Yoga as a complex intervention and its development for health-related quality of life in adult cancer

Marcy McCall MacBain

A thesis submitted for the degree of
Doctor of Philosophy in Evidence-Based Health Care

Kellogg College, Department of Continuing Education
University of Oxford
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ABSTRACT

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The aim of this thesis was to develop yoga as a complex intervention in health care for the improvement of health-related quality of life (HRQoL) in adult cancer. As the Indian tradition of practising yoga increases in popularity worldwide, populations in the West are beginning to see yoga as an opportunity to prevent and treat health conditions. The Medical Research Council's framework has provided a methodology to address a paucity of coherent evidence for the myriad of unsupported health claims made by yoga enthusiasts. The thesis structure included a step-by-step approach to investigate biomedical theories of how yoga might work to improve health, to synthesise evidence of yoga interventions, to model their process and outcomes, and to test evaluation procedures in the context of a randomised controlled trial (RCT). The results of a bibliometric analysis indicated an overall increase in the publication rate of yoga research in health care, and in 2005 this research began to focus on cancer. A component analysis, semi-structured patient interviews (n=10) and oncologist surveys (n=29) were successively designed, implemented and analysed to advance a model of yoga intervention specific to adult cancer. The cumulative results were applied to design three yoga interventions randomly allocated to men and women receiving treatment for cancer (n=15). Outcomes of the feasibility study demonstrated that yoga intervention is appropriate for adult patients and can be administered safely in a clinical setting. In its conclusion, this thesis produces evidence-based support for the optimisation of yoga intervention in the context of a large-scale RCT for HRQoL in adult cancer, and it provides recommendations to improve research methodology and reporting of complex interventions in health care.

I dedicate this thesis to the courageous patients of cancer.

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Professor Carl Heneghan and Dr Alison Ward provided the academic supervision of this doctoral thesis. Their expertise in the fields of evidence-based medicine, primary health care and chronic disease management have guided my progress as a researcher. Their respective contributions to my learning have been invaluable, and I am grateful for their astute supervision. I thank the Centre for Evidence-Based Medicine (CEBM), fellow students and administrators within Kellogg College, the Department of Continuing Education and the Department of Primary Care Health Sciences, University of Oxford, whose efforts have made this international DPhil possible. I wish to acknowledge Drs Mike Clarke, Amanda Burls, Ann van den Bruel and Jeremy Howick for their teaching and insights that improved the quality of this thesis. I recognise Dr Kathleen Martin-Ginis of McMaster University and Dr Adam Oliver of London School of Economics and Political Science for their guidance and persuasive introductions to health care research. My gratitude extends to Dr Sally Thorne of the University of British Columbia for her brave and enthusiastic commitment to my research endeavours. I acknowledge the patients and oncologists who volunteered their time, as well as Melanie McDonald and the Vancouver-British Columbia Cancer Agency (BCCA) for sharing their passions of inquiry and patient wellbeing.

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PERSONAL STATEMENT

I was first introduced to the Centre for Evidence-Based Medicine (CEBM), Oxford in early 2010. At that time, I was attending a skills training workshop as the director and chair of a philanthropic organisation administering grants in sectors of maternal health, education and the environment. I became interested in evidence-based medicine and its methods to enhance my role in cost-effective grant making and in health care delivery. This thesis is the result of previous research experiences at McMaster University, London School of Economics and Political Science (LSE), the World Health Organization (WHO) and four years of study in evidence-based health care (EBHC) at the University of Oxford. The practical and theoretical knowledge I have gained throughout this thesis are invaluable to me. I respectfully hope my efforts have positively impacted the wellbeing of patients and encouraged the commitment of evidence-based thinking in yoga and other complex interventions. The logical reasoning and investigative skills I have gained will ultimately serve in my endeavour to improve health care education, research, policy and practice.

STATEMENT OF CONTRIBUTIONS

This doctoral thesis is independent and original work of which I am the sole author. Academic supervisors Professor Carl Heneghan and Dr Alison Ward contributed intellectual guidance on the overall research strategy, protocol, analyses and presentation of results.

Other individuals have made contributions in the following ways:

Nia Roberts (NR): Information Specialist, University of Oxford, Bodleian Library assisted in developing the search strategy for the systematic overview of reviews in Chapter 4 and literature review in Chapter 7.

Bethany Shinkins (BS): Statistician, University of Oxford advised on the statistical methods to complete the component analysis in Chapter 5 and advised on the sample size calculation in Chapter 9.

Caroline Jones (CJ): Senior Researcher, University of Oxford reviewed the research methods of the study protocol in Chapter 6.

Sally Thorne (ST): Professor, University of British Columbia, facilitated the ethical application to the University of British Columbia Behavioural Research Ethics Board in Chapters 6, 7 and 8; she commented on qualitative analysis strategies and edited the published manuscript in Chapters 6 and 8.

Lynda Balneaves (LB): Associate Professor, University of British Columbia, provided protocol advice and co-signed the ethical application to the University of British Columbia Behavioural Research Ethics Board in Chapters 6 and 7.

Sian Harrison (SH): Research Officer, University of Oxford, contributed to the validity assessment of the survey instrument in Chapter 7.

Fiona Walks (FW): Vice President of Safety, Quality and Supportive Care, Vancouver British Columbia Cancer Agency (Vancouver-BCCA) distributed the survey in Chapter 7.

