

EVALUATION OF AN
IYENGAR YOGA INTERVENTION
FOR WOMEN WITH CANCER

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By

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ABSTRACT

Introduction: Cancer poses a substantial burden on the health of Canadians. Although advancements in screening and treatment have reduced, cancer-related morbidity and quality of life remain important concerns throughout cancer treatment and survivorship.

Purpose: This study examined the impact of Iyengar yoga on quality of life and other cancer-related symptoms among people with cancer.

Methods: All individuals registered for the Fall 2006 and Winter 2007, 10-week Iyengar yoga programs, offered by CancerCare Manitoba through private donations, were invited to participate in the study. Participants were asked to complete standard self-report questionnaires and participant diaries at baseline, week-5, week-10, and 6 weeks following the last class. The intervention's impact on study outcomes were determined using repeated measures ANOVAs and paired samples t-tests. Six participant interviews and a review of participant diaries were conducted and analyzed using categorical aggregation and direct interpretation to identify other relevant issues as raised by participants and to document any negative effects of the program.

Results: Nineteen female participants completed the yoga intervention. The mean age of the sample was 50 years and the majority self-identified as Caucasian. Approximately one third had breast cancer and 63% were undergoing treatment for cancer at baseline. Results from the questionnaires showed statistically significant improvements in quality of life, mood disturbance, spiritual well-being, anxiety, nausea, pain, participants' most bothersome symptom at baseline, and trait anxiety. Results from the interviews and participant diaries showed that participants experienced increases in social support, relaxation, mental concentration, and in flexibility, strength, and mobility in problem areas. Participants also expressed that their Iyengar yoga practice was empowering and supported their need to take an active role in their health and take a holistic approach to care. It was suggested that Iyengar yoga might contribute to the benefits reported through an ability to facilitate the development of coping skills or mindfulness.

Conclusions: The Iyengar yoga program for people living with cancer offered by CancerCare Manitoba can be considered a complex, multi-level, multi-modal intervention. Although, due to design limitations, neither causality nor a dose-response relationship between the Iyengar yoga intervention and the improvements in cancer-related outcomes could be inferred, the present study lends support to the assertion that Iyengar yoga is beneficial to the well-being of those living with cancer.

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*This thesis is humbly dedicated to the women who participated in this study
and to all women who live with cancer.*

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LIST OF ABBREVIATIONS

AB	Alberta
ANOVA	Analysis of Variance
Bf-S	Befindlichkeitsskala
CAM	Complementary and Alternative Medicine
CCMB	CancerCare Manitoba
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
EORTC-QLQ-C30	European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30
FACIT-Sp	Functional Assessment of Chronic Illness Therapy-Spiritual
FACT-G	Functional Assessment of Cancer Therapy - General
FAQ	Fatigue Assessment Questionnaire
FBL-R	Freiburger Beschwerdenlist
FLZ	Fragen zur Lebenszufriedenheit
GLTEQ	Godin Leisure-Time Exercise Questionnaire
K-S	Kolmogorov-Smirnov
MBSR	mindfulness-based stress reduction
MET	metabolic equivalent
MID	minimal important difference
MYMOP2	Measure Your Medical Outcome Profile 2
OR	Odds Ratio
POMS-SF	Profile of Mood States- Short Form
POMS	Profile of Mood States
PSO	Psychosocial Oncology
PSQI	Pittsburgh Sleep Quality Index
Qual	qualitative
Quan	quantitative
RAND-36	Research and Development-36
RCT	randomized controlled trial
RM-ANOVA	Repeated Measures Analysis of Variance
SCL-90-R	Hopkins Symptom Checklist 90
SD	standard deviation
SOSI	Symptoms of Stress Inventory
SPSS	Statistical Package for the Social Sciences
STAI-T	State-Trait Anxiety Inventory- Trait
VAS	Visual Analogue Scale

1. INTRODUCTION

The Canadian Cancer Society predicts that in 2007, 159,900 Canadians will be diagnosed with cancer¹. Fortunately, with the advent of more sophisticated methods of detection, high profile screening programs, and effective treatments, life expectancy for many cancers has improved significantly over time. In 2003, the Canadian Cancer Society estimated that the number of cancer survivors living in Canada was approximately 833,100 (roughly 2.6% of the Canadian population), an increase of approximately 60 000 people from the year 2000¹. As survivorship has become more common, treatment goals have shifted from a focus not only on the physical recovery from cancer, but also on psychosocial and spiritual well being, including coping with cancer, managing its symptoms, integrating the cancer experience into one's life experience, and regaining an overall sense of wellness² to reflect this increase in survivorship.

Yoga has been recommended as a complementary strategy to help individuals cope with the various changes associated with cancer^{3,4}. However, very little research has been done in this area and the specific benefits are unclear due to contradictory results. Some studies suggest that Iyengar yoga may alleviate cancer symptoms and treatment side effects and improve overall well-being. However, these have been studies on breast cancer patients^{5,6}, reporting on an almost exclusively female experience. Also lacking from the literature is information concerning the potential for long lasting effects of yoga, as few studies have included a follow-up period of observation. Finally, no studies have examined the effects of Iyengar yoga on cancer patients' spiritual well-being, which has been a prominent theme in the anecdotal evidence. More research is needed to determine and understand the potential benefits of Iyengar yoga for people with cancer.

The Department of Patient and Family Support Services of CancerCare Manitoba (CCMB) has offered an Iyengar yoga program for people with cancer for the past five years. In the client satisfaction surveys collected to date, participants have consistently reported positive outcomes of the program but the director of Patient and Family Support Services was interested in studying the impact of the program in greater depth.

1.1 Research Purpose

Because of the lack of knowledge in this area and due to the program evaluation need, the purpose of the present study was to assess the effectiveness of CancerCare Manitoba's Iyengar yoga program and potentially inform the development of future research questions. Specifically, the objective was to determine the influence of Iyengar yoga on overall quality of life and the severity of symptoms and side effects related to cancer and its treatment in people currently undergoing treatment for cancer and people who have undergone treatment within the six months prior to commencing an Iyengar yoga program.

1.2 Research Questions

The research questions addressed by the present study were:

1. To what extent do quality of life, spiritual well-being, and total mood disturbance change over time while following a 10-week Iyengar yoga program?
2. To what extent do cancer treatment-related symptoms (including anxiety, depression, fatigue, nausea, and pain) change over time while following a 10-week Iyengar yoga program?
3. How does the completion of the Iyengar yoga intervention impact on the participants' self-identified worst symptom identified at baseline?
4. Can any effects of Iyengar yoga be documented at six weeks after completion of the program?
5. What other issues do participants raise when describing the experience of participating in an Iyengar yoga program? Do they

identify a process by which Iyengar yoga influences outcomes related to their cancer experience?

6. Are there any reported negative effects of Iyengar yoga?
7. How feasible is a study evaluating an Iyengar yoga program targeted at cancer patients?

Although no formal hypotheses were put forth prior to the evaluation due to the exploratory nature of the current study, its design limitations, and the contradictory results reported in the relevant literature, it was expected that participants of the Iyengar yoga intervention would experience an increase in quality of life and spiritual well-being, and a decrease in total mood disturbance based on anecdotal evidence from client satisfaction surveys collected by CCMB prior to the evaluation. Therefore, the three-above mentioned outcomes were considered primary outcomes, while those outcomes representing cancer and treatment-related symptoms (i.e., anxiety, depression, fatigue, pain, nausea, and each participant's self-identified worst symptom identified at baseline) were considered secondary outcomes.

1.3 Background and Rationale

1.3.1 Cancer Diagnosis, Treatment, and Outcomes

From the moment of diagnosis, the cancer patient experiences the myriad effects of cancer. Compared to other diagnoses, a cancer diagnosis causes the greatest amount of psychological distress (i.e., anxiety, depression, and stress⁷) for patients regardless of their prognosis⁸, making it a universally traumatic and life-altering experience.

Anxiety and depression are important outcomes of study as they represent two of the more common emotional consequences of a cancer diagnosis and treatment, affecting 77% and 59% of Canadian cancer patients respectively⁹. Because a diagnosis infers many uncertainties with regards to prognosis, cancer symptoms, and treatment side effects, anxiety is increased. In addition, the prevalence of depression and depressive symptoms among cancer patients from the time of diagnosis throughout treatment has been found to be five to twelve times higher than the prevalence in the general population¹⁰. These psychological

ramifications tend to disempower and decrease the overall well-being of those diagnosed with cancer often leading to feelings of apathy and a lack of active participation in the process of recovery and adjustment¹¹. One's sense of control is of critical importance as the amount of stress perceived may have an impact on survival¹² among cancer patients. Because anxiety, depression, and stress can affect immune function¹¹, which might affect the likelihood of recurrence, efforts should be made to minimize these psychological sequelae of cancer diagnosis and treatment.

Fatigue, the most commonly reported outcome associated with cancer and its treatment (affecting 78% of Canadian cancer patients⁹) is a psychosocial symptom correlated with the emotional effects of cancer, particularly depression. As the patient receives treatment for cancer, he or she is often faced with physical side effects such as pain and nausea^{13,14} that, along with fatigue, interfere with his or her ability to work, socialize, and participate in many simple daily activities. Like fatigue, these physical side effects are prevalent among cancer patients, affecting 30-70%¹⁵ and 11%¹⁴ of patients respectively, and along with fatigue, can linger for months and even years after treatment has ceased¹⁶.

The negative impact of a cancer diagnosis and treatment regimen on physical, psychological, and functional well-being also affects quality of life¹³. Because symptoms and side effects of cancer and its treatment can persist after cessation of treatment, poor quality of life is a significant and long-term consequence of cancer^{17,18}. As the ultimate purpose of medicine is to promote and support all aspects (including social, emotional, functional, and physical) of life¹⁹, it is important that caregivers consider the quality of life of people diagnosed with and being treated for cancer.

Another important aspect of quality of life and holistic care is spirituality. Although there is no universal representation of spirituality, it can be defined as attaching a sense of meaning to life by forming and maintaining a relationship with oneself, others, nature, and a higher power through self-transcendence²⁰. In recent studies, spirituality has been noted as an important predictor of various health outcomes related to cancer²⁰. For example, having a sense of spirituality has been

associated with greater levels of overall well-being²¹ and quality of life²², and lower levels of pain, anxiety, and depression^{23,24,25,26}.

Because of the high prevalence and clinical importance of quality of life, spiritual well-being, mood disturbance, anxiety, depression, fatigue, nausea, and pain; these concerns were included as primary and secondary outcomes in the present evaluation.

1.3.2 Complementary and Alternative Medicine (CAM) and Cancer

The National Center for Complementary and Alternative Medicine defines CAM as:

A group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. The list of what is considered to be CAM changes continually, as those therapies that are proven to be safe and effective become adopted into conventional health care as new approaches to health care emerge.²⁷

Studies have shown that certain people are more likely to use CAM than others. For example, CAM users tend to be female, middle-aged, have a post-secondary education, a higher income, an interest in health knowledge, and have one or more chronic illnesses^{28,29,30,31}.

People who use CAM seek out complementary and alternative therapies for many reasons. CAM serves to bridge the gap between the physical, psychosocial, and spiritual aspects of care³² in a manner that supports the many aspects of quality of life, therefore appealing to those who subscribe to a holistic view of health and well-being and those who believe in not only treating the bodily ailment, but also the person with the ailment³³. CAM also appeals to those who are seeking a gentler approach to care and to those who feel disappointed by, or have had negative experiences within, the conventional medical system. For example, one study³⁴ showed that poor patient to doctor communication and perceived ineffectiveness of conventional therapies predicted CAM use among 268 British CAM users. One Canadian study showed that CAM practice can be empowering as it attracts those who believe that the individual should be involved in all aspects of their health, including making decisions related to health and treatment of illness³⁵, known as the self-care belief system. The same study indicated a greater affinity for CAM use among those who valued spirituality and faith compared to those who said

spirituality was not important (OR=2.6)³⁵. Because the philosophies underlying many CAM practices involve aspects of religion, CAM use also appeals to those who feel that the secularization of conventional medicine is alienating and detrimental to the process of seeking meaning in their illness through spirituality³³.

Because a cancer diagnosis tends to be a tumultuous experience marked not only by physical and emotional symptoms and side effects but also a loss of control and sense of self, cancer patients often turn to alternative therapies in order to cope with the effects of cancer, gain more control over their lives, and live beyond cancer with a renewed sense of purpose. A study by Astin²⁸ showed that “having a transformational experience that change[s] the person’s worldview” (which often happens following a cancer diagnosis) was predictive of CAM use among a random sample of American adults. Studies found that cancer patients chose to use CAM with the belief that CAM would help manage their cancer symptoms and treatment side effects that conventional medicine could not address (for example, fatigue), enable them to gain a sense of control over their health³⁶, increase their sense of hope, prevent a recurrence, and enhance their overall sense of well-being³⁷. For Canadians living with cancer, CAM practice is predominantly adopted as a complementary therapy to conventional cancer treatment rather than as a complete substitution. This integrative approach to health has been steadily gaining in popularity as it appeals to patients and caregivers alike in the way it maximizes the benefits of both conventional and complementary¹¹ approaches to health care.

An increasing number of health care professionals are recommending CAM for cancer patients³². In 1995, 70% of oncology centers in Great Britain provided some form of complementary therapy¹³. In 2002, a study reported that 27% of oncologists in Northern California recommended “movement therapy” such as yoga and T’ai-chi as a complement to chemotherapy and radiotherapy³². The demand for CAM has come from patient interest as well. In one study 82% of the participants felt their oncologist should initiate discussions of physical activity as part of their oncology consultation³⁸. This interest in complementing conventional cancer care has resulted in an increase in use of various CAM modalities. A recent survey found

that 10-60% of cancer patients use at least one CAM modality as a complementary therapy after being diagnosed^{39, 40, 41}.

According to the National Center for Complementary and Alternative Medicine⁴² one CAM modality, mind-body medicine/interventions:

focuses on the interactions among the brain, mind, body, and behavior, and the powerful ways in which emotional, mental, social, spiritual, and behavioral factors can directly affect health. It regards as fundamental an approach that respects and enhances each person's capacity for self-knowledge and self-care, and it emphasizes techniques that are grounded in this approach⁴².

A review of studies evaluating mind-body interventions indicated that they improved quality of life, mood, the severity of cancer symptoms and treatment-related side-effects, and coping among people living with cancer⁴³. The same study concluded that mind-body interventions appeal to cancer patients because they are seen as gentle and natural complements to conventional medicine, that don't typically inflict harmful side effects on the practitioner⁴³. Cancer patients are also drawn to these interventions because they provide a means through which they can learn to relax, reconnect with their bodies, and re-establish a sense of centeredness in their lives. Iyengar yoga is one mind-body intervention.

1.3.3 What is Iyengar Yoga?

For over 5000 years yoga has been practiced in different parts of the world and has been recognized as an art form, a branch of science, and even a way of life by many groups⁴⁴. The word yoga originates from the Sanskrit word "yuj", which means union⁴⁵ of the physical, mental, emotional, social, and spiritual aspects of being⁴⁴. The practice of yoga encourages the yogi (or yoga practitioner) to use the mind, body, and breath together in order to calm the fluctuations of one's consciousness and thereby bring balance to all aspects of one's life⁴⁴. Therefore, yoga philosophy is used with the aim to improve the yogi's physical, mental, emotional, social, and spiritual well-being⁴⁴.

Yoga philosophy can be broken down into eight limbs (known as Ashtanga) describing eight spiritual practices. The first four limbs are known as external cleansing practices⁴⁶ and are called yama, niyama, asana, and pranayama. Once the yogi has mastered asana (bodily postures that promote a strong and healthy body⁴⁶)

and pranayama (breathing techniques that allow the mind to become still and focused⁴⁴), he or she can progress on to yama and niyama. Yama is the daily practice of ethical principles, which include non-violence, truthfulness, non-stealing, abstinence, and non-avariciousness⁴⁵ that, in combination, reflect a virtuous life. Niyama is the practice of self-discipline and includes practicing inner and outer body purification, contentment, austerity, study of the self or of spiritual scriptures, and self-surrender⁴⁵.

Once the external practices have been mastered, the yogi can move on to the internal cleansing practices⁴⁶, which are the final four limbs of Ashtanga yoga. The fifth limb, pratyahara, is the “withdrawal of the senses from the external, physical world to the mental, intellectual, and spiritual world”⁴⁴. Pratyahara prepares the yogi for dharana, the practice of uninterrupted concentration of the mind, which in turn prepares the yogi for dhyana, a state of prolonged meditation⁴⁴. The final limb, samadhi, is the peak of meditation, where the yogi is capable of self-actualization, the definitive purpose of yoga⁴⁴.

As the yogi becomes more experienced, he or she has the potential, depending on his or her level of experience, expectations, and readiness, to progress through the four stages of yoga that correspond to the ashtangas. The first stage, arambhavastha, is practice at the physical level. At the second stage of practice, ghatavastha, the yogi’s physical practice is enhanced by the simultaneous involvement of the mind. At the third stage, parichayavastha, the intelligence, an acute sensory awareness and sensitivity in each cell of the body⁴⁷, is integrated with the body during practice. In the last stage, nispatyavastha, the yogi practices “in a state of perfection”⁴⁵.

In recent years, yoga has been marketed as empowering to well-being and an effective way to reduce stress⁴⁸. While there are many types of yoga, Iyengar yoga, developed by yoga master BKS Iyengar⁴⁹ is one of the most well-known. Iyengar yoga is an accessible form of physical activity because it does not require sophisticated equipment, and is ideal for beginners or people with physical limitations or injuries as it is easy to learn and uses props, such as chairs, foam

blocks, and straps to help the body accomplish the correct postures to achieve the desired therapeutic effect⁴⁹.

The goal of Iyengar yoga is to increase “flexibility, strength, and sensitivity of mind, body, and spirit”⁴⁹. On a physical level (arambhavastha), Iyengar yoga’s focus on maintaining correct alignment allows for anatomically correct development of the body, which ensures that the yogi does not suffer pain or injury. Emphasis is also placed on correct sequencing of postures to achieve a potent cumulative therapeutic effect. Timing is vital to Iyengar yoga as it is important to hold a pose for enough time to allow the muscles to stretch and relax and therefore, experience the full effect of each pose⁴⁹, which, according to Mr. Iyengar, includes restoring balance to the yogi’s mental state, silencing his or her thoughts and worries. In doing so, the yogi is able to restore equilibrium to his or her emotional state⁴⁵.

When diagnosed with cancer it is often a patient’s reaction to stop exercising and “take it easy” while he or she undergoes treatment⁵⁰, often in response to doctor’s orders. Nonetheless, physical activity appears to have a positive effect on the many aspects of life that are affected by a cancer diagnosis. With some types of cancer, however, patients are unable to engage in high intensity physical activities. Because Iyengar yoga is a gentle, low-impact form of physical activity with modifications made specifically to facilitate participation among cancer patients, there is less risk of injury resulting in a higher rate of participation⁵. Thus, Iyengar yoga offers cancer patients a less intimidating way to remain active and as a result, potentially decrease their symptoms, and possibly prevent cancer recurrence and other diseases related to inactivity, while increasing quality of life.

2. LITERATURE REVIEW

2.1 Yoga Studies and Cancer Outcomes

Only a few studies have tested the effect of Iyengar yoga on cancer symptoms and treatment side effects. One pilot study⁵ assessed the physical and psychological benefits of a yoga therapy intervention for female breast cancer survivors. The authors gave a thorough summary of the poses included in the program, which they claimed was influenced by Iyengar yoga and kinesiology. Thirty-eight adult cancer survivors were randomly assigned to either a wait-list control group or the yoga therapy intervention and participated in 75-minute, weekly yoga classes for 7 weeks. Participants were administered a series of self-report questionnaires including the Profile of Mood States (POMS), the Symptoms of Stress Inventory (SOSI), the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30 (EORTC-QLQ-C30), the Leisure Score Index, as well as several physiological measures. Measures were taken at baseline and immediately following the seven week intervention in order to assess for a change in mood states, stress symptoms, quality of life, and fitness, respectively. Compared to the wait-list controls, participants in the yoga intervention reported a significant improvement in quality of life and anxiety over the duration of the study. However, contrary to expectation they found no between-groups changes in fatigue or fitness, and only trends towards an improvement in some mood states (including anxiety and depression) and stress symptoms. The authors gave a detailed assessment of the pilot study's limitations and strengths but did not discuss whether or not they contemplated the lack of significance was the result of a lack of questionnaire sensitivity or even inappropriate selection of questionnaires. This would have been an important consideration in the context of a pilot study where there is room for the exploration, via qualitative methods, of

constructs considered important to the population under study. Also, no follow-up was done to assess lasting effects of the yoga intervention and the authors suggested including other types of cancer and male participants in order to have a more complete picture of the effects of yoga therapy on cancer symptoms and treatment side effects.

Another randomized control trial of the same yoga program was done in 2005 by the same authors to assess the effect of yoga on quality of life, mood disturbance, and salivary cortisol levels, a physiological measure of stress⁵¹. Twenty participants with a variety of cancer diagnoses were randomly assigned to either a control group or a yoga group. Participants completed the EORTC-QLQ-C30, POMS, and gave a saliva sample before and after the intervention. Results showed that those in the yoga group reported a statistically significant increase in quality of life and decrease in mood disturbance, but no difference in salivary cortisol levels. Because only a conference proceeding abstract was available, very little detail was included regarding analysis and consideration of the study's strengths and limitations although the small sample size was listed as a potential explanation for lack of statistically significant findings.

