument with 65 items that assesses six affective dimensions and produces a Total Mood Disturbance (TMD) score (McNair et al., 1971). Psychosocial interventions (including psychological adaptation to diagnosis and treatment of cancer) frequently use this scale. This instrument measures state (vs. trait) attributes, therefore the POMS scale is an appropriate instrument for repeated measures as previous administrations do not influence later administrations. The Kuder-Richardson overall internal consistency measure of the six subscales ranged from 0.84 (Confusion) to 0.95 (Depression) in two separate studies, with test-retest stability ranging from 0.65 (Vigor) to 0.74 (Depression) over approximately a 20 day period. This

is consistent with this particular instrument as a measure of mood states, which are expected to vary over time, and supports its construct validity.

Secondary Outcome Measures

Calgary Symptoms of Stress Inventory (CSOSI). This measure is a 56-item scale and is a recent revision of the 95-item Symptom of Stress Inventory (SOSI). The original SOSI and the CSOSI are both scales that are designed to measure multiple domains of symptoms of stress, including psychological and physical expressions of stress. The CSOSI is the product of exploratory factor analysis on SOSI assessment data collected from individuals diagnosed with cancer who attended the Tom Baker Cancer Centre's MBSR program (Carlson & Thomas, 2007). A five-point scale ("never" to "very frequently") is used to rate items based on frequency of stress-related symptoms during a specified time frame selected by the researcher (i.e., the past week). The CSOSI items form eight subscales: 1) Depression, 2) Anger, 3) Muscle Tension, 4) Cardiopulmonary Arousal, 5) Sympathetic Arousal, 6) Neurological/GI, 7) Cognitive Disorganization, and 8) Upper Respiratory symptoms. High internal consistency (0.80 to 0.95) has been demonstrated for both the total and subscale scores, as well as good convergent and divergent validity with other well-validated measures (Carlson & Thomas, 2007). The original SOSI instrument has been used to measure change in symptoms of stress associated with MBSR participation in cancer populations (Carlson et al., 2003; Carlson et al., 2004; Speca et al., 2000).

Posttraumatic Growth Inventory (PTGI). This self-report scale is a 21-item inventory that measures the individual's subjective perception of positive changes following adversity (Tedeschi & Calhoun, 1996). Individuals are asked to record, on a

scale of 0 (not at all) to 6 (very great degree), the level to which their perspective changed as a result of their adversity. Reliability was 0.90 for the normative sample and 0.95 in a sample of individuals with cancer. The test–retest reliability that was measured in the normative sample two months later was 0.71.

Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp). This scale is designed to measure spirituality in people with life threatening or chronic illnesses, and includes 12 questions that provide two subscales scores and an overall measure of spirituality (Peterman et al., 2002). The two subscales (meaning/peace and faith) correspond to one’s sense of meaning and/or purpose in life (e.g., My life lacks meaning and purpose) and one’s comfort and support from their personal faith (e.g., I receive support from my faith). The FACIT-Sp has been established as valid and reliable in individuals with cancer and HIV (Tedeschi & Calhoun, 1996). Cronbach’s alpha was 0.87 for the overall of spirituality, 0.88 for the faith subscale and 0.81 for the meaning/peace subscale (Peterman et al., 2002).

Five Facet Mindfulness Questionnaire (FFMQ). Baer and colleagues determined that the combined pool of 112 items from five separate mindfulness measures contain five interpretable facets of mindfulness (Baer et al., 2006). The analysis revealed five factors that accounted for 33% of the variance. The five facets included in this measure of mindfulness are: attending to sensations, perceptions, thoughts and feelings; describing experience with words; acting with awareness; nonjudging of experience; and nonreactivity to inner experience. The FFMQ showed incremental validity in predicting psychological symptoms and correlated strongly to conceptually related variables (Baer et al., 2006).

Adverse events

All participants are requested to record and disclose any adverse events in their homework logs, and to report them to the group instructor or the research coordinators. The group instructor also inquires about the participants' weekly experiences at each class session. Participants are welcomed and strongly encouraged to contact research staff to discuss any questions or events they consider problematic or issues for them regarding the study.

Analytic Strategy

Analysis of Power for Primary Effects. The target sample size for this study was based on achieving adequate power for the secondary analyses (since the primary analyses were proportions based on feasibility). The goal was to have 80% power at a significance level of .05, to test the efficacy of the online MBCR intervention in reducing mood disturbance, compared to the control group. On the basis of observed means and standard deviations in three F2F comparable trials (Carlson et al., 2001; Speca et al., 2000; Carlson et al., 2003): the estimated effect sizes for group differences in pre- to post-intervention change on the POMS Total Mood Disturbance score was 0.72, 0.51 and 0.58 respectively. Based on the three trials above, and following the more conservative estimation rule proposed by Dattalo (Dattalo, 2008) to use t-test estimations for RM-ANOVA designed studies, 26 participants are required for each group to detect a significant difference between the groups. Taking into account the likelihood of 20% attrition as observed in F2F MBSR trials, a total of 32 participants will be recruited for each group—a total sample size of 64 participants.

Data Analysis. All data analysis will be carried out at the completion of the study using the most up-to-date version of SPSS for Windows. Tests will be performed with a two-sided alternative hypothesis, at a critical significance level of 5%. To ensure the appropriateness of the

analysis the distributional normality of the data will be confirmed. Wherever possible, p-values and effects sizes will be reported.

Demographic Variables. Participants will be compared using t-tests or chi-square analyses (as appropriate) on primary demographic and psychological variables at baseline to ensure randomization success.

Primary Objective – Feasibility. Feasibility will be assessed at the completion of the study through the following measures: 1) Proportion “interested”: this is difficult to ascertain as our reach is hard to know (i.e. the denominator), but we will use the number of invitation letters sent out through the Alberta Cancer Registry as a proxy denominator. The number of patients who phone in with interest in the study will be the numerator (target: 5%). 2) Proportion “eligible”: the number who meet eligibility criteria, over the number who called in (target: 30% - this number is low primarily due to the distress score greater than or equal to 4/10 inclusion criteria). 3) Proportion “consented”: the number of those who consented to the study over the total number who were eligible (target: 85%). Reasons for non-consent will be captured where possible. 4) Proportion “completed”: the number who completed the online intervention, over the number who consented (Target: 85%). Reasons for non-completion will be captured. The study will be deemed feasible if we are within 5% of each target value. Program satisfaction will be assessed through an evaluation form created for the study which assesses participants’ experiences of the MBSR program, the online group, and with the technology.

Secondary Objective – Primary Outcome. Total Mood Disturbance scores will be examined with a 2 (groups) x 2 (time) RM-ANOVA to examine main effects of time and group, and any interactions between time and group. Post-hoc analyses will be conducted to examine the simple main effects for treatment if a significant interaction is detected.

Secondary Objectives – Secondary Outcomes. The same analytic strategy will be applied to the secondary outcomes of symptoms of stress, mindfulness, spirituality and posttraumatic growth.

Discussion

Recruitment for this trial has proceeded as anticipated; with participants arriving through the Alberta Cancer Registry via study invitation letters, through rural cancer centre posters, pamphlets, advertisements, and community-based networks. To date, 1800 individuals have been contacted through the Alberta Cancer Registry through mailed study invitation with 157 responding. Of those, 41 were ineligible (eight deceased, three outside of primary treatment inclusion criteria, 12 had scheduling conflicts, nine had low distress, six had no computer/high-speed Internet, two were living outside Alberta, and one individual was not diagnosed with cancer). Fifty-four declined participation (with the majority stating they were not interested in the intervention, while 10 stated they were effectively managing stress through other methods. Five asked to be contacted later or considered for the program at a later date. Fifty-seven participants have been enrolled thus far in the program: two withdrew (one MBCR, one wait-list). Reasons for discontinuing with the study included treatment related issues and schedule change. Forty-seven have completed the program or in the process of completing the study. No adverse events have been reported. Final analysis of the data is not yet available to compare the intervention and control groups; however, several preliminary comments and conclusions can be made from the experience of the trial to date.

Recruitment Challenges

While recruitment began slower than our initial anticipated timeline for the trial, recruitment through the Alberta Cancer Registry has resulted in enrolling individuals diagnosed

with cancer who are distressed and interested in participating in an online MBCR program, and who would otherwise be unable to access such a program. Recruitment will plan to continue through April 2013, with full analysis of data to follow.

Limited or slow Internet access or computer-illiteracy has restricted some participants enrolling in the program; however, statistics in Alberta for rural Internet connectivity and the rising rates of computer use are encouraging, and multiple avenues of recruitment have provided successful recruitment of eligible participants to date.

The online MBCR intervention, as with F2F MBSR programs require participants to be willing to commit to attending 8-weekly 2-hour Wednesday evening classes and a Saturday full day retreat. Many individuals interested in the program have busy schedules, especially the individuals currently receiving medical treatments, and the program is a significant time commitment. Nevertheless, significant research team efforts have allowed for successful recruitment strategies. Initial response to the intervention from participants has been positive.

Study Benefits

Online MBSR interventions offer promise for improving the accessibility of evidence-based psychosocial interventions for underserved individuals. Synchronous online therapy is available to anyone with Internet access. By allowing individuals diagnosed with cancer to participate in group interventions without leaving their homes, common reasons for not attending or prematurely discontinuing F2F groups may be reduced, including long travel distances and issues with mobility (which may include driving issues, busy roads, parking, walking etc.).

F2F MBSR programs reduce mood disturbance, decrease symptoms of stress, and improve quality of life in individuals diagnosed with cancer, but due to geographical and illness-related barriers, it is often inaccessible. This trial is incorporating sophisticated real-time

technology to reach underserved individuals diagnosed with cancer who are currently often excluded from MBSR programs, with the goal of improving access to psychosocial interventions for a difficult to reach population.

Online MBSR programs led by experienced instructors have the potential to disseminate psychosocial interventions, regardless of both participant and instructor geographical location. Despite the demonstrated effectiveness of F2F MBSR, and ease of use of available technology, the effectiveness of an online MBSR program for individuals diagnosed with cancer has yet to be evaluated. Such a program could potentially improve access to evidence-based psychosocial programs in Alberta and beyond. The results of this study may help propel further research in this area.

Competing Interests

Kelley McCabe is the CEO and Founder of eMindful. Kelley McCabe also has an investment in eMindful. Kelley McCabe will provide in-kind support for the facilitation of the online MBSR programs through eMindful, but has played only a technical role in study design and will not be involved in data analysis or interpretation. Steven Flowers is an employee of Mindful Living Programs. Steven Flowers has been involved in the implementation of this trial by facilitating the online mindfulness classes, and will help with interpretation by editing manuscripts, but has not, or will not have involvement in the funding of this trial or data analysis.

Author's Contributions

All authors participated in the design of the study and development of research protocols, as well as contributing to and approval of the final manuscript. All authors read and approved the final manuscript.

**CHAPTER 3: A RANDOMIZED WAIT-LIST CONTROLLED TRIAL
OF FEASIBILITY AND EFFICACY OF AN ONLINE
MINDFULNESS-BASED CANCER RECOVERY PROGRAM: THE
ETHERAPY FOR CANCER APPLYING MINDFULNESS TRIAL**

Preface

Following the publication of the eCALM Trial manuscript, the originally proposed data analytic strategy was modified for the secondary objectives. All other proposed data analytic procedures remained unchanged. As described in chapter two, for the secondary objectives, a 2 (groups) x 2 (time) RM-ANOVA was proposed to examine main effects of time and group, and any interactions between time and group for mood disturbance, symptoms of stress, mindfulness, spirituality and posttraumatic growth. Instead, linear mixed models (LMMs) for repeated measures was employed to analyze all secondary objective data. LMMs are recommended so that all participants with baseline questionnaire data are included in the analyses (Heck, Thomas & Tabata, 2011; Shek & Ma, 2011). LMMs are recommended over repeated measures ANOVAs as LMMs account for missing data in clinical trials through the use of sophisticated statistical imputation of missing random data, rather than simpler methods such as complete case analysis or single imputation of missing data (e.g., last observation carried forward or mean imputation). Furthermore, mixed effects methods employing a random intercept model take into account the variances between both between- and within-subjects (Heck et al., 2011; Shek & Ma, 2011). Therefore, the data analytic strategy for the secondary objectives was changed to LMM as it provides a stronger statistical test.

Abstract

Objective

A treatment-as-usual (TAU) randomized wait-list controlled trial was conducted to investigate the feasibility and impact of an online synchronous Mindfulness-Based Cancer Recovery (MBCR) group program for underserved distressed cancer survivors.

Methods

Sixty-two men and women, exhibiting moderate-to-high distress, within three years of completing primary cancer treatment without access to in-person MBCR were randomized to either immediate online MBCR ($n = 30$) or to wait for the next available program ($n = 32$). Participants completed questionnaires pre- and post-intervention or wait period online. Program evaluations were completed post MBCR. Feasibility was tracked through monitoring eligibility and participation through the protocol. Intent-to-Treat mixed model analyses for repeated measures were conducted.

Results

Feasibility targets for recruitment and retention were achieved and participants were satisfied and would recommend online MBCR. There were significant improvements and moderate Cohen's d effect sizes in the online MBCR group relative to controls following MBCR for total scores of mood disturbance ($p = .049$, $d = 0.44$), stress symptoms ($p = .021$, $d = 0.49$), spirituality ($p = .040$, $d = 0.37$), and mindfully acting with awareness ($p = .026$, $d = 0.50$). Main effects of time were observed for posttraumatic growth and remaining mindfulness facets.

Conclusions

Results provide evidence for the feasibility and efficacy of an online adaptation of MBCR for the reduction of mood disturbance and stress symptoms, as well as an increase in spirituality and mindfully acting with awareness compared to a TAU wait-list. Future study employing larger active control RCT designs is warranted.

Trial Registration

Clinical Trials.gov: NCT01476891

Keywords

Mindfulness Meditation; Cancer; Oncology; Randomized Wait-List Controlled Trial; Online; Synchronous

Introduction

A wide range of effective psychosocial interventions have been developed to assist individuals in overcoming life challenges posed by cancer, and in management of cancer-related distress and symptomatology (Kash, Mago, & Kunkel, 2005). Clinical distress is reported by approximately 35% to 45% of people diagnosed with cancer, and psychosocial interventions are in high demand (Carlson et al., 2004; Carlson & Bultz, 2003; Sellick & Edwardson, 2007; Zabora et al., 2001; Carlson et al., 2009). Within all stages and types of cancer, people commonly present with anxiety and mood disturbance, highlighting the importance of testing accessible psychosocial interventions intended to mitigate such disease and treatment-related effects. One program that has received considerable research attention in the oncology field to treat these symptoms is Mindfulness-Based Stress Reduction (MBSR) and the cancer-specific adaptation Mindfulness-Based Cancer Recovery (MBCR).

MBSR and MBCR

Mindfulness-Based Stress Reduction (MBSR), modelled after the program developed by Kabat-Zinn and colleagues, cultivates the practice of present moment awareness with an open, accepting and non-judgmental attitude through formal and informal mindfulness practice (Kabat-Zinn, 1990). The 8-week intervention consists of training in mindfulness meditation and Hatha yoga originally intended to treat symptoms of chronic illness, pain and stress (Kabat-Zinn, 1990). Mindfulness-Based Cancer Recovery (MBCR) is an adaptation of MBSR for an oncology population. MBSR and MBCR programs within oncology have now been extensively studied (Carlson et al., 2009; Labelle et al., 2010), and Lengacher and colleagues in 2011 reported MBSR was

one of the most frequently researched interventions for individuals diagnosed with cancer between the years 2000 to 2009 (Lengacher, Kip, Post-White, Fitzgerald, Newton et al., 2011). For people living with cancer, MBSR results in decreased mood disturbance, symptoms of stress, fatigue and anger, with concurrent increases in spirituality, health related quality of life, post-traumatic growth, sleep quality and general well-being (Lamanque & Daneault, 2006; Brown & Ryan, 2003; Carlson et al., 2001; Carlson & Garland, 2005; Garland et al., 2007; Shapiro et al., 2003; Speca et al., 2000; Tacon et al., 2004; Tacon, 2006; Lengacher et al., 2009; Hoffman, Ersser, Hopkinson, Nicholls, Harrington et al., 2012; Henderson et al., 2012; Branstrom et al., 2010; Lerman, Jarski, Rea, Gellish, & Vicini, 2012). Meta-analytic and comprehensive reviews of the effects of face-to-face (F2F) MBSR and MBCR within oncology concluded it is a clinically valuable evidence-based intervention for individuals living with cancer (Matchim & Armer, 2007; Ott et al., 2006; Smith et al., 2005; Ledesma & Kumano, 2009; Matchim et al., 2011; Musial et al., 2011).

Benefit Finding

Although much research within psychosocial oncology has focused on the amelioration of negative symptoms consequent to a cancer diagnosis, there has been a more recent shift toward investigating the possible benefits resulting from the experience of cancer. Despite the struggle to adjust to living with cancer and potential decrease in physical functioning, many people living with cancer identify positive changes, including greater appreciation for life, personal growth, and increased spirituality (as defined by sense of meaning, peace and religious concerns) (Andrykowski & Hunt, 1993; Cordova et al., 2001).

Two of these specific benefits identified following a cancer diagnosis are the development of spirituality and posttraumatic growth (PTG), also known as “benefit finding”. Although consensus is lacking regarding a definition, spirituality generally refers to the experience and feelings associated with the search for connection to others and to something larger than oneself, and the subjective sense that a person’s life has purpose, value and meaning (Peterman et al., 2002; Lechner et al., 2008; Visser et al., 2010). PTG refers to the experience of searching for or discovering positive benefits through adversity such as cancer (Lechner & Antoni, 2004; Linley & Joseph, 2004). In the cancer context, PTG specifically refers to benefits perceived following a diagnosis that exceed pre-cancer adjustment levels (Linley & Joseph, 2004). Spirituality and PTG have been linked to other positive outcomes, such as increased positive affect, psychological adjustment and quality of life, as well as decreased physical discomfort and dysfunction following a diagnosis of cancer (Carver & Antoni, 2004; Cotton, Levine, Fitzpatrick, Dold & Targ, 1999; Katz, Lantz & Zemencuk, 2001; Krupski et al., 2006).

Psychosocial interventions that increase perceived benefits for people living with cancer may support adaptation and coping for successful long-term survivorship. Thus, there is a need to investigate interventions that have the potential to not only treat distressing symptoms, but also encourage a spectrum of positive changes following a potentially traumatic event such as a diagnosis and subsequent treatment of cancer. Research has only begun to investigate the impact of F2F MBCR positive outcomes, but it may also be the case that online adaptations may provide this benefit as well.

Online Interventions

Despite efficacy of F2F MBCR and other specialized psychosocial interventions, many people remain unable to access programs due to practical barriers such as geographical distance, transportation issues, and cancer-related illness (Christensen & Griffiths, 2007; Barak et al., 2008; Owen et al., 2005). As one predictor of improved psychological functioning over time is referral to psychosocial care and accessing available services, supports and interventions (Carlson et al., 2013), the internet represents a promising alternative method of delivering empirically supported psychosocial interventions to underserved people diagnosed with cancer. In 2013 CancerChatCanada reported increased access to professionally-led support groups via real-time internet-based chat groups increased cancer-related support to underserved individuals, and high level of participation and satisfaction showcased an acceptance and need for additional internet-based interventions for cancer survivors (Stephen et al., 2013).

The present investigation expands the evidence-base of MBCR by assessing the feasibility of an online “real-time” synchronous adaptation of an MBCR program through the evaluation of recruitment, retention, attendance and participant satisfaction in a sample of moderately to highly distressed people diagnosed with cancer. Participants were considered underserved if they did not have access to any MBCR program resources. This trial also examines the impact of an 8-week online MBCR program on mood and stress, as well as several other positive participant-reported psychological aspects of well-being including spirituality, posttraumatic growth and mindfulness immediately following the intervention through a randomized treatment-as-usual (TAU)

controlled trial design. It was hypothesized that: 1) participants would be willing to enrol in and complete the 8-week online intervention; 2) people who participated in the online MBCR treatment condition would experience: a) greater reduction in symptoms of stress and mood disturbance over the course of the intervention compared to a TAU wait-list control; and b) greater increase in mindfulness, spirituality and posttraumatic growth over the course of the 8-week intervention compared to the TAU wait-list condition.

Methods

The trial design and detailed procedures for this study have been described elsewhere and will therefore only be briefly reviewed (Zernicke et al., 2013). Ethical approval from the Conjoint Health Research Ethics Board of the University of Calgary/Alberta Health Services was obtained before commencement of the trial.

Participants

Participants were recruited in Alberta through media outreach, promotional pamphlets, community based networks, and mailing of study invitation letters to potentially eligible people living with cancer from Alberta Cancer Registry case records.

Inclusion: 1) age 18 years or older; 2) speak and read English to sufficiently complete questionnaires; 3) diagnosis of any type/stage of cancer; 4) completed primary cancer treatment within the last three years; 5) exhibited at least moderate distress as established by Distress Thermometer score of four or greater (out of ten); 6) no access to an F2F MBCR program; 7) access to high-speed Internet; 8) and resident of Alberta.

Exclusion: 1) concurrent self-reported diagnosis by medical professional of psychosis, bipolar disorder, substance abuse or suicidality, however self-reported

diagnosis of a depressive, anxiety or adjustment disorder did not prevent enrolment; 2) previous participation in F2F MBCR.

Interventions

Online Mindfulness-Based Cancer Recovery. Components of the online MBCR program were modelled after the F2F MBCR program at the Tom Baker Cancer Centre in Calgary, Alberta, Canada (See Carlson & Speca (Carlson & Speca, 2010) for a step-by-step program description). Co-author (SF) lead all MBCR intervention groups, and is a licensed clinician specializing in behavioral medicine with 15 years of experience teaching online MBSR. SF was trained in the cancer-adapted MBSR for this trial by study authors (LEC and MS). The programs consisted of weekly two hour sessions for eight weeks. Didactic instruction, experiential practice and group process were emphasized components of the group, as well as opportunity for extended practice during an online six hour retreat between weeks six and seven of the MBCR course. Guided meditation recordings and videos were distributed to support the home practice of 45 minutes of Hatha yoga and mindfulness meditation daily. During the online class sessions, the instructor guided experiential activities of Hatha yoga intended as “mindful movement”, qigong mindful movement, and various meditations such as sitting, walking, and loving-kindness meditations. The instructor encouraged communication and support within the online environment to enhance group process.

Headsets, webcams and MBCR program manuals were provided to all participants via post before beginning the course. In collaboration with the online education company eMindful Inc. (www.emindful.com) participants were able to see, hear and interact in real-time with other group members and the instructor during the

online synchronous intervention. The virtual classroom allowed multiple webcams to be viewed by all participants and the instructor simultaneously. Technical support was continuously provided by eMindful during all online sessions to address any technical issues, while all other study questions were directed to research coordinators. Before the intervention started, participants were able to set up an individual orientation to the equipment.

Treatment as Usual (TAU) Wait-list Control Condition. In parallel with the online MBCR intervention group, the TAU condition completed pre (T1) and post (T2) assessment measures online before and after their wait period. Following the wait period, the TAU control group completed the online MBCR intervention as described above, and completed a post-MBCR intervention assessment (T3).

Objectives

Primary Aim – 1) feasibility – to determine whether distressed people living with cancer would be willing to participate and complete the online MBCR intervention.

Secondary Aims – 2) to examine the efficacy of an online synchronous adaptation of MBCR compared to a TAU wait-list control condition on a range of participant-reported outcomes including mood, symptoms of stress, spirituality, mindfulness and posttraumatic growth.

Primary Outcome - Feasibility

Feasibility was assessed through the following measures: 1) Proportion “interested” in the program, as estimated through the response rate following study invitation letters sent through the Alberta Cancer Registry (while this number may have underestimated the denominator as we also used other recruitment methods, most eligible

participants would have been targeted with the letters); 2) Proportion “eligible” as estimated by the number of interested participants who met study eligibility; 3) Proportion “consented” as estimated by the number of eligible people who consented to participate; and 4) Proportion “completed” as estimated by the number of consenting participants who completed the study protocol (see Figure 3.1).

Secondary Outcomes

Profile of Mood States (POMS). This scale scores six dimensions: Anxiety, Depression, Anger, Vigor, Fatigue and Confusion (McNair et al., 1971). The Total Mood Disturbance (TMD) score is calculated by summing the six subscale scores. This scale has been used within medical populations, including cancer, and lower scores indicate less mood disturbance. Kuder-Richardson internal consistency of the six subscales ranged from .84 (Confusion) to .95 (Depression) in two studies, with test-retest reliability of .65 (Vigor) to .74 (Depression) over approximately a three week a period. This is consistent for a measure of mood states, which are expected to vary over time, and supports its construct validity.

Calgary Symptoms of Stress Inventory (CSOSI). This scale measures behavioural, psychological and physical responses to situations deemed stressful (Carlson & Thomas, 2007). The CSOSI has been validated in a Canadian study of cancer patients at our centre, where the depression scale showed satisfactory internal consistency (alpha = 0.90) and strong correlations with the emotional functioning scale (EF) of the EORTC QLQ-C30 (- 0.76) and Depression-Dejection scale of the POMS-65 (0.87). Eight subscales are calculated from 56 items, and the total scale is obtained from summing subscale scores (Carlson & Thomas, 2007).

Posttraumatic Growth Inventory (PTGI). This self-report 21-item inventory measures an individual's subjective perception of positive changes following adversity and the total scale score was calculated for analysis (Tedeschi & Calhoun, 1996). The normative sample internal consistency was 0.90 and 0.95 in a sample of cancer patients. Test-retest reliability, measured in the normative sample eight weeks later, was reported within acceptable standards (0.71).

Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp). This scale is designed to measure spirituality in people with life threatening or chronic illnesses, with 12 questions summing to the total score which was used in the trial analysis (Peterman et al., 2002). Internal reliability of the subscales was reported as good ($\alpha = 0.81-0.88$).