Melanie McDonald (MMcD): Social Worker, Vancouver-BCCA, facilitated the ethical application to the Vancouver-BCCA Research Ethics Board, edited the study protocol and assisted in the implementation of the feasibility study in Chapter 8.

Research Assistant (RA): Christiane Banmeyer, a professional colleague unrelated to the study, performed random shuffling and distribution of masked participants' envelopes to yoga groups in Chapter 8.

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LIST OF ABBREVIATIONS

Abbreviation	Meaning
ACL	Anxiety Checklist
AMED	The Allied and Complementary Medicine Database
AMSTAR	Assessing the methodological quality of systematic reviews
BCCA	British Columbia Cancer Agency
BCCRC	British Columbia Cancer Research Centre
BDI	Beck Depression Inventory
BMI	Body Mass Index
BMR	Basal Metabolic Rate
BP	Blood Pressure
BWY	British Wheel of Yoga
CAM	Complementary and Alternative Medicine
CAMQuest	Complementary and Alternative Medicine search portal
CEBM	Centre for Evidence-Based Medicine
CENTRAL	Cochrane Central Register of Controlled Trials
CES-D	Centre for Epidemiological Studies – Depression Scale
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMDQ	Cornell Musculoskeletal Discomfort Questionnaire
CONSORT	Consolidated Standards of Reporting Trials
CVD	Cardiovascular Disease
DMI	Distressed Mood Index
DNA	Deoxyribonucleic Acid
EMBASE	Excerpta Medica Database, Elsevier
EORTC-QLQ	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire
FACT-B	Functional Assessment of Cancer Therapy (Breast)
FACT-G	Functional Assessment of Cancer Therapy (General)
FLIC	Functional Living Index – Cancer
FSI	Fatigue Symptom Inventory
GABA	Gamma-aminobutyric Acid
GCP1	Good Clinical Practice, guidelines for ethical aspects of clinical study
GHQ-12	General Health Questionnaire
GIGO	Garbage In, Garbage Out
GP	General Practitioner
GRADE	The Grading of Recommendations Assessment, Development and Evaluation
GSDS	General Sleep Disturbance Scale

Abbreviation	Meaning
GSH	Glutathione
HADS	Hospital Anxiety and Depression Scale
HAS	Hamilton Anxiety Scale
HCP	Health Care Professional
HPA	Hypothalamic-pituitary-axis
HRQoL	Health-Related Quality of Life
IAYT	International Association of Yoga Therapy
ID	Interpretive Description Method
IES	Impact of Events Scale
IndMED	National Database of Indian Medical Journals
MANE	Morrow Assessment of Nausea and Emesis
MBSR	Mindfulness-Based Stress Reduction
MEDLINE / PubMed	United States National Library of Medicine Database
MENSI	Menopausal Self-Inventory
MeSH	Medical Subject Heading
MOS	Medical Outcomes Study
MPQ	McGill Pain Questionnaire
MRC	Medical Research Council
No.	Number
n.r	Not Reported
NHP	Nottingham Health Profile
NHS	National Health Service, United Kingdom
NICE	National Institute for Health and Care Excellence, United Kingdom
NK	Natural Killer Cells
NLM	National Library of Medicine
OR	Odds Ratio
OxLIP+	Oxford Libraries Information Platform
OXTREC	Oxford Tropical Research Ethics Committee
PANAS	Positive and Negative Affect Scale
PaT Plot	Part and Timing, software tool creating graphic depictions of randomised trials
PEDro	Physiotherapy Evidence Database
PFS	Piper Fatigue Scale
PICO	Population/Problem, Intervention, Comparator, Outcome
PNS	Parasympathetic Nervous System
POMS	Profile of Mood States
PPI	Present Pain Index
PSQI	Pittsburgh Sleep Quality Index
PSS	Perceived Stress Scale
PsycINFO	Behaviour Sciences and Mental Health Database

Abbreviation	Meaning
PTSD	Post-Traumatic Stress Disorder
QALYs	Quality-Adjusted Life Years
QOL-CA/CS	Quality of life of cancer patients and survivor scale
QUAL	Qualitative research method
QUANT	Quantitative research method
RCT	Randomised Controlled Trial
REB	Research Ethics Board
RSCL	Rotterdam Symptom Checklist
SCL-90-R	Symptoms Checklist (Revised)
SCOPUS	Scientific journals, books and conference proceedings database
SD/s.d	Standard Deviation
SF-12/36	Short Form Quality of Life Scale
SIO	Society for Integrative Oncology
SIP	Sickness Impact Profile
SMD	Standardised Mean Difference
SNAQ	Snake Attitude Questionnaire
SNS	Sympathetic Nervous System
SOSI	Symptom of Stress Inventory
SPORTDiscus	Sports Medicine Database
SR	Systematic Review
STAI	State-Trait and Anxiety Inventory
T-cell	Thymus cells or lymphocytes
TAS	Total Antioxidant Status
$TAS^{\pm}$	Taylor's Anxiety Scale
TCI	The Complex Intervention (i.e. yoga)
TCPS	Tri-Council Policy Statement: Ethical conduct for research involving humans
UBC	University of British Columbia
UK	United Kingdom: England, Scotland, Wales and Northern Ireland
USB	Universal Serial Bus
USD	United States Dollar
VAS	Visual Analogue Scale
WHO	World Health Organization
Y-ACT	The Yoga for Adult Cancer Trial (Feasibility Study)
Y-BOCS	Yale-Brown Obsessive Compulsive Scale
£	British Pounds Sterling