In 2004 a proceeding from the 37th Annual Communicating Nursing Research Conference summarized another study⁵² that proposed a qualitative approach to the evaluation of an eight week, 16-class Iyengar yoga intervention for breast cancer patients. Seven participants were interviewed post-intervention and three were interviewed at approximately the same time after receiving standard care as a comparison. As the summary was in the form of an abstract, very little information was made available regarding the study rationale, the intervention itself, or the methodology, including sampling and analytic strategy. However, by identifying interpretive phenomenology as their approach the authors clarified their intent to explore both themes (i.e., aggregates of events) and exemplars (i.e., single instances of phenomena) leading to a wide range of experience. Preliminary findings indicated that participants disclosed an overall positive quality of life and physical improvement as well as the formation of an informal and unexpected

support group as a result of the yoga program. Conclusions from the evaluation were not yet available.

Studies evaluating the effects of yoga programs influenced by different traditions have involved cancer patients and survivors. A study done in India in 1983⁵³ was one of the first studies to examine the effect of yoga on cancer-related outcomes. The study evaluated a yoga program, transcendental meditation program, and group therapy program, all offered at the same cancer center, at once. Very little detail about the yoga intervention or its duration was provided other than two 90-minute sessions took place each week. The author stated that information was collected via questionnaire but did not specify the name or psychometric properties of the questionnaire that was used or how it was administered other than it was completed after interviews with each of the 50 participants. Results were presented descriptively, as frequencies of stated benefits. These benefits included increase appetite (stated by 11 participants), improved sleep (11 participants), improved bowel habits (13 participants), and feeling of peace and tranquility (10 participants). The author also revealed that the participants tended to blame the adverse effects of radiation on their participation in the yoga class and that at two months post-intervention all yoga participants had ceased practicing yoga. Despite these downsides and the fact that the study design and methodology precluded the use of causal inference, the author concluded that yoga “contributed significantly in improving the quality of life of cancer patients”⁵³. Given the large sample size of this study (125 participants), it seems a waste of resources that a more scientifically rigorous study (i.e., with the use of standardized questionnaires and a control group) was not undertaken.

A controlled study of a seven-week Tibetan yoga program, which aimed to improve quality of life and psychological adjustment, was published in 2004⁵⁴. Tibetan yoga differs from Iyengar yoga in that it adds visualization and mindfulness techniques to the traditional focus on poses and breathing (asanas and pranayama), although few details were given about the program itself. Thirty-nine lymphoma patients were assigned using sequential minimization to either a wait-list control group (19 participants) or the yoga program (20 participants), a design strategy that

facilitated the use of the more statistically powerful regression analysis. At baseline, one-week, one-month, and three-months after the intervention measures of distress, anxiety, depression, fatigue, and sleep disturbance were taken using the Impact of Events Scale, Spielberger State Anxiety Inventory, Centers for Epidemiologic Studies- Depression, Brief Fatigue Inventory, and Pittsburgh Sleep Quality Index scales respectively. All participants in the yoga group considered the yoga program beneficial. The results showed that those in the yoga group reported a significantly greater improvement in overall quality of sleep than the control group but no significant differences in anxiety, depression, or fatigue. Despite the lack of measured effect, a three month follow-up showed that over 80% of patients in the yoga group continued practicing yoga at least once a week, perhaps indicating the presence of an unmeasured benefit of yoga. In the discussion, the authors considered the possibility that the lack of significant findings could have been due to lack of sensitivity of the questionnaires used and suggested the use of non-clinical alternatives (for example the POMS) in order to detect smaller changes in mood states.

In an abstract published in 2005, the same authors studied the same intervention, using the same methodology with the addition of measures of various cancer-related symptoms and quality of life, in a population of 58 breast cancer patients⁵⁵ and found that as in the first trial, those in the yoga group did not experience any improvement in mood or quality of life. Contrary to the first trial however, the second did not find a change in sleep quality. Despite fewer reported cancer-related symptoms and less psychological distress during the follow-up period, quality of life did not change as the result of the Tibetan yoga intervention.

A more recent pilot study evaluated the effect of the Yoga of Awareness Program on pain, fatigue, distress, invigoration, acceptance, and relaxation in a group of 13 women with metastatic breast cancer⁵⁶. The study design included an uncontrolled, pre-post assessment using visual analogue scales (VAS), efficient and validated measures, for each of the symptoms. After the post assessments, a focus group was conducted with ten of the participants to determine how the program could be improved. At the same time participants completed a focus group

questionnaire, which asked participants to rate on a ten-point scale how successful the program was in alleviating the above-mentioned symptoms. The program was structured so that participants attended two-hour classes each week for eight weeks. The philosophy underlying the program was explained to be an innovative behavioral intervention based on Indian yoga. The program included postures, breathing exercises, meditation techniques, study of relevant topics, and group discussions. No details were given regarding the schedule of poses or the specific yoga tradition followed, but the primary author did include a note instructing readers to contact him for further information. The authors used mixed modeling to analyze the quantitative data despite the fact that their sample size was too small to use such a statistically powerful test. No details were given on the subject of qualitative data analysis. The results showed that over time participants indicated statistically significant improvements in invigoration and acceptance and that greater at-home practice was associated with significant improvements in pain, invigoration, and acceptance, and trends towards improvements in fatigue and relaxation. When participants were tested the day following the last class, the results showed improvements in pain, fatigue, invigoration, acceptance, and relaxation. Results from the focus group and focus group questionnaires indicated a high level of satisfaction with the yoga program, that participants valued being in a group of women with the same type of cancer, and that they felt that the yoga program helped alleviate their symptoms. In their discussion, the authors addressed some of the limitations of the study, although they did not consider the effect of repeated testing (post and 1-day after post), as a potential source of testing bias, on the study's internal validity.

These yoga and cancer studies were relevant to the current evaluation as they served to inform the researcher of the present study of outcomes and scales that are relevant to cancer, design limitations, and directions for future research. In particular, these studies were helpful in determining what was missing from the literature and how the present study could contribute to this area of study. First and foremost, many of the studies reviewed above were available only as conference proceedings and as a result, limited information was available.

Due to the lack of detail in the yoga and cancer literature regarding the poses practiced and in some cases the specific yoga traditions followed, it is very difficult to compare the results across yoga programs. This might be the reason for the contradiction in quality of life, mood, and anxiety findings among the randomized controlled trials of the Iyengar-based yoga⁵ and Tibetan yoga programs^{54, 55}. Furthermore, practitioners of Iyengar yoga would argue that Iyengar yoga cannot be modified as done in the studies^{5, 51} out of the Tom Baker Cancer Centre in Calgary, AB, and still be considered Iyengar yoga. Therefore, the effect of Iyengar yoga on cancer is still unclear.

Although most of the published yoga and cancer studies are randomized controlled trials, and therefore considered methodologically sound, the literature is not without methodological problems. Many studies, particularly those presented as conference proceedings, lacked details with regard to methodology and methods, limiting the assessment of each study's validity and credibility. Despite the fact that many of the studies reviewed above were designated pilot studies, there is no documentation of any qualitative inquiry having been done in order to assess for the appropriateness of the outcomes chosen for study, therefore putting to question whether or not the appropriate instruments were chosen. This oversight might account for the contradiction found between the POMS and SOSI anxiety and depression subscale results. Similarly, despite the fact that people with cancer consistently identify spirituality as an important aspect of their quality of life⁵⁷, no studies in the yoga and cancer literature include a measurement of spirituality. The authors of several of the studies commented that the lack of power due to small sample sizes was a study limitation (especially in the uncontrolled studies), a problem that could be lessened by the use of repeated measures. Finally, no studies included a follow-up period which is important when considering the lasting effects of an intervention and its eligibility for recommendation by health care professionals and uptake by patient groups.

2.2 Mindfulness, Mindfulness-Based Stress Reduction, and Cancer

Mindfulness, according to adherents of Buddhism, such as Jon Kabat-Zinn, is “non-judgmental moment-to-moment awareness”⁵⁸. Johnson defines it slightly

differently, as “a condition of relaxed alertness in which we awaken into an awareness of what is real”⁵⁹. Both insist that mindfulness begins with a sensory awareness of the body and continues on to include an awareness of the mind and emotions. With a focus on proper structural alignment, tension is reduced enabling a heightened awareness of emotion and sensations both of which serve to quiet what Johnson calls the “involuntary internal monologue of the mind”, characterized and dominated by “judgments and criticism, hopes, regrets, and fears”⁵⁹. When one focuses on this internal monologue over what is occurring in the present field of experience¹¹, one perceives a sense of helplessness or loss of control, which promotes anxiety and depression^{60,61}. These symptoms of psychological distress can, in turn have a negative effect on mortality and morbidity.

Because of Iyengar yoga’s focus on total self-awareness, via concentration on bodily postures and breathing, it is appropriate to draw from research in the area of mindfulness-based stress reduction (MBSR), which includes a yoga component. One randomized controlled trial done in 2000⁶² assessed the effect of an MBSR intervention on mood disturbance and stress responses among a group of 90 cancer outpatients undergoing treatment or follow-up for cancer. Participants were recruited using convenience sampling and randomized to either the MBSR group or a wait-list control group. The intervention took place over eight weeks where participants met for 90 minutes each week, with a full day silent retreat taking place at week six. The intervention was comprised of three components: the instruction of relaxation, meditation, and the mind-body connection; meditation practice including yoga, at the group meetings and at home; and problem-solving group sessions. In a descriptive schedule of events, the authors revealed that yoga was instructed and practiced in depth at weeks two through four, although it is possible that it was practiced every week. Home-based MBSR practice was assisted through the provision of audio tapes and printed materials given to participants. To test the effect of the MBSR intervention, the POMS and SOSI measurement tools were used before and after the intervention. The authors were thorough in their consideration of confounding factors, in the verification of the effects of randomization (i.e., independent samples t-tests showed that the control and intervention groups were

equivalent with regard to mood disturbance at baseline), and in comparing the participants to the withdrawals for systematic differences (the drop-outs were more likely to report a greater disturbed mood). The authors also considered two methods of analyzing their data: using ANOVA to analyze the raw scores and using independent samples t-test to analyze the change scores (calculated by subtracting scores at T1 from those at T2 for both groups). They found a significant improvement in depression, anger, confusion, and total mood disturbance for intervention participants over control participants (similarly significant results from the change score analysis included anxiety and vigor). In order to provide a more conservative estimate of the intervention's effect on mood, the authors did an intent-to-treat analysis, including the baseline data from those who withdrew from the study. Because no drop-out post-intervention data were available, the authors used the baseline data, assuming that no change would occur in drop-outs. The use of the exact same data is questionable as this minimizes the variance among drop-outs and could either over- or under-estimate the true effect, therefore, it might have been better to match the pre- and post- scores of drop-outs by variance and score. Using the drop-out data, the authors did two intent-to-treat analyses. They ran an ANOVA on the raw scores and found that there were no statistically significant differences on any mood measures between groups. They also ran an independent samples t-test to analyze change scores and found that the treatment group showed significantly greater improvement on the anxiety, depression, anger, vigor, confusion, and total mood disturbance. No justification was ever provided for the use of both statistical analyses, nor was any explanation provided as to which analysis (raw scores or change scores) was considered more valuable to the authors and therefore, which one was used as the basis for the study's conclusions. Because the SOSI includes anxiety and depression subscales, the authors had the opportunity to make a comparison between the SOSI and POMS. They found using raw scores that the intervention group showed a significantly greater improvement in depression but no change in anxiety compared to the control group. Using the change scores, they found no significant change in either depression or anxiety. The intent-to-treat analyses showed no significant changes in either subscale for either analysis. No

speculation was put forth by the authors as to why the discrepancies between measurement tools emerged. The authors did however, give a good assessment of their study's limitations, noting that other elements of the intervention were not accounted for due to the study design, including the relationship between participants and MBSR instructors, relationships among participants, expectancy effects, and problems relating to generalizability of results as participants might have had greater motivation to learn, participate, and succeed at MBSR due to a higher-than-average levels of distress and mood disturbance at baseline.

Another, uncontrolled study was done by the same group in 2003 assessing the effects of the same MBSR intervention on 42 outpatients with early stage breast or prostate cancer⁶³. In addition to the measurement tools used in the earlier trial (POMS and SOSI were used to assess mood disturbance and stress respectively), the authors added a questionnaire to measure health behaviors, as well as the EORTC-QLQ-C30 to measure participants' quality of life. All measures were collected from all participants before and after the intervention in a pre-post, one-group design and were analyzed using a paired-samples t-test. The authors found a significant improvement in quality of life and stress but no change in mood. They reasoned that a floor effect might have accounted for the lack of change in mood as the mean mood disturbance score at baseline was so low that an improvement would be difficult to document. Interestingly, while neither the anxiety nor the depression subscales from the POMS showed any significant change, both corresponding subscales from the SOSI indicated a significant improvement over time. The authors did not include a discussion of this discrepancy in their report. Again, the authors gave a fair account of their study's limitations, pointing out that the lack of control group prevented an assessment of the intervention's contribution to the measured effects over time.

In 2005, the same authors⁶⁴ did another uncontrolled, one-group, pre-post study of the same MBSR intervention's effects on the mood, stress, fatigue, and sleep of cancer outpatients. Similar to their previous studies, the POMS and SOSI were used to measure mood disturbance and stress and the Pittsburgh Sleep Quality Index (PSQI) was added to measure sleep disturbance. All measures were taken

before and after the intervention took place. Results showed that contrary to previous studies, a significant improvement in all POMS outcomes including anxiety, depression, fatigue, anger, confusion, vigor, and mood disturbance occurred over the course of the intervention. Similar to their previous studies, the anxiety and depression subscales from the SOSI indicated a significant improvement in both areas. This study marked the first time that results from the anxiety and depression subscales from the POMS and SOSI were in agreement. The authors also used a Pearson product-moment correlation to assess the association between change scores of all subscales to one another. Of interest, they found that an improvement in sleep was not associated with an improvement in fatigue. While the authors speculated that this might have occurred because of a lack of sensitivity of the fatigue subscale of the POMS, this seems unlikely as the subscale on its own was sensitive enough to detect a change over time. Another explanation that the authors pointed out was that fatigue and sleep are two separate constructs and perhaps the change in sleep occurred as a result of the mindfulness meditation component, whereas the improvement in fatigue occurred as the result of the yoga component, which the authors considered a form of physical activity. Therefore, for future research, the authors recommended that the yoga component be evaluated separately to determine its effects on both outcomes. The authors gave a good assessment of their study's limitations citing the many possible threats to the study's internal validity and defended their choice of study design by saying that the study was exploratory.

An abstract published in 2003 summarized another uncontrolled observational study, involving 24 cancer patients, evaluating a ten-week, multi-modal, MBSR-dominant intervention's effects on quality of life and fatigue⁶⁵. The EORTC-QLQ-C30 was used to measure quality of life and the Fatigue Assessment Questionnaire (FAQ) was used to measure fatigue. Both questionnaires were used before and after the intervention. No details were given regarding the intervention or the analytic strategy and results were only available for 18 participants. Although the authors stated that the evidence showed a significant improvement in fatigue but no change in quality of life over time, given the study's limitation and lack of details

regarding the program and analysis, it is difficult to critically assess the validity of these results and claims.

Finally, a German study looked at the effect of an eight-week MBSR intervention on the quality of life, physical and emotional well-being, and overall psychological distress of 21 people living with chronic physical or psychological illnesses, two of which had been diagnosed with cancer⁶⁶. Although generalization of study results to the rest of the MBSR and cancer literature was extremely limited due to the heterogeneity of the study sample, it is interesting to note that this study included a follow-up assessment and is the only one that employed a qualitative component, in the form of semi-structured interviews at two time points during the study. The participants met for 2.5 hours each week for eight weeks and for seven hours at week 6. The intervention included meditation and yoga exercises and instructors encouraged participants to practice at home at least 30 minutes per day. Participants were also given written materials and audiotapes to guide their home practice. Measurement tools included the Fragen zur Lebenszufriedenheit (FLZ) used to measure quality of life, the General Condition subscale from the Freiburger Beschwerdenlist (FBL-R) used to measure physical well-being, the Befindlichkeitsskala (Bf-S) used to measure emotional well-being, and the German version of the revised Hopkins Symptom Checklist 90 (SCL-90-R) was used to measure psychological distress. All questionnaires were self-administered pre- and post- intervention and three months post-intervention. Nonparametric tests were used because the data was ordinal (and therefore non-normal) and the sample size was small. Participants were interviewed post-intervention and at the three-month follow-up. No details were given regarding the analysis of the interview data. Results showed a statistically significant improvement in all outcomes over the course of the intervention. The authors concluded that because the baseline quality of life scores were similar to those observed in clinical samples, the change in scores indicated that the MBSR intervention under study was clinically relevant. Results from the interviews revealed that participants felt the intervention was a positive experience and that they felt they had undergone “positive qualitative changes in their abilities to live their daily lives in terms of awareness, mindfulness,

calmness and a less encumbered sense of self⁶⁶. Due to lack of detail regarding the analysis of the interview data, it was difficult to attest to the credibility of the qualitative findings.

A common problem with all of the studies investigating the effect of MBSR interventions on cancer is that although ample detail was given regarding the mindfulness meditation aspect of the intervention, very few details were given regarding the yoga component (i.e., schedule of poses or amount of time devoted to yoga) other than to say that Hatha yoga was practiced. Therefore, similar to the yoga and cancer literature, it was difficult to compare these interventions with other yoga interventions. The second problem plaguing all of the above MBSR studies is that because MBSR is a multi-modal intervention (involving mindfulness meditation, group work, and Hatha yoga) it is near impossible to tease out what component of the intervention is making a difference, even using a randomized controlled trial design. One systematic review of the MBSR literature⁶⁷ noted that in pragmatic trials this might not be an issue, while the German study pointed out that the inclusion of semi-structured interviews could shed some light on the problem⁶⁶.

Therefore the objective of the present study was to fill in some of the gaps in knowledge regarding the influence of Iyengar yoga on cancer, as evidenced by the above-mentioned lack of follow-up assessments, measure of spiritual well-being, and repeated assessment of the study outcomes. It was also anticipated that the above-mentioned and recurrent contradictory results would be elucidated by including a qualitative component to the evaluation.

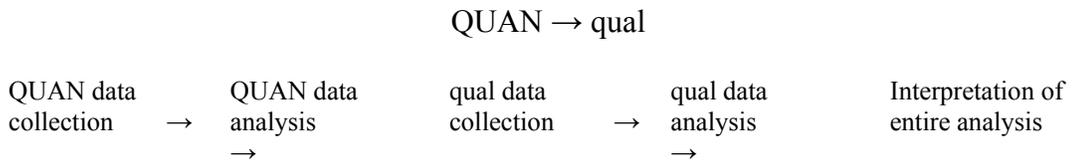
3. METHODOLOGY

3.1 Design

This was a prospective, follow-up study using a one-group, pre-post, mixed methods design. Centered in pragmatism which prioritizes the research problem over prescribed methodology⁶⁸, mixed method study designs reflect the complementarities of quantitative and qualitative methods in their capacity to be responsive to the research context while minimizing the weaknesses and maximizing the strengths typical of each individual method⁶⁹. This study used a quantitative-dominant, sequential explanatory mixed methods design, conducted in two phases. In the first phase, quantitative research questions addressed, with the collection of numeric data from the study sample, the impact of attending an Iyengar yoga program on the quality of life, spiritual well-being, total mood disturbance, and the severity of cancer symptoms and treatment side effects in people currently undergoing cancer treatment or those who have undergone treatment in the previous six months. In the second phase, qualitative interviews were conducted with six participants to elucidate findings from the statistical analysis⁷⁰ in order to further describe the effect of yoga on quality of life and other concerns and symptoms affecting people living with cancer, and to reveal any effects not captured by the quantitative questionnaires.

A mixed methods design was chosen for its ability to obtain information from a large group of participants with cancer and then follow up with a few participants in order to elaborate on and interpret the statistical results in language that resonates with individuals living with cancer⁷¹. Because of this ability, this design was deemed more suitable than either a quantitative or qualitative approach to address the inconsistencies in the literature, while retaining characteristics (such as the use of similar measurement instruments) that enabled the results from this

study to be compared to the existing literature. Methods were mixed at three stages of the present study: research objectives/questions, by including both qualitative and quantitative research questions; data collection, by using an instrument (MYMOP2) that included both open and close-ended items; and interpretation, by comparing information from both methods in the discussion section. The study design can be depicted as follows:



An exploratory, clinical outcomes study framework guided the quantitative phase of the present study. This framework was chosen for its ability to systematically monitor study outcomes over time in a clinical, or “real life”, setting in order to determine if the yoga intervention was safe and if it offered any benefit to the participants⁷².

Case study was chosen as the method of naturalistic inquiry for its ability to provide a detailed study of an entity while maintaining a consideration for the context in which that entity is embedded⁷³. The flexibility inherent in case study easily lent itself to the directional unpredictability of data collection and the ensuing emergence of emic issues⁷⁴. Because the current study called for a more general understanding of the issues related to a more complete evaluation of the Iyengar yoga program omitted by the quantitative questionnaires, as opposed to an in-depth understanding of one participant case in particular, the present study employed instrumental case study to provide insight into the relevant issues at hand⁷⁴. Several participants served as cases so as to address concerns regarding the lack of range, representation and generalizability of results common with intrinsic case study⁷⁴. Therefore, the qualitative inquiry was called instrumental collective case study.

Random assignment was not feasible due to ethical and practical considerations. Because the study participants registered for a yoga program they were less likely to accept being randomized to a control group. Also, because of the vulnerable nature of the study sample, the fact that the intervention was well-

established, and because study stakeholders (including the director of CCMB's Patient and Family Support Services and the lead instructor at Yoga North) were convinced of the intervention's benefits based on past client satisfaction surveys, it was deemed unacceptable to deny participation in the intervention on moral and ethical grounds. Finally, because the program was funded from private donations, it was considered inappropriate and unethical to refuse or delay participation in the yoga program when funds and places were available for all those interested in registering for the yoga program.