Five Facet Mindfulness Questionnaire (FFMQ). The five facets included in this measure of mindfulness are: attending to sensations, perceptions, thoughts and feelings (Observe facet); describing experience with words (Describe facet); acting with awareness (Acting with Awareness facet); non-judging of experience (Nonjudge facet); and non-reactivity to inner experience (Nonreact facet) (Baer et al., 2006). As recommended, these five facets were calculated separately and used in the analysis. The FFMQ showed incremental validity in predicting psychological symptoms and correlated strongly to conceptually related variables (Baer et al., 2006).

Sample Size

Target sample size was based on achieving adequate power for the primary secondary analysis (since the primary analyses were proportions based on feasibility). The goal was to have 80% power at .05 significance level, to test the efficacy of the

online MBCR in reducing POMS TMD, compared to the TAU control group. On the basis of observed means and standard deviations in three F2F comparable trials conducted at the Tom Baker Cancer Centre, the estimated effect sizes for group differences in pre- to post-intervention change on the POMS TMD score varied between 0.51 and 0.72. Following Dattalo (2008) estimation recommendations, 26 participants were estimated to be required for each group to detect a significant difference between the groups (Dattalo, 2008).

Randomization and Blinding

Participants were randomly allocated to either the immediate MBCR or TAU wait-list condition using a computer-based random number generation program on a cohort-by-cohort basis and remained blind to group allocation until after completion of baseline T1 assessments. The nature of the group assignment and intervention did not allow for masking of participants. However, research tasks were assigned to separate members of the team in order to ensure that primary investigators remained blind to participant status, and all questionnaires were completed online to attenuate the influence of bias on the part of research assistants.

Data Analysis

All data provided by participants were included in the analyses. Data were tested for normality and homogeneity of variance. To verify that the intervention and control groups were comparable on continuous and categorical demographic variables and psychological variables at pre-intervention, a series of independent samples t-tests and Chi-squared tests were conducted. Results of baseline group comparisons were reported if differed.

To evaluate the impact of the online MBCR intervention on the secondary outcome measures of mood disturbance, stress symptoms, mindfulness, spirituality and posttraumatic growth, linear mixed models (LMMs) for repeated measures analyses were performed using an ITT principle, so that all participants who provided baseline data were included in the analyses (Heck et al., 2011; Shek & Ma, 2011). LMMs is an appropriate statistical method for longitudinal designs with missing data in clinical trials due to sophisticated statistical imputation of missing at random data. Mixed-effects methods with a random intercept model can also account for the variances between-subjects and within-subjects. ITT analyses were calculated. For each dependent measure a 2 (group) x 2 (time) LMM for repeated measures with maximum likelihood estimation of parameters was conducted followed by pair-wise contrasts for the two groups.

For each of the models, the random effect was the intercept and the fixed effects were baseline scores, group (online MBCR or TAU control), time, and the time by group interaction. Time was also set as a repeated measure. The restricted maximum likelihood estimate method was used to estimate the model parameters and standard errors of missing parameters with an identity covariance structure, and is more conservative than an unstructured covariance structure (Heck et al., 2011; Shek & Ma, 2011). Type III fixed effects were used and set statistical significance of p values as $< .05$. The least significant difference method was used for multiple comparisons. Between-group Cohen's d effect sizes were calculated using the T2-T1 change scores and pooled standard deviations to measure the impact of the online MBCR intervention (Table 3.3) as recommended by Cohen (Cohen, 1988). Program evaluation, satisfaction and recommendation ratings were

calculated as well as retention rates for the clinical trial feasibility assessment. All data analysis was conducted with IBM SPSS v. 19.

Results

Participant Characteristics

The flow of participants including screening, eligibility, consent and retention are provided in Figure 3.1. Recruitment spanned from March 2011 to August 2012 and participants were randomized in four cohorts in spring, fall or winter. Four cohorts were conducted, and within each class there was a range of 4-11 participants. The majority of people were women (73%), in a coupled relationship (82%) and White (92%). The most common cancer type was breast (34%). Participants ranged in age from 29 -79 years with a mean age of 57 years. Twenty one participants (34%) were retired or employed full-time (24%) and the majority had completed some type of post-secondary training (77%). Table 3.1 provides participant characteristics separated by treatment condition.

Attrition and Compliance

Drop-out rates for intervention and control groups differed significantly, (online MBCR, $n = 5$, 16.66%; TAU, $n = 0$, 0%; $p = .016$). Of the 30 immediate MBCR participants, 25 completed at least 5 or more classes (more than half the sessions), and all 32 people waiting to take the program completed the wait period and second questionnaire (Figure 3.1). The mean number of MBCR classes attended was six out of nine including the six hour online silent retreat ($SD=3.0$, range 0-9). The mean amount of home meditation and yoga practice reported, which did not include the weekly class practice or retreat time, was 150 minutes per week. All online MBCR and control group baseline and post-intervention estimated marginal means and standard errors for total

scales are presented in Table 3.2. All online MBCR and control group baseline and post-intervention unadjusted means and standard deviations, as well as standardized mean differences between treatment and control conditions (Cohen's *d* effect sizes) are presented in Table 3.3.

Primary Outcome

Feasibility. All target feasibility estimates and actual trial percentages are presented in Figure 1. Feasibility was considered achieved if actual percentages were within 5% of target estimate. Targets were estimated based on previous recruitment and retention numbers from in-person MBCR trials conducted by the senior author (LEC), taking into account the broad and diverse group of survivors invited, and approved in advance in our study protocols.

Feasibility was assessed through the following measures: 1) Proportion “interested” was estimated at 5%. One thousand eight hundred people were invited to participate with mailed invitation letters through the Alberta Cancer Registry with 180 responding (10% response rate). 2) Proportion “eligible” was estimated at 30% due to the strict distress score eligibility criteria. This target was met with sixty-seven participants (37%) eligible and interested to participate. 3) Proportion “consented” was targeted at 85%. Sixty-two participants (93%) completed the required consent forms, enrolled in the study, completed baseline T1 assessment and were subsequently randomized into the treatment conditions (online MBCR $n = 30$, TAU wait-list $n = 32$). 4) Proportion “completed” accounted for dropout during MBCR or wait (85% target). At T2 83% (MBCR) and 100% (wait-list) completed, and at T3 81% of the original TAU wait-list group completed the online MBCR program after their wait condition.

Program Evaluation and Satisfaction

Online MBCR program satisfaction and program recommendation ($n = 51$) data from all participants who completed the intervention (intervention plus TAU wait-list participants) revealed 100% of the participants were satisfied with the program (49% satisfied that the program met their expectations, and 51% positively surprised by the online program which exceeded expectations). Of the 51 participants who completed program recommendation data, 48 would recommend the program to other cancer survivors with no hesitation, while three participants indicated that they would recommend the program with reservation. Reservations were 1) requirement of adequate space around the computer for yoga and meditation, 2) requirement of quiet space to meditate and 3) an interest in exploring mindfulness.

Secondary Outcomes - Psychological Participant-Reported Outcomes

The statistical details of the ITT linear mixed model analysis are presented in Table 3.2.

Profile of Mood States. POMS TMD scores revealed a time by group interaction, $F(1,113) = 3.95, p = 0.049$ which indicated that the group effect varied with time and vice versa (Figure 3.2). Testing of simple effects indicated TMD scores were reduced from pre to post intervention for the MBCR treatment group ($p = .002$) (Figure 3.2). Effect size was 0.44, indicating a medium sized effect.

Symptoms of Stress. ITT analyses of the CSOSI total score revealed a time by group interaction, $F(1,1113) = 5.48, p = 0.021$. Testing of simple effects indicated that overall symptoms of stress were reduced from pre- to post-intervention for the MBCR treatment group ($p = .001$) (Figure 3.2). Cohen's d effect size was 0.49 (medium).

Spirituality. ITT analyses of the FACIT-Sp total score revealed a time by group interaction, $F(1,1113) = 4.31, p = 0.040$. Compared to the control condition, simple effects testing indicated that spirituality scores increased from pre- to post-intervention for the MBCR treatment group ($p = .002$) (Figure 3.2). Cohen's d effect size was 0.37 (small).

Posttraumatic Growth. Results of the LMM analyses on the PTGI total scores revealed main effects of time, $F(1,113) = .19.69, p < .001$. Results of follow-up analyses indicated that, regardless of group assignment, total scores for PTG increased at the 8-week assessment compared to baseline scores.

Mindfulness. ITT analyses of the FFMQ Acting with Awareness facet total score revealed a time by group interaction, $F(1,113) = 5.11, p = 0.026$. Testing of simple effects indicated that the mindfulness facet of Acting with Awareness increased from pre- to post-intervention for the MBCR treatment group ($p = .004$) (Figure 3.2). Effect size was medium (0.50). A main effect of time was observed for all four of the other FFMQ subscale total scores; Observing, $F(1,113) = 1.13, p = 0.73$, Describing, $F(1,113) = .18, p = 0.67$, Nonjudging of Inner Experience, $F(1,113) = 2.66, p = 0.12$, and Nonreacting to Inner Experience, $F(1,113) = 0.10, p = 0.75$. Post-hoc analyses revealed higher total scores at 8-week assessment when compared to baseline, regardless of group assignment for the Nonjudge ($p = .050$), however the Observe, Describe and Nonreact facet simple effects testing did not reveal significant differences over time.

Discussion

This trial is the first to assess the feasibility of providing an online synchronous MBCR program to underserved people living with cancer. The eCALM trial is also the

first to compare an online synchronous MBCR intervention to a TAU wait-list control condition for distressed cancer survivors. As predicted, feasibility estimates were met. Given that psychosocial interventions in general are taken up by a minority of cancer survivors, and because this is a very specialized intervention requiring interest in learning meditation and yoga online over a period of eight weeks, we did not expect more than 5-10% of those broadly targeted in a mailed invitation letter based only on geographic location to be interested. Hence, we were pleased to have met this target. Enrolled participants were not only willing to enrol and complete the online MBCR program, but were satisfied with the online format of MBCR – which either met or exceeded all participants' expectations. All participants also indicated they would recommend the online program to other people living with cancer.

Consistent with our hypothesis, there were statistically significant improvements and medium effect sizes for the online MBCR group relative to controls following 8-week MBCR for total mood and stress symptom scores. Compared to Ledesma and Kumano's F2F MBSR meta-analysis of a medium effect size for mental health factors ($d = 0.48$) (Ledesma & Kumano, 2009), and Musial and colleagues calculated effect size for mood ($d = 0.42$) or distress ($d = 0.58$) (Musial et al., 2011), the current online synchronous program results are comparable with medium effect sizes for both total mood disturbance ($d = 0.44$) and overall symptoms of stress ($d = 0.49$). Effect sizes on mood were also similar to those reported by our group in studies of F2F MBSR (Speca et al., 2000; Carlson et al, 2001; Carlson et al, 2003). The POMS minimally important difference (MID) is a half standard deviation or 18.40; the intervention group exceeded this cut-off with an average change of 20.53, compared to the TAU wait-list change of

6.47. Additionally, 22 participants in the treatment group achieved significant change versus eight in the waiting group. Hence, the changes seen are likely meaningful in the day-to-day lives of participants. With improvements over and above a TAU wait-list in reduction of both mood disturbance and stress symptoms in the distressed sample, additional research into the online synchronous format to reach underserved cancer survivors is warranted.

Regarding positive outcomes, we found an increase in spiritual well-being. This is consistent with findings from Garland et al., (2007) and Henderson et al., (2012) with F2F MBSR. However, a recent review by Cramer and colleagues did not report a significant effect on spirituality following F2F MBSR (Cramer et al., 2012). These discrepancies could be explained by the use of differing spirituality measures or differences between F2F and online MBSR formats. While differing measures and modalities make comparisons challenging, the results from our trial echo the increases in spirituality in F2F MBSR observed in a previous trial from our research group (Garland et al., 2007). However, contrary to hypotheses, we did not see an effect of the intervention on PTG – instead both the intervention and control groups increased over time. While we do not know why there was not a significant interaction effect for PTG, a potential reason for the time effect may have to do with the effects of repeatedly completing questionnaires on PTG, a form of self-monitoring, or perhaps at the second time point, TAU wait-list participants were anticipating imminently starting the program and may have been feeling more hopeful as a result. Previous research has demonstrated increases in PTG post F2F MBSR (Garland et al., 2007), however this research did not include a wait-list comparison, highlighting the importance of including a control group,

and the need for future MBCR trials to utilize active control conditions to help determine specificity of the interventions.

Previous research indicates increases in mindfulness following participation in mindfulness-based interventions (MBIs) are correlated with improved psychological outcomes in cancer populations (Garland et al., 2012; Dobkin & Zhao, 2011; Branstrom et al., 2010) and within the general population (Cash & Whittingham, 2010; Branstrom, Duncan & Moskowitz, 2011; Bowlin & Baer, 2012; Hill & Updegraff, 2012). This is the first study to examine mindfulness facets following an online synchronous MBCR intervention. Our trial did not demonstrate a statistically significant interaction effect of MBCR participation on mindfulness facets, apart from Acting with Awareness ($d = 0.50$). The mindfulness facet Acting with Awareness, viewed as a key component of mindfulness, can be described as the opposite of automatically acting while attention is focused elsewhere (Brown & Ryan, 2003). Increased awareness of internal experiences is hypothesized to be a foundational aspect of mindfulness and required before modification of subsequent cognitions or actions can occur. Within the online MBCR program, people are first encouraged to pay attention to emotions, cognitions and behaviours in a non-evaluative manner. This practice is hypothesized to create space for re-perceiving, or fostering alternative ways to respond to negative emotional experiences (Shapiro et al., 2006). Consistent with a dissertation examining effect sizes for each of the mindfulness facets as mediators, increased present focused attention/awareness was the strongest mediator of the effect of the in-person MBCR program on mood disturbance and stress symptoms (Labelle, 2012, Brown & Ryan, 2003).

Consistent with the eCALM results, Garland and colleagues reported a medium effect size evaluating a F2F MBCR intervention for Acting with Awareness, however in contrast to our results, they also indicated medium effects for describing and nonjudging scales as well, and large effect sizes for observing and nonreacting to inner experience scales (Garland, Tamagawa, Todd, Speca & Carlson, 2013). Computation of the FFMQ total score is not recommended by the scale authors and therefore not calculated (Baer et al., 2006) preventing comparison to trials that reported this result. Investigation into the mechanisms of action in F2F MBCR, determining whether increases in mindfulness contribute to better mental health, or if other mechanisms mediate these benefits, will help inform future research of this online format. Preliminary investigations of decreases in rumination (Jain, Shapiro, Swanick, Roesch, Mills et al., 2007, Labelle et al., 2010) and more recently experiential avoidance (Robins, Keng, Ekblad & Brantley, 2012) are possible areas of future research.

This study is characterized by several strengths. Participants were randomized to a manualized MBCR program or to wait, and only people with moderate-to-high levels of distress were recruited in order to mitigate floor effects seen in other psychosocial intervention trials. The generalizability of these results is maximized by the inclusion of men and women with heterogeneous cancer types and stages.

There are also limitations to this trial. All data collected was self-report, which may be influenced by social desirability bias. To partially mitigate this bias, we actively reassured participants regarding the confidentiality of their responses to the online questionnaires. The pre-post TAU wait-list trial design limited long-term follow-up, preventing conclusions about efficacy of the online treatment to maintain effects

following the intervention. As an initial step, a TAU wait-list design can control for the influences of pre- and post-treatment assessment, symptom self-monitoring, natural recovery from cancer treatments and spontaneous remission or deterioration of symptoms, as well as regression to the mean over time in this moderately to highly distressed sample. Future research will benefit from using a control group matched for attention and time across the entire 8-week online MBCR period, and extended follow-up. While our intent in choosing a synchronous online group format was to mimic as closely as possible in-person group interactions, a limitation of this format is that it does not alleviate the scheduling issues inherent in group scheduling that asynchronous interventions ameliorate. Due to several different components included in the online MBCR program, such as mindfulness meditation, Hatha yoga, psychoeducation and group discussion, the MBCR intervention is typically evaluated as a treatment package rather than identifying specific components that produce benefits. Future dismantling studies could be helpful to elaborate on more reductionistic research questions for the F2F mindfulness research as well as the online adaptations. Time since cancer diagnosis was not included for this sample, and could be an interesting factor to consider in future investigations. To generalize our results to a broader group of cancer patients and further explore the positive psychological outcomes associated with MBCR, inclusion of both distressed and non-distressed patients may increase accessibility to cancer patients who, while not initially distressed, may still benefit from enhancement of spirituality, PTG and other positive outcomes.

In summary, the eCALM trial incorporated sophisticated real-time technology to reach underserved people diagnosed with cancer who are currently excluded from F2F

MBCR programs, with the goal of improving access to psychosocial interventions for a difficult to reach population, while simultaneously reducing mood disturbance and stress symptoms, and increasing spirituality and some aspects of mindfulness. Programs utilizing similar synchronous technology could potentially improve access to highly specialized evidence-based psychosocial programs in oncology and extend reach to other illness populations. We hope the results of this study will encourage further research into the integration of mind-body medicine and technology for underserved populations.

TABLE 3.1. Participant demographics

	Mindfulness Group (n=30)	Wait-list Group (n=32)
Sex		
Female	22 (73.3%)	23 (71.9%)
Male	8 (26.7%)	9 (28.1%)
Age	58 (<i>SD</i> =8.2)	58 (<i>SD</i> =13.0)
Cancer Stage		
Stage 1	10 (33.3%)	11 (34.4%)
Stage 2	8 (26.7%)	7 (21.9%)
Stage 3	7 (23.3%)	2 (6.3%)
Stage 4	4 (13.3%)	5 (15.6%)
Not available ⁺	1 (3.3%)	7 (21.9%)
Cancer Type		
Breast	14 (46.7%)	7 (21.9%)
Blood/Lymph	1 (3.3%)	6 (18.8%)
Colon/Gastrointestinal	5 (16.7%)	2 (6.3%)
Prostate	2 (6.7%)	2 (6.3%)
Female Genitourinary	1 (3.3%)	5 (15.6%)
Thyroid	3 (10.0%)	1 (3.1%)
Other**	4 (13.3%)	9 (28.1%)
Relationship Status		
Married/living with partner	25 (83.3%)	26 (81.3%)
Divorced or Separated	3 (10.0%)	5 (15.6%)
Widowed	2 (6.7%)	1 (3.1%)
Employment Status		
Full-time	8 (26.7%)	7 (21.9%)
Part-time	5 (16.7%)	3 (9.4%)
Unemployed	1 (3.3%)	2 (6.3%)
Retired	10 (33.3%)	11 (34.4%)
Disability	6 (20.0%)	9 (28.1%)
Education		
Primary/Secondary School	3 (10.0%)	4 (12.5%)
High-school graduate	5 (16.7%)	2 (6.3%)
College/Associate/Tech	9 (30.0%)	15 (46.9%)
Degree		
University Degree	5 (16.7%)	7 (21.9%)
Masters/Post-graduate degree	7 (23.3%)	4 (12.5%)
Doctoral Degree	1 (3.3%)	-

* Percentages may not equal 100% due of rounding

+ Cancer stage not specified or available in medical chart review

** Other cancer types include: bone, brain, esophageal, kidney, liver, lung, testicular

Table 3.2: Statistical details of linear mixed model analyses assessing psychological outcome total scale scores for intent to treat (ITT) sample (MBCR n = 30; TAU Control n=32)

Outcome	Group	Estimated Marginal Group Mean (SE)		LMM statistical tests: F (df) [p] (Type III tests of fixed effects)		
		Assessment Time		Group Effect	Time Effect	Group*Time Interaction
		Baseline (T1)	Post (T2) (8 weeks)			
POMS¹	Online MBCR	39.57 (3.67)	18.31 (4.10)	5.25 (1,113)	13.89 (1,113)	3.95 (1,113)
	TAU Control	40.72 (3.55)	37.21 (3.55)	[.024]	[.000]	[.049]
CSOSI¹	Online MBCR	62.49 (3.12)	40.29 (3.49)	7.00 (1,113)	21.83 (1,113)	5.48 (1,113)
	TAU Control	63.49 (3.02)	56.12 (3.02)	[.009]	[.000]	[.021]
FACITsp¹	Online MBCR	26.32 (.81)	31.78 (0.90)	6.85 (1,113)	21.19 (1,113)	4.32 (1,113)
	TAU Control	25.86 (.78)	27.92 (0.87)	[.010]	[.000]	[.040]
PTGI²	Online MBCR	50.77 (2.18)	61.84 (2.44)	.56 (1,113)	19.69 (1,113)	.31 (1,113)
	TAU Control	50.35 (2.11)	58.95 (2.11)	[.456]	[.000]	[.578]
FFMQ –awa¹	Online MBCR	27.53 (.57)	30.10 (.64)	4.17 (1,113)	4.87 (1,113)	5.11 (1,113)
	TAU Control	27.65 (.55)	27.62 (.55)	[.044]	[.029]	[.026]
FFMQ –obs²	Online MBCR	24.65 (.62)	26.56 (.70)	.06 (1,113)	7.18 (1,113)	1.13 (1,113)
	TAU Control	24.72 (.60)	26.19 (.60)	[.816]	[.008]	[.725]
FFMQ –des²	Online MBCR	25.17 (.50)	26.45 (.56)	.01 (1,113)	8.93 (1,113)	.18 (1,113)
	TAU Control	24.91 (.48)	26.67 (.48)	[.936]	[.003]	[.671]
FFMQ –nrea²	Online MBCR	19.31 (.50)	21.72 (.56)	.51 (1,113)	19.95 (1,113)	.10 (1,113)
	TAU Control	19.10 (.48)	21.20 (.48)	[.478]	[.000]	[.753]
FFMQ –njud²	Online MBCR	27.28 (.60)	30.09 (.67)	1.59 (1,113)	8.77 (1,113)	2.66 (1,113)
	TAU Control	27.51 (.58)	28.32 (.58)	[.210]	[.004]	[.106]

¹ = Significant Interaction Effect; ² = Significant Time Effect

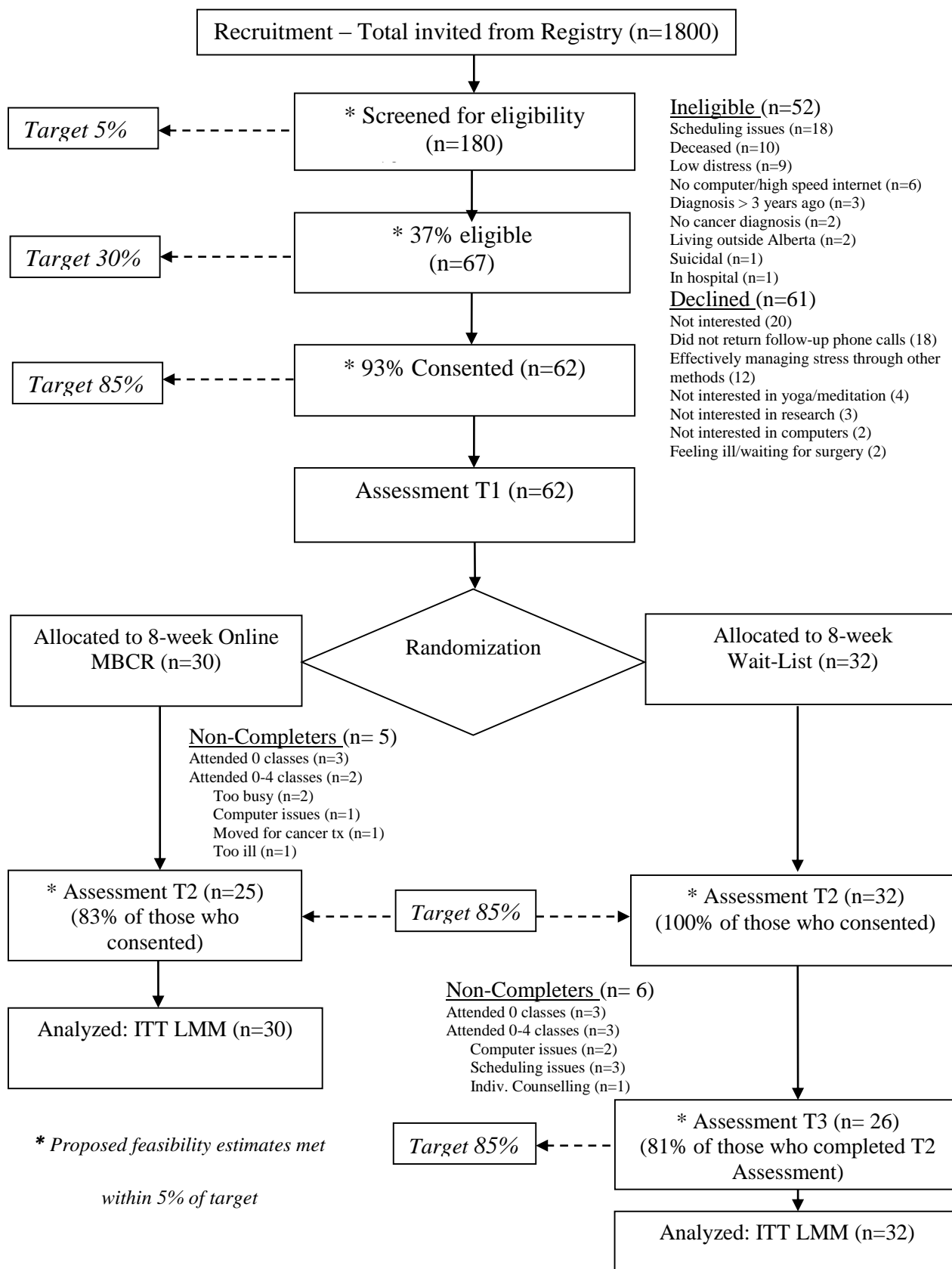
TABLE 3.3. Unadjusted means and standard deviations and standardized mean difference between treatment and control group effect sizes for outcome total scores for MBCR and TAU groups

	Online MBCR Group Mean (SD) (n=30)	TAU Wait-list Group Mean (SD) (n=32)	Cohen's <i>d</i>*
POMS			
Baseline (T1)	37.43 (35.69)	42.16 (27.40)	
Post-Treatment (T2)	17.16 (30.72)	35.69 (31.52)	0.44
CSOSI			
Baseline (T1)	59.70 (32.52)	66.10 (33.77)	
Post-Treatment (T2)	36.83 (21.87)	58.72 (37.38)	0.49
FACITsp			
Baseline (T1)	27.60 (9.95)	24.78 (9.05)	
Post-Treatment (T2)	33.04 (8.08)	26.84 (8.66)	0.37
PTGI			
Baseline (T1)	51.97 (22.29)	49.38 (22.43)	
Post-Treatment (T2)	62.96 (17.57)	57.97 (23.02)	0.11
FFMQ - observe			
Baseline (T1)	24.53 (6.29)	24.88 (7.23)	
Post-Treatment (T2)	26.29 (5.02)	26.34 (6.06)	0.05

FFMQ - describe			
Baseline (T1)	26.17 (6.20)	23.81 (7.28)	
Post-Treatment (T2)	28.13 (6.03)	25.53 (6.73)	0.06
FFMQ – act with awareness			
Baseline (T1)	27.17 (7.67)	27.78 (6.05)	
Post-Treatment (T2)	30.21 (5.00)	27.80 (5.64)	0.50
FFMQ – nonjudge			
Baseline (T1)	26.63 (7.06)	28.03 (7.12)	
Post-Treatment (T2)	29.50 (5.68)	28.84 (5.86)	0.32
FFMQ – nonreact			
Baseline (T1)	19.73 (4.68)	18.75 (4.07)	
Post-Treatment (T2)	22.13 (3.71)	20.84 (4.81)	0.07

* Cohen's *d* formula used = difference between two mean changes between groups (T2-T1 change scores) divided by the pooled standard deviations.