CHAPTER ONE

Introduction

1 INTRODUCTION

1.1 OVERVIEW OF THESIS

This thesis explored the evidence for yoga intervention and its use in adult health conditions. In the early development phase, the biomedical theories of yoga and characteristics of adult populations with health-related outcomes were investigated to understand yoga's potential role in health care. Evidence synthesis was completed first through a literature review of the underlying mechanisms of how yoga intervention might work, followed by a bibliometric analysis of yoga publications in health care literature and an overview of systematic reviews of yoga intervention in acute and chronic adult health conditions. The results identified improvements in patient anxiety, pain and depression as outcomes most highly correlated with yoga, and indicated an emerging interest and knowledge gap for adult cancer populations. In response to these findings, the thesis aimed to develop an evidence-based yoga intervention for health-related quality of life (HRQoL) in adult cancer patients.

A component analysis was performed to determine characteristics of yoga intervention previously administered in randomised controlled trials (RCTs). Patient interviews and oncologist surveys further explored aspects of yoga delivery, including its reported benefits, risks and characteristics in a clinical setting. The results derived from the component analysis, patient interviews and oncologist surveys were combined to design a framework for three yoga interventions that were detailed with input from yoga instructors in the context of a mixed methods feasibility study. The feasibility study was implemented in Vancouver, British

Columbia with aims to determine the appropriateness and acceptability of delivering yoga intervention to adult cancer patients.

1.2 AIM OF THESIS

This thesis aimed to develop yoga as a complex intervention in health care for the improvement of health-related quality of life (HRQoL) in adult cancer patients.

1.3 RESEARCH METHODOLOGY

The evidence-based strategy to achieve this aim included a multiphase mixed methods design and application of the Medical Research Council's (MRC) framework for complex interventions[1].

1.4 RESEARCH OBJECTIVES

The research objectives of this thesis were to:

1. Consider yoga from traditional and conventional health care perspectives:
    1.1 Collect and summarise traditional and health-related definitions of yoga.
    1.2 Explore yoga as a complex intervention in health care and define its development within the context of the MRC framework.
    1.3 Identify medical hypotheses of how yoga might improve health-related outcomes in adult populations.
2. Synthesise the evidence base of yoga in adult health care:
    2.1 Analyse the publication trends of yoga in peer-reviewed health care journals.
    2.2 Collect, evaluate and summarise the current evidence of yoga intervention for acute and chronic health conditions.

2.3 Identify knowledge gaps, limitations in current evidence and epidemiological evidence to identify populations and their health conditions most likely to benefit from yoga intervention.

3. Advance the modelling of yoga intervention for HRQoL in adult cancer:
   3.1 Summarise the characteristics of yoga intervention, its delivery and processes to optimise implementation for HRQoL in adult cancer.
   3.2 Determine the type of yoga, its optimal dose and delivery mechanism to improve health-related outcomes in adult cancer patients.
   3.3 Explore patient-perceived benefits and their reasons for practising yoga during cancer treatment.
   3.4 Document patient-perceived barriers to practising yoga, and identify their preferences for yoga delivery in a clinical setting.
   3.5 Investigate the perceptions, patterns of use and current knowledge of yoga as a complementary therapy from the oncologist's perspective.
   3.6 Determine the willingness of oncologists to recommend yoga to their patients, and identify their particular concerns, beliefs or applications of yoga for adult cancer in a clinical setting.
4. Develop a randomised controlled trial (RCT) of evidence-based yoga intervention to improve HRQoL in adult cancer patients:
   4.1 Perform and analyse a mixed methods feasibility study to optimise yoga intervention for randomisation in male and female cancer patients.
   4.2 Assess the patient adherence, acceptability and efficacy of delivering yoga intervention in a clinical setting.
   4.3 Improve the study design and yoga protocol for a pragmatic RCT.

1.5 STRUCTURE OF THESIS

1.5.1 Chapter 2. Yoga in Health Care

Chapter 2 outlines yoga and its use in health care. It discusses the historical context, current definitions and the integration of yoga as a complex intervention in westernised health care. The MRC framework for developing complex interventions in health care is presented and outlines the research methodology and methods of this thesis. A literature review and systematic search of biomedical theories explores the underlying mechanisms of how yoga could improve health outcomes.

1.5.2 Chapter 3. Bibliometric Analysis

In Chapter 3, the results of bibliometric analyses of yoga publications in health care, including biomedical literature from PubMed and a physiotherapy evidence database (PEDro) are reported. The correlation of yoga research publications in terms of adult health conditions and types of articles were reviewed and analysed. Comparative findings indicated a publication shift away from yoga intervention research in cardiovascular disease factors including obesity, towards cancer with a consistently high prevalence of anxiety, pain and depression research since 2005.

1.5.3 Chapter 4. Overview of Systematic Reviews

Chapter 4 explains the design, implementation and results of an overview of systematic reviews performed to determine the effects of yoga intervention in adults with acute and chronic health conditions. Systematic reviews (n=26) confirmed yoga was positively correlated with decreasing anxiety, depression and pain in adult populations. A new hypothesis emerged to suggest yoga would be most beneficial for patients experiencing clusters of symptoms, including pain, anxiety, fatigue and

depression simultaneously and over time. According to the results of this overview of systematic reviews, a bibliometric analysis in Chapter 3 and epidemiological evidence of increasing rates of cancer diagnoses, adult cancer patients and their HRQoL became the subsequent focus of the thesis.