3.2 Participant Characteristics

A total of 19 female participants completed the Iyengar yoga intervention. The mean age of the study sample, with standard deviation was 50.26 years (9.48 years). Of the 19 participants, 84.2% identified their race as Caucasian, one woman self-identified as Asian, one as First Nations, and another preferred to decline self-identification based on race. Approximately two-thirds of the sample were married or living common-law and had completed a post-secondary program or degree. Site of cancer ranged broadly among the sample: 47.4% of the participants were diagnosed with breast cancer, 10.5% with ovarian cancer, 10.5% with lymphoma, and the remaining 31.6% with cancer of a different site each. Approximately two-thirds of the participants stated at baseline that they had not yet completed their treatment regimen (see Table 1 below).

Table 1: Participant Characteristics at Baseline

Variable	Mean (SD) or n (%)
<i>Demographic Variables</i>	
Age (years)	50.26 (9.48)
Sex	
Female	19 (100%)
Race	
Caucasian	16 (84.2%)
First Nations	1 (5.3%)
Asian	1 (5.3%)
Other	1 (5.3%)
Education	
High School Diploma	3 (15.8%)
Some University/College/Trade School	3 (15.8%)
University College/Trade School Degree	11 (57.9%)
Masters Degree	2 (10.5%)
Income	
\$20 000-39 999	4 (21.1%)
\$40 000-59 999	5 (26.3%)
\$60 000-79 999	4 (21.1%)
\$80 000 or higher	6 (31.6%)
Employment	
Full time	4 (21.1%)
Retired/Unemployed	2 (10.6%)
Medical Leave	11 (57.9%)
Other	2 (10.5%)
Marital Status	
Married/Common-law	12 (63.2%)
Divorced/Separated	4 (21.1%)
Single	3 (15.8%)
Living Arrangements	
With spouse/family	14 (73.7%)
With others	1 (5.3%)
Alone	4 (21.1%)
<i>Cancer Variables</i>	
Diagnosis	
Breast	9 (47.4%)
Ovarian	2 (10.5%)
Other ^a	8 (42.1%)
Treatment Status	
On treatment	12 (63.2%)
Not on treatment	7 (36.8%)

^a Other Diagnoses Include: Abdominal, Brain, Lung, Lymphoma, Multiple Myeloma, Non-Hodgkins Lymphoma, Tongue, Uterine (5.3% each)

As seen below in Table 2, the tests done to compare the participants who completed the yoga evaluation to those who withdrew from the evaluation (n=15) showed that the two groups differed only in terms of the mean nausea (U= 83.00; p=0.028) and pain (t(32)=2.84; p=0.008) scores at baseline (see the analysis subsection of the results section for the statistical analysis used to compare the groups). In both cases, those who withdrew reported lower nausea and pain than those who remained in the evaluation.

Table 2: Attrition test: Comparison of Participants who Completed the Iyengar Yoga Intervention (n=19) and Those who Withdrew Early (n=15)

Variable	Test	p-value*
<i>Demographics</i>		
Age	0.588 ^a	0.561
Race	1.686 ^b	0.640
Diagnosis	11.015 ^b	0.610
Treatment Status	1.804 ^b	0.179
Previous yoga experience	0.864 ^b	0.353
Educational attainment	9.699 ^b	0.084
Income	4.308 ^b	0.366
Employment status	3.128 ^b	0.680
Marital Status	2.362 ^b	0.501
Living Arrangements	0.838 ^b	0.658
<i>Baseline Variables</i>		
Quality of Life	-0.593 ^a	0.557
Spiritual Well-being	100.500 ^c	0.145
Mood Disturbance	-0.519 ^a	0.607
Anxiety	-0.236 ^a	0.815
Depression	-1.486 ^a	0.147
Fatigue	0.206 ^a	0.838
Nausea	83.000 ^c	0.028
Pain	2.840 ^a	0.008
Energy expenditure	104.000 ^c	0.181
CAM use	105.000 ^c	0.173
Prescription meds use	101.000 ^c	0.146
Self-care measures	-0.056 ^a	0.955
Psychosocial Services use	139.500 ^c	0.852
Trait Anxiety	-0.645 ^a	0.523

^a Independent samples t-test, t(32)

^b Chi-squared test

^c Mann-Whitney *U* test used because data were not normally distributed

*Significance-level $\alpha=0.05$

Participants were recruited from the CCMB Department of Patient and Family Support Service's Iyengar yoga Program conducted at Yoga North in Winnipeg, Manitoba. The yoga program has taken place three times per year to include a winter, spring, and fall session with each session typically including 20 to 25 participants. In the past, participants undergoing treatment for cancer have learned about the program from a variety of sources including physicians, posters, CCMB staff, CCMB's monthly bulletin, The Navigator, and the CCMB website. To be eligible for registration in the yoga program, participants had to be able to read and write in English and have any type and any stage of cancer but must have been treated for cancer within the six months prior to entry into the yoga program. Priority was given to cancer patients who had not yet taken part in the program, however exceptions were made provided space was available. If a former participant experienced a recurrence of cancer, or was on long-term ongoing treatment, he or she could register more than once. In addition to the program inclusion/exclusion criteria, participants were excluded from the evaluation if they had taken more than four Iyengar yoga classes as part of the yoga and cancer program prior to the start of the evaluation (September, 2006) in the interest of including only those participants who were Iyengar yoga naïve. A diagram illustrating participant flow over the course of the study is depicted in Figure 1 below.

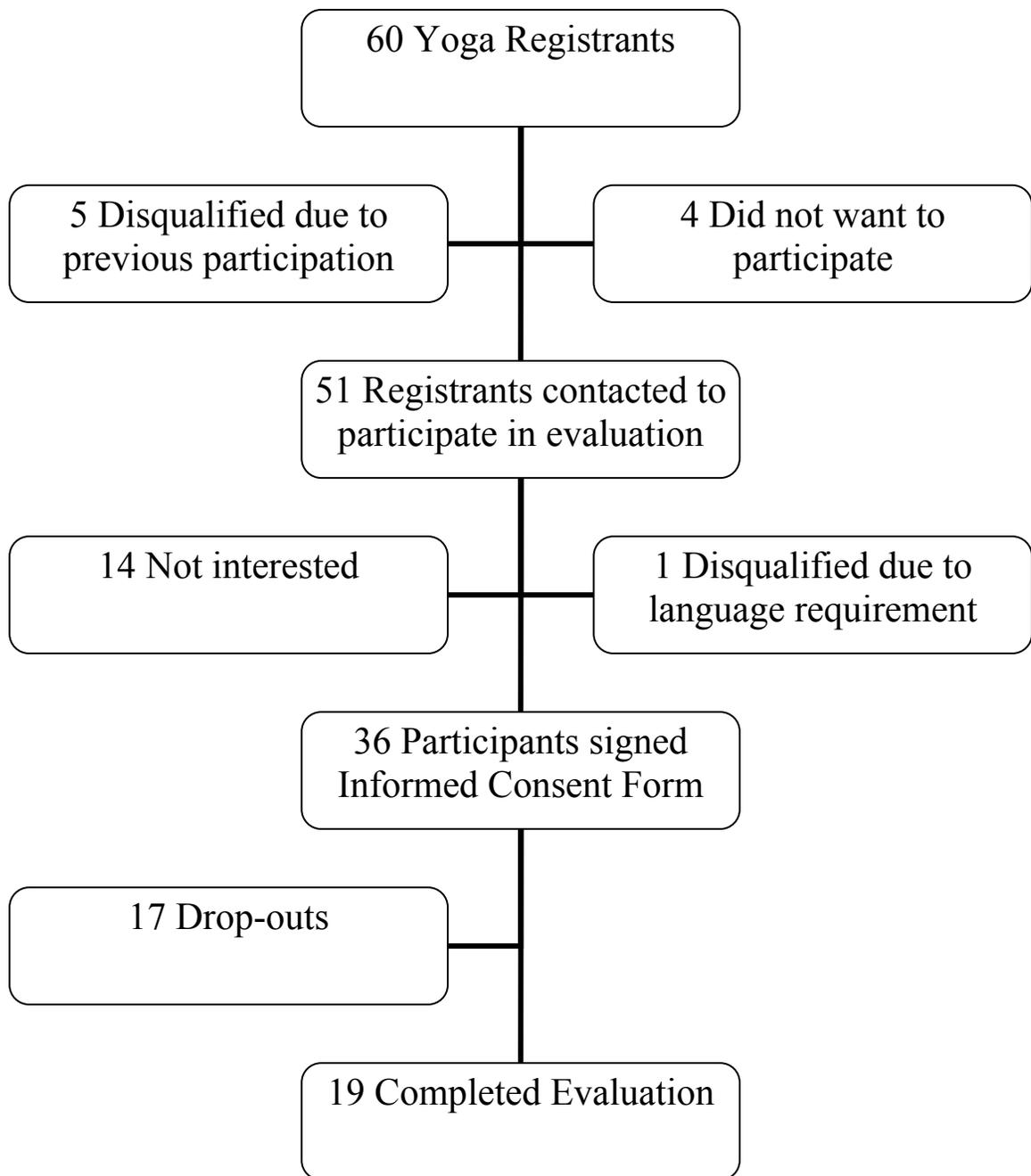


Figure 1: Study Recruitment and Retention

Six participants (over two sessions) were asked to participate in an interview, in addition to completing the study questionnaires, to get a more in-depth account of their experiences with the program. Participants chosen to participate in the interview were selected on the basis of the amount of change they experienced

(as reported by the questionnaires) in overall quality of life and symptom severity over the 10-week yoga intervention. To get the broadest scope of experience and thereby maximize understanding⁷⁴, in each session the participant with the greatest increase, the one with the greatest decrease, and the one with the least amount of change in scores were invited to participate in the qualitative interview.

3.3 Yoga Program

The intervention consisted of 90-minute, once-weekly Iyengar yoga classes and ran for ten weeks. Instruction took place in an environment with minimal distractions as the focus of the program was to develop a sensory awareness of the body and breath. Individual assistance was provided as needed to ensure each participant was capable of assuming each posture with correct alignment. Over the course of the program a number of postures were taught that incorporated four key aspects: restorative and relaxation postures; basic posture/alignment for sitting and standing; basic postures for shoulder problems (targeted at breast cancer patients); and postures to lengthen and release the back. A general restorative program was followed because restorative poses aim to reduce fatigue and pain, and encourage expansion of the chest and good posture which trigger diaphragmatic breathing, which in turn results in concurrent feelings of alertness and calmness, while reducing tension in the chest⁷⁵. Participants were encouraged to practice at home and a manual outlining postures taught in class was written by Yoga North's lead instructor, Val Paape, and was made available to participants.

The yoga instructors at Yoga North were certified by the Iyengar Yoga Association of Canada and, combined, had nearly 30 years experience teaching in the Iyengar method. The instructors were supported by assistants who were long-time Iyengar yoga practitioners and either former teachers or teachers in training. Yoga North is supervised by a senior intermediate teacher to fulfill certification requirements.

3.4 Outcomes

Demographic information (including: sex, race, education level, household income, employment status, marital status, and living arrangements), previous

Iyengar yoga practice, and treatment status were collected at baseline using an intake form to characterize the study sample.

Primary outcomes measured in the present study were quality of life, spiritual well-being, and mood disturbance.

Secondary outcomes measured included anxiety, depression, fatigue, nausea, pain, and other cancer-related symptoms as identified by the participants on the Measure Your Medical Outcome Profile 2 (MYMOP2).

Control variables included: energy expenditure, the use of complementary and alternative medicine, the use of prescription medications, the use of self-care health measures, the use of psychosocial services, and cancer treatment status. Trait-anxiety was measured over the course of the study as a measure of discriminant validity. As trait-anxiety should remain relatively stable over time, no change was expected to be observed over the course of the study. Therefore, it was argued if no change in trait anxiety was observed over the course of the study, then it could be assumed that the study results and conclusions were valid. Demographic information available from CCMB's cancer registry and Psychosocial Oncology's (PSO) patient database were obtained in aggregate form and compared to the demographic characteristics of the study sample in an effort to gauge the generalizability of the study results to cancer patients in the general population.

3.5 Measures

Several important factors must be considered when selecting measurement instruments for the cancer population. As with any other study, instruments should be valid and reliable and appropriate for the population under study. Because this was an exploratory study and feasibility was measured, and because the participants were already under stress due to their diagnoses, it was argued that the instruments should be chosen to obtain an accurate reflection of the participant's experience without adding to the burden experienced by the cancer patient and should therefore be brief and easily completed by the participant. The methods of measurement (administration of questionnaires and interviews) were justified as, in the absence of physical tests, these methods were appropriate for obtaining information on

subjective experiences such as perceived quality of life and severity of symptoms and were done with minimal intrusion to the participants.

3.5.1 Primary Outcome Measures

FACT-G: The Functional Assessment of Cancer Therapy – General (See FACIT-Sp Physical, Social, Emotional and Functional well-being) is easy to complete, has good reliability (with Chronbach's alpha ranging from 0.77 to 0.90⁷⁶), concurrent validity (comparing it to the RAND-36 resulted in significant correlations between 0.21 to 0.73⁷⁷) and sensitivity⁷⁸ and has been used to validate other quality of life measures making it an appropriate measure of quality of life among people with any type of cancer. It is a 27-item self-rated subjective measure of quality of life. Each item is scored from 0 (not at all) to 4 (very much). Four domains make up four subscales namely, functional well-being (7 items), physical well-being (7 items), social well-being (7 items), and emotional well-being (6 items). Scores from negatively worded statements are subtracted from 4 after which all scores are summed to obtain a quality of life score. The higher the score, the higher the quality of life. In order to determine normative and clinical properties of the FACT-G, the scale creators conducted a study of 1075 Americans with cancer⁷⁹. From that study, it was established that the mean quality of life score was 80.1 points with a standard deviation of 18.1 points. The authors also determined that the minimal important difference for clinically significant change was 3 to 7 points which is equivalent to a 2.7 to 6.5% change.

FACIT-Sp: The Functional Assessment of Chronic Illness Therapy-Spiritual well-being subscale (See FACIT-Sp: Sp1-Sp12) is comprised of 12 items divided into two subscales: one, labeled Meaning/Peace (represented by eight items), measures the participant's sense of meaning and peace; the other, labeled Faith (represented by four items), measures the role of faith in illness⁸⁰. The FACIT-Sp is also reliable with Chronbach's alpha ranging from 0.72 to 0.87⁸¹. Spiritual well-being is derived by first subtracting the responses from each negatively worded statement from 4 and then summing the response values of all statements. The higher the score, the higher the spiritual well-being. In a study of 1617 patients the mean spiritual well-being score was 38.5 points with a standard deviation of 8.1

points⁸². In order to derive the minimal important difference score (MID), Webster & Cella's recommendation⁷⁹ to apply the 2.7-6.5% change (from their study of the FACT-G) to the spiritual well-being subscale was followed, resulting in a MID of 1.3-3.1 points (48 points * 2.7% to 48 points *6.5%).

The FACT-G and FACIT-Sp subscale have been combined into one questionnaire, also known as the FACIT-Sp (see Appendix A for the FACIT-Sp), used to measure overall quality of life. An overall quality of life score can be obtained by summing the scores of all subscales of the FACT-G and FACIT-Sp. Although using the EORTC-QLQ-C30 would have facilitated comparisons between the current study and previous yoga and cancer studies, the FACIT-Sp was chosen for its inclusion of spiritual well-being and because it was formed using input from both patients and healthcare professionals⁷⁹ as opposed to the EORTC-QLQ-C30, which was informed only by healthcare professionals⁸³.

POMS-SF: The Profile of Mood States- Short Form measures transient mood states by asking participants to rate a series of adjectives on a 5-point scale ranging from 0 (not at all) to 4 (extremely). Reduced from 65 items to 37, the POMS - Short Form (see Appendix B) allows for easier and faster completion (taking only 3-7 minutes⁸⁴), and might exhibit higher internal consistency than the long form⁸⁵. Six domains are included in the POMS-SF, making six subscales, namely, Anger-Hostility (7 items), Confusion-Bewilderment (5 items), Depression-Dejection (8 items), Fatigue-Inertia (5 items), Tension-Anxiety (6 items), and Vigor-Activity (6 items). The POMS-SF is a reliable and valid measure of mood disturbance with a Chronbach's alpha ranging from 0.78 to 0.91 and factor analysis correlations ranging from 0.55 to 0.89⁸⁵. Subscale scores are obtained by summing the numeric responses of the appropriate adjectives. The higher the score, the higher the level of disturbance on the specific subscale, however, the opposite is true for the Vigor-Activity subscale. Total Mood Disturbance is obtained by subtracting the Vigor-Activity score from the sum of all other subscale scores. The higher the score, the greater the total mood disturbance. In a study of 203 breast cancer survivors, normative data for the POMS-SF were established with the mean and standard deviation reported as 31.67 and 17.3 points respectively⁸⁶. The effect size was

reported as 0.32 in a study by Lemieux et al.⁸⁷ and so the minimal important difference can be calculated by multiplying the effect size by the population standard deviation (0.32 * 17.3 points) to get 5.5 points.

3.5.2 Secondary Outcome Measures

Anxiety, depression, and fatigue were measured using the appropriate subscales of the POMS-SF (refer to the primary outcome measures). Possible scores for anxiety range from 0 to 24, for depression range from 0 to 32, and for fatigue range from 0 to 20. For all three subscales a higher score indicates a greater disturbance in each category. Nausea and pain were measured using the appropriate single-item questions on the physical well-being subscale of the FACIT-Sp (i.e., GP2 and GP4). Scores for each symptom ranged from 0 to 4, with a higher score indicating greater nausea and pain.

MYMOP2: The Measure Yourself Medical Outcome Profile 2 (MYMOP2) is a self-administered, patient-centered measure of health status (see Appendix C). It has been validated (with construct validity coefficients between 0.60 and 0.70) in numerous populations, and has shown a high completion rate⁸⁸. The MYMOP2 is composed of 4-items each scored from 0 (as good as it could be) to 6 (as bad as it could be). The first two items are symptoms that the participant selects as the most bothersome symptoms he or she experiences within a week before the time of administration. The third item is an activity of importance to the participant which is being hampered by his or her cancer or cancer treatment. The fourth item asks the participant to rate his or her sense of general well-being within the week prior to the administration of the MYMOP2. At subsequent administrations the participant again rates the same first four items and is given the option of adding and rating a third symptom. A summary or profile score is typically derived by taking the mean of all scored items⁸⁹. To obtain a change score, the profile score from the first administration is subtracted from the profile score from the subsequent administration. Therefore, a negative change score indicates an improvement in symptom severity, activity impairment, and/or well-being. For the purpose of the current study only the scores from the symptom rated most bothersome at baseline

were compared to determine if a significant change in each participants' self-rated most bothersome symptom occurred over time.

3.5.3 Control Variable Measures

GLTEQ: The Godin Leisure-Time Exercise Questionnaire (see Appendix D) is a valid three-item, self-administered questionnaire used to measure the respondent's usual leisure-time activity, excluding yoga. It allows the administrator to specify his or her own time frame and asks the respondent to record the average duration he or she would engage in strenuous, moderate, and mild exercise in a typical week. Each participant was asked to enter, in minutes, the amount of time they spent engaging in each category of activity during the week prior to questionnaire administration. The response in each category was divided by 60 to get the number of hours per week spent engaging in each level of physical activity. The resulting number in each category was then multiplied by a weighted metabolic equivalent (MET) score (8 METs for strenuous activity, 5 METs for moderate, and 3 METs for mild⁹⁰). Finally, a total energy expenditure score was calculated by summing the MET scores across categories. Therefore the higher the score, the more active the respondent. Test-retest reliability has been demonstrated for the GLTEQ with statistically significant correlation coefficients ranging from 0.46 (moderate exercise) to 0.94 (strenuous exercise)⁹¹.

STAI-T Anxiety (form Y): The State-Trait Anxiety Inventory- Trait Anxiety (see Appendix E) measures trait (i.e., permanent) anxiety by asking participants to rate how they feel "generally" about 20 statements on a scale of 1 (almost never) to 4 (almost always). The STAI-T is a reliable and valid measure with a median Chronbach's alpha of 0.90 and correlations with other questionnaires ranging from 0.73 to 0.85⁹². The STAI-T includes 11 anxiety-present items, which are entered exactly as participants completed the questionnaire, and 9 anxiety-absent items, which are reverse coded⁹². Scores are summed and can range from 20 to 80. A higher score indicates a higher level of trait anxiety.

Participants were also asked to keep yoga diaries (see Appendix F), which were used to collect information on their use of complementary and alternative medicines, prescription medications, any self-care health measures they engaged in,

their use of psychosocial services, and when they received treatments for cancer. The yoga diaries also served to collect information about participants' weekly yoga practice at home, reasons for any missed classes if applicable, and included a section where participants could make comments about anything related to the program and their cancer experience. Information from the yoga diaries was checked in two ways to ensure reliability. To ascertain the accuracy of prescription medications, a CCMB nurse reviewed each participant's CCMB electronic chart and compared it against the entries in the yoga diaries. To verify the accuracy of participants' record of class attendance, responses in the yoga diary were compared to the class attendance record maintained by the yoga instructors at Yoga North.

The above control variables were included in data collection because it was acknowledged that they each could potentially have had an impact on the primary and secondary outcomes under study, independent of participation in the yoga intervention. Initially they were intended to be included as variables in a modeling equation to determine the effect of yoga attendance on each of the outcomes but when sample size prohibited the use of modeling, the control variables were assessed for change over time. It was reasoned that if these control variables did not change over time, they could not have influenced any change observed in the primary or secondary outcomes.

3.6 Procedure

Prior to approaching study participants and commencing data collection, this study was granted ethics approval by the University of Saskatchewan and University of Manitoba research ethics committees and by CancerCare Manitoba's Research Resource Impact Committee (see Appendix G).