Figure 3.1 - eCALM CONSORT Flow Diagram



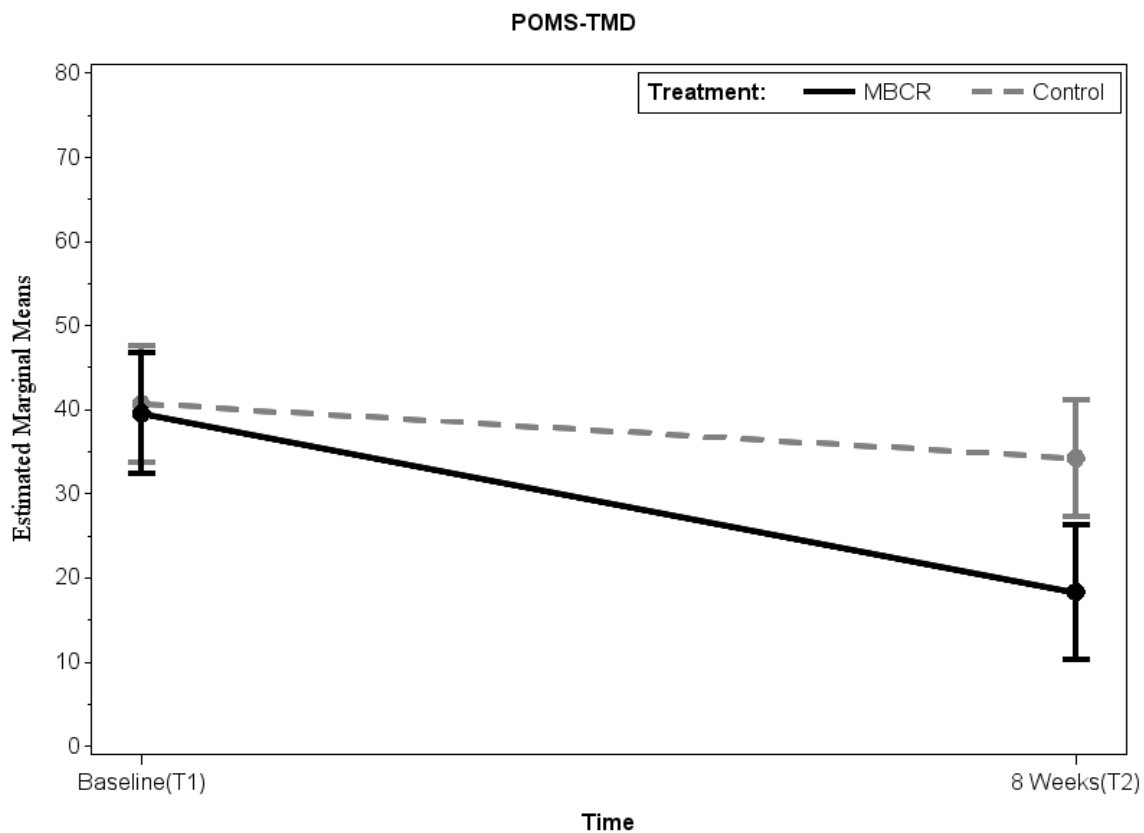


Figure 3.2. Impact of Online MBCR on the Profile of Mood States Total Mood Disturbance Score. Line graph represents the association between group status (Online MBCR vs. TAU Control) and change in total mood disturbance across two time periods.

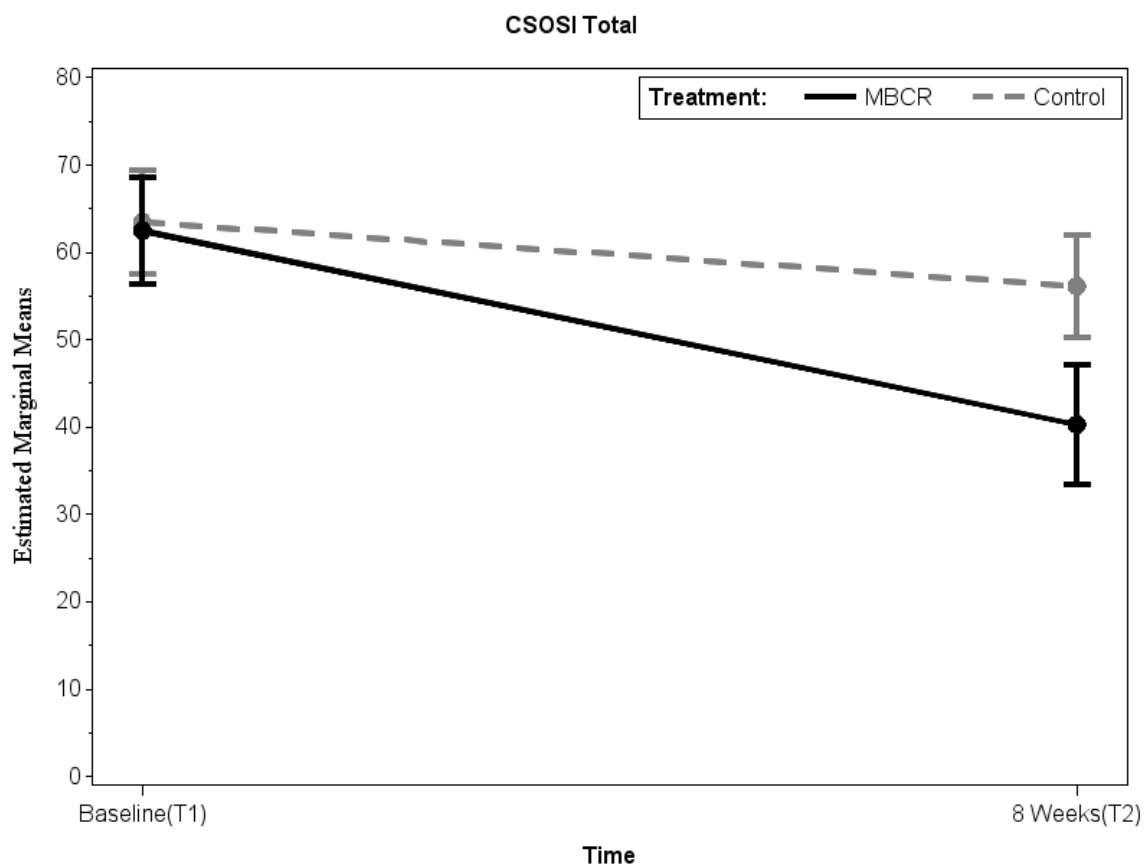


Figure 3.3. Impact of Online MBCR on the Calgary Symptoms of Stress Total Score.

Line graph represents the association between group status (Online MBCR vs. TAU Control) and change in total symptoms of stress across two time periods.

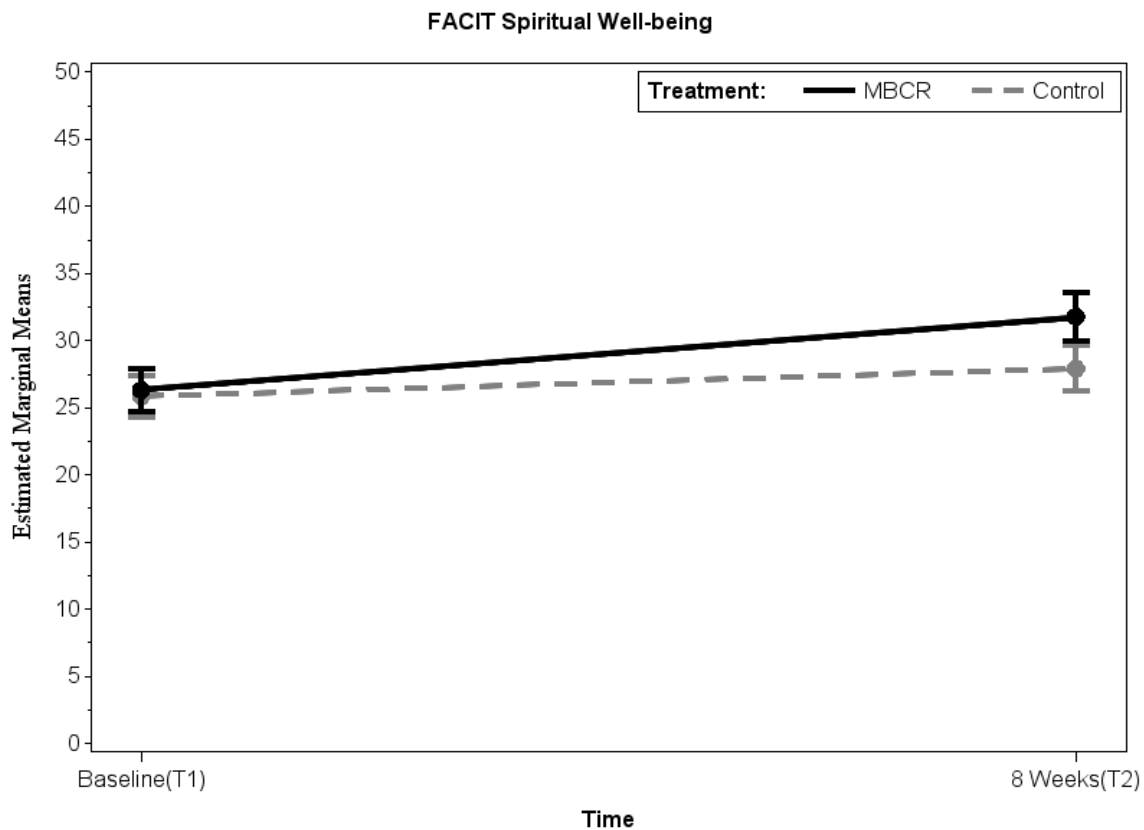


Figure 3.4. Impact of Online MBCR on the Functional Assessment of Chronic Illness Therapy – Spiritual Well-being Total Score. Line graph represents the association between group status (Online MBCR vs. TAU Control) and change in spirituality well-being scores across two time periods.

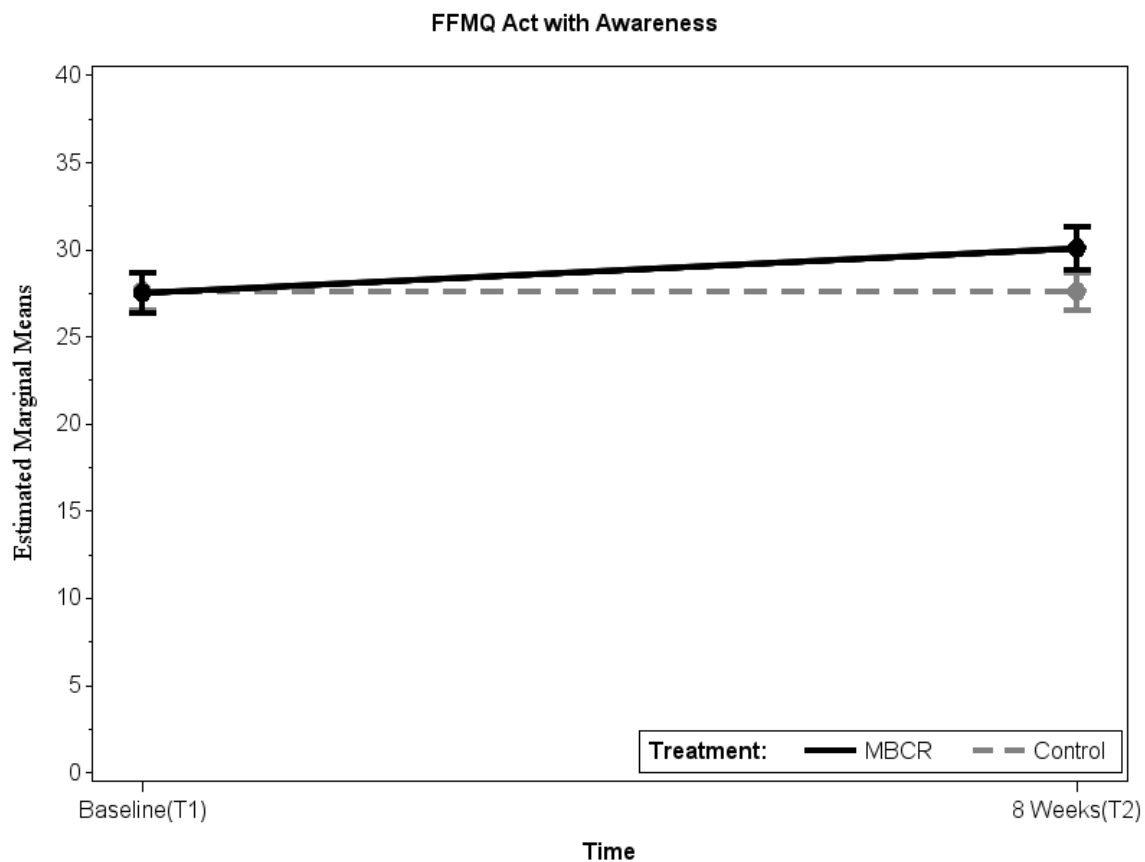


Figure 5. Impact of Online MBCR on the Five Facet Mindfulness Questionnaire Acting with Awareness Total Score. Line graph represents the association between group status (Online MBCR vs. TAU Control) and change in acting with awareness score across two time periods.

**CHAPTER 4: EXPLORATORY ANALYSES OF THE
ASSOCIATIONS BETWEEN ONLINE MINDFULNESS-BASED
CANCER RECOVERY PARTICIPATION AND CHANGES IN
MOOD, STRESS SYMPTOMS, MINDFULNESS, POSTTRAUMATIC
GROWTH AND SPIRITUALITY**

Abstract

Objective

Avenues to increase accessibility of evidence-based psychosocial programs that mitigate cancer related-distress and symptoms are needed, and the internet represents one modality garnering research attention. Mindfulness-Based Cancer Recovery (MBCR) is an evidence-based group psychosocial program adapted to an online “real-time” synchronous format. The objective of this study was to assess the effects of participation in online MBCR on patient reported psychological outcomes in individuals diagnosed with cancer in Alberta, Canada.

Methods

Participants completed self-report symptom measure questionnaires before and immediately after the eight-week online MBCR program. The intervention consisted of weekly two-hour “real-time” online classes and an online weekend six-hour retreat. Mixed model analyses for repeated measures were conducted and subgroup analyses investigated effects of age, sex, and cancer stage on patient-reported outcomes. Standardized subscale change score analysis for mood and stress symptom measures were conducted to evaluate relative improvements over time.

Results

A total of sixty-two distressed participants diagnosed with cancer were enrolled. The most prevalent stage of cancer in this sample was Stage I (34%) and the most common type was breast (34%). Analyses revealed improvements over time on measures of mood, stress, spirituality, posttraumatic growth, and four of five measured mindfulness facets. Relative to older participants, younger participants showed greater improvements in

stress symptoms ($p = .031$), spirituality ($p = .019$), and non-reactivity to experience ($p = .023$). Posttraumatic growth increased more over time in men compared to women ($p = .005$). Within the Profile of Mood Scales subscale analysis, Vigor and Fatigue had the greatest relative improvements, while the Sympathetic nervous system arousal subscale on the Calgary Symptoms of Stress Scale had the greatest relative improvements.

Conclusions

Results are promising in terms of offering an accessible online MBCR approach to helping individuals cope with symptoms associated with cancer and its treatment. The program proved particularly helpful for younger participants and men, and had the greatest effects on improving energy levels while also inducing relaxation.

Keywords

Mindfulness meditation; Cancer; Oncology; Psychological Stress; Online; Synchronous

Background

Following a diagnosis of cancer, distress is a common reaction. For a subset of individuals, coping with diagnosis, treatment, and survivorship can result in disabling symptoms of depression, anxiety, social, and spiritual crisis that significantly impact day-to-day functioning (Holland et al., 2013). Such elevated levels of psychosocial distress can result in worse cancer treatment outcomes, poor quality of life, and higher health care costs (Zabora, J, 2001; Carlson, Angen, Cullum, Goodey, Koopmans et al., 2004). To mitigate these effects, individuals living with cancer are increasingly turning to integrative and complementary mind-body interventions in addition to their conventional medical treatments (Deng & Cassileth, 2013; Rouleau, Garland & Carlson, 2015). Integrative oncology interventions have been developed to mitigate cancer-related distress, and meta-analytic and systematic reviews provide evidence of the salutatory effects of such interventions, enhancing both patient quality of life and reducing emotional distress (Faller et al., 2013). The majority of research attention to date has been concentrated toward alleviating symptom burden and distress, however more recently, the potential beneficial outcomes following adversity, such as living with cancer, have been investigated.

One of the most well researched integrative oncology mind-body interventions that facilitates both reduction of distress as well as improvements in quality of life and positive growth is Mindfulness-Based Stress Reduction (MBSR) (Ledesma & Kumano, 2009; Labelle, Lawlor-Savage, Campbell, Faris, & Carlson, 2015; Rouleau et al., 2015). MBSR is an evidence-based secular psychosocial intervention that is intended to cultivate mindfulness, a focused and purposeful awareness of the present moment, through a lens

of suspended judgment and openness (Kabat-Zinn, 1990). The semi-manualized MBSR program was developed by Jon Kabat-Zinn, rooted in Ancient Buddhist traditions, and adapted for contemporary Western medicine to treat outpatients with chronic pain and illness (Kabat-Zinn, 1982; Kabat-Zinn, 1990; Kabat-Zinn, 1994). The MBSR program has since been adapted for multiple patient populations, with the adapted programs collectively referred to as Mindfulness-Based Interventions (MBIs) (Carlson, 2012). Mindfulness-Based Cancer Recovery (MBCR), our oncology-specific adaptation of MBSR (Carlson & Speca, 2010), follows the traditional eight-week group format of practical instruction and experiential learning of mindfulness meditation and mindful movement (e.g., gentle Hatha yoga) while incorporating adaptations specific to living with cancer (Carlson & Speca, 2010). Following the first randomized wait-list controlled trial in oncology 15 years ago that reported reductions in mood disturbance and perceived stress (Speca et al., 2000), several meta-analyses and reviews have been published within oncology evaluating the effects of MBIs (Ledesma & Kumano, 2009; Matchim, Armer, & Stewart, 2011; Musial, Bussing, Heusser, Choi, & Ostermann, 2011; Shennan, Payne, & Fenlon, 2011; Carlson, 2012; Piet, Wurtzen & Zachariae, 2012). Collectively, these reviews report both the reduction of negative symptoms such as stress, mood disturbance, fatigue and anger, with concurrent increases in quality of life, spirituality, posttraumatic growth, and sleep quality.

While the benefits of MBCR in individuals living with cancer have been reported, practical and psychosocial barriers may diminish access to and participation in face-to-face (F2F) programs, including but not limited to cancer-related illness, geographic distance, fatigue, limited mobility or disability, transportation issues, and time (Howell et

al., 2011; Stephen, Collie, McLeod, Rojubally, Fergus, Speca, et al., 2014). Such barriers to access F2F interventions emphasize the importance of investigating alternative delivery formats to reduce barriers that may prevent individuals living with cancer from receiving evidence-based psychosocial programs. Internet adapted programs offer one option for broader distribution of MBCR by addressing the specific barriers of geographic distance, travel, and limited mobility. Internet-based psychological interventions overall have been shown to be as effective or more effective as in-person interventions (Barak, Klein, & Proudfoot, 2009), and individuals with functional impairments may prefer home-based online programs (Gardner-Nix et al., 2008; Thompson et al., 2010).

Our previously published randomized TAU wait-list controlled eCALM study that enrolled moderately to highly distressed people who did not have access to the face-to-face (F2F) MBCR program provided evidence that an online adaptation of MBCR was feasible. Participants were satisfied and would recommend the program to other people living with cancer. Moreover, results revealed improvements and moderate effect sizes in the online MBCR group relative to controls in overall mood disturbance, stress symptoms, spirituality, and mindfully acting with awareness (Zernicke, Campbell, Speca, McCabe-Ruff, Flowers, & Carlson, 2014). In our previous report, however, we restricted analyses to omnibus measures that were consistent with a priori hypotheses and therefore did not explore effects of the MBCR intervention on subscales of outcome measures for mood and stress. Analyses of subscale scores would provide a more nuanced examination of how online MBCR impacts individuals with cancer and will facilitate comparison to previously published outcomes in our F2F MBCR program.

In addition, research determining for whom MBIs are most beneficial is limited (Shapiro, Brown, Thoresen & Plante, 2011) and even less is known regarding for whom online MBIs are beneficial. Evaluating if there are specific medical or demographic characteristics that maximize or attenuate online intervention effects is important to consider when attempting to broaden the reach of an intervention such as MBCR, and is consistent with the trend toward facilitating choice of treatment in medicine (Tamagawa, Garland, Vaska & Carlson, 2012; Gonzalez-Angulo, Hennessy, & Mills, 2010). Given that the majority of F2F MBCR research participants are middle aged women with lower stages breast cancer, limited investigation into sex, age and stage differences has been conducted. Our heterogeneous online MBCR sample provides an opportunity to evaluate a range of demographic and medical variables to explore impact on patient-reported outcomes of mood disturbance and symptoms of stress following the online program.

We measured several mindfulness facets in our primary outcomes to investigate whether online MBCR facilitates learning mindfulness over the internet similarly to F2F MBCR programs. Mindfulness is hypothesized to help participants develop awareness and acceptance of personal experience, without judgment or attempting to change their experience, and is hypothesized to be a multi-faceted construct (Baer, Smith, Hopkins, Krietemeyer & Toney, 2006). As increases in mindfulness are hypothesized to be foundational to MBCRs beneficial effects, we investigate these facets as well as how medical and demographic variables impact facets of mindfulness following the online program.

Recent research of mindfulness facets has also been shown to mediate the effect of F2F MBCR on positive outcomes of spirituality and posttraumatic growth (PTG)

(Labelle et al., 2015). Spirituality refers to the experiences and emotions associated with the search for value and meaning in life, increasing purpose and connection (Peterman, Fitchett, Brady, Hernandez, & Cella, 2002; Lechner, Stoelb & Antoni, 2008; Visser, Garssen & Vingerhoets, 2010), while PTG refers to the experience of personal growth through adversity (Lechner & Antoni, 2004; Linley & Joseph, 2004). Research supports following a diagnosis of cancer, spirituality and PTG have been associated with positive outcomes (e.g., increased positive affect), as well as decreased physical dysfunction (Carver & Antoni, 2004; Henoeh & Danielson, 2009; Morrill, Brewer, O'Neill, Lillie, Dees, Carey, et al., 2008; Krupski, Kwan, Fink, Sonn, Malinski, & Litwin, 2006; Whitford & Olver, 2012; Tallman, Altmaier & Garcia, 2007).

Hence, the current study expands on the previously reported eCALM trial results by evaluating the potential effects of age, sex, and cancer stage on facets of mood, stress symptoms, mindfulness, posttraumatic growth, and spirituality among participants who completed an online MBCR intervention. In this study we included individuals who initially completed our MBCR program as part of the randomized clinical trial (Zernicke, Campbell, Speca, McCabe-Ruff, Flowers, Dirkse, Carlson, 2013; Zernicke et al., 2014), but combined both the intervention and TAU wait-list groups for pre-post analyses.

Research questions explored are: 1) Does participation in online MBCR decrease total scores of stress symptoms and mood disturbance, as well as increase total scores of spirituality and posttraumatic growth? 2) Was online MBCR equally effective for older and younger survivors? 3) Was online MBCR equally effective for different cancer stages? 4) Was online MBCR equally effective for men and women? 5) On which mood and stress subscales were the largest improvements seen?

Methods

Participants

Potential participants were identified through provincial case records from the Calgary office of the Alberta Cancer Registry, Division of Population Health and Information. Those identified as potentially eligible were mailed a study invitation letter and asked to contact the researcher if interested in participating. Recruitment for this study occurred from March 2011 to August 2012. In total, five online MBCR courses were delivered. Pooling of group condition assignment (immediate and TAU wait-list) resulted in 4 to 20 participants per course.

Inclusion criteria: 1) adults, age 18 years or older, 2) speak and read English to sufficiently complete questionnaires, 3) diagnosis of any type/stage of cancer, 4) completed primary cancer treatment within the last 3 years, 5) reported at least moderate distress as established by Distress Thermometer (DT) with a score of four or greater out of ten (see screening section for details), 6) no access to a F2F MBCR program, 7) access to high-speed Internet, and 8) resident of Alberta.

Exclusion criteria: 1) concurrent self-reported diagnosis by medical professional of psychosis, bipolar disorder, substance abuse or suicidality, however self-reported diagnosis of a depressive, anxiety or adjustment disorder did not prevent enrolment, 2) previous participation in a F2F MBI such as MBCR.