1.5.4 Chapter 5. Component Analysis

Chapter 5 reports a component analysis of yoga interventions that were administered to adult cancer patients in full-scale RCTs. The components of yoga protocols were extracted and evaluated in terms of strength of association with positive outcomes with HRQoL and other outcomes in patients. The results of the component analysis guided the development of patient interview scripts (Chapter 6), the content of oncologist surveys (Chapter 7), and a preliminary model of yoga intervention for the feasibility study (Chapter 8).

1.5.5 Chapter 6. Patient Interviews

Chapter 6 advances the modelling of yoga intervention and describes the first of three primary studies conducted to explore the use of yoga intervention in adult cancer. In-depth interviews in adult cancer patients (n=10) were performed using Interpretive Description (ID) and constant comparative analysis. The purpose of the study was to understand the patient-reported experience of using complementary care during conventional cancer treatment, to document their preferences and list recommendations specific to yoga delivery in a conventional health care setting. The respondents who practised yoga (n=7) said they liked its calming effect and holistic, mind-body approach to healing. Patients listed components they believed would improve efficacy as well as adherence to yoga delivery during treatment. The results

of this set of interviews provided insight into the patient-perceived barriers, preferences and benefits of yoga. The conclusions advanced the understanding of yoga's potential role in adult cancer and provided a rationale for developing a patient-based yoga intervention to improve HRQoL.

1.5.6 Chapter 7. Oncologist Surveys

Chapter 7 enhances the modelling of yoga intervention and describes a mixed methods survey that was piloted to determine the perceived benefits, risks and acceptability of yoga intervention from the oncologist's perspective. The responding oncologists (n=29) had a positive attitude towards yoga, but believed there was a lack of scientific evidence to support its use in health care. Respondents agreed yoga intervention could improve health-related outcomes across all tumour groups and did not believe yoga would pose negative side effects for patients unless wound healing were an issue. Results also suggested yoga is currently being recommended to some adult cancer patients for relief of symptoms including anxiety, depression and fatigue. All respondents said they would recruit patients to a clinical trial of yoga intervention, and some strongly believed (n=3) it should be implemented to test efficacy in areas of HRQoL versus exercise.

1.5.7 Chapter 8. Feasibility Study

Chapter 8 summarises a mixed methods feasibility study of three yoga interventions randomised to adult cancer patients (n=15). This mixed methods study was developed to determine the deliverability and patient preferences of three yoga interventions designed through evidence-based analysis and input from yoga instructors. In the context of a clinical setting and randomised trial, the rate of patient

recruitment, adherence to the intervention and suitability of yoga and its components were estimated, as well as acceptability of online data collection tools. Evaluations of the research design and study methods were conducted using quantitative and qualitative input from cancer patients, yoga instructors and research facilitators. The reported preferences of cancer patients and opinions of expert yoga instructors were used to establish the feasibility of yoga intervention for delivery within a future RCT.

1.5.8 Chapter 9. Discussion and Conclusion

Chapter 9 summarises the thesis and its contribution to knowledge in the field of yoga research in health care and adult cancer. The final discussion addresses methodological strengths and limitations of the thesis and provides strategic direction of how to improve the reporting and conduct of yoga trials for health care. As part of the discussion, a summary table of the methodological approach used in this thesis provides a synopsis of research questions and methods that may guide future study of complex interventions in health care. The cumulative evidence suggests that a larger-scale pilot or RCT of yoga intervention for HRQoL warrants implementation, and in its conclusion, this thesis provides sufficient evidence to suggest the clinical and academic relevance of yoga research in adult cancer.

1.6 CHAPTER REFERENCE

[1] Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M., & Medical Research Council Guidance. (2008). Developing and evaluating complex interventions: The new medical research council guidance. *BMJ (Clinical Research Ed.), 337*, a1655.

CHAPTER TWO

Yoga in Health Care

2 YOGA IN HEALTH CARE

Features of this chapter are published in the following peer-reviewed journals:

1. McCall, M. C. (2012). Yoga beyond union. *International Journal of Yoga, 5*(2), 160. doi:10.4103/0973-6131.98249

2. McCall, M. C. (2013). How might yoga work? An overview of potential underlying mechanisms. *Journal of Yoga and Physical Therapy, 3*(1). doi:10.4172/2157-7595.1000130

2.1 CHAPTER AIM AND OBJECTIVES

The aim of this chapter is to explore the definitions of yoga from traditional and westernised health care perspectives. The primary objective is to establish yoga as a complex intervention in health care. The secondary objective is to identify medical hypotheses of how yoga might improve health-related outcomes in adult populations.

2.2 YOGA

Yoga is a complex history of spiritual exploration, philosophical ideas, scientific evolution and creative expression[2]. The earliest writings on yoga are found in ancient Hindu spiritual texts known as the Vedas, (meaning "knowledge"), originating from before 1100 BCE[2]. Following the vedic period, three additional texts were composed to describe the philosophy and practice of yoga which include: the Upanishads[3], the Bhagavad Gita[4] and the Yoga Sutras of Patanjali[5]. As a Hindu theistic philosophy, yoga is a Sanskrit word for union, that teaches suppression of all activity of the body, mind and will so the Self may realise its distinction from them and attain liberation[6]. It is explained in the Bhagavad Gita, that by training the mind, yoga aspirants seek a

kind of spiritual evolution and continuous flow of awareness[7]. The four main paths to yoga include: *jnana yoga* (the knowledge and discrimination of disidentifying body and senses from the Self); *bhakti yoga* (the yoga of devotion to a God, Lord or other mystic); *karma yoga* (the yoga of selfless action and dedication of life in service of others); and *raja yoga* (the yoga of meditation to reach a place of healing stillness to merge mind with Self)[8].