When potential participants phoned to register for the Iyengar yoga program they were invited by the CCMB Patient and Family Support Services Department secretary (who was provided with a standard script) to participate in the study. Those who indicated interest in learning more about the study were assigned a two-digit participant number and were contacted by the study coordinator shortly thereafter to describe the evaluation in greater detail and to answer any questions. Those who agreed to read the informed consent form (see Appendix H) were sent a

copy via regular mail. Depending on each participant's availability and preference, a meeting was scheduled with the study coordinator at CCMB to go over the informed consent form and complete the baseline series of questionnaires, comprised of the FACIT-Sp, POMS-SF, MYMOP2, GLTEQ, STAI-T, yoga participant diary, and a generic intake form (see Appendix I) designed to capture demographic and control variable-related information. However, most participants preferred to do all study procedures in the comfort of their own homes. Therefore the informed consent form, along with the baseline series of questionnaires, and the Yoga Diary #1 (to be used from the first yoga class until week 5), were mailed to most participants. Participants were given explicit directions to read and sign the informed consent form prior to completing the baseline questionnaires and to complete the entire baseline package within the two week period prior to their first yoga class. Within four days of sending the informed consent forms, the study coordinator phoned the prospective participants to enquire as to whether they had any questions regarding the study or procedures to ensure that informed consent was being given. The participants then started the ten-week yoga intervention. At each class, attendance was noted by the Yoga North instructors. At mid-session (i.e., at the fifth yoga class) the participants received the Week 5 questionnaire package including the FACIT-Sp, POMS-SF, GLTEQ, STAI-T, and the Yoga Diary #2 (covering the time between week 5 and week 10) via mail and were asked to complete the questionnaires after the fifth class but prior to the sixth class. Completed questionnaires including the Yoga Diary #1 were mailed to the coordinator. At week 10 participants were mailed the post-session battery of tests including the FACIT-Sp, POMS-SF, MYMOP2, GLTEQ, STAI-T, and the Yoga Diary #3 (covering the follow-up period, between week 10 and week 16). Completed questionnaires were returned within one week of the final yoga class via mail along with the Yoga Diary #2. Six weeks after completion of the yoga session, participants completed the FACIT-Sp, POMS-SF, GLTEQ, and STAI-T. These questionnaires along with the Yoga Diary #3 were collected in the same manner as the previous questionnaires. Within the three week period following the final yoga class, qualitative interviews were conducted with those selected, in person at CCMB. The interviews were audio

recorded and transcribed and a copy was mailed to each participant for member-checking.

Due to the small size of the yoga class, all study procedures were carried out for the Fall 2006 and Winter 2007 (i.e., two) yoga sessions.

To further assess the study's feasibility, all participants who withdrew from the study were contacted to establish the reason for their withdrawal. However, several actions were carried out to maximize participant retention and compliance. At each measurement, the questionnaires were sent with personalized letters on CCMB letterhead. These letters ended with an invitation to contact the coordinator at the participant's convenience in the event that they had any questions or concerns. Each mail-out was followed by a phone call to the participant to assess for adverse events, to maintain rapport and trust with the coordinator, and to verify each participant's continued participation in both the yoga program and study. The baseline intake form included a space for the name and number of a person that could be contacted in the event that the participant was not reachable by phone or mail (i.e., they moved away). Extra precautions were taken to ensure the completion of forms and questionnaires. All recruitment and other study materials were attractive and professional. Post-it notes indicated where participants should initial and sign the informed consent form, and indicated examples describing how to complete the forms. To reduce the burden on participants, the coordinator entered the appropriate dates in each Yoga Diary and labeled each questionnaire with the appropriate participant number prior to sending the packages to the participants. The return envelopes were addressed, with postage included, and a post-it note, listing items to be returned in it, was attached to the outside of the return envelope as a reminder to participants.

Throughout the entire study a study log was maintained to keep track of the study progress and communication with participants.

3.7 Analysis

In order to get a fair representation of the Iyengar yoga's effect on study outcomes a critical attendance level was set at five classes. Therefore, only information from participants who attended at least five yoga classes was included

in the analyses. Despite this exclusion criterion, no information was omitted because all participants met the minimum attendance level.

In order to characterize the study sample, descriptive analyses of demographic information and a review and categorization of participants' reasons for joining the Iyengar yoga class were done to characterize the study sample. All quantitative data were double checked by the coordinator before being imputed by hand and analyzed using SPSS (version 13).

Information from the participant diaries was collapsed into categories reflecting the following: CAM modalities, prescription medications, self-care activities, and psychosocial support services. Frequencies for each category were averaged at every data collection point to obtain a weekly mean value in each category for each data collection period.

3.7.1 Intervention (Quantitative) Analysis

To assess the impact of the yoga intervention on all primary, secondary outcomes (with the exception of the MYMOP2 data) and to assess for change among control variables, repeated measures analysis of variance (RM-ANOVA) procedures were done using data from the first 3 (baseline, week 5, and week 10) data collection periods. The same analyses were used to determine change in control variables from baseline to week 10. Baseline and week 10 scores from the MYMOP2 were compared using a paired-samples t-test to determine change over time in participants' self-identified most bothersome symptom.

3.7.2 Follow-up Analysis

To determine if there was an impact of the intervention six weeks following completion, baseline and week 16 (follow-up) measurements were compared, using paired-samples t-tests, for all primary and secondary outcomes (except data from the MYMOP2 as no data was collected at follow-up). The same analyses were used to determine change in control variables from baseline to follow-up.

3.7.3 Validity Analysis

Discriminant validity was assessed by analyzing scores from the STAI-T Anxiety using an RM-ANOVA. Generalizability of the results was assessed by comparing demographic information from the study sample, general population of

cancer patients in Manitoba, and those participating in other CCMB PSO programs using independent-samples t-tests or chi-square tests depending on whether the data provided was interval/ratio or categorical/nominal.

3.7.4 Missing Data

When participants omitted questions on any of the questionnaires, a prorated subscale score was calculated by multiplying the number of questions answered by the sum of the items score and dividing that product by the total number of questions included in the subscale. For example, if a participant answered only six out of seven items on the social well-being subscale of the FACIT-Sp and the sum of those six items came to 20, the prorated social well-being subscale would be calculated as:

$$20 \times (7/6) = 23.33.$$

3.7.5 Interview Determination

To determine who qualified for an interview, scores from the baseline assessment were subtracted from the week 10 assessment to obtain change scores for each participant. Changes in anxiety, depression, fatigue, nausea, and pain were calculated for each participant. In order to make the change scores comparable across symptoms, the change scores from all multi-item symptom scales (i.e., anxiety, depression, and fatigue) were divided by the number of items in each respective symptom scale. An overall adjusted symptom severity change score was calculated by summing the adjusted change scores from each symptom scale. Similarly, an adjusted quality of life change score was obtained by dividing the overall quality of life change score (from the FACIT-Sp) by 39 (the number of questions on the FACIT-Sp). A composite change score was then derived by adding the overall adjusted symptom severity change score to the adjusted quality of life change score. Positive scores indicated an overall improvement in quality of life and/or symptom severity whereas a negative score indicated the reverse. A score of zero indicated no change over the course of the yoga program. Participants selected for an interview were those who had the highest (positive) change score, the lowest (negative) change score, and the change score closest to zero, in order to represent

the participants who experienced the greatest improvement, the greatest decline, and no change over the course of the Iyengar yoga intervention.

3.7.6 Instrumental Collective Case Study Analysis

Analysis of the interview data was an iterative process taking place throughout and after the data collection period. In other words, analysis guided the interviews determining which questions were asked, and therefore guided what data were collected (see Appendix J for interview guide). At the end of each interview, the main points were summarized by the researcher for purposes of member checking for credibility and researcher understanding. As interview transcription took place and as the transcripts were verified by participants, categories of interest emerged and were refined. When the interview transcripts were returned, the data were coded according to themes and categories and emergent meaning was largely based on repeated or consistent occurrence of emic issues, a process called categorical aggregation⁷⁴. This preponderance in the use of categorical aggregation to reveal meaning is common in instrumental case study where cases serve to provide information for theory development or understanding of a phenomenon of interest in greater depth⁷⁴. However, direct interpretation was used when a significant event occurred only once, for example, when the participant cases relayed the down-sides of the Iyengar yoga program, which were expected to be unique to each participant's experience.

Credibility, the qualitative equivalent of internal validity, was verified by member checking both during and after the interview by summarizing interview results and allowing the participants to verify the interview transcripts. Triangulation was also used to verify the case study's credibility. Emerging categories of observation and themes were triangulated by verification with study stakeholders (i.e., the lead instructor at Yoga North) with pre-existing literature and theory relevant to those categories, with the use of multiple sources of information (i.e., several participant cases), and by checking the consistency of information provided in the interview against the information obtained in the participant diaries⁹³. Confirmability was assured with the use of an audit trail⁹³, which included the preservation of all original raw data (i.e., interview transcripts with comments,

and all Yoga diaries), and a qualitative study log maintained by the researcher/coordinator to document the data collection and analysis processes, including the products of data analysis and synthesis⁹³. Also, an attempt was made to ensure the transferability of assertions to other contexts with the inclusion of description in the form of quotes⁹³. The inclusion of quotes also served to allow readers to draw their own conclusions from the data.

3.7.7 Feasibility Assessment

Finally, in order to assess the feasibility of an evaluation of a yoga program targeted at cancer patients, response rates were determined for all diaries and questionnaires by summing the number of diaries and questions completed across all measurements and dividing that number by the total number of diaries and questions asked over the course of the study. These calculations were done using Microsoft Office Excel 2003.

3.7.8 Attrition Test

In order to assess the effect of attrition, participants who completed the study were compared to those who withdrew from the study on a number of variables and scale scores collected at baseline including: age, sex, race, diagnosis, treatment status, previous yoga practice, educational level, employment status, household income, marital status, living arrangements, quality of life, spiritual well-being, total mood disturbance, anxiety, depression, fatigue, nausea, pain, energy expenditure, and use of complementary and alternative medicines, prescription medicines, self-care measures of health care, psychosocial services, cancer treatment status, and trait anxiety. These comparisons were done using independent-samples t-tests, chi-squared tests, and Mann-Whitney *U* tests, depending on the nature of the data used, using SPSS (version 13).

3.7.9 Statistical Test Assumptions

Prior to comparing means using an independent-samples t-test, related-samples t-test, or RM-ANOVA, two assumptions had to be tested and met. The first, the assumption of normality, is the assumption that the samples being compared come from normally distributed populations⁹⁴. For all variables this assumption was assessed using the Kolmogorov-Smirnov (K-S) test, a goodness of fit test that

compares the study sample to a normally distributed theoretical sample⁹⁵. The second assumption, the homogeneity of variance assumption, posits that the samples being compared came from populations with equal variances⁹⁴. When comparing the means of two independent groups this assumption was tested using Levene's test for equality of variances. When comparing the means of two related-samples, this homogeneity of variances was automatically assumed. Finally, when comparing several means using the RM-ANOVA, a non-significant Mauchly's Test of Sphericity was used to confirm the assumption of homogeneity of variance⁹⁵. When either or both of the assumptions were violated, prohibiting the use of an independent-samples t-test, or a paired-samples t-test, a non-parametric Mann-Whitney *U* test, or Wilcoxon signed-ranks test, respectively, were done to compare ranks of the outcome responses in each group⁹⁴. When the outcome variable was dichotomous, McNemar's test was used instead of using the paired-samples t-test⁹⁴. When the normality assumption was violated when calculating a RM-ANOVA, its non-parametric equivalent, Friedman's chi-squared test was used in all cases except when the outcome variable was dichotomous, in which case Cochran's Q test was used⁹⁴. When the RM-ANOVA homogeneity of variance (sphericity) assumption was violated, the most commonly used correction⁹⁵, the Greenhouse-Geisser F-statistic was used to determine the magnitude of the change over time.

3.7.10 Multiple Comparisons

Because of the exploratory nature of the present study several statistical tests were conducted. While this multiple hypothesis testing served to provide useful information, it did pose a problem. Namely, when several tests are executed using the same data set, the probability of finding a statistically significant result is much higher than if only one test is being conducted, an effect known as inflation of the alpha level⁹⁶. Consequently, the risk of making a Type I error (rejecting the null hypothesis, when it is in fact true) is amplified. Therefore researchers who perform multiple statistical tests using the same data set (known as a "family of tests"⁹⁶) run the risk of concluding that the intervention under study produced an effect or change when in fact it produced no change. The following formula is used to assess the

probability of making at least one Type I error when considering a family of tests using the same data set:

$$\alpha_{FW} = 1 - (1 - \alpha_T)^C$$

where α_{FW} is the alpha level for the family of test (i.e., family-wise alpha), α_T is the alpha level of each test (i.e., test-wise alpha), and C is the number of tests or comparisons performed on the data set.

In the present study the alpha level of each test was 0.05 and 31 tests were performed on the data set (15 outcomes/variables (primary, secondary, and control) assessed to test the effect of both the intervention and of the follow-up period; and the comparison using the MYMOP2 data). Therefore the adjusted, family-wise⁹⁶ alpha level is 0.78, indicating a high probability of making at least one Type I error among the 31 tests.

Measures can be taken to correct for the inflation of the alpha value brought on by multiple comparisons. The most popular method is called the Bonferonni correction and proposes that the alpha level of each test be adjusted by choosing a fixed family-wise alpha level (for example, 0.05) and dividing that number by the number of tests performed. While the Bonferonni correction is easy to compute, it often yields test-wise alpha levels that are too conservative⁹⁶ therefore increasing the Type II error and decreasing the power of the test. This is the case in the present study ($\alpha_{FW} = 0.05/31 = 0.00161$). A slightly less conservative alpha level can be obtained through the use of the Šidák formula which is as follows:

$$\alpha_T = 1 - (1 - \alpha_{FW})^{1/C}$$

When tests within a study are dependent, as in the present case, the above formula gives a lower-bound⁹⁷ and hence, comparatively conservative estimation of α_T which, in the present case, was calculated at 0.00165.

Other multiple testing methods, such as the Holm method, involve ordering the hypotheses and p-values and testing the hypotheses sequentially until the resulting p-value exceeds the adjusted alpha value after which all subsequent hypotheses are assumed null⁹⁷. This approach was deemed inappropriate because the hypotheses testing control variables could not logically be prioritized among the hypotheses testing primary and secondary variables. Although the Šidák correction

was judged the most appropriate correction for the present study, because such a low alpha value decreased the power of the study it was preferable to consider the study's exploratory nature and set the family-wise alpha value at 0.05 while acknowledging there could be a potential increase in the risk of Type I error.

4. RESULTS

4.1 Yoga Expectations

To further characterize the study sample, participants were asked the following open-ended question at baseline: “What do you hope to get out of the Iyengar yoga program?” It was clear from the responses that many participants had definite expectations associated with participation in a yoga program, particularly one that included only people living with cancer. Responses were coded and grouped in the following categories:

Physical benefits: Participants hoped to obtain some relief from cancer and treatment-related symptoms, including pain; engage in physical activity; as well as increase their strength, mobility, flexibility, and energy level.

Social benefits: Several participants looked forward to getting some benefit from being included in a group of others living with cancer. These benefits included meeting new people; fellowship and camaraderie; and peer support.

Psychological benefits: Many participants anticipated a reduction in anxiety and stress as well as an increased capacity to relax as a result of participating in the yoga program.

Spiritual benefits: Several participants believed participating in a yoga program would enable them to build spiritual strength, make time for meditation, and feel more connected and at peace during their treatment and recovery.

Overall health: Approximately one quarter of the participants expected yoga to have a general positive effect on their total sense of well-being. Many of these participants also had expectations that yoga would affect many aspects of the self (i.e., physical, mental, emotional, and spiritual), indicating a perceived importance of a holistic approach to health.

Capacity building resources: Many participants hoped that the yoga would supply them with tools they could use, outside of class, during their treatment and recovery. For example, several participants expected yoga would teach them to relax and deal with the psychological and physical symptoms of cancer.

Mental benefits: Two participants also expected that their yoga practice would improve their ability to focus and think.

Most participants expressed their expectations using pro-active language. For example, one woman expressed a wish to “start taking my body back” another was looking to “reactivate my body after [...] treatment/surgery”

4.2 Statistical Test Assumption Results for Study Outcomes

The requisite statistical test assumptions were met for most of the statistical tests used to analyze the study data. However, the normality assumption was violated for the RM-ANOVAs and paired samples t-tests assessing change in the use of psychosocial services and cancer treatment both throughout the intervention and at follow-up; and for the paired samples t-test that assessed the degree of change in nausea at follow-up. Therefore, Friedman’s chi-square test was used in place of the RM-ANOVA to assess change in the use of psychosocial services throughout the intervention. Cochran’s Q test was used instead of the RM-ANOVA to assess change in cancer treatment over the course of the intervention. Wilcoxon’s signed-rank test was used in place of paired-samples t-tests to assess change in both nausea and use of psychosocial services at follow-up. Finally, McNemar’s test was used instead of a paired-samples t-test to measure the degree of change in cancer treatment status at follow-up. The homogeneity of variance assumption was not met on two occasions over the course of the intervention: when using RM-ANOVAs to assess the degree of change in use of CAM and other self-care health measures. Instead of using the “sphericity assumed” F-test statistic, the Greenhouse-Geisser F-test statistic was used.

4.3 Intervention (Quantitative) Results

4.3.1 Primary Outcomes

As seen below in Table 3, the yoga participants’ quality of life as measured by the FACT-G portion of the FACIT-Sp increased significantly during the 10-week

Iyengar yoga program ($F(2, 36) = 9.694$; $p < 0.001$). Over the course of the 10-week intervention the mean change score of 9.92 points exceeded the minimal important difference of 7 points signifying a positive clinical effect as well. Spiritual well-being showed a similarly significant increase over time both statistically ($F(2, 36) = 10.164$; $p < 0.001$) and clinically, with the mean change score (5.94 points) nearly doubling the minimal important difference of 3.1 points. Finally, total mood disturbance, as measured by the POMS-SF decreased significantly over the course of the intervention. This decrease was both highly statistically ($F(2, 36) = 11.824$; $p < 0.001$.) and clinically significant with a mean change score (13.85 points) more than double the minimal important difference of 5.5 points.

Table 3: Results from the 10-week Iyengar Yoga Intervention

Variable Type	Outcome	Mean at baseline (SD)	Mean at Week 5 (SD)	Mean at Week 10 (SD)	F-test ^a	p-value
Primary Outcome	Quality of Life	64.64 (13.30)	68.43 (17.71)	74.56 (16.67)	9.694	<0.001 ^h
	Spiritual Well-being	31.11 (10.70)	33.47 (10.18)	37.05 (9.27)	10.164	<0.001 ^h
	Mood Disturbance	28.58 (22.55)	24.68 (20.77)	14.73 (20.25)	11.824	<0.001 ^h
Secondary Outcome	Anxiety	7.58 (6.47)	7.89 (5.56)	5.16 (4.80)	7.367	0.002 ^h
	Depression	6.16 (5.05)	5.89 (5.76)	4.56 (5.29)	2.185	0.127
	Fatigue	9.42 (5.03)	8.68 (4.22)	7.39 (3.98)	1.994	0.151
	Nausea	1.32 (1.06)	0.79 (0.92)	0.74 (0.93)	4.353	0.020
	Pain	2.47 (1.12)	1.74 (1.19)	1.84 (1.21)	6.280	0.005 ⁱ
	Most Bothersome Symptom	4.37 (0.83)	-	2.47 (1.81)	4.256 ^b	<0.001
Control Variable	Energy Expenditure (METS)	13.14 (11.62)	13.77 (12.21)	14.49 (12.20)	0.183	0.834
	CAM use	5.39 (6.34)	4.45 (6.14)	5.51 (7.19)	0.447 ^{c,d}	0.586
	Prescription Meds	20.67 (17.17)	17.28 (16.03)	15.18 (16.17)	2.088 ^c	0.140
	Self-Care	13.56 (13.90)	16.15 (17.54)	18.98 (23.54)	0.762 ^{c,d}	0.434
	Psychosocial Services	0.17 (0.51)	0.31 (0.58)	0.38 (0.74)	3.308 ^e	0.191
	Cancer treatment	13 No/ 6 Yes ^f	13 No/ 6 Yes ^f	13 No/ 6 Yes ^f	0.000 ^g	1.000
	Trait Anxiety	43.05 (10.78)	42.36 (12.54)	37.37 (10.51)	10.195	<0.001 ^h

^aOne factor RM-ANOVA (Baseline, Week 5, Week 10), df (2, 36) unless otherwise noted

^bPaired samples t-test, df(18); no measure taken at Week 5

^cOne factor RM-ANOVA, df (2, 34)

^dGreenhouse-Geisser F-test used because sphericity assumption not met

^eFriedman's Chi-Square test (df=2) used because data not normally distributed

^fNo= Not on treatment; Yes= On treatment

^gCochran's (Q) test (df=2) used because data are dichotomous (not normally distributed)

^hSignificant pairwise changes Baseline-Week 10 and Week 5-Week 10

ⁱSignificant pairwise change Baseline-Week 5

4.3.2 Secondary Outcomes

Of the six secondary measures, anxiety, nausea, pain, and the participants' self-identified most bothersome symptom at baseline, reached statistical significance (See Table 3 above). Compared to baseline, participants reported a decrease in anxiety ($F(2, 36) = 7.367$; $p = 0.002$), nausea ($F(2, 36) = 4.353$; $p = 0.020$), pain ($F(2, 36) = 6.280$; $p = 0.005$), and severity of their worst physical or emotional symptom ($t(18) = 4.256$; $p < 0.001$) once the yoga program was finished. The non-significant results for depression ($F(2, 36) = 2.185$; $p = 0.127$) and fatigue ($F(2, 36) = 1.994$; $p = 0.151$) indicated that although some decrease was reported over time for both variables, the mean scores did not change appreciably from one measurement to the next.