Initial Screening

Individuals who responded to recruitment efforts were screened by telephone to ensure they met basic eligibility criteria and presented with a score of 4 or higher on the DT. The DT is a 0 to 10 single visual analogue scale displayed as a thermometer

(National Comprehensive Cancer Network, 2002). Participants are asked to rate how much distress they have been experiencing over the last week, with 0 indicating “no distress”, and 10 indicating “extreme distress”. A cut-off score ≥ 4 has been recommended for both sensitivity and specificity to identify individuals of high distress in a cancer population (Jacobsen, Donovan, Trask, Fleishman, Zabora, Baker, et al., 2005; Mitchell, 2007). If a participant was interested and eligible after screening, consent was obtained, including consent to access medical records to confirm cancer type and stage.

Symptom Scales

Profile of Mood States. The 65 item self-report measure assesses six affective dimensions. Participants are asked to rate how well items describe their mood over the past seven days on a 5-point Likert scale with 0 indicating not at all, to 4 indicating extremely (McNair, Lorr & Droppelman, 1971). Factor analysis resulted in six transient mood states including Tension-Anxiety, Depression, Anger-Hostility, Vigor-Activity, Fatigue, and Confusion-Bewilderment. The Total Mood Disturbance (TMD) score is calculated by summing the six subscale scores (subtracting Vigor subscale). This scale has been used within cancer populations, and lower scores indicate less mood disturbance. Kuder-Richardson internal consistency ranged from .84 (Confusion-Bewilderment) to .95 (Depression). Test-retest reliability over a three week timeframe ranged from 0.65 (Vigor) to 0.74 (Depression).

Calgary Symptoms of Stress Inventory. This 56-item self-report questionnaire is a revision of the 95-item Symptom of Stress Inventory (SOSI). The CSOSI was developed following exploratory factor analysis on SOSI assessment data collected from

individuals diagnosed with cancer (Carlson & Thomas, 2007). Participants are asked to rate on a five-point scale “never” to “very frequently” their symptoms in the past week. Eight subscales are calculated: Depression, Anger, Muscle Tension, Cardiopulmonary Arousal, Sympathetic Arousal, Neurological/GI, Cognitive Disorganization, and Upper Respiratory symptoms. High internal consistency (0.80 to 0.95) has been demonstrated for both the total and subscale scores (Carlson & Thomas, 2007).

Five Facet Mindfulness Questionnaire. This 39-item self-report questionnaire assesses five facets of mindfulness (Baer et al., 2006). Participants are asked to rate on a five-point scale “never true” to “always true” regarding their opinion of what is generally true (e.g., “I’m good at finding words to describe my feelings”). The five facets include Observe, Describe, Act with Awareness, Nonjudge of Inner Experience and Nonreact to Inner Experience. The Observe facet assesses attending to sensations, perceptions, thoughts and feelings; Describe facet assesses labelling present moment experience with words; Act with Awareness assesses intentionally bringing awareness to current actions/behaviours, and is described as the opposite of automatically acting while attention is focused elsewhere; Nonjudge of Inner Experience assesses suspending judgment, while Nonreact to Inner Experience assesses the tendency to allow and “let go” of feelings and thoughts without becoming preoccupied or attached (Baer et al., 2006).

Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being. This 12-item questionnaire provides two subscales scores as well as an overall measure of spirituality. Participants are asked to rate on a five-point scale “not at all” to “very much” how true each statement is for the past week (e.g., “I feel peaceful”). The two subscales (meaning/peace and faith) correspond to one’s sense of meaning and/or purpose in life

and one's comfort and support from their personal faith. The FACIT-Sp has been established as valid and reliable in individuals diagnosed with cancer and HIV (Brady, Peterman, Fitchett, Mo, & Cella, 1999).

Posttraumatic Growth Inventory. This 21-item questionnaire measures subjective perception of positive changes following adversity. Participants rate the degree to which their perspective has changed following adversity on a scale from 0 to 6, with 0 indicating “not at all”, and 6 indicating “a very great degree”. Normative sample reliability was 0.90, and 0.95 for an oncology population. Normative sample test-retest reliability was adequate (0.71) two months later (Tedeschi & Calhoun, 1996).

Procedure

The results of the randomized portion of the eCALM trial comparing intervention and TAU wait-list control groups on primary outcomes have been previously published (Zernicke et al., 2014). The original study was conducted as a randomized wait-list controlled trial. Participants were randomized to either the immediate intervention group or a TAU wait-list control group. The intervention group started the program within two weeks of randomization, while the control group waited until the next available program. All participants completed questionnaires following the eight week intervention or wait period. The MBCR program was then offered to the TAU wait-list control group. The methods and results of the randomized portion of the eCALM trial comparing intervention and TAU wait-list control groups on primary outcomes have been previously published (Zernicke et al., 2013; Zernicke et al., 2014). In the current study, we grouped participants from both the intervention and the control condition together to analyze their respective pre-MBCR and post-MBCR scores, as all participants completed the

questionnaire battery at the same time periods relative to their participation in the program. This pooling allows assessment of the impact of the intervention on all participants concurrently, regardless of group condition assignment. The increase in sample size allows exploration of contributing sources of variance, analysis of subscales and effects of potential demographic variables such as age and sex in subgroup analyses. Ethical approval from the Conjoint Health Research Ethics Board of the University of Calgary/Alberta Health Services was obtained before commencement of the trial.

Intervention – Online MBCR

Components of the online MBCR program were modelled after the in-person MBCR program at the Tom Baker Cancer Centre in Calgary, Alberta, Canada (See Carlson & Speca (2010) for a step-by-step program description). SF, a licensed clinician with over 15 years of experience teaching online MBSR, was the program facilitator. He was trained in the specific adaptation of MBCR by trial study authors (LEC and MS). Weekly two-hour sessions for eight consecutive weeks were conducted online in a synchronous “real-time” format. Experiential practice, didactic instruction and group process were emphasized components, as well as an online 6-hour weekend retreat. Videos and guided meditation recordings were provided to participants to facilitate the recommended 45 minute daily home practice. Guided mindful movement activities (Hatha yoga, qigong, walking meditations) and various sitting, and compassion meditations were facilitated by the instructor in the online environment.

Headsets, webcams, and MBCR program manuals were provided to participants and distributed by mail prior to the start of the program. In collaboration with eMindful Inc. (www.emindful.com), an online mindfulness education company,

participants were able to see and hear in real time other group members and the instructor during the synchronous online MBCR intervention. The virtual classroom allowed multiple webcams to be viewed by all participants and the instructor simultaneously. eMindful provided technical support throughout the classes to address technical issues with software or hardware before beginning the program. Participants were offered the opportunity to set up a one-on-one orientation session to organize equipment and orient to the online platform functions. All study-related questions were directed to the research coordinators, and course related questions were directed to the MBCR teacher.

Data Analysis

All data analysis was conducted with IBM SPSS v. 22. Data were tested for normality and homogeneity of variance. All participants who provided baseline data were included in the analyses. We identified potential baseline demographic and medical characteristics that may influence intervention outcomes, and if a significant association was indicated between the baseline characteristics and the baseline values of the outcome variables, these were included in the model. Linear Mixed Models (LMM) for repeated measures with maximum likelihood estimation of parameters were conducted to evaluate the impact of the online MBCR intervention on the outcome measures of mood disturbance, stress symptoms, mindfulness, spirituality, and posttraumatic growth. Based on the research questions of this study, each model assessed fixed effects of time, sex, age, and cancer severity, and interactions between time and those demographic/medical variables. Age was treated as a continuous variable in the analysis, however for the graphical representation age was dichotomized into younger and older groups by a median split of 59 years. Fixed effects statistical significance of p values was set as <

.05. The least significant difference method was used to correct for multiple comparisons. To determine where the most change had occurred within the subscales of the POMS and CSOSI respectively, and systematically compare the magnitude on each subscale, standardized change scores were calculated and compared using one-sample *t*-tests.

Results

Participants

Demographic characteristics are presented in Table 4.1. Sixty-two participants completed the required consent forms, enrolled in the study, and completed pre-intervention assessment. The most prevalent stage of cancer was Stage I (34%) and the most common cancer type was breast (34%), followed by blood/lymph (11%) and colon/gastrointestinal (11%). The majority of participants were women (73%), and the mean age for all participants was 58 years ($SD = 10.79$).

Attrition and Compliance. Of the 62 participants, 47 (75.8%) completed at least five or more classes. The mean number of classes attended was six out of nine including the online six hour weekend retreat ($SD = 3$, range 0-9). The mean amount of home meditation and yoga practice, not including weekly class practice or retreat, was 134 minutes per week. All pre-and post-intervention estimated marginal means and confidence intervals are presented in Table 4.2.

Symptom Scales

Mood. POMS total mood disturbance scores revealed a time effect, $F(1,48.24) = 23.97$, $p < 0.001$, that indicated a reduction in mood disturbance following the online intervention. The largest subscale improvements occurred on the Vigor subscale, followed by Fatigue, Confusion-Bewilderment, Tension-Anxiety, Depression and Anger-

Hostility. Vigor showed a greater change than Depression ($p = .029$) and Anger ($p = .011$). Fatigue also showed greater change than Depression ($p = .024$) and Anger ($p = .003$), while Confusion showed a greater change than Anger ($p = .032$) (Figure 4.1a).

Stress. CSOSI total scores showed a time by age interaction effect, $F(1,143.81) = 4.807$, $p = 0.03$, which indicated a greater reduction in overall symptoms of stress following the online intervention among younger participants compared to older participants (Figure 2a). The largest improvements occurred on the Sympathetic Arousal subscale, followed by Anger, Cardiopulmonary, Muscle Tension, Depression, Cognitive, Neurological/GI, and Upper Respiratory. The Sympathetic Arousal subscale showed a greater change than the subscales of Depression ($p = .015$), Cardiopulmonary ($p = .041$), Neurological/GI symptoms ($p = .001$), Cognitive Disorganization ($p = .002$), and Upper Respiratory symptoms ($p = .015$) (Figure 4.1b).

Spirituality. Spirituality total scores revealed a time by age interaction, $F(1,41.18) = 5.96$, $p = 0.019$, which indicated a greater increase in spirituality following the online intervention among younger participants compared to older participants (Figure 4.2b).

Mindfulness. A baseline difference on FFMQ Observe scores ($p = .002$) between men and women was included as a covariate in the model. Time effects for Observe $F(1,91) = 11.23$, $p = 0.001$, Acting with Awareness $F(1,46.73) = 8.99$, $p = 0.004$, and Nonjudge $F(1,46.97) = 9.77$, $p = .003$ indicated these FFMQ mindfulness facets increased post intervention. Nonreact scores revealed a time by age interaction effect $F(1,40.48) = 5.12$, $p = 0.029$, with a greater increase in Nonreact facet scores following the online intervention among younger participants compared to older participants post

intervention (Figure 4.2c). Describe facet did not change over time, $F(1,44.79) = 1.13$, $p = 0.294$, as participants remained constant over time.

Posttraumatic Growth. A baseline difference on PTGI scores ($p=.049$) between men and women was included as a covariate in the model. PTGI total scores indicated a time by sex interaction, $F(1,40.42) = 7.37$, $p = 0.010$, with a greater increase in posttraumatic growth scores following the online intervention among men compared to women (Figure 4.2d).

Discussion

The online intervention results are consistent with other studies showing beneficial effects of F2F MBCR for decreased mood disturbance and reduction of stress symptoms (Carlson et al., 2001; Garland et al., 2013; Labelle, Campbell, Faris, & Carlson, 2015). Younger participants experienced a greater reduction in overall symptoms of stress and greater increase in spirituality following the online intervention compared to older participants. Visually it appears a common pattern was for younger people to have somewhat higher stress symptomatology and lower self-reported spirituality at baseline, and to improve more to reach or exceed the same level as the older participants. However, none of the baseline differences between younger and older participants were significantly different. One potential reason for a greater impact with younger participants is age cohort effects related to greater familiarity, comfort, and use of internet-based media, which could be a contributing factor to increased benefit through the online MBCR program. Increased ease of integrating into an online program environment could potentially speed the learning and focus to course content, experience, and skill learning rather than navigating within the online environment. Spirituality

results may also point toward the online intervention potentially facilitating younger individuals diagnosed with cancer to experience a greater increase in feelings of connection, peace and deeper sense of meaning compared to older participants. A previous qualitative analysis of a synchronous online cancer support group revealed that meaningful communication regarding difficult issues, as well as kinship and connection with others were important to participants and developed in an online format, but no analysis regarding age was conducted (Stephen et al., 2013). Deep connection to others through the Internet may develop differentially, with age being one possible factor, and it merits further investigation.

Regarding mood disturbance, the largest improvements occurred on the Vigor and Fatigue subscales, while Sympathetic Arousal showed the greatest comparative reduction for stress symptoms following online MBCR. Such results suggest that immediately following the online intervention, the program was relatively more successful in reducing the physical symptoms associated with mood disturbance and perceived stress than the psychological symptoms. Possible explanations for the reduction in physical symptoms post mindfulness intervention may be due to reduced levels of cortisol as reported following F2F MBCR (Carlson, Speca, Patel, & Faris, 2007; Witek-Janusek, Albuquerque, Chroniak, Chroniak, Durazo-Arvizu, et al., 2008), or potentially reduced muscle tension and relaxation following the gentle stretching/yoga and breathing exercises, however these remain to be investigated.

In contrast to our results, Carlson et al (2001) reported F2F MBCR intervention results immediately following the program that showed greatest change in the POMS Tension-Anxiety subscale. Garland and colleagues (2013) similarly reported a medium

effect size ($d = 0.48$), the largest effect for their analysis (Garland et al., 2013), while Vigor was reported as the smallest effect size ($d = 0.24$) (Garland et al., 2013). Our online MBCR results more closely parallel Carlson et al (2001) 6-month follow-up results showing larger improvements occurring on Vigor followed by Fatigue (Carlson, Ursuliak, Goodey, Angen, & Speca, 2001). While speculative, one possible hypothesis to explain increased Vigor is through the removal of the hassles that additionally expend energy such as traveling, parking, and walking to the group and back. The online participants were instead able to remain in the comfort of their own homes, conserving energy and minimizing hassles, potentially allowing for greater focus on course content rather than taking time to internally adjust from the outside environment.

Our online MBCR results are consistent with F2F results of enhanced positive outcomes of the cancer experience such as PTG and increased spirituality (Birnie, Garland & Carlson, 2010; Henderson, Clemow, Massion, Hurley, Druker et al., 2012; Labelle, Lawlor-Savage, Campbell, Faris & Carlson, 2015). In a recently published mediation analysis, development of self-reported mindfulness skills in a F2F MBCR program appeared to facilitate personal growth, as well as a sense of meaning, connectedness and peace in individuals diagnosed with cancer (Labelle et al., 2015). Investigation of positive effects such as PTG and increased spirituality following diagnosis and treatment, or “benefit finding” is important as both constructs have been linked to other positive outcomes such as increased quality of life, positive affect and psychological adjustment, with concurrent decreased physical discomfort post cancer diagnosis (Carver & Antoni, 2004; Cotton, Levine, Fitzpatrick, Dold, & Targ, 1999; Krupski et al., 2006).

Our results indicate that men experienced a greater increase in posttraumatic growth compared to women. Current research has not explored PTG in a cancer population following an online mindfulness-based intervention, however more broadly there are equivocal data on sex differences in PTG in men and women diagnosed with cancer (Zwahlen, Hagenbuch, Carley, Jenewein, & Buchi, 2010). Women typically score higher on the PTGI scale (Tedeschi & Calhoun, 2004) and this was true for our sample; however further randomized controlled research is needed to explore whether online interventions allow for decreased experiential avoidance and processing in men, and whether the online format allows for greater uptake of the MBCR program by men through potentially reducing common barriers to attendance. Indeed, the composition of the online groups included more men than we see in the parallel F2F groups, which are attended primarily by women. Perhaps men benefit more in terms of PTG across both formats, but the increased participation of men through the online format simply allowed a large enough sample of men to make this sex comparison for the first time. Conversely, it is possible that the online format in its simplicity, relative anonymity and lack of face-to-face social interaction pressures allows for more introspective processing of the cancer experience which facilitates personal growth more in men. This finding merits further exploration.

Regarding changes in mindfulness, four out of the five facets improved over the course of the online MBCR intervention, suggesting an online adaptation of the mindfulness intervention was able to cultivate mindfulness skills learning over the internet. The facets of acting with awareness in daily life (Act), observing present moment experience (Observe), and allowing experience without judgment (Non-judge)

increased following the online intervention, which parallel previous research findings in F2F MBCR in oncology populations (Labelle et al., 2015; Garland et al, 2013). The mindfulness skill of non-reactivity to inner experience (Nonreact) increased post intervention more for younger compared to older participants. Though the Nonreact baseline scores did not statistically differ by age, younger participants reported lower baseline levels of non-reactivity, which may indicate younger participants were initially less skilled in taking a nonreactive stance toward inner experience, and more likely to act out impulsively. The program may have facilitated an increase in the development of these skills that typically develop more slowly with age and experience. This novel finding adds to the discussion of the complexity of beginning to identify subgroups of people who may benefit more from mindfulness-based interventions and more specifically online MBCR.

The mindfulness skill of labelling internal experience with words - the Describe facet, did not change following the intervention. This result contrasts with findings from previous research reporting small to moderate effect sizes (Baer, Carmody & Hunsinger, 2012; Garland, et al., 2013); Labelle et al., 2015). A few investigations into the timing of change for the Describe facet indicate improvement occurs later in the program (Baer et al., 2012; Labelle et al., 2015) and yields the smallest effect size relative to the other mindfulness facets (Labelle et al., 2015). If the Describe facet takes more time to cultivate and effects are relatively smaller than other mindfulness facets, the online MBCR intervention may not have developed this skill as adequately or at the same rate as in-person programs. While speculative, this is an interesting hypothesis that requires further investigation.

There are methodological limitations to the current study. Self-selection to participation limits generalizability to motivated individuals. Without a control condition to compare effects, the present exploratory results should be interpreted with caution as this prevents the ability to ascertain whether improvements are directly attributable to program participation, effects of monitoring, attention and social support, healing and growth from the cancer experience itself, or regression to the mean. Statistical adjustment of age, sex and cancer stage as investigated medical/demographic variables increase risk of over fitting the data and should be interpreted as exploratory. Larger samples to assess additional factors such as amount of home practice, cancer type, as well as gathering information on participant preference or familiarity with online media would be beneficial.

In summary, the current research explored the impact of the online MBCR intervention revealing significant improvements over time for mood disturbance, perceived stress, spirituality, posttraumatic growth and four of five measured mindfulness facets. Younger participants had a greater reduction in stress symptoms, greater increases in spirituality, and nonreactivity, while men's PTG scores increased more over time compared to women. Standardized subscale change score comparisons revealed greater reduction in physical symptoms associated with mood disturbance and perceived stress compared to psychological symptoms.

As many individuals diagnosed with cancer face barriers to accessing evidence-based mind-body interventions, our results are encouraging as online MBCR provides an alternative delivery system. Further, rapid technological improvement in capability to mimic speed of in-person interaction within online groups will likely only increase

acceptability over time, and growing access to high-speed internet will likely also continue to increase potential reach.

Future research is merited to continue investigation of mechanisms of change in online interventions, as well as encourage future evaluation of moderators to pinpoint participants who benefit most from mind-body interventions through the use of technology to continue to decrease barriers and improve access.

TABLE 4.1. Baseline demographic characteristics

	Pre-intervention (N=62)
Sex (n)	
Female	45 (72.6%)
Male	17 (24.4%)
Age (years)	57.56 (SD=10.79)
Cancer Stage	
Stage 1	21(33.9%)
Stage 2	15 (24.2%)
Stage 3	9 (14.5%)
Stage 4	9 (14.5%)
Not available ⁺	8 (13.0%)
Cancer Type	
Breast	21 (33.9%)
Blood/Lymph	7 (11.3%)
Colon/Gastrointestinal	7 (11.3%)
Prostate	4 (6.5%)
Female Genitourinary	6 (9.7%)
Thyroid	4 (6.5%)
Other**	13 (21.0%)
Relationship Status	
Married/living with partner	51 (82.3%)
Divorced/Separated or Widowed	11 (17.7%)
Employment Status	
Full or part-time	31 (50.0%)
Unemployed/retired/disabled	31 (50.0%)
Education	
High-school	14 (22.6%)
College/Associate/Tech Degree	24 (38.7%)
University Degree and above	24 (38.7%)

* Percentages may not equal 100% due of rounding

+ Cancer stage not specified or available in medical chart review

** Other cancer types include: bone, brain, esophageal, kidney, liver, lung, testicular

Table 4.2: Statistical details of linear mixed model analyses assessing psychological outcome total scale scores (N=62)

Outcome (Significant interaction or time effect)	Estimated Marginal Group Mean		95% CI		LMM statistical tests: F (df) [p]
	Pre-MBCR T1	Post-MBCR T2 (8 weeks)	Lower	Upper	
POMS (Time)	32.10	12.46	T1:22.65 T2:2.64	T1:41.53 T2:22.27	23.14 (1,46.95) [.000]
CSOSI (Time*Age)	Younger 58.30	Younger 28.06	T1:45.03 T2:13.68	T1:71.58 T2:42.45	5.00 (1,40.33) [.031]
	Older 49.51	Older 38.05	T1:37.37 T2:25.46	T1:61.65 T2:50.64	
FACIT _{sp} (Time*Age)	Younger 25.03	Younger 31.97	T1:21.62 T2:27.98	T1:28.79 T2:35.95	5.95 (1,41.26) [.019]
	Older 31.16	Older 35.11	T1:27.71 T2:31.58	T1:34.60 T2:38.64	
PTGI (Time*Sex)	Male 44.95	Male 62.36	T1:33.71 T2:50.74	T1:56.18 T2:73.97	8.18 (1,90.00) [.005]
	Female 60.75	Female 66.26	T1:53.82 T2:59.10	T1:67.67 T2:73.42	
FFMQ –awa (Time)	28.55	30.83	T1:26.43 T2:28.64	T1:30.67 T2:33.01	8.65 (1,45.48) [.005]
FFMQ –obs (Time)	23.62	25.86	T1:22.14 T2:24.29	T1:25.11 T2:27.76	11.23 (1,91.00) [.001]
FFMQ –des (Time)	25.82	26.59	T1:23.79 T2:24.51	T1:27.85 T2:28.68	1.19 (1,45.90) [.282]
FFMQ –nrea (Time*Age)	Younger 17.39	Younger 21.61	T1:15.30 T2:19.32	T1:19.49 T2:23.90	5.58 (1,43.74) [.023]
	Older 22.13	Older 23.07	T1:20.21 T2:21.07	T1:24.05 T2:25.06	
FFMQ –njud (Time)	28.78	31.49	T1:26.67 T2:29.30	T1:30.90 T2:33.68	9.52 (1,46.28) [.003]

Abbreviations: CI = confidence interval; MBCR = Mindfulness-Based Cancer Recovery; CSOSI = Calgary Symptoms of Stress Inventory; POMS = Profile of Mood States; FFMQ = Five Facet Mindfulness Questionnaire; FFMQ-awa = Five Facet Mindfulness Questionnaire Act with Awareness total scale; FFMQ-des = Five Facet Mindfulness Questionnaire Describe total scale; FFMQ-obs = Five Facet Mindfulness Questionnaire Observe total scale; FFMQ-nrea = Five Facet Mindfulness Questionnaire Nonreact total scale; FFMQ-njud = Five Facet Mindfulness Questionnaire Nonjudge total scale; FACIT_{sp} = Functional Assessment of Chronic Illness Therapy – Spiritual Well-being total scale; PTGI = Posttraumatic Growth Inventory

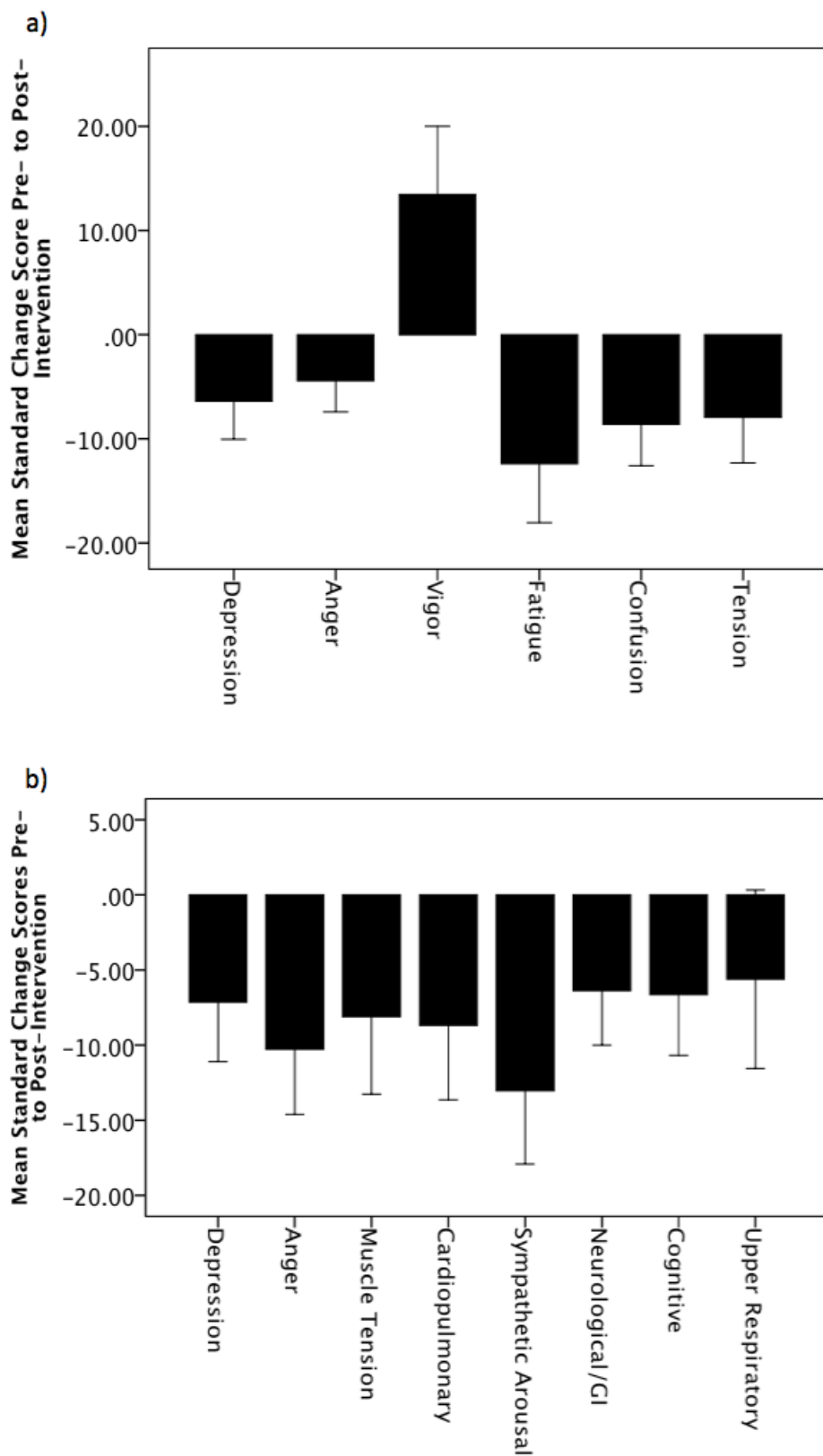


Figure 4.1 Standardized change scores from pre to post intervention of a) POMS and b) CSOSI