The physical practice of yoga incorporates breath control, simple meditation and the adoption of specific bodily postures to enhance health and relaxation[9]. The standard elements of yoga include *asanas* (standing and seated postures), *pranayama* (breathing techniques) *dhyana* (meditative techniques), *mantras* (chants), and *sutras* (wisdom teaching)[10]. The components of yoga are described in eight broad categories, referred to as *ashtanga* or the eight-fold path of Patanjali's Yoga Sutra[11] (Box 2.1).

Box 2.1 The Eight-fold Path of Patanjali's Yoga Sutra

Yama: moral and ethical integrity of nonviolence, truthfulness, non-stealing and non-covetousness.
Niyama: self-discipline, spiritual observances including study of scripture and one's self.
Asana: physical postures of yoga.
Pranayama: breathing techniques and connection to breath as an extension of life force
Pratyahara: withdrawal, detachment from external stimulus.
Dharana: practice of concentration on a single object.
Dhyana: meditation or uninterrupted concentration without focus
Samadhi: enlightenment, profound connection of self with the Universe

In recent history, the adoption of yoga in Europe and North America gained widespread popularity, though it was regarded as a marginal or eccentric pursuit, modern forms of yoga emerged as one of the key phenomena of the 1960s counterculture[12]. As the popularity of yoga increases in cultures outside of India, over 20 million people now do yoga in the United States of America (8.7% of the American population)[13]. From 2008 to 2012, the associated spending on yoga classes and products in the United States has doubled to reach $10.3 USD billion per year[13]. As a national governing body of yoga in the United Kingdom (UK), The British Wheel of Yoga (BWY) accredits and registers yoga teachers and training organisations, of which there are approximately 7,500 members and more than 4,500 certified BWY active teachers in the country[14]. The Yoga Alliance UK registry lists names of another 1,700 certified yoga teachers practicing in the region, and indicates over 3,000 yoga classes are delivered per week[15]. In terms of financial spending on yoga in the UK, assuming an average of ten participants attend each of the 3,000 classes (estimated cost of £12 per class[16-19]), approximately £360,000 of revenue is generated from yoga per week. The National Health Services (NHS) considers yoga as a safe and effective intervention to increase strength, flexibility and balance, as well as a potential treatment for high blood pressure, heart disease, aches and pains, depression, stress and potentially asthma[20,21].

In the United Kingdom, yoga is categorised as a complementary therapy employing mind-body techniques to improve various health conditions[22]. As a therapeutic intervention, yoga is defined as "the process of empowering individuals to progress toward improved health and well-being through the application of the philosophy and practice of yoga"[23]. Yoga was added to the PubMed (MEDLINE)

database as a Medical Subject Heading (MeSH) on 1 January 1999 and attached to broader terms including: complementary therapies, mind-body therapies, spiritual therapies, exercise movement techniques and religious philosophies. According to MeSH, yoga is:

> *A major orthodox system of Hindu philosophy based on Sankhya (metaphysical dualism) but differing from it in being theistic and characterized by the teaching of raja-yoga as a practical method of liberating the self. It includes a system of exercises for attaining bodily or mental control and wellbeing with liberation of the self and union with the universal spirit*[24].

In terms of policy and legislation, yoga remains a non-licensed discipline. Yoga teachers typically require insurance to administer yoga classes in a private or public setting. However, this certification procedure is self-regulated through non-profit and profit-seeking agencies or alliances. One such organisation, the International Association of Yoga Therapists (IAYT) supports research and education in yoga with a mission to establish yoga as a recognised and respected therapy[25]. The IAYT seeks to establish guidelines for yoga therapy programs through professional training and quality monitoring, though education and certification of yoga instructors remain voluntary at this time. In addition, the Society for Integrative Oncology (SIO) is in the process of developing clinical guidelines to evaluate the safety and efficacy of mind-body modalities including yoga[26].

The semantics of yoga, particularly how yoga as a therapeutic intervention and its components are defined in health care literature, is an area of controversy[27-30]. The certification bodies of yoga and health care researchers have not yet agreed upon the language or distinguishable features of what constitutes therapeutic yoga, traditional yoga, secular or modern yoga[31]. Some medical researchers refer to yoga as a mind-

body exercise[32,33]. Others choose to describe aspects of its implementation as breath practice[34]. This terminology in some health care research is deliberately specific to avoid confusion or concern from readers about the religious implications of the term 'yoga'. Notwithstanding the potential implications of a perceived resistance of using the term 'yoga' in a medical context, the current debate and yoga's evolving definitions are outside the scope of this research project. For the purposes of this research, therefore, yoga and yoga intervention are terms that will be used interchangeably and yoga is defined to include any or all aspects of MeSH terminology and the text of the Patanjali's Yoga Sutra (Box 2.1).

2.3 COMPLEX INTERVENTIONS IN HEALTH CARE

The Medical Research Council's (MRC) framework describes a continuum of research methodology to improve the quality of evidence and development of complex interventions in randomised controlled trials (RCTs). As defined by the MRC, complex interventions in health care contain several interacting components, and are variable in the range of possible outcomes or number of elements in the intervention package itself (see Box 2.2)[1].