4.3.3 Control Variables

As seen above in Table 3 the yoga participants' self-reported energy expenditure did not change significantly over the course of the 10-week intervention ($F(2,36) = 0.183$; $p = 0.834$). For the duration of the yoga program, the study participants did not vary their use of complementary and alternative medications ($F(2, 34) = 0.447$; $p = 0.586$), prescription medications ($F(2, 34) = 2.088$; $p = 0.140$), psychosocial services ($\chi^2(2) = 3.308$; $p = 0.191$), or other self-care measures ($F(2, 34) = 0.762$; $p = 0.434$). Also, cancer treatment schedule did not change at all over the period of the yoga program ($Q(2) = 0.000$; $p = 1.000$), with 13 participants not on treatment and 6 participants on treatment at each measurement point throughout the intervention.

4.3.4 Effect Sizes

The effect size of an intervention is the difference that is considered clinically meaningful⁹⁸, and can be calculated by dividing the minimal important difference by the population standard deviation⁹⁴. To give a standard definition of effect size magnitude, Cohen designated an effect size of 0.2 as small, 0.5 as medium, and 0.8 as large⁹⁹. Effect size also impacts the sample size required to show a statistically significant change: for those effect sizes considered small, it is necessary to increase the sample size. Effect sizes were calculated in SPSS for all

normally distributed variables and outcomes analyzed using RM-ANOVAs and paired-samples t-tests and the results can be found in table 4.

Table 4: Effect Sizes from the 10-week Iyengar Yoga Intervention

Variable Type	Outcome	Effect size (Partial Eta ²)	Magnitude of Effect Size
Primary Outcome	Quality of Life	0.350*	Small to medium
	Spiritual Well-Being	0.361*	Small to medium
	Total Mood Disturbance	0.396*	Small to medium
Secondary Outcome	Anxiety	0.290*	Small to medium
	Depression	0.108	Very small
	Fatigue	0.100	Very small
	Nausea	0.195*	Small
	Pain	0.259*	Small
	Most Bothersome Symptom	1.352* ^a	Very large
Control Variable	Energy Expenditure	0.010	Very small
	CAM use	0.023	Very small
	Prescription Meds	0.111	Very small
	Self Care	0.033	Very small
	Trait Anxiety	0.362*	Small to medium

*RM-ANOVA/paired-samples t-test was significant $p < 0.05$ ($p = 0.020 - < 0.001$)

^a Effect size calculated using Cohen's d ($d = \text{mean}_1 - \text{mean}_2 / \sqrt{(\text{std dev}_1^2 + \text{std dev}_2^2)/2}$)

4.4 Follow-up

As seen below in Table 5, compared to baseline, at six weeks after the Iyengar yoga intervention, participants reported a statistically significant increase in quality of life ($t(17) = -3.673$; $p = 0.002$) as well as statistically significant decreases in total mood disturbance ($t(17) = 2.349$; $p = 0.031$), and nausea ($Z = -2.565$; $p = 0.010$).

Table 5: Results from the Follow-up at Week 16: Comparing Baseline to Six Weeks Post-Intervention (n=18)

Variable type	Variable	Mean at baseline (SD)	Mean at Follow-up (SD)	t-test ^a	p-value
Primary Outcome	Quality of Life	65.34 (13.32)	76.19 (16.22)	-3.673	0.002
	Spiritual Well-being	31.44 (10.90)	34.71 (10.20)	-1.526	0.145
	Total Mood Disturbance	28.33 (23.18)	16.39 (24.19)	2.349	0.031
Secondary Outcome	Anxiety	7.67 (6.65)	6.39 (6.60)	1.279	0.218
	Depression	6.11 (5.19)	5.28 (5.06)	0.770	0.452
	Fatigue	9.39 (5.17)	7.33 (4.87)	2.033	0.058
	Nausea	1.28 (1.07)	0.44 (0.70)	-2.565 ^b	0.010
	Pain	2.44 (1.15)	1.89 (1.28)	1.890	0.076
Control Variable	Energy Expenditure (METS)	13.66 (11.72)	18.56 (20.67)	-0.948	0.356
	CAM use	4.94 (6.42)	5.39 (7.44)	-0.294	0.772
	Prescription Meds	17.83 (16.04)	15.55 (15.89)	0.621	0.543
	Self-Care	14.11 (13.70)	18.39 (25.02)	-0.669	0.513
	Psychosocial Services	0.17 (0.51)	0.11 (0.23)	-.406 ^b	0.684
	Cancer treatment	12 No/ 6 Yes ^c	14 No/ 4 Yes ^c	-- ^d	0.727
	Trait Anxiety (STAI-T)	42.50 (10.82)	38.83 (13.53)	1.870	0.079

^aPaired-samples t-test (Baseline, Week 16), df (17) unless otherwise noted; t-test calculated as (Baseline-Week 16)

^bWilcoxon signed-rank (Z) test used because data not normally distributed

^cNo= Not on treatment; Yes= On treatment)

^dMcNemar's test used because data are dichotomous (not normally distributed)

The mean changes in quality of life (10.85 points) and total mood disturbance (11.94 points) both also represent clinically significant differences

compared to the minimal important differences for each (7 and 5.5 points respectively). Participant responses also indicated trends ($p < 0.1$) towards decreases in fatigue ($t(17) = 2.033$; $p = 0.058$), pain ($t(17) = 1.890$; $p = 0.076$), and trait anxiety ($t(17) = 1.870$; $p = 0.079$).

4.5 Validity

4.5.1 Internal Validity

Trait anxiety, the intended measure of discriminant validity, changed significantly over the course of the 16 week evaluation. Specifically, the F-test ($F(2, 51) = 5.523$) showed a significant ($p = 0.002$) decrease in mean trait anxiety.

4.5.2 External Validity

In order to determine whether the study's findings could be generalized to other cancer populations, the ages, gender, and diagnoses of the present study sample were compared to the ages, gender, and diagnoses of both the population of cancer patients accessing PSO services at CCMB, and the general cancer population seeking treatment for cancer in Manitoba.

From September 1, 2006 to March 31, 2007 (roughly the same time period the yoga program spanned), 292 cancer patients accessed services offered through PSO at CCMB. The CCMB cancer registry's most up-to-date information included information on 6240 adults treated for cancer from 2004-2005. Only adults were included in the comparison analyses to match the study inclusion criteria. The variables used for comparison were selected based on availability from both sources. Diagnoses were divided into breast cancer, gynecological cancers (including cancers in reproductive and sex organs), lymphomas, and other cancers. Categories were based on the study sample so that any diagnosis that applied to more than one study participant constituted a group and therefore qualified as its own category.

An independent samples t-test showed that the study sample did not differ from the cancer population accessing services in the PSO department at CCMB ($t(216) = -1.461$, $p = 0.145$). A Pearson's chi-square test was used to determine the degree of similarity between both groups with regard to diagnoses. Results showed that there were no significant differences between the yoga group and cancer

patients accessing PSO services ($\chi^2(3)=1.237$, $p=0.744$). A Pearson's chi-square test was also done to measure the similarity with respect to gender between both groups. The results showed that significantly more males were accessing services provided by PSO than participated in the yoga evaluation ($\chi^2(1)=8.633$, $p=0.003$).

Compared to the general cancer population in Manitoba, the study sample was significantly younger and less varied in age ($U=16503.500$, $p=0.001$), contained more participants with breast cancer and lymphoma and less patients with other cancer diagnoses ($\chi^2(3)=9.547$, $p=0.023$), and contained fewer male participants ($\chi^2(1)=17.760$, $p<0.001$).

4.6 Reliability

The yoga diaries were compared to the electronic charts maintained by CCMB. These charts contained information recorded by oncologists, oncology nurses, pharmacists, dieticians, and social workers working at CCMB. Information recorded included treatment related medications and, when disclosed by patients, other medications and supplements as prescribed by the patients' family physician and other health professionals (for example: allergists, naturopaths, etc.). Due to either inconsistent reporting by health professionals at CCMB or lack of disclosure by the patients, a confirmation of neither complementary and alternative medications, psychosocial services, nor self-care health measures (including supplements) was possible and therefore only prescription medications were verified for reliability.

Overall, 87.56% of prescription medications reported in the yoga diaries also appeared in the electronic charts and vice versa. Because there was a high degree of agreement between the two records with regard to prescription medications, we can assume a similar degree of accuracy in the other categories captured by the diaries.

4.7 Instrumental Collective Case Study Results

The main reason for the inclusion of a qualitative component in the present study was the presupposition, based on contradictory findings in the literature, that the questionnaires used would not completely capture the essence of what an Iyengar yoga program does or does not do for people living with cancer. In the five years prior to this evaluation, CCMB had previously administered a client

satisfaction survey to all participants who completed the Iyengar yoga program, which was met with exclusively enthusiastic and positive anecdotal evidence in favor of the yoga program. The results of these surveys left the current study stakeholders, namely the yoga instructors and the director of CCMB's Patient and Family Support Services Department, convinced of the benefits of yoga for people with cancer. Although new to yoga and cancer research, the coordinator was influenced by the stakeholders' beliefs as well as by her own family history of cancer and her family's resultant belief in the need for and benefit of programs designed to offer support to cancer patients to enhance quality of life and well-being.

For each yoga session, three participants were interviewed based on the amount and direction of change they experienced over the ten-week intervention. To get an idea of the range of participants included by interview, a brief introduction of each participant, organized based on the selection criteria, follows*.

Most improved:

The most improved participant from the fall yoga session was a single 33-year-old Caucasian university graduate. Kate was diagnosed with Non-Hodgkin's lymphoma five months prior to starting the yoga classes and was on treatment and on medical leave when she started the classes. She joined the yoga program because she was bored and had joined everything else that CCMB had to offer. At baseline she reported a low quality of life and spiritual well-being, a moderate mood disturbance, and a low level of physical activity. At the end of the program she reported substantial improvements in all of these areas including her most bothersome symptom, and she reported practicing yoga at home an average of 48 minutes per week during the follow-up period. A very outgoing and talkative woman, she expressed enthusiasm for the Iyengar yoga program, especially the social aspect. She felt that her initial expectations of becoming active again, establishing a routine, meeting others, and starting to take her body back were met and exceeded by the yoga program.

* Pseudonyms were used to protect the identities of the women who were interviewed.

Susan, the woman identified as the most improved participant from the winter yoga session, was a married 42-year-old Caucasian female with some university education. She was diagnosed with breast cancer four months prior to starting the yoga classes and was on radiation and endocrine therapies until the third week of the program after which she switched to just endocrine therapy. At baseline she was on medical leave but by the last class she had started a new job, and had plans to return to university. A former student at Yoga North, she registered for the cancer class because she was eager to continue her Iyengar yoga practice at a level that was suitable to her capabilities, and because she wanted to reduce the side effects of radiation therapy and continue exercising, expectations she felt were met by the yoga program. Over the course of the yoga program she went from reporting a moderate quality of life, spiritual well-being, and mood disturbance, to reporting near-perfect scores, indicating substantial improvements, in all areas including her worst symptom. She also reported practicing yoga at home an average of 3 hours per week during the follow-up and joined another class at Yoga North.

No change:

The participant from the fall session who reported no change was a married 46-year-old Caucasian university graduate named Rebecca. She was diagnosed with head and neck cancer four months prior to the first yoga class and was not on treatment at baseline but underwent surgery the day of the last class. She was very quiet throughout the interview (possibly due to the site of her cancer) but did express that her initial expectations of increasing her flexibility, having a opportunity to relax, and fellowship with the other participants were met by the yoga class. Over the course of the program her quality of life and mood increased by only two points and one point respectively, her worst symptom worsened by one point and her spiritual well-being stayed the same. Despite this lack of measured benefit however, she reported that she practiced yoga at home after the program ended for approximately 72 minutes per week.

The participant from the winter session who reported no change was Mary, a married 63-year-old Caucasian unemployed high school graduate. She was diagnosed with multiple myeloma 10 months prior to commencing the yoga

program and had completed treatment prior to the first class. A self-described caregiver who placed a high priority on her family, she felt it hard to accept help from others and so joined the yoga class as a way to help herself. Her expectations included becoming healthier, improving her coordination, strengthening her body, and learning to relax and she felt these expectations were met by the yoga program. Over the yoga intervention she experienced a slight improvement in quality of life and mood and a substantial improvement in both spiritual well-being and her most bothersome symptom. While she did practice yoga at home when attending classes, she did not continue to practice in the follow-up period.

Most declined:

The participant from the fall session who reported the greatest decline was a divorced 50-year-old Caucasian college graduate. Helen was diagnosed with breast cancer six months prior to starting the yoga classes and had completed treatment prior to the first class. At baseline she was in transition from medical leave to working part-time. An introspective person, she signed up for the yoga classes with the hope that she would develop tools for coping as well as strengthen, relax, and increase flexibility in areas affected by her multiple surgeries, expectations she felt were met by the yoga program. Over the course of the yoga intervention she reported no change in quality of life, spiritual well-being, or most bothersome symptom, but did report a considerable decline in mood disturbance. Although she practiced at home very little while classes were in session, she reported during the follow-up that she practiced yoga at home every day for approximately 25 minutes in order to prepare herself for her daily meditation practice and prayer.

Vicky, the participant from the winter session who reported the greatest decline was a single 55-year-old Caucasian college graduate. She was diagnosed with uterine cancer five months prior to the first yoga class and was on treatment and on medical leave for the entirety of the yoga intervention. A fun-loving and vivacious woman, she joined the yoga class because she felt it was important to join all programs offered by CCMB and because she hoped to make friends, find a way to relax, and increase the mobility of areas affected by surgery. She felt all of her expectations were exceeded by the program. Over the course of the yoga

intervention she reported consistently low quality of life and spiritual well-being, and high mood disturbance and severity of her most bothersome symptom. She reported a sizeable decrease in quality of life, minor increases in mood disturbance and worst symptom, and no change in spiritual well-being over the duration of the yoga program. Although she did not practice at home while classes were in session, she reported during the follow-up that she practiced yoga at home approximately 55 minutes per week.

As the coordinator had never been diagnosed with cancer, it was necessary for her to familiarize herself with the context surrounding a cancer diagnosis and treatment. Although the coordinator was aware that the participants might not feel comfortable discussing their diagnoses and treatments, once trust was established between each participant and the coordinator, the participants were for the most part surprisingly forthcoming about their experiences. Thus the coordinator gained a moderately better understanding of what it means to be diagnosed with and treated for cancer. Those who did share their experiences expressed feeling different emotions following their diagnoses and treatment, shedding light on the reality that cancer is a complex and personal experience. Susan described her cancer diagnosis as a frightening and anxiety-inducing experience: “The diagnosis and all the fears and unknowns can really shake you up”. Mary alluded to the depressive effect of a cancer diagnosis: “As soon as you mention cancer, there is a sense of hopelessness in the air”. Kate viewed her diagnosis more philosophically; as a turning point: “[being diagnosed] is a life-altering event... When you get diagnosed all the thoughts that go through your head...you really have to look deep in yourself [and ask] ‘what do you want out of life and how are you going to deal with this’.” She experienced cancer treatment as a source of uncertainty: “There’s a lot of changes. I find the doctors only know what they know at that time.” For Helen, treatment was a source of trauma and disempowerment: “The things that I went through with repeated surgeries...my body [became] somebody else’s commodity and I had no, minimal, say and not much control over what happened at that point.”

When the participants were asked at the beginning of the interviews to relate their experiences in the yoga program most recounted the positive effects it had on

their physical, mental, and/or emotional sense of well-being. Kate, Rebecca, Mary, Helen, and Vicky all specified that their Iyengar yoga practice had helped them to strengthen, stretch, or relieve tension in problem areas, which they defined mostly as areas that had been affected by surgery or radiation. Mary, Helen, and Vicky related that Iyengar yoga enabled them to open up their body cavities (i.e., chest and abdominal), an ability they considered a benefit as it aided the release of tension. Similarly, everyone but Rebecca said that they experienced a deep relaxation during class, conducive to the relief of anxiety and/or stress. In addition to feeling relaxed at the end of the class, Kate, Susan, Rebecca, and Mary, the four participants selected because they showed the greatest improvement and no change over time, all reported that they felt energized or invigorated immediately after class, despite their feelings of fatigue, lethargy, and weakness. Everyone expressed Iyengar yoga's ability to focus the mind as a mental benefit, resulting in a calm alertness. Finally, Kate and Susan, the two women interviewed because they reported the greatest improvement over time, felt that their yoga practice helped them improve their posture, resulting in the unexpected benefit of increased self-confidence.

Almost all of the participants, including Kate, Susan, Rebecca, Mary, and Helen alluded to the value they each placed on a holistic approach to care and the way Iyengar yoga underscored the interconnectedness of the aspects of one's self (i.e., the mind-body connection). This concept was illustrated by Helen: "focusing on different muscle groups... focusing on the breath quiet[s] the mind [...] which helps to still emotional things." She went on to say that she felt Iyengar yoga is an activity well suited for people looking to practice holistic health care.

One of the most highly valued aspects of the yoga program was the social aspect. Although participants often did not talk to one another about cancer directly, most participants felt being in a class of people living with cancer was not only important to ensure they received instruction appropriate to their activity and energy levels, but also to provide a new social network capable of providing various forms of social support.

Several participants, including Kate, Susan, Helen, and Vicky, reported receiving affective support in the form of empathic listening and understanding that

they felt could not be provided by their friends and family members who had not experienced cancer directly. Susan summarized her feelings in the following statement:

Being with others like me was valuable because I knew there I would be understood. I wasn't different, for once. I was like everyone else and didn't have to deal with the awkwardness one deals with when meeting people who don't know what to say or do for a cancer patient.

The fact that they all shared a common experience (i.e., cancer) left most with a sense of solidarity. Mary expressed this sense of fellowship when she said, "You felt like, [you're] all in the same boat, you're not alone". Kate and Vicky even expressed a feeling of camaraderie, saying they had made friends in the program.

Informational support was another benefit of being in a program with other cancer patients at various stages in their experience. Vicky illustrated this support:

Cancer people, they've been through it [...] so you can ask questions: 'has this happened to you?' or 'how did you feel?' or 'how long did it take for your hair to come back, like is this little fuzz normal?' so you can get a lot of answers [...] you're always learning.

Susan explained that the instructors were helpful sources of information:

I enjoyed the fact that Karen was there, she was a nurse who works in CancerCare. If we had any concern, she welcomed us to come and talk with her [...] Sometimes we'd get information that way. I appreciated that Val, our teacher, is a breast cancer survivor herself. It gives us hope and she gives us tools that were useful to her in getting through her illness.

Finally, appraisal support, which is the provision of information helpful for self-evaluation, social comparison, or affirmation¹⁰⁰, was important for several participants. Mary and Vicky both felt by comparing their health status to others allowed them to adopt a different perspective of their illness and to appreciate their physical capabilities. Helen felt her experience went beyond comparison and self-evaluation; she explained how being with the group helped her integrate her cancer experience into her life: "Being in a group of like-situated people, for me, created some comfort with the reality of things like scars and changes in your body and the reality of cancer as an everyday part of your life."

Each participant commented on their appreciation of the care and understanding teachers showed in modifying the yoga poses to ensure that everyone could participate up to their level and experience a feeling of mastery and

accomplishment, resulting in an increase in self-efficacy. To illustrate this point Rebecca said, “Even if I had problems with some of the postures, the people there would help me get in the right position for me. So they would modify the stretches so that I could do them without having any discomfort.”

The combination of social support and personalized instructional style created a positive atmosphere conducive to a sense of well-being. As Kate summarized, “It’s just a nice place to come to and relax and forget your worries. I don’t remember I have cancer there.”

Almost all of the participants said they valued taking an active role in their healing and felt this characteristic attracted them to the Iyengar yoga program. Kate explained: “You have to [be] someone who wants to take care of themselves and is fighting”. Some participants, like Kate, Mary, Helen, and Vicky said that Iyengar yoga made them realize the importance of taking an active role in their cancer experience. Kate put this relationship in plain words: “Iyengar yoga has changed my whole outlook on [...] taking care of me.” She and Susan felt that Iyengar yoga was the way through which they were able to take an active role in their health during their cancer experience.

Most participants, including Kate, Susan, Mary, Helen, and Vicky disclosed that their yoga practice was empowering. Helen believed a salient benefit of yoga was “finding that there are things that you can do...physically you can do something that helps you to feel better and adds to your sense of well-being.” This sense of empowerment brought on by an increase in self-efficacy also demonstrated Iyengar yoga’s capacity to improve coping skills. Several participants, including Kate, Susan, Mary, and Helen said they felt more capable of dealing with their illness and other stressors, and that they would be able to face uncertainty in the future. Helen explained,

I see [yoga] as giving me some tools...it’s helping to give me more resources to deal with things that I continue to have to deal with. When treatment does happen again, I’m in a better position to just sort of not roll over and play dead...I can approach appointments or medical situations with less stress and anxiety.

Susan agreed, saying, “I do feel more balanced and can cope better with the various demands of my life. I feel stronger.”

Kate, Susan, Mary, and Helen all identified yoga as a way to increase their capacity for mindfulness, or “non-judgmental, moment-to-moment awareness”⁵⁸, a practice that all four felt was of value. Susan elucidated the link between yoga and mindfulness by saying, “Iyengar yoga focuses a lot on the details of the poses and it takes you away from your thoughts, it quiets that chatter-box that’s always going inside your head. [It] does help you live more in the present and not sweat the small stuff.” Mary’s experience was similar: “That’s, I guess, why [it] gives you such wonderful feelings, because you’re basing yourself in the present and staying where you should be.” Susan pointed out the absence of judgment when describing the atmosphere created by the program saying, “Everyone is accepted as such”, while Mary underscored yoga’s role in putting each participant on a “level playing ground”, making judgment of others and the self less likely. She explained, “No matter how beautiful you are or were, or no matter how rich you are or were, you’re all basically the same”.

Those participants who experienced mindfulness as a benefit of yoga also felt that yoga practice facilitated a development of, or underscored an importance of spirituality in their lives. Mary explained that yoga enhanced her sense of well-being. When asked what well-being meant to her, she explained, citing the postulates of spirituality, “A feeling of hope, that your life was meaningful and worth living.” Kate was certain of the association between spirituality and yoga saying, “[Yoga] does open the door for spirituality.”