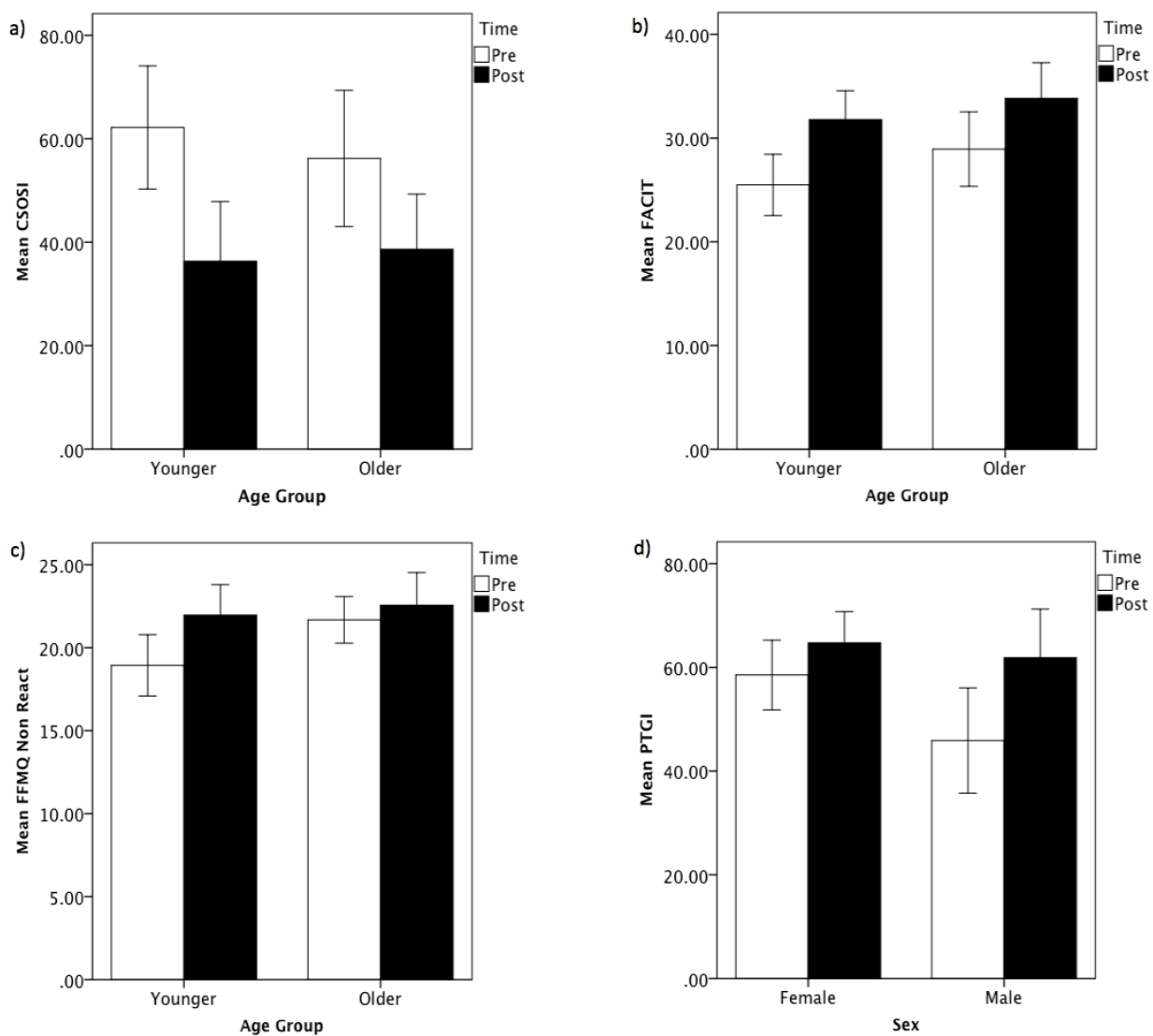


Figure 4.2 Time x Age interaction effects for a) CSOSI, b) FACIT-Sp, c) FFMQ Nonreact, and Time x Sex interaction effect for d) PTGI
 ***median split age for graphical representation = 59 years

CHAPTER 5: DISCUSSION

Summary of Chapters

This thesis examined the feasibility and impact of an online “real time” synchronous MBCR program for distressed individuals diagnosed with cancer in Alberta, Canada. In the first chapter overall cancer prevalence, distress, as well as potential perceived “positive changes” from a cancer diagnosis are reviewed. The description and review of the efficacy of Mindfulness-Based Stress Reduction programs is provided, including the cancer-specific adaptation of Mindfulness-Based Cancer Recovery (MBCR). Chapter one highlights the different emerging methods of providing online therapy—separated by asynchronous and synchronous formats—to chronic health and mental health populations, ending with a review of the literature supporting the use of synchronous online interventions to disseminate empirically supported mindfulness-based programs to chronic health populations, including cancer.

The second chapter includes the published eCALM trial design manuscript in its entirety: *The eCALM Trial—eTherapy for Cancer AppLYing Mindfulness: Online mindfulness-based cancer recovery program for underserved individuals living with cancer in Alberta: protocol development for a randomized wait-list controlled clinical trial*. The eCALM Trial’s primary objective was to determine feasibility—to examine whether moderately to highly distressed individuals diagnosed with cancer would be willing to participate in internet-based online MBCR groups and complete the 8-week intervention. This objective was assessed through evaluation of recruitment, retention, attendance, adherence, and participant satisfaction ratings. The secondary objective was to examine the efficacy of the online synchronous adaptation of MBCR for individuals diagnosed with cancer compared to a treatment-as-usual (TAU) wait-list group on a range

of previously studied patient-reported outcomes including mood, symptoms of stress, post-traumatic growth, spirituality and five facets of mindfulness. Outcome assessments were completed before and immediately after finishing the intervention.

The third chapter presents the results of the feasibility and program satisfaction data as well as the comparison of the randomized wait-list controlled trial in the published format: *A Randomized Wait-List Controlled Trial of Feasibility and Efficacy of an Online Mindfulness-Based Cancer Recovery Program: The eTherapy for Cancer AppLYing Mindfulness Trial*. This work demonstrated for the first time that an online synchronous MBCR RCT intervention is feasible for distressed cancer survivors who are not able to attend F2F MBCR in Alberta. Surpassing feasibility, participants completed the intervention with drop-out rates below typical F2F MBCR estimates, and all participants reported the program met or exceeded their expectations, resulting in full recommendation to other cancer survivors.

Within the RCT, improvements and medium effects sizes for total mood and stress symptom scores were observed after the online MBCR intervention for the treatment group relative to controls. These effect sizes were consistent with a F2F oncology population MBI meta-analysis (Ledesma & Kumano, 2009) as well as a systematic review (Musial et al., 2011). This online adaptation of MBCR also produced comparable mood effect sizes to the in-person TBCC MBCR program (Specia et al., 2000; Carlson et al., 2001; Carlson et al., 2003). Moreover, 22 participants in online MBCR vs. 8 in the TAU wait-list surpassed clinical cut off for the minimally important difference POMS total score, emphasizing changes in mood likely resulted in meaningful improvement in functioning day-to-day for individuals living with cancer.

Regarding positive outcomes reported in the RCT, there was an increase in spirituality in the online MBCR group relative to controls ($d = 0.37$). This was consistent with previous F2F MBSR results (Garland et al., 2007; Henderson et al., 2012; Labelle et al., 2015), although in contrast to a review that did not report overall improvements in spirituality (Cramer et al., 2012). This small meta-analysis included 2 trials, one of which was Henderson and colleagues' trial that did report improvements (2012), and a trial that did not use the same spirituality scale following a 6 week MBI (Lengacher et al., 2009). These discrepancies could have been due to differences in spirituality measures or potentially due to differences between in-person and internet formats. Nevertheless, encouragingly our online trial was consistent with the F2F MBCR trial from our research group (Garland et al., 2007).

Regarding PTG, both the intervention and TAU wait-list groups increased over time. One explanation could be TAU wait-list participants may have been feeling more hopeful as they completed their follow-up questionnaires just before starting the online MBCR program. Garland and colleagues (2007) reported increases in PTG post F2F MBCR, although this research did not include a control condition, which may have accounted for contradictory findings.

The current study is the first RCT to evaluate mindfulness facets following an online MBCR program. Through measurement with the FFMQ, the Acting with Awareness subscale improved following online MBCR compared to controls ($d = 0.50$). This facet has been described as an important component of mindfulness, and the opposite to acting on "auto pilot" (Brown & Ryan, 2003). This medium effect size is consistent with Garland and colleagues results for Acting with Awareness. Contrary to

our time effects for the other four mindfulness facets measured, however, those authors reported medium effect sizes for Describing and Nonjudging, and large effect sizes for Observing and Nonreacting (Garland et al., 2013). Those findings raise the question of whether our TAU wait-list control design could account for such differences between trials.

The fourth and final manuscript-based chapter expands on the third chapter's randomized trial results by combining both the intervention and TAU wait-list groups to conduct exploratory analyses evaluating participant demographics and the associations between online MBCR participation and changes in self-reported mood disturbance, stress symptoms, spirituality, posttraumatic growth and mindfulness. The manuscript that will emanate from this study is in preparation for submission to a peer reviewed journal: *Exploratory analyses of the associations between online mindfulness-based cancer recovery participation and changes in mood, stress symptoms, mindfulness, posttraumatic growth and spirituality.*

Results from exploratory analyses revealed younger participants had greater reductions in self-reported stress symptoms as well as greater increases in spirituality compared to older participants following online MBCR. Hypothetically, the greater impact with younger participants may be age cohort effects or potentially connection to others through the Internet may develop differentially, with age being one possible factor, meriting further investigation.

With mood disturbance and stress symptom subscale comparisons, the online MBCR program was more successful in reducing the physical symptoms associated with mood disturbance and perceived stress compared to the psychological symptoms, which

is in contrast to results from our F2F MBCR program results (Carlson et al., 2011; Garland et al., 2013). Our online MBCR results more closely parallel Carlson et al (2001) 6-month follow-up results showing larger improvements occurring on Vigor followed by Fatigue.

Our results indicate that men experienced a greater increase in posttraumatic growth compared to women. Tedeschi and Calhoun report women generally score higher on the PTGI scale (2004), and this was true for our sample. Further research is required to explore whether online interventions allow for decreased experiential avoidance and processing in men, whether the online format allows for greater uptake by men, or if components of the online format allow for greater introspective processing of the cancer experience in men. These results merit in-depth investigation.

Exploration of the changes in mindfulness following the online MBCR intervention revealed Act, Observe, and Nonjudge facets increased, corresponding to F2F MBCR in oncology (Labelle et al., 2015; Garland et al., 2013). The Nonreact facet increased more for younger participants. Potentially, online MBCR may have increased the development of taking a non-reactive, less impulsive stance in younger participants that may develop over time with experience. The Describe facet did not change following the intervention. That result contrasts previous research reporting small-to-moderate effect sizes (Baer, Carmody & Hunsinger, 2012; Garland, et al., 2013); Labelle et al., 2015). Online MBCR investigations into the magnitude, timing, and sequence of change in mindfulness skills are required to compare to preliminary research within F2F MBIs assessing timing and sequencing of mindfulness facets (Baer et al., 2012; Labelle et al., 2015).

Strengths of the Current Work

Randomization and Intent-To-Treat Analysis for RCT Results

Participants were randomly assigned to a semi-manualized MBCR intervention or to a TAU wait-list. Randomization to the concurrent wait-list control allows for evaluation of the program compared to similar individuals not receiving the intervention, addressing the internal validity threats of distressed participants regressing to the mean, time or maturation, historical cohort effects, as well as the effects of filling out pre-post questionnaires. Regression to the mean is a statistical phenomenon that threatens internal validity when repeated measurements are made on the same participant, and subsequent measurements regress toward the mean, occurring due to random error (Barnett, van der Pols, & Dobson, 2005). A TAU wait-list control group provides a mean change estimate for this random error, ensuring changes reported are not due to random error but due to change from treatment effect (Barnett et al., 2005). Maturation threatens internal validity when biological or psychological characteristics of participants change during the experiment, influencing their follow-up results, whereas the internal threat of history occurs when participants experience an external event (e.g., death of a family member) that affects their follow-up scores (Dimitrov & Rumrill, 2003). A randomized TAU wait-list control condition can allow for estimate of this error, strengthening validity that reported changes are due to treatment effects. Finally, randomized TAU wait-list conditions provide an estimate of the interaction or possible sensitization of participants following baseline assessment (Dimitrov & Rumrill, 2003), strengthening validity.

An additional strength is that data were analyzed using an ITT procedure. ITT analyses attempt to preserve the baseline equivalence of groups that was created through

randomization, and ITT analyses reduce bias by avoiding analysis of only a subset, or selective retention of participants (e.g., Peduzzi, Henderson, Hartigan, & Lavori, 2002; Coyne, Lepore, & Palmer, 2006), and mitigate against bias in the discarding of data for some participants whose results could change the outcome of the study (Coyne et al., 2006). While research within online interventions within oncology cite a common limitation of significant dropout rates (Ruland et al., 2013; Everts et al., 2015) our randomized trial result dropout rates were comparable to or better than in-person MBCR programs, with 83% of online MBCR participants completing the program (or 17% dropping out), and 100% completing the TAU wait-list condition. This is a significant strength of the trial. Using ITT analyses allowed for inclusion of the participants who did not complete the intervention to be included in the analyses to mitigate the potential biases described previously. Taken together, randomization, ITT analysis and low dropout rates were significant strengths of this online intervention trial.

Distress Screening

In the eCALM trial we specifically included participants who were suffering from significant distress at baseline, following clinical guidelines set by the National Comprehensive Cancer Network with the Distress Thermometer screen, to mitigate the “floor” effects that may impact ability to detect significant treatment effects (Linden & Satin, 2007; Henderson et al., 2012). Psychosocial interventions may be most beneficial for individuals diagnosed with cancer who are experiencing elevated distress (Schneider, Moyer, Knapp-Oliver, Sohl, Cannella et al., 2010), as the intent of the MBCR online intervention was to treat existing distress, rather than prevent distress from occurring. While many researchers recommend including only distressed participants in clinical

trials, in practice this eliminates approximately 70% of otherwise eligible participants, and is not always practical within the constraints of clinical research. That we managed to reach our target recruitment numbers within the scheduled timeframe of the study is a significant strength of this work, and testament to the possibility of using this more rigorous approach in other studies.

While this is a substantial strength, in order to increase generalizability to a broader population of individuals living with cancer, future trials may benefit from inclusion of both distressed and non-distressed participants, as they may still experience potential benefits of enhancing personal growth and spirituality.

An added strength is that we recruited a relatively heterogeneous sample, which increases generalizability. Although a third of participants in this study had been diagnosed with breast cancer, or had stage one disease, the sample also included a substantial portion of men, participants with a variety of other cancer types, included all stages of cancer within three years post primary cancer treatment. Furthermore, there was a range of ages which allowed the exploratory analyses of younger and older participants to be conducted.

As discussed in chapter two of this document, adverse events were monitored throughout the trial through homework log recordings as well as the facilitator asking participants at the beginning of each class regarding their experiences. This is a strength as often trials do not explicitly monitor or report adverse events in the mindfulness literature. No adverse events were reported during the course of the eCALM trial. If an adverse event would have occurred, the trial supervisor was to be notified immediately to follow up directly with the participant to recommend additional resources as needed. If

there would have been immediate concern of harm, participants were instructed to call emergency services.

Addressing Issues of Access

The eCALM Trial attempted to target individuals diagnosed and living with cancer in Alberta who were outside the cancer treatment centre in Calgary, Alberta, where the F2F MBCR programs are offered, or were unable to attend the in-person programs due to transportation issues or illness related symptoms. This goal to target a subset of the population where it is difficult to get such services is a worthy endeavor in our province. In 2011, a pan Canadian guide was released reviewing survivorship services offered to adults (Howell et al., 2011). Recommendations emphasized the need for provision of psychological and supportive care services—not limited to specialist cancer care settings—and called for further research into underserved patient populations in Canada as their specific needs and support requirements could not be included in the review due to lack of data on this vulnerable population (Howell, et al., 2011).

Geographic location has been identified as one factor in limiting access to cancer care services (Maddison, Asada, & Urquhart, 2011), and synchronous online interventions remove that barrier for people, as individuals can access the online MBCR course wherever they have access to the Internet. While high-speed internet is not available equally at this time for all Albertans, it is estimated over two thirds of the Canadian population in rural areas or smaller towns have access, and this number is expected to continue to increase over time. Participants in our trial commonly accessed the Internet from their home computers, however some participants participated from their workplace computers depending on scheduling, high-speed internet access and

preference. This format of intervention greatly increases the flexibility that participants have to choose participation location, something that in-person groups cannot accommodate. By targeting distressed individuals that did not have access to the in-person MBCR programs, we were able to expand the reach of traditional MBCR to those who were motivated to participate but previously were unable to do so through traditional in-person formats.

Challenges and Limitations of the Current Work

Control Condition

The eCALM trial utilized a randomized TAU wait-list control condition, and as such is subject to the criticisms that apply more generally to the body of wait-list controlled MBI research, both in F2F and online formats (MacCoon, Imel, Rosenkranz, Sheftel, Weng et al., 2012; Gotink et al., 2015; Goyal et al., 2014; Piet et al., 2012). These include lack of blinding as well as lack of allocation concealment. Further discussion of the limitations of a TAU wait-list control are provided below.

The primary purpose of this trial was to assess feasibility, therefore we deemed it premature to directly compare online MBCR to an active treatment condition, prior to any feasibility trials reported. Although it may have been desirable, we were unable to compare the online program to a F2F group as one of the inclusion criteria was that participants did not have access to or were unable to attend F2F groups, which are only offered in one city in our province. Due to the nature of the intervention, participants were not masked to the intervention, and were aware when they were in the active treatment condition once randomization and baseline assessments were completed. Unblinded treatments introduce risk of bias through participants' attitudes as potential

placebo effects in the intervention groups, or potential “frustrebo response” or frustration/disappointment in the control group for not receiving the mindfulness intervention immediately (Power & Hopayian, 2011; Gotink et al., 2015).

A potential threat to the validity of the comparison is the possibility that expectations of improvement may differ between the treatment and control group, as the control group is aware they are waiting and may have less reason to expect positive change. Conversely, possible underestimation of effects due to contamination of the control group may occur if participants, while waiting, engage in practicing mindfulness or gather mindfulness resources/information. Research participants were informed they could not take an in-person MBCR course while waiting, however informal mindfulness research or practice was not tracked or discouraged. Additionally, the “post” assessment for the TAU wait-list group occurred right before they were finally going to get the intervention, so increases in their scores from baseline may be due to a positive anticipatory state.

Mohr, Spring, Freedland, Beckner, Arean et al., (2009) describe options for control conditions, including specific (such as additive or dismantling designs) and non-specific (such as attention/amount of contact, clinician empathy, social support or interaction between group members) that need to be considered when developing a control condition for RCTs (Mohr et al., 2009). To investigate the efficacy of online MBCR’s “active” components requires a comparison of online MBCR to an active control that mirrors MBCR in non-specific factors (e.g., structure, time, group interaction, receiving attention) but does not contain mindfulness in the intervention (MacCoon et al., 2012). An in-person active control condition designed to

test the specific effects of MBSR was developed and termed the Health Enhancement Program (HEP; MacCoon, Sullivan, Davidson, Stoney, Young, Thurlow, et al., 2011; MacCoon et al., 2012). MBSR and HEP were created to be structurally equivalent groups with the same class schedule, amount of class time including an all-day retreat, qualified experts who conducted the interventions, equivalent type and amount of practice and homework assigned, and encouragement to engage in experiential and didactic experiences. Rather than mindfulness, HEP involves participants engaging in aerobic exercise (such as walking), functional movements, music therapy and nutritional didactics (MacCoon et al., 2011).

This type of active control condition allows comparisons between in-person groups, however questions remain as to what would constitute a possible active control condition for an online synchronous mindfulness program. To date, non-specific control conditions are utilized in online interventions trials, and online discussion forums have been proposed as an adequate active control condition for asynchronous internet-based interventions as they can control for computer time and online discussion (Andersson et al., 2011; Andersson et al., 2012; Carlbring et al., 2011). Development of an online synchronous active control condition for MBCR is warranted for development, and could potentially parallel the HEP program but be adapted to online teaching.

Follow-Up Assessment

The eCALM Trial adds to the growing body of literature that synchronous online interventions are feasible, and that MBCR can have salutary effects on general measures of cancer-related distress, however without additional follow-up assessment, investigation into the observed changes beyond completion of the program is not

possible. This represents a particularly important design characteristic for future trials and efforts should be made to include additional post-treatment assessments in trials of online MBCR. Online MBCR trials may benefit from continuing to distribute assessment measures for extended longer-term follow-up time points through online protected portals to reduce burden to participants, as well as provide electronic reminders to complete follow-up assessments.

Ljotsson and colleagues from Sweden published data supporting treatment gains were maintained for internet-delivered CBT that included both systematic exposure and mindfulness components 15-18 months post treatment for IBS (Ljotsson et al., 2011c). Such results are encouraging for the potential for longer lasting effects of internet-delivered MBIs, and merit further follow-up assessments to be added to future online MBCR trials.

An important consideration for designing trials with longer follow-up assessments would be to include assessment or tracking of home practice after the MBCR course has ended to evaluate if continued mindfulness meditation practice influences follow-up assessment outcomes. The impact of electronic practice reminders, or even investigation of the impact of “booster” or online “drop-in” sessions, or potentially providing long term access to an online discussion forums to support practice continuation after the online course would be a direction for future research.

Formal Measure of Treatment Fidelity

The eCALM trial followed the semi-manualized MBCR treatment protocol, the facilitator had extensive training in MBSR, was specially trained in the MBCR adaptation for a cancer population, and monitoring of treatment implementation was conducted

through review of weekly recorded videos to ensure agenda topics and mindfulness exercises were completed each week. However no formal evaluation form was used to provide a “check-list” style quantified evaluation report to formally assess treatment fidelity. As with in-person MBCR groups, there was variability in length of group discussions between different courses on varying topics, as well as from class to class. Furthermore, level of participant engagement in group discussions or sharing of personal mindfulness homework successes or challenges varied.

As originally designed, MBSR and MBCR programs attempt to avoid “cookie cutter” provision of mindfulness-based interventions; instead the focus is on a patient-centered, systematic, group approach (Kabat-Zinn, 1996; Dobkin et al., 2014). Therefore MBCR is manualized but not scripted, varying based on the needs of the participants which is a strength of the intervention. However this creates challenge for scientific evaluation and quantified comparison. McCown, Reibel, & Micozzi (2010) emphasize the important role of the mindfulness instructor to guide delivery of didactic course content, formal and informal group experiences, and to embody mindful inquiry into participants’ lived experiences with the intervention—highlighting the patient-centered nature of the intervention (McCown, Reibel & Micozzi, 2010), which requires the flexibility and skill to adjust to group and individual participants’ needs.

As an example, one particular group member during the MBCR course received news that their cancer had progressed, and was given a shortened time to live, which was shared with the instructor and group. The agenda items were still completed in this particular class, however, the feelings, emotions and depth of discussion differed greatly compared to even an early class within this same cohort. In the nature of a truly patient-

centered treatment, the needs of this participant were addressed in the moment in a supportive, warm, empathic and mindful way.

The available data collected from the eCALM trial does not quantify or evaluate these differences in non-specific effects across groups or cohorts. Online MBCR utilized a synchronous format to allow for supportive interaction between group members in terms of the meditation practice and application of mindfulness in daily activities. Findings from qualitative analyses of in-person MBCR suggest that group support and cohesion are important components of the in-person intervention (Mackenzie et al., 2007; Imel, Baldwin, Bonus & MacCoon, 2008). Future research is needed to unpack some of the aspects of the group that may enhance or stifle the learning of mindfulness skills, and conducting post online MBCR qualitative interviews may be a possible method to better explore such impacts of the intervention rather than fully focus on quantitative analysis.

Self-Report Data

Self-report data was used to screen for inclusion/exclusion into the study, with participants self-reporting concurrent psychosis, bipolar disorder, substance abuse or suicidality, which is not equivalent to clinician diagnosis or formal diagnostic screening/interviews at the time of entering the trial. We did not exclude participants based on self-reported anxiety, adjustment, or depressive disorders. Nonetheless, relying on self-report is a limitation of the trial.