Box 2.2 Dimensions of Complex Interventions

- The number and interactions between components within the experimental and control interventions
- The number and difficulty of behaviours required by those delivering or receiving the intervention
- The number of groups or organisational levels targeted by the intervention
- The number and variability of outcomes
- The degree of flexibility or tailoring of the intervention permitted

2.3.1 Yoga as a Complex Intervention in Health Care

As outlined in its definition, yoga includes variation of breathing techniques, physical postures and mind-body awareness techniques. In the UK, modern yoga classes are primarily delivered in yoga studios (45 to 120 minutes per session) by certified instructors to groups of adult men and women[35]. Yoga intervention in health care would be considered a complex intervention by the MRC. The extensive variability of yoga, including its different components, as well as its nonstandard means of delivery cause an unpredictability of teacher-participant interaction and irregular outcomes.

An existing framework for the development of yoga intervention in health care or for a RCT is lacking[36]. Therefore, the MRC's framework for developing complex interventions[1] is an appropriate tool to guide the development of yoga intervention for its evaluation in the context of a future RCT. The subsequent chapters and evidence synthesis of this thesis follow the MRC's guidelines for developing complex interventions in health care. In accordance with the MRC framework, the thesis structure and research methods used to investigate yoga as a complex intervention in health care are presented in Table 2.1.

Table 2.1. Overview of thesis structure

Overview of Thesis Structure							
MRC Framework	**Development Phase**					**Feasibility / Pilot**	
	Identify theory	Identify evidence base	Modelling process and outcomes			Testing procedure	Estimating recruitment and adherence
Mixed Methods Approach	**Secondary Research**			**Primary Research**			
				QUAL	QUANT (qual)	QUANT/QUAL	
Research Method	**Design, Implementation and Analysis**						
	Literature Review	Bibliometric Analysis	Systematic Overview of Reviews	Component Analysis	Patient Interviews	Oncologist Survey	Randomised Controlled Trial Feasibility Study

QUANT = quantitative method, QUAL = qualitative method

2.4 LITERATURE REVIEW: HOW YOGA MIGHT WORK

As outlined by the MRC framework[1], it is imperative to understand not only if an intervention shows efficacy but also how might the intervention be responsible for creating change in the health outcomes. In particular, the following literature review aims to identify current medical hypotheses of how yoga might affect health-related outcomes and seeks to determine if clinical evaluation of yoga in health care is an apposite research question from a scientific, evidence-based perspective.

2.4.1 Methods

This literature review included a systematic search for scholarly articles from peer-reviewed journals catalogued on three online health care databases, conferences, yoga websites and manuals. The data collected for this review were coded into categories and presented under appropriate subject headings, which originate from research that included biological or underlying mechanisms associated with yoga.

2.4.1.1 Inclusion criteria

Type of articles

Research articles, reviews or evidence synthesis that sought to understand potential biological or underlying mechanisms for yoga's effect in the context for improving health outcomes in adult populations were included. Only peer-reviewed articles published on-line within public medical research databases were included. The original search and analysis included articles published before 1 December 2012. Results of an updated search (31 July 2014) are included in the discussion. Hypotheses that were presented with minimal scientific evidence were included and

presented as emergent hypotheses. For practical reasons, only articles published in English were considered and therefore a limitation of this review.

Type of mechanisms

The biological mechanisms or description of yoga's potential underlying effects on human health or wellbeing were included. Outcome effects such as reducing body weight or decreasing stress were included in those instances where they were considered as primary prevention of a cardiovascular disease or other disease.

Type of yoga intervention

Any article type or reference to yoga was included for review, which could have included one or more of the following components: pranayama, (breathing techniques), asana (postures) and dhyana (meditation) and/or any other yoga teachings as referred to by authors.

2.4.1.2 Exclusion criteria

Articles that discussed therapies or interventions similar to yoga, such as mindfulness programs, massage, tai chi or talk therapy were excluded. Research protocols or scientific papers that discussed yoga mechanisms in the study rationale or introduction were not included. Qualitative studies or case reports in children or youth populations (less than 18 years of age) were excluded.

2.4.1.3 Search strategy

A comprehensive online search in three scholarly databases included the Cochrane Library, PubMed and Scopus databases (published before 1 December 2012). A rapid systematic search employed free-text terms: (*yoga*) AND [(*mechanism* OR *pathway* OR *effect*) AND (*clinic** OR *review*)]. Bibliographic references from found articles were

also searched. Hand-searches in yoga manuals (n=2)[37,38] were also conducted. Yoga research conferences[39] and a related website[40] were also searched.

2.4.2 Results

The title-search identified 473 potential articles, of which 110 abstracts were screened and 24 full-text articles assessed for eligibility; 328 of the titles were rejected because they were not relevant to yoga. Eighteen original articles were included for an in-depth analysis. See Figure 2.1 for the article flow diagram. Six articles were excluded after initial screening because either the article included interventions other than yoga[41-43], yoga mechanisms were not the focus – where the article referred to outcomes other than biological or underlying effects of yoga, or authors did not present empirical evidence to support their theory[44].