In an effort to further establish the credibility of the results and assertions emerging from the collective case study the themes were presented to the lead instructor at Yoga North, Val Paape. She noted that many of the findings corroborated with what she understood Iyengar yoga was capable of and hence also matched what she was trying to accomplish in her teaching the Iyengar method. She said the participants’ accounts of concurrent relaxation and alertness (i.e., enhanced ability to focus) was in line with the concept of a sattvic state which represents a perfect balance of mind and body and is manifested by a sense of well-being. Val also was not surprised by the premium her students placed on a holistic view of health care as Iyengar yoga asserts an inter-relatedness of the various aspects of the

self. When asked for feedback regarding the importance of taking an active role in one's healing, Val said she felt that about 75% of the time participants came to their first class with this belief but that only after class were participants fully able to reap the benefits of this attitude. Regarding the ability of Iyengar yoga to bolster one's coping skills, Val said that she felt certain that the Iyengar method had the potential to assist her students cope with stressors and that she felt regular Iyengar yoga practice could impact one's coping style to reflect a more dispositional ability to remain resilient in the face of challenges. Val was more reserved when considering the idea that the participants might be engaging in the practice of mindfulness. While she questioned whether or not ten weeks was enough time to be able to become mindful in everyday life, she did say that the yoga class does provide a non-judgmental environment and the yoga practice itself stresses sensory awareness, two prerequisites of mindfulness practice. Regarding spirituality, Val said she feels a sense of spirituality is personal and must come from experience and therefore cannot be taught. For that reason she does not talk directly about spirituality at Yoga North preferring instead to teach things that can be experienced. She did however say that she believes one must experience spirituality prior to being able to learn mindfulness.

4.8 Negative Effects

Each interview participant was asked to identify an actual or potential downside to the yoga or yoga program. One participant reported experiencing dizziness a few times, while another said sharing props could lead to increased risk for catching colds. Two participants saw the time of week and day as a deterrent to those who were still working while another two said the absence of props at home hindered their home-based practice. One participant said she had heard others complaining that there was no parking and another said she could not think of any down-sides of Iyengar yoga. The yoga diaries from all participants were also reviewed for potential negative effects of Iyengar yoga. One participant reported that some of the poses irritated the stiffness in her arthritic knees while another reported that she injured herself while engaging in unsupervised at-home practice. Finally one

participant withdrew from the yoga class because she felt the yoga poses had caused her port catheter to shift, causing her considerable pain.

4.9 Feasibility

When doing exploratory research, the feasibility, or pragmatic concerns, of the study are important considerations. At the outset, this study was deemed feasible as it did not make unethical demands of its participants, it was not expensive, and could be completed within a time frame suitable for a Master's thesis. Also, the supervising researchers had ample experience and interest in the study population and topic, and CCMB's Patient and Family Support Services Department proved a well-organized facility able to support the research, and served as a gateway to the study population¹⁰¹. As recruitment began however, it became clear that participant availability was not as high as originally thought. Most participants of the yoga program were invited to participate in the study prior to attending the first class. Five participants were excluded from the winter evaluation because they had taken more than 4 classes in the previous session and/or had taken part in the fall evaluation. They were excluded because the investigator felt their recent previous experience with the Iyengar yoga program would prohibit the attainment of an accurate baseline of study outcomes. One participant was excluded from the evaluation because she did not meet the language requirement as assessed when the participant failed to give informed consent. Of the 55 registrants who signed up for the fall and winter yoga sessions, only 36 (65.5%) agreed to participate in the evaluation (see Figure 1). Participants refused to partake in the evaluation for reasons which included being too busy with concerns relating to their illness, lack of interest in participating in a study, and concerns regarding the time commitment involved and the legal nature of the informed consent form.

As the evaluation progressed attrition became a concern. Of the 36 participants who signed the informed consent form, 17 (47.2%) withdrew from the evaluation before the intervention ended, resulting in just 52.8% retention. The majority of those who withdrew from the evaluation, did so because they were no longer able to attend the yoga class. Reasons for withdrawing from the yoga class included conflicts with treatment scheduling and other commitments, discovery that

practicing yoga was not of interest, and being with others living with cancer was not conducive to full recovery. The most common reason for withdrawal from the class was treatment-related illness. Two participants withdrew from the evaluation but remained participants in the yoga class. One woman withdrew because she had become the primary caregiver to her mother during the study and felt overburdened by the study's commitments. The other participant said she was not well enough to complete the week 5 questionnaires, misplaced the week 10 questionnaires while on vacation, and because she felt she did not contribute throughout the intervention, did not see the point in completing the week 16 questionnaires. One participant completed assessments for the duration of the intervention but did not complete the follow-up questionnaires. Despite numerous attempts to contact her to inquire as to the reason for her withdrawal, no response was given.

Of those who did complete the evaluation, compliance, in terms of completion of questionnaires and diaries was high. Overall, 97.92% of the questions included on the questionnaires were completed and 94.32% of the diaries were completed. One participant lost her Yoga Diary #1 accounting for the lower overall diary completion rate.

Attendance records showed that all of those who took part in the evaluation attended at least 50% of the yoga classes with 74% of participants attending at least seven out of ten of the classes. During the follow-up, participants were asked to report how many minutes per week they practiced yoga at home. An overwhelming 89.5% reported that they continued practicing yoga at home while 42% reported that they practiced Iyengar yoga at home at least one hour per week during the six weeks after the intervention ended.

5. DISCUSSION

As with the client satisfaction surveys that have been completed by previous yoga participants, the participants in this study unanimously valued their participation in the Iyengar yoga intervention and expressed that their expectations related to Iyengar yoga prior to their participation were met if not exceeded.

Participants reported experiencing a substantial increase in quality of life, and spiritual well-being; as well as a reduction in mood disturbance, anxiety, nausea, pain, most bothersome cancer-related symptom, and trait anxiety over the time during which they participated in the 10-week Iyengar yoga intervention. While the interviews and yoga diaries reinforced some of what was measured by the questionnaires, they also served to uncover many different outcomes and benefits that were not captured by the quantitative aspect of the study. These additions included increases in social support, coping, mindfulness, self-efficacy, and relaxation.

5.1 Comparisons to Other Studies, Programs, and Theory

The quantitative results supported most of the findings from a set of randomized controlled trials of a similar yoga program and people with cancer^{5, 51}. All studies, including the present study, found an increase in quality of life. This study also served to reinforce a finding of reduced mood disturbance, which was statistically significant in the present case, the study done by Carlson et al.⁵¹, and was noted as a trend (though not statistically significant) in the Culos-Reed et al. study⁵. The present study also confirmed the results from the Culos-Reed et al. study⁵ indicating a reduction in anxiety, but as with the other Iyengar yoga studies^{5, 51} did not find a statistically significant change in depression or fatigue scores. This similarity in findings between the present study and the randomized controlled trials

might be used as support for a causal link between the Iyengar yoga intervention and the beneficial outcomes observed.

It is more difficult to compare the findings from this study to those from the MBSR interventions for several reasons. The first reason is that the yoga portions of the MBSR interventions were not described in adequate detail. The second reason is that in many of the MBSR interventions both the POMS and SOSI were used to measure anxiety and depression and often resulted in conflicting results. Finally, in one of the MBSR studies, different conclusions were made depending on the different analyses and data used. Therefore, the increase in quality of life observed in the present study was similar to findings in two studies^{63, 66}, but conflicted with the findings observed by Spahn et al. in 2003⁶⁵. Similarly, the decrease in total mood disturbance that was observed in the present study was a confirmation of the results found in the 2005 study done by Carlson and Garland⁶⁴, but a contradiction of the results obtained by Carlson et al. in 2003⁶³. It is possible that the conflicting results among the MBSR studies are due to the fact that most of these studies^{62, 63, 64, 65} assessed symptoms and quality of life in cancer outpatients, a population that might be more unpredictable than cancer survivors.

Results from the collective case study revealed that participants perceived their participation in the Iyengar yoga program as a positive experience, which was also found in the MBSR study in Germany⁶⁶. Also, much like the qualitative study of an Iyengar yoga intervention⁵², participants in the present study reported physical improvements, such as improved flexibility and strength in problem areas, the formation of a support group within the setting of the yoga class, and a positive change in quality of life.

The finding that Iyengar yoga offers several types of social support is in line with social network and social support theory. Over the course of the intervention, participants made new social network linkages with others who were experiencing a situation similar to their own, which according to theory, increases empathic understanding thus ensuring that the support offered is what the recipient needs and judges appropriate¹⁰⁰. Irrespective of stress levels, a sense of belonging and companionship common in social networks such as the one created in the Iyengar

yoga class, promote well-being, health, and serve as a way to access new information and develop problem solving skills¹⁰². The empowering sense of accomplishment felt by participants thanks to pose modifications increased participants' self-efficacy and perceived control. In combination, accessing new information, improving problem solving skills, and increasing perceived control enhances one's ability to cope and moderates the relationship between stressors and health, acting as a protective factor¹⁰⁰.

Several themes brought up by participants in both the interviews and participant diaries reflect the correlates of positive psychological adjustment to cancer as identified by Hack and Degner¹⁰³. These themes include problem-based coping, self-efficacy, social support, fighting spirit, and hopefulness. This might explain why, despite the lack of improvement in outcomes such as depression and fatigue, participants reported a positive change in quality of life and mood disturbance after participating in the Iyengar yoga intervention.

The qualitative results of the present study also indicated that the Iyengar yoga program shared many commonalities with other psychosocial interventions. Numerous participants stated that the fact that the program involved participation in a group of women living with cancer led to a coincidental formation of a support group, similar to those purposefully created within psychosocial oncology, particularly oncology peer support groups where people living with cancer "come together to provide mutual help and support"¹⁰⁴. As in oncology peer support groups, the yoga group served, for some, to satisfy the need and natural tendency for human beings to connect based on a common experience. Through that connection, participants experienced a decrease in isolation and obtained empathic understanding and acceptance from the other participants in an environment where cancer was the norm. Some participants even formed what they thought would be life-long friendships. The Iyengar yoga intervention also incorporated a combination of education and behavioral training¹⁰⁵, often used in PSO therapies, by teaching about the body and specific relaxation and meditative techniques that simultaneously built a culture of mind-body awareness and fostered a sense of

mastery, self-efficacy, and empowerment, which enabled participants to strengthen or develop coping skills.

5.2 Unexpected Findings and the Justification for Mixed Methodology

One surprising, although common^{5, 51}, finding was the lack of significant change in depression scores over time, as depression is one of the major psychological sequelae of cancer diagnosis and treatment⁷. After reviewing the results of the MYMOP2, however, and finding that no participants identified depression as their most bothersome symptom, this finding could be attributed to a floor effect; namely, perhaps their depression was not severe enough at baseline to display a statistically significant change over time. This is a likely possibility as the mean depression score of the sample (6.16; 0.77 adjusted for the number of items) was well below the mean depression score for psychiatric patients (28.0; 1.87 adjusted for the number of items)¹⁰⁶, indicating that the participants in the study sample were not clinically depressed. An alternative explanation for this finding is that the depression subscale of the POMS-SF lacked the sensitivity to detect a change. Similarly, the small depression-related effect size of the intervention could be an indication that either a larger sample size or a more accurate scale would be needed in order to detect a significant change. Finally, it might be that Iyengar yoga practice does not have an impact on depression.

Similar to the depression results, the lack of change in fatigue (which is often cited as the most common symptom experienced by people with cancer¹⁰⁷) in the current intervention, or in any other Iyengar yoga studies^{5, 51}, was of particular interest. As in the case with depression, this lack of change could be the result of instrument sensitivity or lack of power. However, given that participants often reported a perceived increase in energy in yoga diaries, a finding which was also mentioned by interview participants, and approximately 20% reported fatigue as their most bothersome symptom on the MYMOP2, the results of which were statistically significant, suggest that the reason for this contradiction may be more complex than just statistical power and scale sensitivity. Specifically, this contradiction in results is may be due to the way fatigue is defined. Unlike depression and anxiety, whose symptoms are well-established by the DSM-IV, no

definitive operational definition of fatigue exists, despite the fact that it is the most commonly reported complaint among cancer patients. A commonly accepted conceptual definition of fatigue is an absence of energy, however the women in this study simultaneously reported the presence of fatigue (quantitatively, on the POMS-SF fatigue sub-scale) and an increase in energy (qualitatively, in interviews and quantitatively, on the MYMOP2). This quantitative increase in energy was also verified by a post-hoc analysis of the vigor-activity subscale of the POMS-SF which was conducted after the contradiction was discovered. This seemingly incongruous evidence calls into question the accuracy of the above definition of fatigue. In 1994, Winningham et al.¹⁰⁸ introduced fatigue as a complex, subjective, and multidimensional concept, in part illuminating why defining fatigue has been difficult: fatigue can occur through various mechanisms (for example: treatment status; comorbid cancer symptoms, such as anxiety and depression; sleep deprivation; nutritional status, etc); it can manifest itself in different ways (for example: anxiety; depression; inability to concentrate; apathy; sleepiness; reduced social activity, etc.); and being a subjective experience, it varies person to person. These tenets were incorporated into Cella et al.'s definition of fatigue as, "a subjective state of overwhelming and sustained exhaustion and decreased capacity for physical and mental work that is not relieved by rest."¹⁰⁹

More recently, Olson proposed that fatigue is the result of a diminished ability to adapt to long-term stress and can be alleviated by good coping skills¹¹⁰. Both Winningham's and Olson's conceptualizations are relevant to the present study for several reasons. First, without an accurate and comprehensive definition of fatigue, it is impossible to construct a measurement tool with adequate content validity, defined as the extent to which the questions that make up the questionnaire reflect the basic content of the phenomenon under study¹¹¹. Although the POMS-SF fatigue subscale was validated, it is possible that it was unable to completely capture all of the aspects of cancer-related fatigue. In other words, it is possible that the fatigue sub-scale of the POMS-SF is unidimensional, focusing only on the physical domain of fatigue and a more multidimensional scale should be used to accurately capture the experience of people undergoing an Iyengar yoga intervention. This is

an important consideration as the results from the qualitative interviews suggested that the Iyengar yoga intervention facilitated the development of self-efficacy, coping skills, and mindfulness, which may have alleviated emotional and mental fatigue (domains that are not incorporated into the POMS-SF fatigue subscale) and thus contributed to an increase in energy. These qualitative and quantitative findings raise the possibility that fatigue and energy can co-exist and that participants might have conceptualized energy as the presence of emotional, physical, and mental stamina and motivation and not as the capacity for doing physical work¹¹².

The multi-dimensionality of fatigue suggests that it is a holistic concept. This makes it difficult to successfully construct a questionnaire that encompasses every aspect of fatigue without breaking it down into its parts and losing some of the meaning in the process. Therefore, perhaps the MYMOP2 results relating to fatigue were significant because by saying (or writing) the word fatigue, the participant might assume an understanding of what fatigue means to them, a meaning that might not be captured by the five adjectives that comprise the fatigue subscale on the POMS-SF.

In this intervention these fatigue findings confirm that scales cannot always clearly identify or measure symptoms affecting those with cancer, and therefore provide justification for the use of a mixed methods design in the present study. As illustrated above, it may be necessary to include the participant's perspective to get a better grasp of the complexity of the outcome (in this case fatigue, for example) or intervention (in this case Iyengar yoga) under study due to the holistic nature of either the outcome or the intervention. The inclusion of qualitative inquiry also made possible the assessment of the quality of change experienced by the women in the study, something a standardized, fixed-item questionnaire could not do. For example, Kate, who reported an improvement in fatigue over the course of the intervention, described the change in the following terms: "I felt I was even more tired afterwards but it was a good tired". Without this component, perceived benefits of the intervention would have gone unnoticed and its effectiveness underestimated.

Another example of the advantage of using a mixed methods design in the present study can be seen in the use of the MYMOP2. The ability of the MYMOP2

questionnaire to measure holistic concepts (as speculated above, using fatigue as an example) is in tune with, and conducive to the evaluation of CAM-based holistic therapies, such as Iyengar yoga, which often produce synergistic effects, as opposed to the reductionist tendencies of standardized, fixed-item questionnaires. It is possible that allowing the participant to personalize the questionnaire by selecting her own symptom and the wording of that symptom has the effect of making that symptom more relevant to the participant than the symptoms measured by generic adjectives that appeared in a list of several other adjectives. In other words, patient-centered questionnaires have the advantage of including only the more salient issues facing a participant while excluding those items that the participant considers irrelevant. This feature increases the content validity of a questionnaire which could in part account for the high statistical significance of the MYMOP2 results by reducing the standard error of the mean. Therefore, the use of the MYMOP2 and other participant-directed measures might be more useful assessment than fixed item questionnaires in determining whether or not Iyengar yoga has an impact on concerns affecting those living with cancer.

Another rationalization for the inclusion of the MYMOP2 is because it incorporates the individual participant's experiences and perspective, it can be considered a powerful tool for measuring the participant's experience of change over the course of the intervention much like the use of qualitative data. Compared to standardized questionnaires, the MYMOP2 might also serve as a more appropriate clinical tool as the structure of the questionnaire closely approximates what takes place in a clinical setting, the results are easy to interpret at the individual level, and they have the potential to bring to light the most vital aspects of the patient's disease and experience.

Giving respondents the ability to tailor the questionnaire according to their own experience and language also likely contributed to the high responsiveness to the MYMOP2 in the current evaluation, as the patient-centered aspect might have made the participant more invested in completing the questionnaire at both time points. Another possible reason for the high rate of completion of the MYMOP2 is that by declaring a "most-bothersome symptom", the participant is in fact declaring

a highly prioritized health-related goal. Although it is unclear whether or not the symptoms chosen by participants in the current study reflected expectations specific to participation in a yoga intervention, dedication to the attainment of this goal might have served to further motivate the participant to complete the questionnaire in a way that accurately assessed change over the duration of the intervention.

On the other hand, it could be that there are characteristics inherent in the MYMOP2 that cause an over-estimation of beneficial change. In her qualitative assessment of the MYMOP, Charlotte Paterson¹¹³ stated one impediment to an assessment of real change over time is a phenomenon she called “response shift”, defined as when “people shift their ‘goalposts’ or standards over time so that even if a condition remains unchanged it is scored differently by self-report questionnaires”¹¹³. This might have contributed to the observed beneficial change over time if something occurred over the course of the intervention to cause a shift in the participants’ prioritization of the severity of their symptoms. For example, if a participant’s prognosis improved, in anticipation of their recovery, they might view their pain as less severe post-treatment compared to pre-treatment despite no actual change. It is difficult to measure the magnitude of this possible confounder as very few participants discussed their prognoses where the opportunity allowed (i.e., in the yoga diaries, interviews, or on the MYMOP2 follow-up questionnaire). Another possibility is if at post-intervention the participant experienced a new symptom that overshadowed the previous and resulted in the participant rating the first symptom as improved despite no actual change. Again, this phenomenon is difficult to assess as only eight out of 19 participants identified a new symptom when given the opportunity on the MYMOP2 follow-up questionnaire, administered at week 10. However, out of those eight, only three rated their new symptom as more severe than the old symptom, making the possibility that the new symptoms were overshadowing the old symptom enough to affect the magnitude of the MYMOP2 test statistic, unlikely. An alternate scenario is if participants began the intervention with a moderate level of symptom severity and then experienced an increase in severity in the middle of the intervention followed by a return back to moderate at the end. The participants’ experience at the middle could have changed their

perception of severity causing them to rate the severity post-intervention as improved compared to pre-intervention despite no real change. However, when pairwise comparisons were done to verify the possibility that symptom severity increased at week 5 and then decreased at week 10, no evidence of this scenario was found.

5.3 Follow-up

Results from the six week follow-up period indicated that the intervention had a lasting beneficial effect on several symptoms and concerns that people with cancer face while receiving treatment and during the stages of recovery, including quality of life, total mood disturbance, and nausea. Although spiritual well-being did not display a statistically significant change over the entire evaluation period (including the follow-up period) the mean difference during this period exceeded the minimal important difference indicating that although no statistically significant benefit was observed, a clinically significant benefit was apparent. A few of the results from the follow-up analysis were surprising. Fatigue did not change in a statistically significant sense during the intervention but decreased almost to the level of statistical significance ($p=0.058$) at follow-up. This could have occurred for a number of reasons, including progression of disease towards recovery or because of findings from the collective case study which indicated physical improvements such as increased strength, stamina, and energy level. Given that so many participants continued their home-based yoga practice after the intervention, this trend in fatigue reduction at follow-up could be an indication that it takes more than ten weeks for that benefit to take effect.

The opposite trend was found with both spiritual well-being and anxiety, which were shown to respectively increase and decrease significantly over time during the intervention and then revert back to baseline levels six weeks after the intervention ended. This reduction of benefit after the cessation of the Iyengar yoga intervention might lend evidence to support the assertion that the intervention caused an increase in spiritual well-being and a reduction in anxiety among those who participated in the intervention.

5.4 Validity

Trait anxiety, which is a stable characteristic and therefore, not supposed to change over time, showed a highly statistically significant decrease over the course of the evaluation. Because this variable was intended to gauge the study's discriminant validity, this finding might indicate a lack of validity. Another possibility for this change is that participants either did not read, or misread the instructions (participants were asked to rate how they felt generally) which, in combination with the fact that the STAI-T followed the POMS-SF, led participants to respond as though it was another measure of state anxiety. While it is difficult to assess whether or not the participants did not read the STAI-T instructions, it is unlikely that the order of questionnaire administration affected their response as the trait anxiety subscale normally follows the state anxiety subscale in the administration of the full STAI questionnaire. Finally, this change might be an indication that the intervention truly caused a lasting change in participants' dispositional anxiety via a change in coping style or mindfulness practice as suggested in the interviews. Two studies of Iyengar yoga's effect on young adults with depression¹¹⁴ and distressed women¹¹⁵ showed a similar, statistically significant decrease in trait anxiety although no plausible explanations were put forth in either article. Regardless of whether or not Iyengar yoga can affect stable characteristics over time, trait anxiety was an inadequate indicator of discriminant validity in the present study.