Additionally, all data collected was obtained through online participant self-report. While the risk of social desirability bias may be lessened by the privacy of the online process, as with all self-report it cannot be eliminated. To partially mitigate this bias, participants were reminded of the confidentiality of their responses to the online

questionnaires. Participants were also reminded again that the group facilitator would remain completely blind to this data, as participants developed alliance and rapport with the instructor throughout the course, potentially influencing response demand biases. The online questionnaire format may potentially have allowed participants to feel less demand to fill out the questions in a socially desirable manner, as they did not have to meet in-person with research coordinators to return their questionnaires, and submitted them electronically. To supplement self-report symptom measure data, future research could consider paralleling F2F MBSR biological investigations in cancer populations such as assessing autonomic system function such as gathering resting blood pressure and heart rate data (Carlson et al., 2007; Campbell, Labelle, Bacon, Faris, & Carlson, 2012) or biomarkers such as salivary cortisol (Carlson, Speca, Patel, & Goodey, 2004).

Additional questions remain in the literature as to whether participants can accurately recollect and report personal change in skills or levels of mindfulness, posttraumatic growth or spirituality, and more broadly there is debate regarding what constitutes “mindfulness” altogether. Further discussion of this ongoing debate is included in the future research directions section.

Previous meditation and yoga practice or experience was collected through self-report during participant screening, however this was not examined within the scope of this dissertation, and is a limitation of this research.

Directions for Future Research

In addition to the previously discussed future recommendations of employing a larger randomized active control design, follow-up assessments post-intervention with record of ongoing skill practice, and adding outcome measures that do not solely rely on

self-report data, several additional broader considerations regarding future directions could be considered.

Component-Controlled Trials

As previously discussed, active control conditions such as the HEP program adapted for an online synchronous format warrant future development and assessment, however, in addition to comparing online MBCR to an active control, component-controlled or “dismantling” designs can permit additional research into potential mechanisms of action for online MBCR.

As previously described in chapter one of this document, a research group from Sweden conducted a component-controlled randomized trial to investigate whether exposure had specific incremental benefits in a multi-component asynchronous online treatment for IBS (Ljotsson et al., 2014). Authors compared two versions of the program, one with the exposure component and one without, while matching all other program differences, to assess the impact of exposure in the online intervention. Authors contend exposure produced added symptomatic relief, stating exposure facilitated incremental improvement of IBS symptoms compared to the treatment package that did not include exposure (Ljotsson et al., 2014). Future research utilizing these types of component controlled designs specifically targeting proposed mechanisms of change in online mindfulness interventions will facilitate gradually disentangling what are the essential components to online mindfulness programs to increase efficiency and guide adaptations. Evaluation of the proposed mechanisms of action or “active” elements driving change in online MBCR through dismantling designs are merited, as well as investigating unanswered questions to date in the field related to what “dose” of online MBCR is

required to receive the beneficial effects, as well as when these improvements are expected to take place during the program. Such data will inform future adaptations of the program to ensure participants are completing an adequate dose while not overburdening individuals living with cancer.

Economic Evaluations

With chronic disease costs in Canada rising, group interventions, such as MBCR, have the advantage of reaching more people with less resource allocation compared to individual interventions. It is reasonable to consider the possibility that a stress reduction program with demonstrated efficacy for improving both physical and psychological health in various mental and physical health populations, could result in decreased utilization of health care resources. Therefore, an emerging area of research with group in-person mindfulness interventions is cost-effectiveness analysis. Recently, an Ontario-based research group conducted a large ($N = 1730$) prospective study of meditation novices to assess if a 10-week MBSR program impacted outpatient physician/lab resource utilization for participants over a one and two year pre-post observation (Knight, Bean, Wilton & Yin, 2015). MBSR participants were compared to control groups who did not engage in other active interventions, but were intended to control for other factors such as age, sex, geographic location, and socioeconomic status variables. Results indicated MBSR decreased outpatient health care utilization of physician and lab services one year post intervention, but this difference was not maintained at two year follow-up. Two significant limitation to this ambitious prospective trial are that authors did not track continued practice post 10-week course which may have impacted follow-up results, and no outcome measure of perceived stress was included. The authors state that future

research would benefit from prospective investigation into how much mindfulness meditation practice is necessary to establish a level of perceived stress that may conceivably result in decreased health care utilization (Knight et al., 2015). There is potential for future research to not only continue to explore cost effectiveness of in-person MBSR programs in healthy and chronic illness populations such as cancer, but to also extend economic evaluations to online formats of MBCR.

Investigation into Group Factors

As MBCR is a group intervention, and the course encourages discussion between group members focused on weekly meditation practice and application of mindfulness skills in daily activities, group cohesion would be an interesting aspect to measure in future online MBCR trials. For in-person mindfulness programs, “non-mindfulness” or “non-specific” factors, such as contact with a warm, empathic group facilitator, or sharing with fellow participants may stimulate therapeutic changes in F2F mindfulness programs (Baer et al., 2012). As previously noted, one avenue to explore such potentially enhancing or limiting factors would be to conduct qualitative interviews. Results from F2F MBSR and MBCR interventions within cancer settings indicate group support and group cohesion are important to participants (Dobkin, 2008; Mackenzie et al., 2007; Imel et al., 2008), however the impact of the online format and technology on group cohesion in online MBCR is unknown, and merits future investigation.

While the intervention was an online support group rather than a mindfulness program, Stephen and colleagues conducted qualitative theme analyses within a text-based format for people living with cancer, and one theme directly related to the importance of the emotional bond that developed within the online groups, as well as a

feeling of comfort and ease of accessing such support from their own homes (Stephen et al., 2014). Combining reported themes in the F2F MBCR literature with the online support group qualitative research may provide direction to develop qualitative interview questions for future study. While many factors could be assessed post-online MBCR intervention, other possible pre-intervention “non-mindfulness” factors that may also be important to assess such as participants’ expectations of change with the intervention, their motivation to change, or reason for participating, and perceived importance of the group as a therapeutic factor (Imel et al., 2008; Malpass et al., 2011).

Investigation into Individual Participant Characteristics

Time since diagnosis as well as cancer treatment status would be important factors to gather for group comparisons, as well as to record specific reasons as to why access to in-person groups was not possible (e.g., location, transportation issues, scheduling, illness-related factors etc) to strengthen the case for improved access.

According to population statistics, the vast majority (89%) of Canadians who develop cancer are over the age of 50 (Canadian Cancer Statistics, 2015), and participants in the eCALM trial ranged in age from 29 - 79 years (mean 58 years). The age span of participants who were interested in, completed, and benefited from the online MBCR intervention showcases online interventions are feasible for a wide range of ages. However, an important direction for future work is to assess if there are unique barriers to online participation in individuals diagnosed with cancer over the age of 50, as they create the majority of people diagnosed with cancer.

Future studies could also consider whether individual characteristics of participants, such as personality factors or interest/familiarity with either complementary

therapies or online media moderate the impact of online MBCR on symptom measure outcomes, or impact participation or retention in the trial. Recently, it was reported that in-person MBCR participants with higher scores of neuroticism attended more in-person MBCR classes, while participants with higher defensiveness scores attended fewer classes (Tamagawa et al., 2015). An important future research focus will be to not only determine whether online MBCR is effective, as was the focus of this eCALM trial, but to extend to how online MBCR is effective, and for whom online MBCR is most effective (Shapiro et al., 2011, Labelle et al., 2015).

Measuring Mindfulness

As mentioned in the limitations section, the majority of in-person and online MBSR/MBCR trials to date have utilized self-report questionnaires to assess psychological constructs, including mindfulness. Debate in the literature exists regarding whether the construct of mindfulness can be validly assessed through currently developed self-report mindfulness questionnaires. One argument is that mindfulness scale items may have different meanings for experienced vs. unexperienced meditators, and this could impact the validity of these measures, and that rather than “mindfulness” being measured, perceptions of change are actually measured with self-report scales rather than actual mechanisms of change (Grossman & Van Dam, 2011). Grossman and Van Dam posit an alternative to using current self-report mindfulness measures could be to ask participants to assess the extent to which they value specific qualities or behaviours rather than ask participants to assess how much they think they have improved in mindfulness skills. Additional research is needed to investigate whether current self-report questionnaires of “mindfulness” measure aspects of mindfulness practice, preconditions or consequences of

mindfulness practice (Coffey et al., 2010). Mindfulness-Based Cancer Recovery mechanisms research may be limited by the lack of clarity in the measurement of mindfulness (e.g., Grossman & Van Dam, 2011), however on the other side of this argument, there is data to support current mindfulness scales show good internal consistency, test-retest reliability, and correlate in expected directions with psychological variables in both experienced and unexperienced meditators (e.g., Baer et al., 2006; Brown, Ryan, Loverich, Biegel & West, 2011; Quaglia et al., 2015). An important argument for self-report measures of mindfulness is that they are an important means to allow for research into statistical models of meditation, to attempt to clarify whether the development of mindfulness (as measured by these scales validly, even if imperfectly) actually leads to the beneficial changes for people who practice these mindfulness-based interventions (Baer et al., 2006; Brown & Ryan, 2003; Coffey et al., 2010; Shapiro et al., 2006). Efforts to integrate self-report mindfulness questionnaire data with qualitative interviews and physiological measures may clarify psychological and physiological mechanisms of mindfulness, and mindfulness-based interventions such as MBCR (Garland & Gaylord, 2009; Shapiro et al., 2006; Labelle et al., 2015). Developing technology, such as Ecological Momentary Assessment (EMA), typically recorded through mobile electronic devices (e.g., cellular telephones), may also provide a platform for collecting “in the moment” data that does not require lengthy retrospection as well facilitating the investigation of how mindful states relate to real-world environmental contexts and behaviours (Hill & Updegraff, 2012; Quaglia et al., 2015).

Conclusion

In summary, this randomized, TAU wait-list controlled trial represents the first study to evaluate an online synchronous adaptation of MBCR to distressed people living with cancer who did not have access or could not attend established in-person programs. The online MBCR program was well received by participants, evidenced by feasibility targets for recruitment and retention achieved, in addition to high ratings of program satisfaction and statements they would recommend the program to other people living with cancer. RCT results indicate reduction in mood disturbance and stress symptoms, as well as an increase in spirituality and mindfully acting with awareness compared to the TAU wait-list control condition. Further, we conducted exploratory analyses of the relative change on mood disturbance and stress symptom subscales, which revealed the online MBCR program was relatively more successful in inducing relaxation and improving energy levels, as well as particularly helpful for younger participants.

The eCALM trial emphasized the feasibility, interest and participant satisfaction of a synchronous MBCR intervention for a proportion of the population in Alberta that does not currently have access to such a program. An online synchronous MBCR intervention expands treatment options, creating a new delivery format to reduce the symptom burden experienced by individuals living with a diagnosis of cancer through the use of sophisticated real-time technology. Furthermore, additional online trials are warranted to compare the MBCR program to an active control condition. Programs using similar synchronous technology could potentially improve access to highly specialized evidence-based psychosocial programs in oncology, and a broader implication for the findings of this dissertation point toward consideration of expanding such formats to

other chronic illness underserved populations, encouraging further research into the integration of mind-body medicine and internet-based treatments.

REFERENCES

- Abbott, R. A., Whear, R., Rodgers, L. R., Bethel, A., Coon, J. T., Kuyken, W., ... & Dickens, C. (2014). Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomized controlled trials. *Journal of Psychosomatic Research, 76*(5), 341-351.
- Anand, J., Srivastava, A., & Dalal, A. K. (2001). Where suffering ends and healing begins. *Psychological Studies, 46*, 114–126.
- Andersson, G., Cuijpers, P., Carlbring, P., Riper, H., & Hedman, E. (2014). Guided Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: a systematic review and meta-analysis. *World Psychiatry, 13*(3), 288-295.
- Andersson, G., & Titov, N. (2014). Advantages and limitations of Internet-based interventions for common mental disorders. *World Psychiatry, 13*(1), 4-11.
- Andrews, G., Cuijpers, P., Craske, M. G., McEvoy, P., & Titov, N. (2010). Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: A meta-analysis. *PloS one, 5*(10), e13196.
- Andrykowski, M. A., & Hunt, J. W. (1993). Positive psychosocial adjustment in potential bone marrow transplant recipients: Cancer as a psychosocial transition. *Psycho-Oncology, 2*(4), 261-276.
- Baer, R. A. (2003). Mindfulness training as a clinical intervention: A conceptual and empirical review. *Clinical Psychology: Science & Practice, 10*, 125-143.
- Baer, R. A., Smith, G. T., & Allen, K. B. (2004). Assessment of mindfulness by self-report the Kentucky inventory of mindfulness skills. *Assessment, 11*(3), 191-206.

- Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment, 13*(1), 27-45.
- Baer, R. A. (2011). Measuring mindfulness. *Contemporary Buddhism, 12*(1), 241-261.
- Baer, R., Carmody, J., & Hunsinger, M. (2012). Weekly change in mindfulness and perceived stress in mindfulness-based stress reduction program. *Journal of Clinical Psychology, 68*(7), 755-765
- Bargh, J. A., & McKenna, K. Y. A. (2004). The Internet and social life. *Annual Review of Psychology, 55*, 573–90.
- Barak, A., Hen, L., Boniel-Nissim, M., & Shapira, N. (2008). A comprehensive review and a meta-analysis of the effectiveness of Internet-based psychotherapeutic interventions. *Journal of Technology in Human Services, 26*, 109-160.
- Barak, A., & Suler, J. (2008). Reflections on the psychology and social science of cyberspace. In A. Barak (Ed.), *Psychological Aspects of Cyberspace: Theory, Research, Applications*. (pp. 1-12). Cambridge, UK: Cambridge University Press.
- Barak, A., Klein, B., & Proudfoot, J. G. (2009). Defining Internet-supported therapeutic interventions. *Annals of Behavioral Medicine, 38*(1), 4-17.
- Barnett, A. G., van der Pols, J. C., & Dobson, A. J. (2005). Regression to the mean: what it is and how to deal with it. *International Journal of Epidemiology, 34*(1), 215-220.
- Bidstrup, P. E., Johansen, C., & Mitchell, A. J. (2011). Screening for cancer-related distress: Summary of evidence from tools to programmes. *Acta Oncologica, 50*(2), 194–204.

- Birnie, K., Garland, S. N., & Carlson, L. E. (2010). Psychological benefits for cancer patients and their partners participating in mindfulness-based stress reduction (MBSR). *Psycho-Oncology, 19*(9), 1004-1009.
- Bishop, S. R. (2002). What do we really know about mindfulness-based stress reduction? *Psychosomatic Medicine, 64*, 71-83.
- Boettcher, J., Astrom, V., Pahlsson, D., Schenstrom, O., Andersson, G., & Carlbring, P. (2014). Internet-based mindfulness treatment for anxiety disorders: A randomized controlled trial. *Behavior Therapy, 45*(2), 241-253.
- Boettcher, J., Carlbring, P., Renneberg, B., & Berger, T. (2013). Internet-based interventions for social anxiety disorder: An overview. *Verhaltenstherapie, 23*(3), 160–168.
- Bohlmeijer, E., Prenger, R., Taal, E., & Cuijpers, P. (2010). The effects of mindfulness-based stress reduction therapy on mental health of adults with a chronic medical disease: a meta-analysis. *Journal of Psychosomatic Research, 68*(6), 539-544.
- Bowlin, S. L., & Baer, R. A. (2012). Relationships between mindfulness, self-control, and psychological functioning. *Personality and Individual Differences, 52*(3), 411-415.
- Brady, M. J., Peterman, A. H., Fitchett, G., Mo, M., & Cella, D. (1999). A case for including spirituality in quality of life measurement in oncology. *Psycho-Oncology, 8*(5), 417-428.
- Branstrom, R., Kvillemo, P., Brandberg, Y., & Moskowitz, J. T. (2010). Self-report mindfulness as a mediator of psychological well-being in a stress reduction

- intervention for cancer patients—A randomized study. *Annals of Behavioral Medicine*, 39(2), 151-161.
- Branstrom, R., Duncan, L. G., & Moskowitz, J. T. (2011). The association between dispositional mindfulness, psychological well-being, and perceived health in a Swedish population-based sample. *British Journal of Health Psychology*, 16(2), 300-316.
- Brennan, J. (2001). Adjustment to cancer – Coping or personal transition? *Psycho-Oncology*, 10, 1-18.
- Brown, K. W., & Ryan, R. M. (2003). The benefits of being present: Mindfulness and its role in psychological well-being. *Journal of Personality and Social Psychology*, 84(4), 822.
- Brown, K. W., & Ryan, R. M. (2004). Perils and promise in defining and measuring mindfulness: Observations from experience. *Clinical Psychology: Science and Practice*, 11(3), 242-248.
- Brown, K. W., Ryan, R. M., & Creswell, J. D. (2007). Mindfulness: Theoretical foundations and evidence for its salutary effects. *Psychological inquiry*, 18(4), 211-237.
- Brown, K. W., Ryan, R. M., Loverich, T. M., Biegel, G. M., & West, A. M. (2011). Out of the armchair and into the streets: Measuring mindfulness advances knowledge and improves interventions: Reply to Grossman (2011). *Psychological Assessment*, 23(4), 1041-1046.
- Bultz, B.D. & Carlson, L.E. (2006). Emotional distress: The 6th vital sign in cancer care. *Psycho-Oncology*, 15, 93-95.

- Campbell, T. S., Labelle, L. E., Bacon, S. L., Faris, P., & Carlson, L. E. (2012). Impact of mindfulness-based stress reduction (MBSR) on attention, rumination and resting blood pressure in women with cancer: a waitlist-controlled study. *Journal of Behavioral Medicine, 35*(3), 262-271.
- Canadian Cancer Society's Advisory Committee on Cancer Statistics (2014). *Canadian Cancer Statistics 2014*. Toronto, ON: Canadian Cancer Society
- Canadian Cancer Society's Advisory Committee on Cancer Statistics (2015). *Canadian Cancer Statistics 2015*. Toronto, ON: Canadian Cancer Society
- Cardaciotto, L., Herbert, J. D., Forman, E. M., Moitra, E., & Farrow, V. (2008). The assessment of present-moment awareness and acceptance: The Philadelphia Mindfulness Scale. *Assessment, 15*, 204-223.
- Cash, M., & Whittingham, K. (2010). What facets of mindfulness contribute to psychological well-being and depressive, anxious, and stress-related symptomatology? *Mindfulness, 1*(3), 177-182.
- Carlson, L. E., Ursuliak, Z., Goodey, E., Angen, M., & Speca, M. (2001). The effects of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients: 6-month follow-up. *Supportive Care in Cancer, 9*, 112-123.
- Carlson, L. E., Bultz, B. D. (2003). Cancer distress screening: Needs, methods and models. *Journal of Psychosomatic Research, 55*, 403-409.
- Carlson, L. E., Speca, M., Patel, K. D., & Goodey, E. (2003). Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress, and immune

parameters in breast and prostate cancer outpatients. *Psychosomatic Medicine*, 65(4), 571-581.

Carlson, L. E., Angen, M., Cullum, J., Goodey, E., Koopmans, J., Lamont, L., et al. (2004). High levels of untreated distress and fatigue in cancer patients. *British Journal of Cancer*, 90(1), 2297-2304.

Carlson, L. E., Speca, M., Patel, K. D., & Goodey, E. (2004). Mindfulness-based stress reduction in relation to quality of life, mood, symptoms of stress and levels of cortisol, dehydroepiandrosterone sulfate (DHEAS) and melatonin in breast and prostate cancer outpatients. *Psychoneuroendocrinology*, 29(4), 448-474.

Carlson, L. E., & Garland, S. N. (2005). Impact of mindfulness-based stress reduction (MBSR) on sleep, mood, stress and fatigue symptoms in cancer outpatients. *International Journal of Behavioral Medicine*, 12(4), 278-285.

Carlson, L. E., & Speca, M. (2007). Managing daily and long-term stress. In *Handbook of cancer survivorship* (pp. 339-360). Springer US.

Carlson, L. E., Speca, M., Faris, P., & Patel, K. D. (2007). One year pre–post intervention follow-up of psychological, immune, endocrine and blood pressure outcomes of mindfulness-based stress reduction (MBSR) in breast and prostate cancer outpatients. *Brain, Behavior, and Immunity*, 21(8), 1038-1049.

Carlson, L. E., & Thomas, B. C. (2007). Development of the Calgary symptoms of stress inventory (CSOSI). *International Journal of Behavioral Medicine*, 14(4), 249-256.

- Carlson, L.E., Labelle, L.E., Garland, S.N., Hutchins, M.L., & Birnie, K. (2009). Mindfulness-based interventions in oncology. In F. Didonna (Ed.), *Clinical handbook of mindfulness* (pp.383–404). New York, NY: Springer.
- Carlson, L. E., & Speca, M. (2010). *Mindfulness-based cancer recovery: A step-by-step MBSR approach to help you cope with treatment and reclaim your life*. Oakland, CA: New Harbinger.
- Carlson, L. E. (2012). Mindfulness-based interventions for physical conditions: A narrative review evaluating levels of evidence. *ISRN Psychiatry*. doi: 10.5402/2012/651583.
- Carlson, L. E., Doll, R., Stephen, J., Faris, P., Tamagawa, R., Drysdale, E., & Speca, M. (2013). Randomized controlled trial of mindfulness-based cancer recovery versus supportive expressive group therapy for distressed survivors of breast cancer (MINDSET). *Journal of Clinical Oncology*, JCO-2012.
- Carlson, L. E., Waller, A., Groff, S. L., Giese-Davis, J., & Bultz, B. D. (2013). What goes up does not always come down: Patterns of distress, physical and psychosocial morbidity in people with cancer over a one year period. *Psycho-Oncology*, 22(1), 168–176.
- Carmody, J., & Baer, R. A. (2009). How long does a mindfulness-based stress reduction program need to be? A review of class contact hours and effect sizes for psychological distress. *Journal of Clinical Psychology*, 65(6), 627-638.
- Carver, C. S., & Antoni, M. H. (2004). Finding benefit in breast cancer during the year after diagnosis predicts better adjustment 5 to 8 years after diagnosis. *Health Psychology*, 23(6), 595-598.

- Cavanagh, K., Strauss, C., Forder, L., & Jones, F. (2014). Can mindfulness and acceptance be learnt by self-help?: A systematic review and meta-analysis of mindfulness and acceptance-based self-help interventions. *Clinical Psychology Review, 34*(2), 118-129.
- Coffey, K. A., Hartman, M., & Fredrickson, B. L. (2010). Deconstructing mindfulness and constructing mental health: Understanding mindfulness and its mechanisms of action. *Mindfulness, 1*(4), 235-253.
- Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, NJ: Lawrence Earlbaum.
- Cordova, M. J., Cunningham, L. L., Carlson, C. R., & Andrykowski, M. A. (2001). Posttraumatic growth following breast cancer: A controlled comparison study. *Health Psychology, 20*(3), 176-185.
- Cotton, S. P., Levine, E. G., Fitzpatrick, C. M., Dold, K. H., & Targ, E. (1999). Exploring the relationships among spiritual well-being, quality of life, and psychological adjustment in women with breast cancer. *Psycho-Oncology, 8*(5), 429-438.
- Coyne, J. C., Lepore, S. J., & Palmer, S. C. (2006). Efficacy of psychosocial interventions in cancer care: Evidence is weaker than it first looks. *Annals of Behavioral Medicine, 32*(2), 104-110.
- Cramer, H., Lauche, R., Paul, A., & Dobos, G. (2012). Mindfulness-based stress reduction for breast cancer—a systematic review and meta-analysis. *Current Oncology, 19*(5), e343.

- Cuijpers, P., van Straten, A., & Andersson, G. (2008). Internet-administered cognitive behavior therapy for health problems: a systematic review. *Journal of Behavioral Medicine, 31*(2), 169-177.
- Cuijpers, P., Marks, I. M., van Straten, A., Cavanagh, K., Gega, L., & Andersson, G. (2009). Computer-aided psychotherapy for anxiety disorders: A meta-analytic review. *Cognitive Behaviour Therapy, 38*(2), 66–82.
- Dattalo P. (2008). *Determining sample size: Balancing power, precision and practicality – Pocket guide to social work research methods*. New York: Oxford University Press.
- Davidson, R. J. (2010). Empirical explorations of mindfulness: conceptual and methodological conundrums. *Emotion, 10*(1), 8-11.
- Deng, G., & Cassileth, B. (2013). Complementary or alternative medicine in cancer care - myths and realities. *Nature Reviews Clinical Oncology, 10*(11), 656-664.
- De Vibe, M., Bjorndal, A., Tipton, E., Hammerstrom, K. T., & Kowalski, K. (2012). Mindfulness based stress reduction (MBSR) for improving health, quality of life, and social functioning in adults. *Campbell Systematic Reviews, 8*(3).
- Dimidjian, S., Beck, A., Felder, J. N., Boggs, J. M., Gallop, R., & Segal, Z. V. (2014). Web-based Mindfulness-Based Cognitive Therapy for reducing residual depressive symptoms: An open trial and quasi-experimental comparison to propensity score matched controls. *Behaviour Research and Therapy, 63*, 83-89.
- Dimitrov, D. M., & Rumrill, P. D. (2003). Pretest-posttest designs and measurement of change. *Work-Andover Medical Publishers Incorporated, 20*(2), 159-165.

- Dobkin, P. L. (2008). Mindfulness-based stress reduction: What processes are at work?. *Complementary Therapies in Clinical Practice, 14*(1), 8-16.
- Dobkin, P. L., & Zhao, Q. (2011). Increased mindfulness—The active component of the mindfulness-based stress reduction program? *Complementary Therapies in Clinical Practice, 17*(1), 22-27.
- Dobkin, P. L., Hickman, S., & Monshat, K. (2014). Holding the heart of mindfulness-based stress reduction: balancing fidelity and imagination when adapting MBSR. *Mindfulness, 5*(6), 710-718.
- Dolbeault, S., Mignot, V., Gauvain-Piquard, A., et al. (2003). Evaluation of psychological distress and quality of life in French cancer patients: validation of the French version of the memorial distress thermometer. *Psycho-Oncology, 12*, S225.
- Dominick, S. A., Natarajan, L., Pierce, J. P., Madanat, H., & Madlensky, L. (2014). The psychosocial impact of lymphedema-related distress among breast cancer survivors in the WHEL Study. *Psycho-Oncology, 23*(9), 1049-1056.
- Everts, F. Z. B., van der Lee, M. L., & de Jager Meezenbroek, E. (2015). Web-based individual Mindfulness-Based Cognitive Therapy for cancer-related fatigue - A pilot study. *Internet Interventions, 2*(2), 200-213.
- Faller, H., Schuler, M., Richard, M., Heckl, U., Weis, J., & Kuffner, 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*(6), 782-793.