A variety of outcome effects were measured for association with yoga, including: psychological wellbeing, relaxation, amount of depression and anxiety, treatment and prevention of cardiovascular disease (CVD), diabetes, obesity and improvement in pain management. To a lesser extent, arthritis, cancer, epilepsy, erectile dysfunction and sleep quality were also reported. The included articles (n=18) consisted of one systematic review, literature reviews (n=13), one RCT and other clinical trials (n=3). See Table 2.2 for a summary of characteristics of included articles.

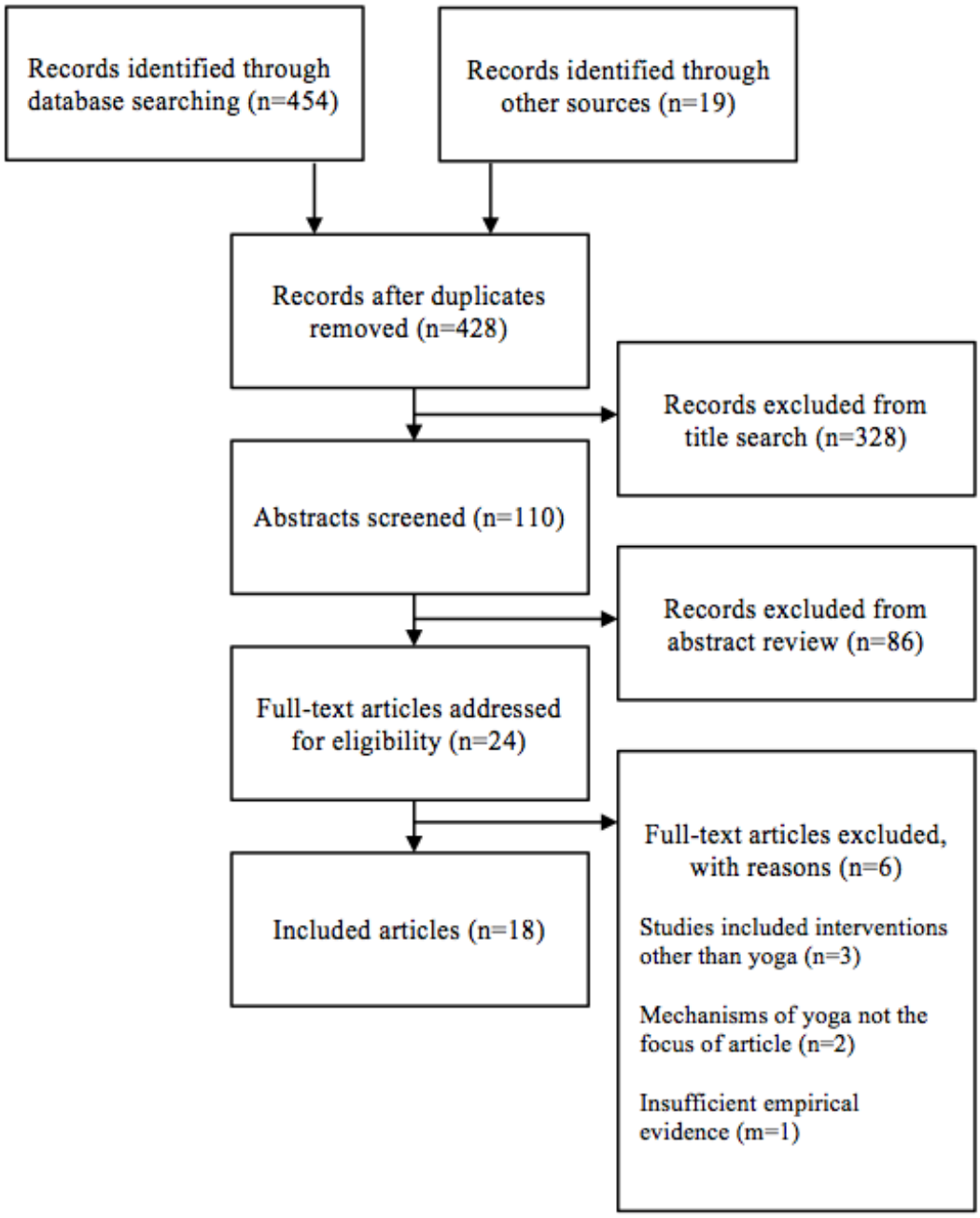


Figure 2.1. Article flow diagram for literature review

Table 2.2. Characteristics of included studies

Author	Type of studies	Outcomes effects	Description of mechanism(s)
Balaji 2012[45]	RCT, CI, OBS§	treatment and prevention of diabetes, obesity, arthritis, cancer, immune disorders	improves respiration, reduces cardiovascular risk, body mass index, blood pressure, hormone regulation, cellular metabolism
Balk 2011[46]	RCT, CI§	improve bone health, reducing fracture risk	improves balance, increases strength, reducing falls, reducing hyper kyphosis and inflammation
Brotto 2009[47]	CI, OBS§	treat erectile dysfunction, enhanced sexuality	serotonin regulation, enhanced awareness, mental focus
Dunn 2008[48]	RCT, CI§	improve mood disorders, decrease perceived stress, anxiety, increased wellbeing, relaxation prevention of chronic diseases: CVD, cancer, diabetes, Alzheimer's	Improves cardio-respiration (decreases basal metabolic rate), cortisol regulation, increases feelings of satisfaction and self-control, stimulation of PNS and decrease of SNS, hypothalamic-pituitary-adrenal (HPA) axis, increases bioavailability and blood levels of nitric oxide, vasodilation of the CV system, increase levels of total antioxidant status (TAS) and decreases other oxidative stress markers
Field 2011[49]	RCT, CI, OBS§	prevention of CVD, obesity, decrease injury, improve wellbeing, QOL, immunity, decrease perceived stress, pregnancy complications, improves pain management	exercise-training effects for cardiovascular and respiratory health, decrease in food consumption and speed of eating and positive food choices, attenuates weight gain, increase muscular strength and balance, decreases salivary cortisol, enhances deep sleep leading to less P substance, stimulates Gate theory
Hegde 2011[50]	CI	reduce oxidative stress, diabetes management	reduces body mass index, improves glycemic control, levels of malondialdehde, glutathione and vitamin C
Innes 2005[51]	RCT	prevention of CVD, decrease risks associated with insulin resistance syndrome	metabolism of glucose, insulin, lipid profiles anthropometric characteristics, blood pressure, oxidative stress, coagulation profiles, sympathetic activation, cardiovagal function
Kiecolt-Glaser 2010[52]	CI	minimise stress and inflammation	minimises inflammatory response and endocrine response
Kinser 2012[53]ᵒ	RCT, CI§	mitigate depressive symptomatology	hormonal regulation (decrease cortisol), HPA axis, increase levels of gamma-aminobutyric acid (GABA), vagus nerve stimulation via neurotransmitter, behaviour modification and group effect on mood

Author	Type of studies	Outcomes effects	Description of Mechanism(s)
Kulkarni 2009[54]°	RCT, CI, OBS§	optimal health, stress reduction, increase immunity, heightened awareness, stillness by increasing the body's store of prana, or flow of vital energy	cortical and hypothalamo-pituitary-adrenal axis (HPA) interactions with a deep reach molecular action on cellular, neuro-humoral and immune system