Compared to the established cancer patient population norms, at baseline the present sample reported lower quality of life and spiritual well-being and a greater mood disturbance, fatigue, and pain^{77, 80, 106, 116, 117, 118}. However, the sample was comparable at baseline to the general cancer population with regards to anxiety and depression¹¹⁸. In terms of physical activity, the study sample expended exactly the same amount of energy (13.14 METs) as a larger sample of 2769 breast cancer survivors⁹⁰. As energy expenditure did not change appreciably over time, it can be said that in this regard, the study sample was typical of the general cancer survivor population and therefore perhaps slightly more active than the general cancer patient population. Because the sample in the present study was mixed with regard to cancer treatment status, comparisons to other studies and the cancer literature were

difficult to make as the literature frequently separated cancer patients from survivors and often did not specify what constituted cancer survivorship.

Therefore, given the nature of the sample and the results of the comparisons of this sample to other cancer populations, the results should only be generalized to females who are currently on treatment for cancer or within 6 months of their last treatment, who tend to seek psychosocial support, and are willing to take part in a yoga program. The comparisons might also be limited to those who experience lower quality of life and spiritual well-being and higher mood disturbance, fatigue, and pain than the average cancer patient. The participants' expectations and motivation regarding yoga might also have implications for the external validity of the study findings. Results may also only be applicable to those who value taking an active role in their health and see health as a holistic construct.

5.5 Instrumental Collective Case Study

As was expected, each participant case was unique. It was also expected that some similarities and difference according to selection criteria would be observed, however, that expectation was not met. This might reflect a lack of accuracy in the selection criteria used to distinguish those who experienced the greatest improvement, decline, and no change during the yoga program. For example, a true measure of improvement might be denoted by a simultaneous increase in symptom severity and quality of life. A variety of factors (for example, returning to the workforce, cancer recurrence, or family problems) not considered in the questionnaires could have influenced the participants' interview results or quality of life scores. Such might have been the case for the participant who showed the greatest decline in the fall yoga program yet enthusiastically enumerated the benefits of Iyengar yoga and stated that she wished to continue her yoga practice as it had changed her life for the better. Alternatively, a change could have occurred between the last yoga class and the interview to influence the participants' interview results. Finally, a more accurate determination of degree of change might have come from comparing the baseline to week 10 scores on the participant-centered MYMOP2 as opposed to the scores on the standardized questionnaires.

Although a process analysis was not feasible, findings from the collective case study may suggest that Iyengar yoga served to build capacity for the practice of mindfulness which altered participants' dispositional coping style, the "relatively stable, generalized way of behaving that affects a person's emotional or functional reaction to a stressor associated with a strong sense of meaningfulness and commitment to self, a vigorous attitude toward life and an internal locus of control"¹⁰⁰. This process might explain the change observed in the primary and secondary evaluation outcomes. It might also explain the change in trait anxiety scores over the course of the evaluation, which, like dispositional coping style, is supposed to remain constant over time. By staying focused on the present moment, participants were able to reduce their tendency for anticipatory anxiety and appraise stressful situations more positively than before¹⁰⁰.

5.6 Negative Effects

In contrast to previous studies of Iyengar yoga^{48, 119, 120, 121}, participants in the present study reported a few negative effects they experienced that they felt was directly linked to their yoga practice. The participant who experienced dizziness while doing upper left arm stretches felt her dizziness might have occurred because of the presence of a brain tumor on the same side. She did mention that it did not occur every time she did the stretches and felt that the dizziness might have occurred in part because her "blood was low". The possibility that the Iyengar yoga practiced dislodged a port catheter was deemed medically unlikely by nurses who were consulted about the adverse event. The results from the present study indicated that Yoga North's Iyengar yoga program, while suitable for a wide range of people living with cancer, might not be suitable for those who were either too ill to participate or those who are well enough to return to work. Pre-existing joint pain might preclude participation in some of the poses that involved areas affected by arthritis but interview participants repeatedly stated that physical limitations were accommodated by modifying poses through the use of props. Finally, it is possible that for Iyengar yoga beginners, unsupervised at-home practice should be done with caution to avoid injury.

5.7 Feasibility

The evaluation of Yoga North's Iyengar yoga program was not without its feasibility-related challenges, namely lower-than-expected recruitment and low retention. One reason for the lower-than-expected recruitment could have been due to low participant motivation. Because the Iyengar yoga program was well established prior to the evaluation, study participants knew they would get into the class regardless of whether or not they participated in the evaluation. However, despite these challenges, this study was deemed feasible for several reasons. Ample resources were available to carry out the evaluation, participants were subject to minimal intrusion or inconvenience throughout the 16-week time commitment, and questionnaire completion rates were very high. One could argue that because statistically significant changes over time were observed, the evaluation displayed adequate statistical power despite the low sample size. Furthermore, the program was well attended and participants reported continuing their at-home yoga practice beyond their participation in the intervention.

5.8 Challenges, Limitations, and Strengths

The design of the current study presents both the study's greatest strength and its greatest challenge. By using a mixed methods design the researcher was able to include the experiences and voices of the women who participated in the evaluation enriching it with context and the perceptions of women with cancer, characteristics typically found in qualitative studies. By including the collection of numeric data using standardized questionnaires, the results of the current study were made comparable to other studies and cancer population norms, comparisons that are more commonly achieved through the use of quantitative methods. Through the combination of the two methodologies, it was possible to corroborate results from both paradigms. For example, in the quantitative analysis, results showed an improvement in quality of life, mood disturbance, anxiety, and those symptoms that participants considered their most bothersome. These results were confirmed in interviews and yoga diaries with participants expressing a perceived improvement in overall well-being, anxiety and other mood-related problems, and in their most salient physical symptoms.

By combining quantitative and qualitative data collection, the present study also revealed some interesting if not surprising contradictions as well. As illustrated earlier with the example of fatigue, which was defined in the current study as an absence of energy, the lack of quantitative change directly contradicted the qualitative improvement (increase in energy) reported in the interviews and diaries. Similarly, in a post-hoc analysis of the change over time in social well-being (a subscale of the FACIT-Sp) that was not included in the present study, the results showed no statistically significant change, which is, again, in opposition to the interview results where participants overwhelmingly reported social support as a benefit of the intervention. These contradictions show the need for an investigation of how outcomes affecting those with cancer are defined and quantified.

By including the qualitative components to a quantitative-dominant study, it was possible to elaborate on the quantitative results. For example, elaboration was evident in the way participants chose to word their worst symptom on the MYMOP2 enabling a more accurate account of each participant's experience. Also, although the qualitative results were not complete enough (i.e., did not reach saturation) to assert the process(es) through which Iyengar yoga exerts an impact on concerns affecting women living with cancer, the qualitative results of the present study do open the door for an explanatory process analysis in the future. Finally, by mixing methods, the present study increased its potential for knowledge transfer and translation as the results can be understood and used by a broader spectrum of groups. Overall, the inclusion of both methodological traditions made the results and conclusions of the present study richer and likely more credible and reliable.

Despite the advantages of using a mixed methods design, there were some challenges and limitations relating to the methodology used in the quantitative component. To ensure the conclusions based on the quantitative results are valid, under ideal circumstances the study design would include the three key characteristics of a randomized, controlled trial (RCT): randomization, a control group, and manipulation of the independent variable¹¹¹. Although RCTs are considered the gold standard of research designs in many areas, their reductionistic tendencies do not easily lend themselves to researching CAM therapies. In their

attempt to control for confounding variables and human factors, randomized controlled trials often prioritize a specific, pre-determined effect as its most valuable effect. In contrast, the therapeutic benefits resulting from complementary therapies are often non-specific or synergistic in nature, unique to the individual, and accompanied by changes in the human factors (such as changes in beliefs and behaviors) that RCTs seek to eliminate⁷². Another problem with RCTs is that although they often display excellent internal validity, the external validity of the findings can be very limited⁷². Similarly, while RCTs often assay whether or not the intervention works under ideal or laboratory conditions (i.e., the efficacy of the intervention), they often overlook or under-value whether or not the intervention works under normal conditions (i.e., the effectiveness of the intervention), which is important when studying CAM as CAM users tend to use CAM in uncontrolled settings. Finally, because consumers and practitioners of CAM have distinct preferences, when studying CAM, using an RCT design is more difficult and impractical as RCT designs assume impartiality on the part of patients and medical practitioners⁷². Therefore, it is often more desirable to research CAM therapies using a variety of methods and designs in pragmatic trials as opposed to randomized controlled trials⁷².

The present study called for such a pragmatic, mixed methods trial. Because it took place in a clinical setting and was a well-established program, randomization was not feasible, and there were not enough participants involved to include a wait-list control group given the size of the yoga class. Further precluding the use of an RCT design was the fact that, as with the MBSR interventions, the multi-modality of the Iyengar yoga intervention disallowed the isolation of the Iyengar yoga practice from the other components of the program (i.e., peer group support, physical activity, or yoga philosophy/behavioral training). The complexity of the program presents a challenge as it raises the possibility that any or all of the program's component factors could have influenced the degree of benefit reported by participants, making it difficult to determine the yoga practice's contribution to the improvements observed. This aspect also makes comparison with other yoga programs difficult. Personal factors further added complexity to the yoga practice.

Depending on experience, expectations, readiness, attendance, and home-based practice, participants were engaged at different stages of yoga practice. Also, modifications were unique to the individual participant's needs and physical limitations and might have impacted the extent of benefit received by the participant.

The consequence of the design limitations is that it is difficult to establish the study's internal validity, in other words, the extent to which the yoga program caused the observed changes, raising numerous alternate reasons for the improvements. It is possible that participants adapted to their treatments, following the natural trajectory of recovery or acceptance of cancer as a part of their lives. Also, to some extent perhaps a strong belief or expectation of the benefits of yoga might have led some participants to overestimate the benefit they received from the program.

The internal validity of the study can be compromised by several biases. One possibility is that the improvements reported were the result of social desirability. Perhaps out of a desire to show appreciation for the positive relationship built between the participants and the class instructors, one of whom designed the program, and to show appreciation for the opportunity of participating in the class free of charge, participants might have down-played the severity of their symptoms.

Testing bias, where the initial questionnaire administration influences responses on subsequent questionnaire administrations¹⁰¹, could be applicable in this case as participants are completing the same questionnaires four times in a 16 to 18-week period. Also the fact participants are being measured on certain constructs might serve to increase their awareness of those constructs and therefore impact their response on subsequent administrations of the questionnaires.

Attrition¹⁰¹ also potentially introduces bias which could threaten the internal validity of the study. Over the course of the study, 47% of the sample withdrew from the study. Whenever attrition occurs, it is important to determine whether those who drop out differ systematically from those who remain in the study. This was done and the results showed that the drop-outs had less nausea and pain than the participants who completed the intervention. This finding indicates that pain and

nausea are not barriers to yoga practice among those living with cancer and perhaps a yoga class for people living with cancer is less suited for those who are farther in their recovery and therefore healthier. However because the two groups differed on only two variables of many, it does not appear that attrition posed a threat to the internal validity of the current study.

Another source of bias could have been regression to the mean where initially extreme scores tend to migrate toward the population mean over time¹²² for statistical reasons unrelated to the passing of time. Because many of the baseline scores (for example: quality of life, spiritual well-being, mood disturbance, fatigue, and pain) were more extreme than their respective population means, a significant change could have arisen from the tendency for scores to become less extreme at subsequent measurements.

Maturation¹⁰¹ is another bias with the potential to compromise the internal validity of the study. Though less common when studying adults compared to children, maturation (particularly emotional and spiritual) is common among people with cancer who often describe their cancer experience as a life-altering experience. Therefore, changes in emotionality, spirituality, beliefs, and priorities not attributable to the practice of yoga (i.e., other support services such as psychosocial therapies, or religious group membership) could have affected participants' scores over the course of the study. Also, changes in disease status over time, particularly related to recovery made it difficult to say that changes in outcomes over time occurred because of the yoga intervention and not because participants were improving in health or coming to terms with their illness.

Another threat to internal validity includes history, whereby an event outside of the research context serves to influence outcome responses. For example, over the course of the study, the Manitoba *inMotion* strategy was made public which might have caused an increase in physical activity and consequently impacted scores as physical activity has been shown to affect the outcomes measured in this study. Also, due to their repeated contact with CCMB and particularly Patient and Family Support Services, participants could have become more cognizant of

services and programs available to them as cancer patients and survivors which could have impacted their questionnaire scores.

Finally, without the inclusion of a control group, the internal validity is also threatened by the Hawthorne effect. Namely, it cannot be ruled out that the test scores obtained during this study were not a reflection of the participants' reaction to being subject to study¹¹¹.

The internal validity of the present study was however, strengthened by the consistent application of study procedures, which is considered a "critical component of control"¹⁰¹. Because the same questionnaires were used and administered for each participant in at the same time in the same way, and the same coordinator collected and entered all of the data according to the protocol, instrumentation bias was avoided.

The main problem affecting the external validity is the fact that the study participants were self-selected¹⁰¹. The participants in this study might have represented a specific subset of people living with cancer who are motivated to participate in a yoga program and a study. This motivation might have been influenced by unique traits that impacted the results and therefore the study sample may not have been a true representation¹⁰⁰ of the general cancer population in Manitoba. On the other hand, given the heterogeneous nature of the sample (the study inclusion criteria were quite liberal and participants varied in terms of cancer diagnosis, staging, and treatment status), the results may be more generalizable to the general cancer population compared to a homogeneous sample¹⁰¹. Statistical procedures were carried out in an attempt to compare the study population to both the general cancer population in Manitoba and the cancer population seeking psychosocial services at CCMB's Patient and Family Support Services Department and found that the study sample was similar to females accessing PSO services but not those in the general cancer population. However, limited information was available concerning these larger populations limiting the extent to which a complete comparison could be made.

The small sample size was another limitation of the current study as it precluded the use of more powerful statistical techniques. Instead information on

key control variables was collected over the course of the study with the assumption that the consistency of these variables over time would control for some factors that could influence a change in the primary and secondary outcomes. None of the control outcomes changed over time lending support for the conclusion that it was the Iyengar yoga intervention that caused the beneficial changes reported over time. With these results, it can be concluded that it is unlikely that the changes in primary and secondary outcomes observed over time were due to the participants' physical activity, use of complementary and alternative or prescription medicines, self-care measures, psychosocial services, or changes in cancer treatment. However, without a more powerful statistical analysis, for example marginal means modeling, it was impossible to properly control for potentially confounding variables or explore for possible interactions among the variables making it difficult to determine for certain the contribution of each of these control variables to the study outcomes, the relationship between these control variables and the intervention, and their joint relationship with the study outcomes, nor the degree to which attendance in the Iyengar yoga intervention caused the changes observed. Another problem posed by the small sample size is that it might have limited the capabilities of those outcomes and variables with very low effect sizes to show a significant change over time. Therefore, it is possible that no statistically significant changes were reported in depression, fatigue, energy expenditure, or use of CAM, prescription medication, or other self-care health measures because the sample size was not large enough to detect a change. However, the sample size of the present study was large enough to detect statistically significant changes in pain which had a low effect size (0.195). Also, despite the above problems, the study design and power were strengthened by the use of repeated measures which both reduced the number of participants required and allowed participants to serve as their own controls, making for an economical study.

Power is an important, although often neglected, consideration in quantitative research. A study's power is its ability to discern an effect when one truly exists. Therefore, when a study has low power, a negative result (i.e., a result showing a lack of significance)⁹⁸ might not be an indication that the variable being

tested did not have an effect on the outcome, but that the inadequacy of the study's power precluded the ability to recognize the true effect. In other words, the lower the power of a study, the higher the probability of making a Type II error which is the error made when the null hypothesis is erroneously accepted.

In order to assess the power of a study that uses RM-ANOVA as its statistical test information must be known regarding the study's significance level (α), test directionality, sample size, effect size, number of repeated measures, and the autocorrelation parameter⁹⁸. At the outset of the study only the study's significance level (0.05), and number of repeated measures (three) were known, making an a priori power analysis impossible. A post-hoc power analysis was advised against based on the argument that if the test-statistics were statistically significant, the study exhibited enough power to detect a change when one truly existed. Therefore, a post-hoc power analysis would show that the sample size obtained was excessive and thus, the study was methodologically unethical. The fact that the p-values of many statistical tests, including all primary outcomes ($p < 0.001$) were lower than the significance level adjusted for multiple testing ($\alpha = 0.00165$) shows that despite the small samples size, the study exhibited enough statistical power to detect true differences in all primary outcomes when differences existed.

Several measures were taken to validate the findings from the collective case study. Information was made available regarding the researcher's presuppositions, history, and motives relevant to the present study. The methods of participant selection and data analysis were well documented and measures were taken to disconfirm the major assertions put forth⁷⁴. Quotes, direct from the participant interviews and yoga diaries, were included to minimize a distortion of meaning in the "translation from experiential language to formal language"⁷⁴ and to allow readers to make their own generalizations⁷⁴. Finally, an account of the study stakeholders' reactions⁷⁴ to the conclusions allows readers to verify the credibility of the study findings.

5.9 Lessons Learned and Future Research

The results and limitations of the present study afforded the opportunity to inform future research. For example, the absence of a control group was the study's

largest limitation, preventing the use of causal inferences. Therefore, in future research, a wait-list control group is desirable and would elucidate the Iyengar yoga program's contribution to the improvements observed in the current study. A suitable alternative control group would be a peer support group as the results from the current evaluation indicated that the Iyengar yoga program included the unexpected benefit of social support from the yoga participants. Therefore, a comparison between the two groups would serve to control for peer support and enable a more accurate appraisal of Iyengar yoga's impact on the outcomes assessed in the present study.

Judging from the baseline "surveys" of expectations, diary comments, and interview results, increased mobility, flexibility, and fitness were important anticipated and actualized benefits of yoga. It might therefore be important in future research to add physiological measures, for instance, a sit and reach test, to assess whether or not change in these outcomes can be measured quantitatively.

Because cancer treatment can cause instability in all of the outcomes assessed in this study, cancer patients constitute a volatile population. Therefore, in order to eliminate confounding introduced by treatment status, it might be advisable in future research to limit the eligibility criteria to cancer survivors. Another option is to consider an analysis stratified by treatment status once a large enough sample is accrued. This option is perhaps better suited to the present program given that it is open to anyone currently undergoing cancer treatment or having undergone treatment within six months prior to the yoga program and therefore would not exclude any participants.

In contrast to the abundance of significant changes observed over the course of the intervention, very few outcomes were significantly different at follow-up compared to baseline. Perhaps by shortening the follow-up period to four weeks it would be possible to determine how long after the intervention, if at all, improvements are maintained among outcomes that were significant at the end of the intervention. Alternatively, in the future, researchers could lengthen the follow-up period to explore whether or not scores for the outcomes that were significantly different at follow-up ever return to baseline levels.

Finally, in light of the contradictory results regarding fatigue, it would be interesting to conduct a focus group with female Iyengar yoga participants with cancer to determine the full content domain of cancer-related fatigue and energy with the objective of eventually measuring these concepts with greater accuracy.

In the near future the results and conclusions of the present study will be strengthened by the addition of data from the Spring, 2007 Iyengar yoga session. However, due to time limitations those data were not included in this thesis.

5.10 Theoretical Implications

This study contributes significant knowledge to Iyengar yoga's effects on cancer and cancer treatment symptoms by including participants with mixed diagnoses, a measure of spiritual well-being, a thorough follow-up, and a mixed methods design. Furthermore, because of the promising results, this exploratory study could lay the groundwork for a larger controlled study to generate stronger evidence.

5.11 Practical Implications

One interesting consideration brought up by the present study is how Iyengar yoga as a mind-body, complementary and alternative therapy fits within PSO and cancer care in general. The Iyengar yoga program shares many commonalities with other interventions that are considered standard care within psychosocial oncology. For example both have shown to be used predominantly by women with above average education and household income, both can be educative, promote behavioral changes that decrease distress and increase coping, and provide the participant with a new social network of like-situated people, with the cumulative effect of increasing the quality of life among those living with cancer. These similarities in benefit and the fact that several cancer centers across North America have offered yoga classes to cancer patients and survivors mark the opportunity for yoga to establish itself among the spectrum of PSO services offered as standards of care. However, the fact that very few men have been represented in the yoga and cancer literature, little is known about yoga's long-term effects, and the fact that some people may object to yoga philosophy as being contradictory to their own

religious beliefs indicate the presence of barriers to the imminent integration of yoga into PSO as a tertiary prevention intervention.

Evidence of whether or not Iyengar yoga is being integrated within cancer care in general is clearer. Given that CCMB is a multi-disciplinary cancer center, it was surprising to find that the information included in the participants' charts was limited, for the most part, to cancer treatment medications and other prescription medications and very few mentioned the use of supplements, psychosocial services, and complementary and alternative medicines despite the inclusion of these items in participant diaries. This indicates either a lack of communication between patients and clinical oncology staff (i.e., oncologists and oncology nurses) regarding, or a disregard of, the use of self-care and complementary and alternative medicine. Either way, it shows that although CAM has made some headway into conventional medicine, when it comes to cancer care, an integrative health paradigm is still a challenge.

6. CONCLUSIONS

The Iyengar yoga program for women living with cancer offered at Yoga North by CCMB's Patient and Family Support Services Department can be considered a complex, multi-level, multi-modal intervention. As with many other psychosocial oncology programs and CAM therapies, the Iyengar yoga program is congruent with the health beliefs of those who partake: people who hold a holistic view of health and value resource building in an attempt to take an active role in one's health care. Because of the interconnectedness of its components, it is a difficult intervention to evaluate in the traditionally acceptable way (i.e., randomized, controlled trials) necessitating the use of observational and qualitative methods as seen in the present study. However, this design dilemma can be taken as a moot point as the multi-modal aspect of this program was highly valued by its participants, and likely contributed both to the high attendance observed and the satisfaction expressed by participants.