- Feldman, G., Hayes, A., Kumar, S., Greeson, J., & Laurenceau, J. P. (2007). Mindfulness and emotion regulation: The development and initial validation of the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R). *Journal of Psychopathology and Behavioral Assessment, 29*(3), 177-190.
- Fortner, B. V., Stepanski, E. J., Wang, S. C., Kasprovicz, S., & Durrence, H. H. (2002). Sleep and quality of life in breast cancer patients. *Journal of Pain and Symptom Management, 24*, 471-480.
- Gardner-Nix, J., Backman, S., Barbati, J., & Grummitt, J. (2008). Evaluating distance education of mindfulness-based meditation program for chronic pain management. *Journal of Telemedicine and Telecare, 14*, 88-92.
- Garland, S. N., Carlson, L. E., Cook, S., Lansdell, L., & Speca, M. (2007). A non-randomized comparison of mindfulness-based stress reduction and healing arts programs for facilitating post-traumatic growth and spirituality in cancer outpatients. *Supportive Care in Cancer, 15*(8), 949-961.
- Garland, S. N., Tamagawa, R., Todd, S. C., Speca, M., & Carlson, L. E. (2013). Increased mindfulness is related to improved stress and mood following participation in a mindfulness-based stress reduction program in individuals with cancer. *Integrative Cancer Therapies, 12*(1), 31-40.
- Garland, S. N., Carlson, L. E., Stephens, A. J., Antle, M. C., Samuels, C., & Campbell, T. S. (2014). Mindfulness-based stress reduction compared with cognitive behavioral therapy for the treatment of insomnia comorbid with cancer: A randomized, partially blinded, noninferiority trial. *Journal of Clinical Oncology, JCO-2012*.

- Gluck, T. M., & Maercker, A. (2011). A randomized controlled pilot study of a brief web-based mindfulness training. *BMC Psychiatry, 11*(1), 175.
- Gonzalez-Angulo, A. M., Hennessy, B. T., & Mills, G. B. (2010). Future of personalized medicine in oncology: A systems biology approach. *Journal of Clinical Oncology, 28*, 2777–2783.
- Gotink, R. A., Chu, P., Busschbach, J. J., Benson, H., Fricchione, G. L., & Hunink, M. M. (2015). Standardised mindfulness-based interventions in healthcare: An overview of systematic reviews and meta-analyses of RCTs. *PloS One, 10*(4).
- Goyal, M., Singh, S., Sibinga, E. M., Gould, N. F., Rowland-Seymour, A., Sharma, R., ... & Haythornthwaite, J. A. (2014). Meditation programs for psychological stress and well-being: a systematic review and meta-analysis. *JAMA internal medicine, 174*(3), 357-368.
- Greene, P. B., Philip, E. J., Poppito, S. R., & Schnur, J. B. (2012). Mindfulness and psychosocial care in cancer: Historical context and review of current and potential applications. *Palliative and Supportive Care, 10*(04), 287-294.
- Griffiths, K. M., & Christensen, H. (2007). Internet-based mental health programs: A powerful tool in the rural medical kit. *Australian Journal of Rural Health, 15*(2), 81-87.
- Grossman, P., Niemann, L., Schmidt, S., & Walach, H. (2004). Mindfulness-based stress reduction and health benefits: A meta-analysis. *Journal of Psychosomatic Research, 57*, 35-43.

- Grossman, P. (2011). Defining mindfulness by how poorly I think I pay attention during everyday awareness and other intractable problems for psychology's (re) invention of mindfulness: Comment on Brown et al. (2011).
- Grossman, P., & Van Dam, N. T. (2011). Mindfulness, by any other name...: trials and tribulations of sati in western psychology and science. *Contemporary Buddhism, 12*(01), 219-239.
- Heck, R. H., Thomas, S. L., & Tabata, L. N. (2011). *Multilevel and longitudinal modeling with IBM SPSS*. Routledge Taylor & Francis Group: NY, London.
- Henderson, V. P., Clemow, L., Massion, A. O., Hurley, T. G., Druker, S., & Hebert, J. R. (2012). The effects of mindfulness-based stress reduction on psychosocial outcomes and quality of life in early-stage breast cancer patients: a randomized trial. *Breast Cancer Research and Treatment, 131*(1), 99-109.
- Henoch, I., & Danielson, E. (2009). Existential concerns among patients with cancer and interventions to meet them: an integrative literature review. *Psycho-Oncology, 18*(3), 225-236.
- Hill, C. L. M., & Updegraff, J. A. (2012). Mindfulness and its relationship to emotional regulation. *Emotion, 12*(1), 81-90.
- Hoffman, C. J., Ersser, S. J., Hopkinson, J. B., Nicholls, P. G., Harrington, J. E., & Thomas, P. W. (2012). Effectiveness of mindfulness-based stress reduction in mood, breast-and endocrine-related quality of life, and well-being in stage 0 to III breast cancer: a randomized, controlled trial. *Journal of Clinical Oncology, 30*(12), 1335-1342.

- Hofmann, S. G., Sawyer, A. T., Witt, A. A., & Oh, D. (2010). The effect of mindfulness-based therapy on anxiety and depression: A meta-analytic review. *Journal of Consulting and Clinical Psychology, 78*(2), 169.
- Holland, J. C., Andersen, B., Breitbart, W. S., Buchmann, L. O., Compas, B., Deshields, T. L., ... & Freedman-Cass, D. A. (2013). Distress management. *Journal of the National Comprehensive Cancer Network, 11*(2), 190-209.
- Howell, D., Hack, T. F., Oliver, T. K., Chulak, T., Mayo, S., Aubin, M., ... & Sinclair, S. (2011). Survivorship services for adult cancer populations: a pan-Canadian guideline. *Current Oncology, 18*(6), e265-e281. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/22184494>.
- Huang, H. P., He, M., Wang, H. Y., & Zhou, M. (2015). A meta-analysis of the benefits of mindfulness-based stress reduction (MBSR) on psychological function among breast cancer (BC) survivors. *Breast Cancer, 1*-9.
- Imel, Z., Baldwin, S., Bonus, K., & MacCoon, D. (2008). Beyond the individual: Group effects in mindfulness-based stress reduction. *Psychotherapy Research, 18*(6), 735-742.
- Internet World Stats. Miniwatts Marketing Group. Accessed 2015 May 16. Internet Usage Statistics: The Internet Big Picture: World Internet Users and Population Stats URL: <http://www.internetworldstats.com/stats.htm>
- Jacobsen, P. B., Donovan, K. A., Trask, P. C., Fleishman, S. B., Zabora, J., Baker, F., & Holland, J. C. (2005). Screening for psychologic distress in ambulatory cancer patients. *Cancer, 103*(7), 1494-1502.

- Jain, S., Shapiro, S. L., Swanick, S., Roesch, S. C., Mills, P. J., Bell, I., & Schwartz, G. E. (2007). A randomized controlled trial of mindfulness meditation versus relaxation training: Effects on distress, positive states of mind, rumination, and distraction. *Annals of Behavioral Medicine, 33*(1), 11-21.
- Johansson, B., Bjuhr, H., Karlsson, M., Karlsson, J. O., & Ronnbock, L. (2015). Mindfulness-Based Stress Reduction (MBSR) Delivered Live on the Internet to Individuals Suffering from Mental Fatigue After an Acquired Brain Injury. *Mindfulness, 1-10*.
- Kabat-Zinn, J. (1982). An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: Theoretical considerations and preliminary results. *General Hospital Psychiatry, 4*(1), 33-47.
- Kabat-Zinn, J. (1990). *Full catastrophe living: Using the wisdom of your body and mind to face stress, pain and illness*. New York: Delacourt.
- Kabat-Zinn, J. (1994). *Wherever you go, there you are: Mindfulness meditation in everyday life*. New York, NY: Hyperion.
- Kabat-Zinn, J. (1996). Mindfulness meditation: What it is, what it isn't, and its role in health care and medicine. In Y. Haruki & M. Suzuki (Eds.), *Comparative and psychological study on meditation* (pp. 161–170). Delft, Netherlands: Eburon Publishers.
- Kabat-Zinn, J. (2003). Mindfulness-based interventions in context: Past, present, and future. *Clinical Psychology: Science & Practice, 10*, 144-156.

- Kangas, M., Henry, J., & Bryant, R. (2005). The relationship between acute stress disorder and posttraumatic stress disorder following cancer. *Journal of Consulting and Clinical Psychology, 73*, 360–364.
- Kash, K. M., Mago, R., & Kunkel, E. J. (2005). Psychosocial oncology: supportive care for the cancer patient. *Seminars in Oncology, 32*(2), 211-218.
- Katz, S. J., Lantz, P. M., & Zemencuk, J. K. (2001). Correlates of surgical treatment type for women with noninvasive and invasive breast cancer. *Journal of Women's Health & Gender-Based Medicine, 10*(7), 659-670.
- Khoury, B., Lecomte, T., Fortin, G., Masse, M., Therien, P., Bouchard, V., ... & Hofmann, S. G. (2013). Mindfulness-based therapy: A comprehensive meta-analysis. *Clinical Psychology Review, 33*(6), 763-771.
- Kissane, D. W., Grabsch, B., Love, A., Clarke, D. M., Bloch, S., & Smith, G. C. (2004). Psychiatric disorder in women with early stage and advanced breast cancer: A comparative analysis. *The Australian and New Zealand Journal of Psychiatry, 38*(5), 320-326.
- Knight, R. W., Bean, J., Wilton, A. S., & Lin, E. (2015). Cost-Effectiveness of the Mindfulness-Based Stress Reduction Methodology. *Mindfulness, 1*-8.
- Krupski, T. L., Kwan, L., Fink, A., Sonn, G. A., Maliski, S., & Litwin, M. S. (2006). Spirituality influences health related quality of life in men with prostate cancer. *Psycho-Oncology, 15*(2), 121-131.
- Krusche, A., Cyhlarova, E., King, S., & Williams, J. M. G. (2012). Mindfulness online: a preliminary evaluation of the feasibility of a web-based mindfulness course and the impact on stress. *BMJ Open, 2*(3), e000803.

- Labelle, L. E., Campbell, T. S., & Carlson, L. E. (2010). Mindfulness-based stress reduction in oncology: Evaluating mindfulness and rumination as mediators of change in depressive symptoms. *Mindfulness, 1*(1), 28-40.
- Labelle, L. E. (2012). *How does mindfulness-based stress reduction (MBSR) improve psychological functioning in cancer patients* [Doctoral dissertation, doctoral thesis] University of Calgary, Calgary, Alberta, Canada).
- Labelle, L., Campbell, T., Faris, P., & Carlson, L. (2015). Mediators of mindfulness-based stress reduction (MBSR): Assessing the timing and sequence of change in cancer patients. *Journal of Clinical Psychology, 71*(1), 21-40.
- Labelle, L., Lawlor-Savage, L., Campbell, T., Faris, P., & Carlson, L. (2015). Does self-report mindfulness mediate the effect of mindfulness-based stress reduction (MBSR) on spirituality and posttraumatic growth in cancer patients? *The Journal of Positive Psychology, 10*(2), 153-166.
- Lakhan, S. E., & Schofield, K. L. (2013). Mindfulness-based therapies in the treatment of somatization disorders: a systematic review and meta-analysis. *PloS One, 8*(8), e71834.
- Lam, W. W. T., Soong, I., Yau, T. K., Wong, K. Y., Tsang, J., Yeo, W., ... & Fielding, R. (2013). The evolution of psychological distress trajectories in women diagnosed with advanced breast cancer: a longitudinal study. *Psycho-Oncology, 22*(12), 2831-2839.
- Lamanque, P., & Daneault, S. (2006). Does meditation improve the quality of life for patients living with cancer? *Canadian Family Physician, 52*(4), 474-475.

- Lange, A., Schrieken, B., van de Ven, J., Bredeweg, B., Emmelkamp P.M.G., van der Kolk, J., et al. (2000). Interapy: the effects of a short protocolled treatment of posttraumatic stress and pathological grief through the Internet. *Behavioural and Cognitive Psychotherapy*, *28*, 175–192.
- Lau, M. A., Bishop, S. R., Segal, Z. V., Buis, T., Anderson, N. D., Carlson, L., ... & Devins, G. (2006). The Toronto mindfulness scale: Development and validation. *Journal of Clinical Psychology*, *62*(12), 1445-1468.
- Lauche, R., Cramer, H., Dobos, G., Langhorst, J., & Schmidt, S. (2013). A systematic review and meta-analysis of mindfulness-based stress reduction for the fibromyalgia syndrome. *Journal of Psychosomatic Research*, *75*(6), 500-510.
- Lawrence, M., Booth, J., Mercer, S., & Crawford, E. (2013). A systematic review of the benefits of mindfulness-based interventions following transient ischemic attack and stroke. *International Journal of Stroke*, *8*(6), 465-474.
- Lechner, S. C., & Antoni, M. H. (2004). Posttraumatic growth and group-based interventions for persons dealing with cancer: What have we learned so far? *Psychological Inquiry*, *15*, 35-41.
- Lechner, S.C., Stoelb, B. L., Antoni, M.H. (2008) Group-based therapies for benefit finding in cancer. In S. Joseph and A.P. Linley (Eds.) *Trauma, recovery, and growth: Positive psychological perspectives on posttraumatic stress*. Hoboken, NJ. 207-231.
- Ledesma D, & Kumano H. (2009). Mindfulness-based stress reduction and cancer: A meta-analysis. *Psycho-Oncology*, *18*, 571–579.

- Lengacher, C. A., Johnson-Mallard, V., Post-White, J., Moscoso, 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), 1261-1272.
- Lengacher, C. A., Kip, K. E., Post-White, J., Fitzgerald, S., Newton, C., Barta, M., ... & Klein, T. W. (2011). Lymphocyte recovery after breast cancer treatment and mindfulness-based stress reduction (MBSR) therapy. *Biological Research for Nursing*, 1099800411419245.
- Lerman, R., Jarski, R., Rea, H., Gellish, R., & Vicini, F. (2012). Improving symptoms and quality of life of female cancer survivors: a randomized controlled study. *Annals of Surgical Oncology*, *19*(2), 373-378.
- Leykin, Y., Thekdi, S. M., Shumay, D. M., Muñoz, R. F., Riba, M., & Dunn, L. B. (2012). Internet interventions for improving psychological well-being in psycho-oncology: review and recommendations. *Psycho-Oncology*, *21*(9), 1016-1025.
- Lieberman, M. A., Golant, M., Giese-Davis, J., Winzlenberg, A., Benjamin, H., Humphreys, K. et al. (2003). Electronic support groups for breast carcinoma: A clinical trial of effectiveness. *Cancer*, *97*, 920-925.
- Linden, W., & Satin, J. R. (2007). Avoidable pitfalls in behavioral medicine outcome research. *Annals of Behavioral Medicine*, *33*(2), 143-147.
- Linley, P. A., & Joseph, S. (2004). Positive change following trauma and adversity: A review. *Journal of Traumatic Stress*, *17*(1), 11-21.
- Ljotsson, B., Falk, L., Vesterlund, A. W., Hedman, E., Lindfors, P., Ruck, C., ... & Andersson, G. (2010). Internet-delivered exposure and mindfulness based therapy

for irritable bowel syndrome—a randomized controlled trial. *Behaviour Research and Therapy*, 48(6), 531-539.

Ljotsson, B., Andersson, G., Andersson, E., Hedman, E., Lindfors, P., Andréewitch, S., ... & Lindefors, N. (2011a). Acceptability, effectiveness, and cost-effectiveness of internet-based exposure treatment for irritable bowel syndrome in a clinical sample: a randomized controlled trial. *BMC Gastroenterology*, 11(1), 110.

Ljotsson, B., Hedman, E., Andersson, E., Hesser, H., Lindfors, P., Hursti, T., ... & Andersson, G. (2011b). Internet-delivered exposure-based treatment vs. stress management for irritable bowel syndrome: a randomized trial. *The American Journal of Gastroenterology*, 106(8), 1481-1491.

Ljotsson, B., Hedman, E., Lindfors, P., Hursti, T., Lindefors, N., Andersson, G., & Ruck, C. (2011c). Long-term follow-up of internet-delivered exposure and mindfulness based treatment for irritable bowel syndrome. *Behaviour Research and Therapy*, 49(1), 58-61.

Ljotsson, B., Hesser, H., Andersson, E., Lackner, J. M., El Alaoui, S., Falk, L., ... & Hedman, E. (2014). Provoking symptoms to relieve symptoms: A randomized controlled dismantling study of exposure therapy in irritable bowel syndrome. *Behaviour Research and Therapy*, 55, 27-39.

Lounsberry, J. J., MacRae, H., Angen, M., Hoerber, M., & Carlson, L. E. (2010). Feasibility study of a telehealth delivered, psychoeducational support group for allogeneic hematopoietic stem cell transplant patients. *Psycho-Oncology*, 19(7), 777-781.

- Ludwig, D. S., & Kabat-Zinn, J. (2008). Mindfulness in medicine. *JAMA*, *300*(11), 1350-1352.
- Mackenzie, M. J., Carlson, L. E., & Speca, M. (2005). Mindfulness-based stress reduction (MBSR) in oncology: Rationale and review. *Evidence-Based Integrative Medicine*, *2*(3), 139-145.
- Mackenzie, M. J., Carlson, L. E., Munoz, M., & Speca, M. (2007). A qualitative study of self-perceived effects of mindfulness-based stress reduction (MBSR) in a psychosocial oncology setting. *Stress and Health*, *23*(1), 59-69.
- MacCoon, D. G., Sullivan, J. C., Davidson, R. J., Stoney, C. M., Young, P. D., Thurlow, J. P., & Lutz, A. (2011). Health-enhancement program (HEP) guidelines. Permanent URL: <http://digital.library.wisc.edu/1793/28198>
- MacCoon, D. G., Imel, Z. E., Rosenkranz, M. A., Sheftel, J. G., Weng, H. Y., Sullivan, J. C., ... & Lutz, A. (2012). The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR). *Behaviour Research and Therapy*, *50*(1), 3-12.
- Madden, M. (2010). Chronic disease and the internet. Pew Internet & American Life Project [online]. Retrieved May 12, 2010, from <http://pewinternet.org/Reports/2010/Chronic-Disease.aspx>
- Maddison, A. R., Asada, Y., & Urquhart, R. (2011). Inequity in access to cancer care: a review of the Canadian literature. *Cancer Causes & Control*, *22*(3), 359-366.
- Matchim, Y., & Armer, J. (2007). Measuring the psychological impact of mindfulness meditation on health among patients with cancer: A literature review. *Oncology Nursing Forum*, *34*(5), 1059-1066.

- Matchim, Y., Armer, J. M., & Stewart, B. R. (2011). Mindfulness-based stress reduction among breast cancer survivors: A literature review and discussion. *Oncology Nursing Forum*, 38(2), E61-71.
- McCown, D., Reibel, D., & Micozzi, M. S. (2010). *Teaching mindfulness: a practical guide for clinicians and educators* (3rd ed.). New York, NY: Springer.
- McNair, D. A., Lorr, M., & Droppelman, L. F. (1971). *Profile of mood states*. San Diego: Educational and Industrial Testing Service.
- Meyer, B., Berger, T., Caspar, F., Beevers, C., Andersson, G., & Weiss, M. (2009). Effectiveness of a novel integrative online treatment for depression (Deprexis): A randomized controlled trial. *Journal of Medical Internet Research*, 11, e15.
- Mitchell, A. J. (2007). Pooled results from 38 analyses of the accuracy of distress thermometer and other ultra-short methods of detecting cancer-related mood disorders. *Journal of Clinical Oncology*, 25(29), 4670-4681.
- Mohr, D. C., Spring, B., Freedland, K. E., Beckner, V., Arean, P., Hollon, S. D., ... & Kaplan, R. (2009). The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychotherapy and Psychosomatics*, 78(5), 275.
- Monti, D. A., Peterson, C., Kunkel, E. J. S., Hauck, W. W., Pequignot, E., Rhodes, L., & Brainard, G. C. (2006). A randomized, controlled trial of mindfulness-based art therapy (MBAT) for women with cancer. *Psycho-Oncology*, 15(5), 363-373.
- Morledge, T. J., Allexandre, D., Fox, E., Fu, A. Z., Higashi, M. K., Kruzikas, D. T., ... & Reese, P. R. (2013). Feasibility of an online mindfulness program for stress

- management—a randomized, controlled trial. *Annals of Behavioral Medicine*, 46(2), 137-148.
- Morrill, E. F., Brewer, N. T., O'Neill, S. C., Lillie, S. E., Dees, E. C., Carey, L. A., & Rimer, B. K. (2008). The interaction of post-traumatic growth and post-traumatic stress symptoms in predicting depressive symptoms and quality of life. *Psycho-Oncology*, 17(9), 948-953.
- Musial, F., Bussing, A., Heusser, P., Choi, K. E., & Ostermann, T. (2011). Mindfulness-based stress reduction for integrative cancer care: A summary of evidence. *Forsch Komplementmed*, 18(4), 192-202.
- National Comprehensive Cancer Network (2002). *NCCN clinical practice guidelines in oncology: Distress management*. Fort Washington, PA.
- National Comprehensive Cancer Network (2013). *NCCN clinical practice guidelines in oncology: Distress management*. Version 2. Fort Washington, PA.
- National Comprehensive Cancer Network. (2014). Practice guidelines in oncology – version 1.2015: *Distress management*. Retrieved from http://www.nccn.org/professionals/physician_gls/pdf/distress.pdf
- Ott, M. J., Norris, R. L., & Bauer-Wu, S. M. (2006). Mindfulness meditation for oncology patients: A discussion and critical review. *Integrative Cancer Therapies*, 5(2), 98-108.
- Owen, J. E., Klapow, J. C., Roth, D. L., Shuster, J. L., Bellis, J., Meredith, R., & Tucker, D. C. (2005). Randomized pilot of a self-guided internet coping group for women with early-stage breast cancer. *Annals of Behavioral Medicine*, 30(1), 54-64.

- Peduzzi, P., Henderson, W., Hartigan, P., & Lavori, P. (2002). Analysis of randomized controlled trials. *Epidemiologic Reviews*, *24*(1), 26-38.
- Perini, S., Titov, N., & Andrews, G. (2008). The Climate Sadness program: an open trial of Internet-based treatment for depression. *Sensoria: A Journal of Mind, Brain & Culture*, *4*(2), 18-24.
- Perini, S., Titov, N., Andrews, G. (2009). Clinician-assisted internet-based treatment is effective for depression: Randomized controlled trial. *Australian and New Zealand Journal of Psychiatry*, *43*, 571-578.
- Peterman, A. H., Fitchett, G., Brady, M. J., Hernandez, L., & Cella, D. (2002). Measuring spiritual well-being in people with cancer: The functional assessment of chronic illness therapy-spiritual well-being scale (FACIT-Sp). *Annals of Behavioral Medicine*, *24*(1), 49-58.
- Piet, J., Wurtzen, H., & Zachariae, R. (2012). The effect of mindfulness-based therapy on symptoms of anxiety and depression in adult cancer patients and survivors: A systematic review and meta-analysis. *Journal of Consulting and Clinical Psychology*, *80*(6), 1007.
- Ploos van Amstel, F. K. P., van den Berg, S. W., van Laarhoven, H. W., Gielissen, M. F., Prins, J. B., & Ottevanger, P. B. (2013). Distress screening remains important during follow-up after primary breast cancer treatment. *Supportive Care in Cancer*, *21*(8), 2107-2115.
- Praissman, S. (2008). Mindfulness-based stress reduction: A literature review and clinicians' guide. *Journal of the American Academy of Nurse Practitioners*, *20*, 212-216.

- Proulx, K. (2003). Integrating mindfulness-based stress reduction. *Holistic Nursing Practice, 17*, 201-208.
- Quaglia, J.T., Brown, K.W., Lindsay, E.K., Creswell, J.D., & Goodman, R.J. (2015). From conceptualization to operationalization of mindfulness. In Brown, K. W., Creswell, J. D., & Ryan, R. M. (Eds.), *Handbook of mindfulness: Theory, research and practice*. (pp.151-170). New York, NY: Guildford Publications.
- Rajguru, P., Kolber, M. J., Garcia, A. N., Smith, M. T., Patel, C. K., & Hanney, W. J. (2014). Use of mindfulness meditation in the management of chronic pain: A systematic review of randomized controlled trials. *American Journal of Lifestyle Medicine, 15*, 598-27614522580.
- Reger, M. A., & Gahm, G. A. (2009). A meta-analysis of the effects of internet-and computer-based cognitive-behavioral treatments for anxiety. *Journal of Clinical Psychology, 65*(1), 53-75.
- Reiner, K., Tibi, L., & Lipsitz, J. D. (2013). Do mindfulness-based interventions reduce pain intensity? A critical review of the literature. *Pain Medicine, 14*(2), 230-242.
- Riley, K. E., & Kalichman, S. (2014). Mindfulness-based stress reduction for people living with HIV/AIDS: preliminary review of intervention trial methodologies and findings. *Health Psychology Review, 1*-20.
- Robins, C. J., Keng, S. L., Ekblad, A. G., & Brantley, J. G. (2012). Effects of mindfulness-based stress reduction on emotional experience and expression: a randomized controlled trial. *Journal of Clinical Psychology, 68*(1), 117-131.

- Roehlen, A. B., Zach, J. S., & Speyer, C. (2004). Online therapy: Review of relevant definitions, debates, and current empirical support. *Journal of Clinical Psychology, 60*, 269-283.
- Roscoe, J. A., Morrow, G. R., Hickok, J. T., Bushunow, P., Matteson, S., Rakita, D., & Andrews, P. L. (2002). Temporal interrelationships among fatigue, circadian rhythm and depression in breast cancer patients undergoing chemotherapy treatment. *Supportive Care in Cancer, 10*, 329-336.
- Rouleau, C. R., Garland, S. N., & Carlson, L. E. (2015). The impact of mindfulness-based interventions on symptom burden, positive psychological outcomes, and biomarkers in cancer patients. *Cancer Management and Research, 7*, 121.
- Ruland, C. M., Andersen, T., Jeneson, A., Moore, S., Grimsbo, G. H., Borosund, E., & Ellison, M. C. (2013). Effects of an internet support system to assist cancer patients in reducing symptom distress: a randomized controlled trial. *Cancer Nursing, 36*(1), 6-17.
- Schneider, S., Moyer, A., Knapp-Oliver, S., Sohl, S., Cannella, D., & Targhetta, V. (2010). Pre-intervention distress moderates the efficacy of psychosocial treatment for cancer patients: a meta-analysis. *Journal of Behavioral Medicine, 33*(1), 1-14.
- Segal, Z. V., Teasdale, J. D., & Williams, J. M. G. (2004). Mindfulness-Based Cognitive Therapy: Theoretical Rationale and Empirical Status. In S. C. Hayes, V. M. Follette, & M. M. Linehan (Eds.), *Mindfulness and relationship: Expanding the cognitive behavioral relationship* (pp. 45-65). New York: The Guilford Press.

- Sellick, S.M., & Edwardson, A. D. (2007). Screening new cancer patients for psychological distress using the hospital anxiety and depression scale. *Psycho-Oncology, 16*(6), 534–542.
- Shapiro, S. L., Bootzin, R. R., Figueredo, A. J., Lopez, A. M., & Schwartz, G. E. (2003). The efficacy of mindfulness-based stress reduction in the treatment of sleep disturbance in women with breast cancer: an exploratory study. *Journal of Psychosomatic Research, 54*(1), 85-91.
- Shapiro, S. L., Carlson, L. E., Astin, J. A., & Freedman, B. (2006). Mechanisms of mindfulness. *Journal of Clinical Psychology, 62*(3), 373-386.
- Shapiro, S. L., Brown, K. W., Thoresen, C., & Plante, T. G. (2011). The moderation of mindfulness-based stress reduction effects by trait mindfulness: Results from a randomized controlled trial. *Journal of Clinical Psychology, 67*(3), 267-277.
- Shek, D. T., & Ma, C. (2011). Longitudinal data analyses using linear mixed models in SPSS: concepts, procedures and illustrations. *The Scientific World Journal, 11*, 42-76.
- Shennan, C., Payne, S., & Fenlon, D. (2011). What is the evidence for the use of mindfulness-based interventions in cancer care? A review. *Psycho-Oncology, 20*(7), 681-697.
- Shepherd, L., Goldstein, D., Whitford, H., Thewes, B., Brummell, V., & Hicks, M. (2006). The utility of videoconferencing to provide innovative delivery of psychological treatment for rural cancer patients: Results of a pilot study. *Journal of Pain and Symptom Management, 32*, 453-461.

- Shigaki, C. L., Glass, B., & Schopp, L. H. (2006). Mindfulness-based stress reduction in medical settings. *Journal of Clinical Psychology in Medical Settings, 13*(3), 209-216.
- Simpson, R., Booth, J., Lawrence, M., Byrne, S., Mair, F., & Mercer, S. (2014). Mindfulness based interventions in multiple sclerosis-a systematic review. *BMC Neurology, 14*(1), 15.
- Smith, J. E., Richardson, J., Hoffman, C., & Pilkington, K. (2005). Mindfulness-based stress reduction as supportive therapy in cancer care: Systematic review. *Journal of Advanced Nursing, 52*(3), 315-27.
- Specia, M., Carlson, L. E., Goodey, E., & Angen, M. (2000). A randomized, wait-list controlled clinical trial: The effect of a mindfulness meditation-based stress reduction program on mood and symptoms of stress in cancer outpatients. *Psychosomatic Medicine, 62*(5), 613-622.
- Spek, V., Cuijpers, P., Nyklíček, I., Riper, H., Keyzer, J., & Pop, V. (2007). Internet based cognitive behaviour therapy for symptoms of depression and anxiety: A meta-analysis. *Psychological Medicine, 37*, 319–328.
- Stanton, A. L., Bower, J. E., Low, C. A. Posttraumatic growth after cancer. In: Calhoun, L. G., Tedeschi, R. G. eds. (2006) *Handbook of posttraumatic growth: Research and practice*. Lawrence Erlbaum Associates Publishers, Mahwah, NJ, pp. 138-175.
- Statistics Canada. (2010). Individual internet use and e-commerce. *The Daily*. Retrieved from <http://www.statcan.gc.ca/daily-quotidien/111012/dq111012a-eng.htm>

- Stephen, J., Rojubally, A., MacGregor, K., McLeod, D., Speca, M., Taylor-Brown, J., ... & Mackenzie, G. (2013). Evaluation of CancerChatCanada: A program of online support for Canadians affected by cancer. *Current Oncology*, *20*(1), 39-47.
- Stephen, J., Collie, K., McLeod, D., Rojubally, A., Fergus, K., Speca, M., ... & Elramly, M. (2014). Talking with text: communication in therapist-led, live chat cancer support groups. *Social Science & Medicine*, *104*, 178-186.
- Tacon, A. M., Caldera, Y. M., & Ronaghan, C. (2004). Mindfulness-based stress reduction in women with breast cancer. *Families, Systems & Health*, *22*(2), 193-203.
- Tacon, A. M. (2006). Mindfulness effects on symptoms of distress in women with cancer. *Journal of Cancer Pain and Symptom Palliation*, *2*(2), 17-22.
- Tallman, B. A., Altmaier, E., & Garcia, C. (2007). Finding benefit from cancer. *Journal of Counseling Psychology*, *54*(4), 481.
- Tamagawa, R., Garland, S., Vaska, M., & Carlson, L. (2012). Who benefits from psychosocial interventions in oncology? A systematic review of psychological moderators of treatment outcome. *Journal of Behavioral Medicine*, *35*(6), 658-673.
- Tamagawa, R., Speca, M., Stephen, J., Pickering, B., Lawlor-Savage, L., & Carlson, L. E. (2015). Predictors and Effects of Class Attendance and Home Practice of Yoga and Meditation Among Breast Cancer Survivors in a Mindfulness-Based Cancer Recovery (MBCR) Program. *Mindfulness*, 1-10.

- Tedeschi, R. G., & Calhoun, L. G. (1996). The Posttraumatic Growth Inventory: Measuring the positive legacy of trauma. *Journal of Traumatic Stress, 9*(3), 455-471.
- Tedeschi, R. G., & Calhoun, L. G. (2004). Posttraumatic Growth: Conceptual Foundations and Empirical Evidence. *Psychological Inquiry, 15*(1), 1-18.
- Teixeira, M. E. (2008). Meditation as an intervention for chronic pain: an integrative review. *Holistic Nursing Practice, 22*(4), 225-234.
- Thompson, N. J., Walker, E. R., Obolensky, N., Winning, A., Barmon, C., DiIorio, C., & Compton, M. T. (2010). Distance delivery of mindfulness-based cognitive therapy for depression: project UPLIFT. *Epilepsy & Behavior, 19*(3), 247-254.
- Toneatto, T., Nguyen, L. (2007). Does mindfulness meditation improve anxiety and mood symptoms? A review of the controlled research. *Canadian Journal of Psychiatry, 52*, 260–266.
- Veehof, M. M., Oskam, M. J., Schreurs, K. M., & Bohlmeijer, E. T. (2011). Acceptance-based interventions for the treatment of chronic pain: a systematic review and meta-analysis. *PAIN, 152*(3), 533-542.
- Visser, A., Garssen, B., & Vingerhoets, A. (2010). Spirituality and well-being in cancer patients: a review. *Psycho-Oncology, 19*(6), 565-572.
- Walach, H., Buchheld, N., Büttenmüller, V., Kleinknecht, N., & Schmidt, S. (2006). Measuring mindfulness—the Freiburg mindfulness inventory (FMI). *Personality and Individual Differences, 40*(8), 1543-1555.

- Walker, M. S., Zona, D. M., & Fisher, E. B. (2006). Depressive symptoms after lung cancer surgery: Their relation to coping style and social support. *Psycho-Oncology, 15*(8), 684-693.
- Whitford, H. S., & Olver, I. N. (2012). The multidimensionality of spiritual wellbeing: Peace, meaning, and faith and their association with quality of life and coping in oncology. *Psycho-Oncology, 21*(6), 602-610.
- Wolever, R. Q., Bobinet, K. J., McCabe, K., Mackenzie, E. R., Fekete, E., Kusnick, C. A., & Baime, M. (2012). Effective and viable mind-body stress reduction in the workplace: a randomized controlled trial. *Journal of Occupational Health Psychology, 17*(2), 246.
- Witek-Janusek, L., Albuquerque, K., Chroniak, K. R., Chroniak, C., Durazo-Arvizu, R., & Mathews, H. L. (2008). Effect of mindfulness-based stress reduction on immune function, quality of life, and coping in women newly diagnosed with early stage breast cancer. *Brain, Behavior, and Immunity, 22*(6), 969-981.
- Zabora, J., Brintzenhofeszoc, K., Curbow, B., Hooker, C., & Piantadosi, S. (2001). The prevalence of psychological distress by cancer site. *Psycho-Oncology, 10*, 19-28.
- Zainal, N. Z., Booth, S., & Huppert, F. A. (2013). The efficacy of mindfulness-based stress reduction on mental health of breast cancer patients: a meta-analysis. *Psycho-Oncology, 22*(7), 1457-1465.
- Zernicke, K. A., Campbell, T. S., Specia, M., McCabe-Ruff, K., Flowers, S., Dirkse, D. A., & Carlson, L. E. (2013). The eCALM Trial-eTherapy for Cancer AppLYing Mindfulness: online mindfulness-based cancer recovery program for underserved individuals living with cancer in Alberta: Protocol development for a randomized

wait-list controlled clinical trial. *BMC Complementary and Alternative Medicine*, 13(1), 34.

Zernicke, K., Campbell, T., Speca, M., McCabe-Ruff, K., Flowers, S., & Carlson, L. (2014). A randomized wait-list controlled trial of feasibility and efficacy of an online mindfulness-based cancer recovery program: The etherapy for cancer applying mindfulness trial. *Psychosomatic Medicine*, 76(4), 257-267.

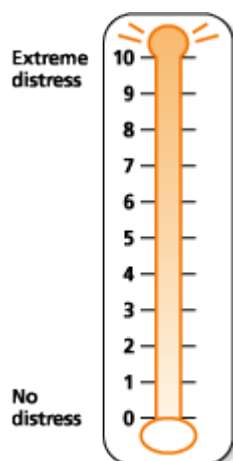
Zwahlen, D, Hagenbuch, N., Carley, M., Jenewein, J., & Buchi, S. (2010). Posttraumatic growth in cancer patients and partners – effects of role, gender and the dyad on couples' posttraumatic growth experience. *Psycho-Oncology*, 19(1), 12-20.

APPENDICES

Paper-based versions of questionnaires that were transferred to online format for the study:

DISTRESS THERMOMETER

Instructions: Please circle the number (0-10) that best describes how much distress you have been experiencing in the past week, including today.



Medical and Demographic Information

Date: _____ Study (Admin Use): _____ Participant ID: _____

Cancer Diagnosis:


Treating Doctor's Name:

Alberta Cancer Board Number:



Cancer Treatments Received:
(e.g., surgery/chemotherapy/radiation)

Type of treatment:
Date started:
Date ended:

4. Which of the following best describes your marital status?

- currently married and living together, or living with someone in a marriage-like relationship
- never married  place an "X" over this circle if you have ever lived with someone in a marriage-like relationship
- separated
- divorced
- widowed

5. What is your current employment status? Check ALL that apply.

- Working full time for pay  number of hours per week _____
- Working part time for pay  number of hours per week _____
- Not currently employed, looking for work
- Retired
- Homemaker
- Disabled (Not working because of a permanent or temporary disability)
- Other (please, specify): _____

PREVIOUS MEDITATION / YOGA EXPERIENCE

6. Do you currently practice yoga and/or meditation on a regular basis?

Yes No

If Yes, please indicate how often you practice:

Yoga:

- daily
- weekly
- monthly
- less often than every month

Meditation:

- daily
- weekly
- monthly
- less often than every month

7. Have you had any previous experience with yoga and/or meditation?

Yes No

If Yes, please indicate the length of time you practiced:

Yoga:

- none
- less than 1 year
- 1 to 5 years
- 5 to 10 years
- more than 10 years

Meditation:

- none
- less than 1 year
- 1 to 5 years
- 5 to 10 years
- more than 10 years

CALGARY SYMPTOMS OF STRESS INVENTORY (CSOSI)

This questionnaire is designed to measure the different ways people respond to stressful situations. The questionnaire contains sets of questions dealing with various physical, psychological and behavioral responses. We are particularly interested in the frequency with which you may have experienced these stress related symptoms during the **past week**.

		Never	Infrequently	Sometimes	Often	Very frequently
<i>Stress is often accompanied by a variety of emotions. During the last week, have you felt:</i>						
D1	Like life is entirely hopeless	0	1	2	3	4
D2	Unhappy and depressed	0	1	2	3	4
D3	Alone and sad	0	1	2	3	4
D5	That worrying gets you down	0	1	2	3	4
D4	Like crying easily	0	1	2	3	4
D6	That you wished you were dead	0	1	2	3	4
D7	Frightening thoughts keep coming back	0	1	2	3	4
D8	You suffer from severe nervous exhaustion	0	1	2	3	4
<i>Does it seem:</i>						
A1	You become mad or anger easily	0	1	2	3	4
A2	When you feel angry, you act angrily toward most everything	0	1	2	3	4
A3	You are easily annoyed and irritated	0	1	2	3	4
A4	That little things get on your nerves	0	1	2	3	4
A5	Angry thoughts about an irritating event keep bothering you	0	1	2	3	4
A6	You let little annoyances build up until you just explode	0	1	2	3	4
A7	Your anger is so great that you want to strike something	0	1	2	3	4

Kindly select the frequency with which you may have experienced these symptoms during the **past week**.

		Never	Infrequently	Sometimes	Often	Very frequently
<i>Muscle tension is a common way of experiencing stress. Have you noticed excessive tension, stiffness, soreness or cramping in the muscles in your:</i>						
MT1	Shoulders	0	1	2	3	4
MT2	Neck	0	1	2	3	4
MT3	Back	0	1	2	3	4
MT4	Jaw	0	1	2	3	4
MT5	Forehead	0	1	2	3	4
MT6	Eyes	0	1	2	3	4
MT7	Hands or arms	0	1	2	3	4
MT8	Tension headaches	0	1	2	3	4
<i>Does it seem:</i>						
C1	Thumping of your heart	0	1	2	3	4
C2	Rapid or racing heart beats	0	1	2	3	4
C3	Rapid breathing	0	1	2	3	4
C4	Irregular heart beats	0	1	2	3	4
C5	Difficult breathing	0	1	2	3	4
C6	Pains in your heart of chest	0	1	2	3	4
<i>Do you experience:</i>						
SA1	Difficulty in staying asleep at night	0	1	2	3	4
SA2	Hot or cold spells	0	1	2	3	4
SA3	Having to get up in the night to urinate	0	1	2	3	4
SA4	Sweating excessively even in cold weather	0	1	2	3	4
SA5	Having to urinate frequently	0	1	2	3	4
SA6	Early morning awakening	0	1	2	3	4
SA7	Flushing of your face	0	1	2	3	4
SA8	Difficulty in falling asleep	0	1	2	3	4
SA9	Breaking out in cold sweats	0	1	2	3	4

Kindly select the frequency with which you may have experienced these symptoms during the **past week**.

		Never	Infrequently	Sometimes	Often	Very frequently
<i>Have you experienced:</i>						
NG1	Feeling faint	0	1	2	3	4
NG2	Feeling weak and faint	0	1	2	3	4
NG3	Spells of severe dizziness	0	1	2	3	4
NG4	Nausea	0	1	2	3	4
NG5	Blurring of your vision	0	1	2	3	4
NG6	Severe pains in your stomach	0	1	2	3	4
<i>Does it seem:</i>						
CD1	You must do things very slowly to do them without mistakes	0	1	2	3	4
CD2	You get directions and orders wrong	0	1	2	3	4
CD3	Your thinking gets completely mixed-up when you have to do things quickly	0	1	2	3	4
CD4	You have difficulty in concentrating	0	1	2	3	4
CD5	You become suddenly frightened for no good reason	0	1	2	3	4
CD6	You become so afraid you can't move	0	1	2	3	4
<i>Have you experienced:</i>						
UR1	Colds	0	1	2	3	4
UR2	Hoarseness	0	1	2	3	4
UR3	Colds with complications (e.g. Bronchitis)	0	1	2	3	4
UR4	Nasal stuffiness	0	1	2	3	4
UR5	Having to clear your throat often	0	1	2	3	4
UR6	Sinus headaches	0	1	2	3	4

Profile of Mood States (POMS)

Below is a list of words that describe feelings that people have. Please read each one carefully. Then circle ONE number corresponding to the adjective phrase which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY. The numbers refer to the following descriptive phrases:

0 = Not at all

1 = A little

2 = Moderately

3 = Quite a bit

4 = Extremely

		<i>Not at All</i>	<i>A Little</i>	<i>Moderately</i>	<i>Quite a Bit</i>	<i>Extremely</i>
1.	Friendly	0	1	2	3	4
2.	Tense	0	1	2	3	4
3.	Angry	0	1	2	3	4
4.	Worn-out	0	1	2	3	4
5.	Unhappy	0	1	2	3	4
6.	Clear-headed	0	1	2	3	4
7.	Lively	0	1	2	3	4
8.	Confused	0	1	2	3	4
9.	Sorry for things done	0	1	2	3	4
10.	Shaky	0	1	2	3	4
11.	Listless	0	1	2	3	4
12.	Peeved	0	1	2	3	4
13.	Considerate	0	1	2	3	4
14.	Sad	0	1	2	3	4
15.	Active	0	1	2	3	4
16.	On edge	0	1	2	3	4
17.	Grouchy	0	1	2	3	4
18.	Blue	0	1	2	3	4
19.	Energetic	0	1	2	3	4
20.	Panicky	0	1	2	3	4
21.	Hopeless	0	1	2	3	4
22.	Relaxed	0	1	2	3	4

		<i>Not at All</i>	<i>A Little</i>	<i>Moderately</i>	<i>Quite a Bit</i>	<i>Extremely</i>
23.	Unworthy	0	1	2	3	4
24.	Spiteful	0	1	2	3	4
25.	Sympathetic	0	1	2	3	4
26.	Uneasy	0	1	2	3	4
27.	Restless	0	1	2	3	4
28.	Unable to concentrate	0	1	2	3	4
29.	Fatigued	0	1	2	3	4
30.	Helpful	0	1	2	3	4
31.	Annoyed	0	1	2	3	4
32.	Discouraged	0	1	2	3	4
33.	Resentful	0	1	2	3	4
34.	Nervous	0	1	2	3	4
35.	Lonely	0	1	2	3	4
36.	Miserable	0	1	2	3	4
37.	Muddled	0	1	2	3	4
38.	Cheerful	0	1	2	3	4
39.	Bitter	0	1	2	3	4
40.	Exhausted	0	1	2	3	4
41.	Anxious	0	1	2	3	4
42.	Ready to fight	0	1	2	3	4
43.	Good-natured	0	1	2	3	4
44.	Gloomy	0	1	2	3	4
45.	Desperate	0	1	2	3	4
46.	Sluggish	0	1	2	3	4
47.	Rebellious	0	1	2	3	4
48.	Helpless	0	1	2	3	4
49.	Weary	0	1	2	3	4
50.	Bewildered	0	1	2	3	4
51.	Alert	0	1	2	3	4
52.	Deceived	0	1	2	3	4

		<i>Not at All</i>	<i>A Little</i>	<i>Moderately</i>	<i>Quite a Bit</i>	<i>Extremely</i>
53.	Furious	0	1	2	3	4
54.	Efficient	0	1	2	3	4
55.	Trusting	0	1	2	3	4
56.	Full of pep	0	1	2	3	4
57.	Bad-tempered	0	1	2	3	4
58.	Worthless	0	1	2	3	4
59.	Forgetful	0	1	2	3	4
60.	Carefree	0	1	2	3	4
61.	Terrified	0	1	2	3	4
62.	Guilty	0	1	2	3	4
63.	Vigorous	0	1	2	3	4
64.	Uncertain about things	0	1	2	3	4
65.	Bushed	0	1	2	3	4

FACIT Spirituality Subscale

Below is a list of statements that other people have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days.

	Not at all	A little bit	Some -what	Quite a bit	Very Much
1. I feel peaceful	0	1	2	3	4
2. I have a reason for living	0	1	2	3	4
3. My life has been productive	0	1	2	3	4
4. I have trouble feeling peace of mind	0	1	2	3	4
5. I feel a sense of purpose in my life	0	1	2	3	4
6. I am able to reach down deep into myself for comfort	0	1	2	3	4
7. I feel a sense of harmony within myself	0	1	2	3	4
8. My life lacks meaning and purpose	0	1	2	3	4
9. I find comfort in my faith	0	1	2	3	4
10. I find strength in my faith	0	1	2	3	4
11. My illness has strengthened my faith	0	1	2	3	4
12. I know that whatever happens with my illness, things will be okay.	0	1	2	3	4

FIVE FACET MINDFULNESS QUESTIONNAIRE

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you.

<i>Never True</i>	<i>Rarely True</i>	<i>Sometimes True</i>	<i>Often True</i>	<i>Always True</i>
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>

1. When I'm walking, I deliberately notice the sensations of my body moving.	1	2	3	4	5
2. I'm good at finding words to describe my feelings.	1	2	3	4	5
3. I criticize myself for having irrational or inappropriate emotions.	1	2	3	4	5
4. I perceive my feelings and emotions without having to react to them.	1	2	3	4	5
5. When I do things, my mind wanders off and I'm easily distracted.	1	2	3	4	5
6. When I take a shower or bath, I stay alert to the sensations of water on my body.	1	2	3	4	5
7. I can easily put my beliefs, opinions, and expectations into words.	1	2	3	4	5
8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	1	2	3	4	5
9. I watch my feelings without getting lost in them.	1	2	3	4	5
10. I tell myself I shouldn't be feeling the way I'm feeling.	1	2	3	4	5
11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	1	2	3	4	5
12. It's hard for me to find the words to describe what I'm thinking.	1	2	3	4	5
13. I am easily distracted.	1	2	3	4	5
14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	1	2	3	4	5
15. I pay attention to sensations, such as the wind in my hair or sun on my face.	1	2	3	4	5
16. I have trouble thinking of the right words to express how I feel about things	1	2	3	4	5

<i>Never True</i>	<i>Rarely True</i>	<i>Sometimes True</i>	<i>Often True</i>	<i>Always True</i>
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>

17. I make judgments about whether my thoughts are good or bad.	1	2	3	4	5
18. I find it difficult to stay focused on what's happening in the present.	1	2	3	4	5
19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	1	2	3	4	5
20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	1	2	3	4	5
21. In difficult situations, I can pause without immediately reacting.	1	2	3	4	5
22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	1	2	3	4	5
23. It seems I am "running on automatic" without much awareness of what I'm doing.	1	2	3	4	5
24. When I have distressing thoughts or images, I feel calm soon after	1	2	3	4	5
25. I tell myself that I shouldn't be thinking the way I'm thinking.	1	2	3	4	5
26. I notice the smells and aromas of things.	1	2	3	4	5
27. Even when I'm feeling terribly upset, I can find a way to put it into words.	1	2	3	4	5
28. I rush through activities without being really attentive to them	1	2	3	4	5
29. When I have distressing thoughts or images I am able just to notice them without reacting.	1	2	3	4	5
30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	1	2	3	4	5
31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	1	2	3	4	5
32. My natural tendency is to put my experiences into words.	1	2	3	4	5
33. When I have distressing thoughts or images, I just notice them and let them go.	1	2	3	4	5
34. I do jobs or tasks automatically without being aware of what I'm doing.	1	2	3	4	5

<i>Never True</i>	<i>Rarely True</i>	<i>Sometimes True</i>	<i>Often True</i>			<i>Always True</i>	
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>			<i>5</i>	
35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.			1	2	3	4	5
36. I pay attention to how my emotions affect my thoughts and behavior.			1	2	3	4	5
37. I can usually describe how I feel at the moment in considerable detail.			1	2	3	4	5
38. I find myself doing things without paying attention.			1	2	3	4	5
39. I disapprove of myself when I have irrational ideas.			1	2	3	4	5

Posttraumatic Growth Inventory (PTGI)

Indicate for each of the following statements the degree to which the change reflected in the question is true in your life as a result of your cancer diagnosis / treatment / recovery using the following scale:

0= I did not experience this change as a result of my crisis.

1= I experienced this change to a very small degree as a result of my crisis.

2= I experienced this change to a small degree as a result of my crisis.

3= I experienced this change to a moderate degree as a result of my crisis.

4= I experienced this change to a great degree as a result of my crisis.

5= I experienced this change to a very great degree as a result of my crisis.

1. I changed my priorities about what is important in life. _____
2. I have a greater appreciation for the value of my own life. _____
3. I developed new interests. _____
4. I have a greater feeling of self-reliance. _____
5. I have a better understanding of spiritual matters. _____
6. I more clearly see that I can count on people in times of trouble. _____
7. I established a new path for my life. _____
8. I have a greater sense of closeness with others. _____
9. I am more willing to express my emotions. _____
10. I know better that I can handle difficulties. _____
11. I am able to do better things with my life. _____
12. I am better able to accept the way things work out. _____
13. I can better appreciate each day. _____
14. New opportunities are available which wouldn't have been otherwise. _____
15. I have more compassion for others. _____
16. I put more effort into my relationships. _____
17. I am more likely to try to change things which need changing. _____
18. I have a stronger religious faith. _____
19. I discovered that I'm stronger than I thought I was. _____
20. I learned a great deal about how wonderful people are. _____
21. I better accept needing others. _____

Meditation Log

Name: _____

ID Number: _____

Week _____

DATES	TOTAL MINUTES IN YOGA	TOTAL MINUTES IN MEDITATION	COMMENTS
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
TOTAL WEEKLY MINUTES:			