Findings from this evaluation support the claim that the Iyengar yoga intervention provided tools necessary for the positive adjustment to a cancer diagnosis and cancer treatment. This conclusion was evidenced quantitatively by statistically and clinically significant improvements in quality of life, spiritual well-being, and mood, as well as statistically significant reductions in the severity of anxiety, pain, nausea, and the symptoms participants identified as their most-bothersome prior to the intervention; and qualitatively by participants' testimonials of enhanced coping abilities, social support, self-efficacy, increased energy levels, and a change toward the practice of everyday mindfulness.

The key strength of the current study was the use of a mixed methods design, particularly in the inclusion of the participant-centered MYMOP2 and qualitative interviews, which both served to make participants substantial

contributors to the evaluation and brought positive meaning to the study. Despite the design- and sample size-related limitations, the study was feasible, the quantitative component had enough power to detect highly significant results in the primary outcomes assessed, and the results were similar to those found in more rigorously designed studies. Therefore, although neither causality nor a dose-response relationship between the Iyengar yoga intervention and the improvements in cancer-related outcomes could be inferred, the present study lends support to the assertion that Iyengar yoga is beneficial to the well-being of those women living with cancer.

APPENDIX A – Functional Assessment of Chronic Illness Therapy- Spiritual
(FACIT-Sp)

Below is a list of statements that other people with your illness have said are important. By **circling one (1) 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
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea.....	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain.....	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill.....	0	1	2	3	4
GP7	I am forced to spend time in bed.....	0	1	2	3	4

		Not at all	A little bit	Some -what	Quite A bit	Very much
GS1	I feel close to my friends.....	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends.....	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
	<i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box <input type="checkbox"/> and go to the next section.</i>					
GS7	I am satisfied with my sex life.....	0	1	2	3	4

By circling one (1) 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
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness.....	0	1	2	3	4
GE3	I am losing hope in the fight against my illness.....	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse.....	0	1	2	3	4

		Not at all	A little bit	Some -what	Quite A bit	Very much
GF1	I am able to work (include work at home).....	0	1	2	3	4
GF2	My work (include work at home) is fulfilling ...	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well.....	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun.....	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

By circling one (1) 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
Sp1	I feel peaceful	0	1	2	3	4
Sp2	I have a reason for living	0	1	2	3	4
Sp3	My life has been productive	0	1	2	3	4
Sp4	I have trouble feeling peace of mind	0	1	2	3	4
Sp5	I feel a sense of purpose in my life	0	1	2	3	4
Sp6	I am able to reach down deep into myself for comfort	0	1	2	3	4
Sp7	I feel a sense of harmony within myself	0	1	2	3	4
Sp8	My life lacks meaning and purpose	0	1	2	3	4
Sp9	I find comfort in my faith or spiritual beliefs	0	1	2	3	4
Sp10	I find strength in my faith or spiritual beliefs	0	1	2	3	4
Sp11	My illness has strengthened my faith or spiritual beliefs	0	1	2	3	4
Sp12	I know that whatever happens with my illness, things will be okay.....	0	1	2	3	4

APPENDIX B – Profile of Mood States- Short Form (POMS-SF)

Describe HOW YOU FEEL RIGHT NOW by circling one number after each of the words listed below:

FEELING	Not at all	A little	Moderately	Quite a bit	Extremely
Tense	1	2	3	4	5
Angry	1	2	3	4	5
Worn out	1	2	3	4	5
Unhappy	1	2	3	4	5
Lively	1	2	3	4	5
Confused	1	2	3	4	5
Peeved	1	2	3	4	5
Sad	1	2	3	4	5
Active	1	2	3	4	5
On edge	1	2	3	4	5
Grouchy	1	2	3	4	5
Blue	1	2	3	4	5
Energetic	1	2	3	4	5
Hopeless	1	2	3	4	5
Uneasy	1	2	3	4	5
Restless	1	2	3	4	5
Unable to concentrate	1	2	3	4	5
Fatigued	1	2	3	4	5
Annoyed	1	2	3	4	5
Discouraged	1	2	3	4	5
Resentful	1	2	3	4	5
Nervous	1	2	3	4	5
Miserable	1	2	3	4	5
Cheerful	1	2	3	4	5
Bitter	1	2	3	4	5
Exhausted	1	2	3	4	5
Anxious	1	2	3	4	5
Helpless	1	2	3	4	5
Weary	1	2	3	4	5
Bewildered	1	2	3	4	5
Furious	1	2	3	4	5
Full of pep	1	2	3	4	5
Worthless	1	2	3	4	5
Forgetful	1	2	3	4	5
Vigorous	1	2	3	4	5
Uncertain about things	1	2	3	4	5
Bushed	1	2	3	4	5

APPENDIX C – Measure Your Medical Outcome Profile 2 (MYMOP2)

Choose one or two symptoms (physical or mental) which bother you the most. Write them on the lines. Now consider how bad each symptom is, over the last week, and score it by circling your chosen number.

SYMPTOM 1:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							
SYMPTOM 2:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							

Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevents you doing. Score how bad it has been in the last week.

ACTIVITY:	0	1	2	3	4	5	6
.....	As good as it could be					As bad as it could be	
.....							

Lastly how would you rate your general feeling of wellbeing during the last week?

	0	1	2	3	4	5	6
	As good as it could be					As bad as it could be	

APPENDIX D – Godin Leisure Time Exercise Questionnaire (GLTEQ)

Considering a typical **7-Day period** (a week) within the past month, how many **minutes** on average do you do the following kinds of exercise, **excluding yoga**, during your **free time** (write on each line the appropriate time).

	Average Minutes per week
<p>STRENUOUS EXERCISE (Heart beats rapidly) (i.e., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)</p>	<p>_____</p> <p>—</p>
<p>MODERATE EXERCISE (Not exhausting) (i.e., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)</p>	<p>_____</p> <p>—</p>
<p>MILD EXERCISE (Minimal effort) (i.e., archery, fishing from river bend, bowling, horseshoes, golf, snow-mobiling, easy walking)</p>	<p>_____</p> <p>—</p>

APPENDIX E – State-Trait Anxiety Inventory- Trait anxiety (STAI-T)

Describe HOW YOU FEEL GENERALLY by circling one number after each of the statements listed below:

1	2	3	4
Almost Never	Sometimes	Often	Almost Always

I feel pleasant	1	2	3	4
I feel nervous and restless	1	2	3	4
I feel satisfied with myself	1	2	3	4
I wish I could be as happy as others seem to be	1	2	3	4
I feel like a failure	1	2	3	4
I feel rested	1	2	3	4
I am 'calm, cool, and collected'	1	2	3	4
I feel that difficulties are piling up so that I can't overcome them	1	2	3	4
I worry too much over something that really doesn't matter	1	2	3	4
I am happy	1	2	3	4
I have disturbing thoughts	1	2	3	4
I lack self-confidence	1	2	3	4
I feel secure	1	2	3	4
I make decisions easily	1	2	3	4
I feel inadequate	1	2	3	4
I am content	1	2	3	4
Some unimportant thought runs through my mind and bothers me	1	2	3	4
I take disappointments so keenly that I can't put them out of my mind	1	2	3	4
I am a steady person	1	2	3	4
I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

Did you undergo cancer treatment this week? Yes No

Did you receive chemotherapy this week? Yes No

Did you receive radiation therapy? Yes No

Did you have a blood transfusion this week? Yes No

If you missed the class this week please state why: _____

How much time did you spend practicing yoga **at home** this week? ____ minutes

Did you use the home-based yoga practice manual this week?

Yes No

If yes, did you find it helpful?

Yes Somewhat No

Comments:

APPENDIX G – Research Ethics Approval Letters



University of Saskatchewan
Behavioural Research Ethics Board (Beh-REB)

1-Aug-2006

Certificate of Approval

PRINCIPAL INVESTIGATOR
Jill Taylor-Brown

DEPARTMENT
Community Health

BEH#
06-209

STUDENT RESEARCHERS
Meghan Duncan

INSTITUTION(S) WHERE RESEARCH WILL BE CONDUCTED (STUDY SITE)
University of Manitoba
University of Saskatchewan

SPONSOR
UNIVERSITY OF SASKATCHEWAN

TITLE
Evaluation of an Iyengar Yoga Intervention for People with Cancer

CURRENT APPROVAL DATE
01-Aug-2006

CURRENT RENEWAL DATE
01-Aug-2007

The University of Saskatchewan Behavioural Research Ethics Board has reviewed the above-named research project. The proposal was found to be acceptable on ethical grounds. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to this research project, and for ensuring that the authorized research is carried out according to the conditions outlined in the original protocol submitted for ethics review. This Certificate of Approval is valid for the above time period provided there is no change in experimental protocol or consent process or documents.

Any significant changes to your proposed method, or your consent and recruitment procedures should be reported to the Chair for Research Ethics Board consideration in advance of its implementation.

ONGOING REVIEW REQUIREMENTS

The term of this approval is five years. However, the approval must be renewed on an annual basis. In order to receive annual renewal, a status report must be submitted to the REB Chair for Board consideration within one month of the current expiry date each year the study remains open, and upon study completion. Please refer to the following website for further instructions: <http://www.usask.ca/research/ethical.shtml>

APPROVED


Dr. John Rigby, Chair,
Behavioural Research Ethics Board
University of Saskatchewan

Please send all correspondence to:

Ethics Office
University of Saskatchewan
Room 306 Kirk Hall, 117 Science Place
Saskatoon SK S7N 5C8
Telephone: (306) 966-2084 Fax: (306) 966-2069



UNIVERSITY
OF MANITOBA

BANNATYNE CAMPUS
Research Ethics Boards

P126-770 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 0W3
Tel: (204) 789-3255
Fax: (204) 789-3414

APPROVAL FORM

Principal Investigator: Ms. J. Taylor-Brown
Sponsor: CCAM/INCAM

Protocol Reference Number: H2006:138
Date of REB Meeting: June 26, 2006
Date of Approval: July 11, 2006
Date of Expiry: June 26, 2007

Protocol Title: "Evaluation of an Iyengar Yoga Intervention for People with Cancer" *on file*

The following is/are approved for use:

- Protocol dated July 7, 2006
- Research Participant Information and Consent Form Version dated July 5, 2006
- GLTEQ dated June 9, 2006
- FACIT-Sp dated June 9, 2006
- MYMOP2 dated June 9, 2006
- POMS-SF dated June 9, 2006
- Baseline Intake Form dated June 12, 2006
- Participant Diary dated June 12, 2006
- Telephone script dated June 9, 2006
- Qualitative Interview Schedule Version dated July 5, 2006
- STAI-T Anxiety Scale submitted July 7, 2006

The above was approved by Dr. Laine Torgrud, Ph.D., C. Psych., Acting Chair, Health Research Ethics Board, Bannatyne Campus, University of Manitoba on behalf of the committee per your two letters dated July 11, 2006. The Research Ethics Board is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement, and the applicable laws and regulations of Manitoba. The membership of this Research Ethics Board complies with the membership requirements for Research Ethics Boards defined in Division 5 of the *Food and Drug Regulations*.

This approval is valid for one year from the date of the REB meeting at which the study was reviewed. A study status report must be submitted annually and must accompany your request for re-approval. Any significant changes of the protocol and informed consent form should be reported to the Chair for consideration in advance of implementation of such changes. The REB must be notified regarding discontinuation or study closure.

This approval is for the ethics of human use only. For the logistics of performing the study, approval should be sought from the relevant institution, if required.

Sincerely yours,

Laine Torgrud

Laine Torgrud, Ph.D., C. Psych.
Acting Chair, Health Research Ethics Board
Bannatyne Campus

Please quote the above protocol reference number on all correspondence.

Inquiries should be directed to the REB Secretary Telephone: (204) 789-3255 / Fax: (204) 789-3414

www.umanitoba.ca/academic/faculties/medicine/research/ethics



675 McDermot Avenue
Winnipeg, Manitoba
Canada R3E 0V9

409 Tache Avenue
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Canada R2H 2A6

**RESEARCH RESOURCE IMPACT COMMITTEE (RRIC)
Approval Form**

Principal Investigator: Ms Jill Taylor-Brown

RRIC Reference # 42-2006

Date: June 28, 2006

“Evaluation of an Iyengar Yoga Intervention for People with Cancer”

This letter is to inform you that the Resource Impact Committee (RRIC) reviewed and provisionally approved the above-mentioned study at the RRIC meeting held on June 28, 2006 pending receipt of REB.

The approval is valid for one year only and a study status report must be submitted annually. Any significant changes in this research must be reported to the Chair for consideration in advance of implementation of such changes. The RRIC must be notified regarding discontinuation or study closure.

The approval is for the RRIC use only. For ethics of human use and/or regulatory bodies, approval should be sought from the relevant parties as required and must be forwarded to the RRIC Secretary as soon as possible.

Yours sincerely,

Charles L.M. Olweny, MD, FRACP
Chair, Resource Impact Committee

Cc: Ms. Erna Stiles, Manager, CIO

Please quote the above RRIC reference number on all correspondence.

Enquiries should be directed to Marilyn Meakin, RIC Secretary, CCMB, 5020-675 McDermot
Telephone: 787-4170 **Fax:** 787-2190 **Email:** marilyn.meakin@cancercare.mb.ca

APPENDIX H – Research Participant Information and Consent Form

STUDY TITLE:

Evaluation of an Iyengar Yoga Intervention for People With Cancer

Principal Investigator: Jill Taylor-Brown, MSW, RSW; CancerCare Manitoba (204)787-1325

Co-Investigator: Anne Leis, PhD; University of Saskatchewan (306) 966-7878

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff. You may take your time to make your decision about participating in this study and you may discuss it with others before you make your decision. This consent form may contain words that you don't understand. Please ask the study coordinator to explain any words or information that you don't understand.

PURPOSE OF STUDY

This research study is being conducted to evaluate the Iyengar yoga program you have joined. The objective of this study is to examine the effect of Iyengar yoga on quality of life and the perceived severity of symptoms and side effects (including pain, nausea, anxiety, depression, and fatigue) related to cancer and its treatment in people currently undergoing treatment for cancer and those who have undergone treatment within the six months prior to commencing the Iyengar yoga program.

It is anticipated that a total of 50 to 75 participants will participate in this study.

STUDY PROCEDURES

If you take part in this evaluation study, you will be asked to complete a series of questionnaires that ask you to rate statements concerning your cancer symptoms or treatment side effects, and quality of life. These questionnaires have been used by thousands of people in several different groups, including groups with cancer and will take less than one hour to complete each time. All of the questionnaires can be completed either in your home, over the phone, or at CancerCare Manitoba, depending on what is most convenient for you at the time. Also, using a participant diary, you will be asked to record your medication use, cancer treatment regimen, physical activities, and use of any other complementary or alternative therapies over the course of the study.

If you give us permission, your CancerCare Manitoba electronic chart will be reviewed to collect information relevant only to your cancer treatment.

Procedure Schedule

It is anticipated that your participation in this study will last for approximately four and a half months and will take place at the following four time points:

- **Baseline:**

Within the two weeks prior to the first yoga class you will be asked to complete the questionnaires and an intake form requesting basic demographic information. You will also

be given a participant diary record your use of any medications or therapies during the first 5 weeks.

- **Week 5:**

Mid-way through the yoga session you will again be asked to complete the questionnaires. You will return the participant diary and will be given a new one to use over the next 5 weeks.

- **Week 10:**

Within the 48-hour period after the last class you will again be asked to complete questionnaires. You will return the participant diary and will be given a new one to use over the next 4 weeks.

- **Week 16:**

One month after your last yoga class you will be asked to complete the questionnaires and return the last participant diary.

At this point an oncology nurse will review your CancerCare Manitoba electronic chart to verify the information you have provided in your patient diaries. Please initial at the end of the sentence if you give permission for your chart to be reviewed _____.

In addition to the questionnaires and the diary, you may also be asked to participate in an interview designed to explore your experiences during the yoga program in greater depth. The interview is anticipated to last approximately 20 minutes to 1 hour and can take place over the phone or in person either at your home or at CancerCare Manitoba depending on what is most convenient for you.

At the end of the study, the results will be compiled and a brief report will be mailed to you unless you indicate otherwise.

RISKS AND DISCOMFORTS

There are no reports of any risks or discomforts associated with the completion of these questionnaires. However, because these questionnaires ask you to reflect on your cancer experience, completing them could potentially be upsetting for some individuals. You are welcome to contact the Department of Psychosocial Oncology at CancerCare Manitoba should you wish to discuss any feelings or issues that may have arisen for you by calling (204) 787-2109 and setting up an appointment with one of the counsellors.

BENEFITS

There may or may not be direct benefit to you from participating in this study. We hope the information learned from this study will benefit other people with cancer in the future.

COSTS

All the procedures (i.e., the administration of questionnaires) that will be performed as part of this study will be done at no cost to you.

PAYMENT FOR PARTICIPATION

You will receive no payment for taking part in this study. If you choose to complete the questionnaires at CancerCare Manitoba, you will be reimbursed for parking expenses. Alternatively, if you choose to complete the questionnaires at home and mail them to the study staff, an envelope with postage will be provided.

If you are chosen to participate in the interview and agree to do it, you will be given a \$20 honorarium for your time upon completion of the interview.

CONFIDENTIALITY

Information gathered in this research study may be published or presented in public forums in aggregate format without any identifying information. All study related documents will bear only your assigned study number. Despite efforts to keep your personal information confidential, absolute confidentiality cannot be guaranteed. Your personal information may be disclosed if required by law.

Medical records that contain your identity will be treated as confidential in accordance with the Personal Health Information Act of Manitoba. Organizations that may inspect and/or copy your research and/or medical records for quality assurance purposes and data analysis include groups such as CancerCare Manitoba, the University of Manitoba Health Research Ethics Board, and/or the University of Saskatchewan's Department of Community Health and Epidemiology.

All records will be kept in a locked secure area for 5 years and only those persons identified will have access to these records. If any of your medical/research records need to be copied to any of the above institutions, your name and all identifying information will be removed. No information revealing any personal information such as your name, address or telephone number will leave CancerCare Manitoba.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time by notifying the study staff. Your decision not to participate or to withdraw from the study will not affect your care at CancerCare nor will it prohibit your participation in the yoga program.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study. The researcher may decide to stop the study if CancerCare Manitoba ceases to offer the yoga program or if the program is stopped for any other reason.

QUESTIONS

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study or if you have a research-related injury, contact the study coordinator, Meghan Duncan at (204)###-#### or the study's investigator, Jill Taylor-Brown, MSW, RSW (CancerCare Manitoba) at (204)787-1325.

For questions about your rights as a research participant, you may contact The University of Manitoba, Bannatyne Campus Research Ethics Board Office at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have read this consent form. I have had the opportunity to discuss this research study with Jill Taylor-Brown and/or the study coordinator, Meghan Duncan. I have had my questions answered in a language I understand. The risks and benefits have been explained to me. I believe that I have not been unduly influenced by any study team member to participate in the research study by any statements or implied statements. Any relationship (such as employer, client, supervisor or family member) I may have with the study team has not affected my decision to participate. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential, but that confidentiality is not guaranteed. I authorize the inspection of any of my records that relate to this study by The University of Manitoba Research Ethics Board, CancerCare Manitoba, and the University of Saskatchewan' Department of Community Health and Epidemiology for quality assurance purposes.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

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

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____ Date _____
(day/month/year)

Signature: _____

Role in the study: _____

APPENDIX I – Baseline Intake Form

Baseline Intake Form

Last Name: _____ First: _____

Address: _____

Postal Code: _____ Phone #: _____

Date of birth: _____ (Day/Month/Year)

Name and Phone # of a contact person: _____

Sex: M F (draw check mark in appropriate box)

Race: Caucasian First Nations Asian Black Other: _____

Diagnosis (type of cancer) & stage: _____

When were you diagnosed with cancer: _____

Are you currently receiving treatment for cancer? Yes No

If yes, please indicate what treatment you are currently receiving:

Chemotherapy Yes No Radiation Therapy Yes No

Other (please specify) _____

If no, when did you last receive treatment? _____

If no, please indicate when you last had treatment:

Chemotherapy _____ Radiation Therapy _____

Other (please specify) _____

Have you previously participated in CancerCare Manitoba's Iyengar yoga program?

Yes No

What do you hope to get out of the yoga program: _____

What is the highest level of education you have attained?

- Some High School
- Graduated from High School
- Some University/College/Trade School
- Trade School/College Diploma
- Undergraduate Degree
- Master's Degree
- PhD

What is your household income?

- Less than \$20 000
- \$20 000 to \$39 999
- \$40 000 to \$59 999
- \$60 000 to \$79 999
- \$80 000 or higher

What is your current employment status?

- Full time
- Part time
- Retired
- Unemployed
- Medical leave
- Other: _____

What is your current marital status?

- Married/Common-law
- Separated
- Divorced
- Widowed
- Single

Which statement best describes your current living arrangements?

- I live alone
- I live with my spouse/family
- I live with others

APPENDIX J – Interview Guide

1. Can you tell me about your experiences throughout the Iyengar yoga program?
Are there any benefits of yoga for a person experiencing cancer?
Any downsides?
2. What influenced your decision to join this Iyengar yoga program?
3. What were your expectations when you signed up for the program? Were they met?
4. How did you feel at the end of a typical Iyengar yoga class?
5. Why did you continue to come to Iyengar yoga classes?
6. Compared to other forms of physical activity (walking, cycling, swimming) how would you evaluate Iyengar yoga? Why?
7. Compared to a support group how would you rate Iyengar yoga? Why?
8. Has Iyengar yoga changed anything in your life? Please explain.
Has it affected your outlook on your future or prognosis?

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