Kuntsevich 2010[55]°	RCT, CI OBS§	optimise health, delay aging, ameliorate chronic illness and stress from disability	promotes restoration of physiologic setpoints to normal after derangements secondary to disease or injury, promotes homeostatic negative feedback loops over non-homeostatic positive feedback loops in molecular and cellular interaction, quenches abnormal "noise" in cellular and molecular signalling networks arising from environmental or internal stresses
Oswal 2011[56]	RCT	speed healing of bone fracture	HPA axis, oxytocin, vasodilation and increased blood flow
Sahay 2007[57]	RCT, CI§	diabetes management	glycemic control (lower levels of fasting, postprandial blood glucose), insulin kinetics, improves body composition
Sengupta 2012[58]	RCT, CI OBS§	obesity, diabetes management, CVD prevention, cancer treatment, mood enhancement, improved sleep	decreases blood lipids, assist ideal body weight and body density, increase cardiorespiratory fitness, increase sensitivity of pancreatic B-cells to the glucose signal, hormonal regulation (noradrenaline, dopamine, aldosterone, luteinizing hormone, testosterone, cortisol, melatonin)
Sharma 2012[59]	CI§	diabetes management	decreases fasting blood glucose
Streeter 2012[60]	CI, OBS§	treatment of epilepsy and depression	reduces allostatic load in stress response systems and restore optimal homeostasis [increases PN, decreases HPA axis; increases GABA activity; stretches receptors in the receptors, chemoreceptors, and other sensors throughout the respiratory structures sends information about the state and activity of the respiratory system through vagal afferents and brainstem relay stations to other CNS structures
Vera 2009[61]	CI	enhances subjective sleep quality (SSQ)	hormone regulation (cortisol, ACTH)
Wren 2011[62]	RCT, CT, OBS§	pain management	decreases SNS activity, reduces inflammatory markers (tumour necrosis factor, interleukin-2, C-reactive protein), reduces stress markers (cortisol), increases strength, flexibility, circulation and cardiorespiratory capacity, reduces social isolation, fosters networks that reinforce physical activity, increases awareness of physical and mental states

Note: RCT = randomised controlled trial; CI = other clinical investigation/trial; OBS = observational study or modelling; ° = systematic review; § = review of studies

2.4.2.1 Quality of included articles

The empirical evidence supporting underlying mechanisms for clinical effects of yoga was limited by its low quality. One included article was a systematic review of underlying mechanisms for yoga[51] and received a high-quality rating (AMSTAR=9)[63,64]. One RCT[56] (n=30) reported double blinding and shows reasonable effort to minimise bias and appears to follow the CONSORT[65] guidelines for transparency and effective reporting procedures. Three controlled trials[50,52,61] were included though their quality of evidence is low due to selective recruitment and lack of randomisation with no mention of blinding techniques across studies. The remaining articles (n=13) were clinical or literature reviews that did not report on methodological aspects such as search protocols, inclusion or exclusion criteria of studies and did not assess the quality of evidence.

2.4.2.2 Overview of evidence for mechanisms

Twelve biomedical theories for yoga's impact on health outcomes were identified. The most frequently cited theories suggested yoga was effective in regulating the endocrine system (n=11), the nervous system (n=11) and improving physical health (n=11). Theories to suggest yoga practice improved metabolism (n=8), circulation (n=7) and behavioural or social function (n=6) were also prevalent. Three emergent hypotheses for immunity, nerve conduction and bio-electromagnetism were separated from other empirical-based theories (n=9) as authors provided indirect or no scientific evidence. See Figure 2.2 for a summary of evidence as expressed in empirical evidence-based theories as well as emergent hypothetical findings.

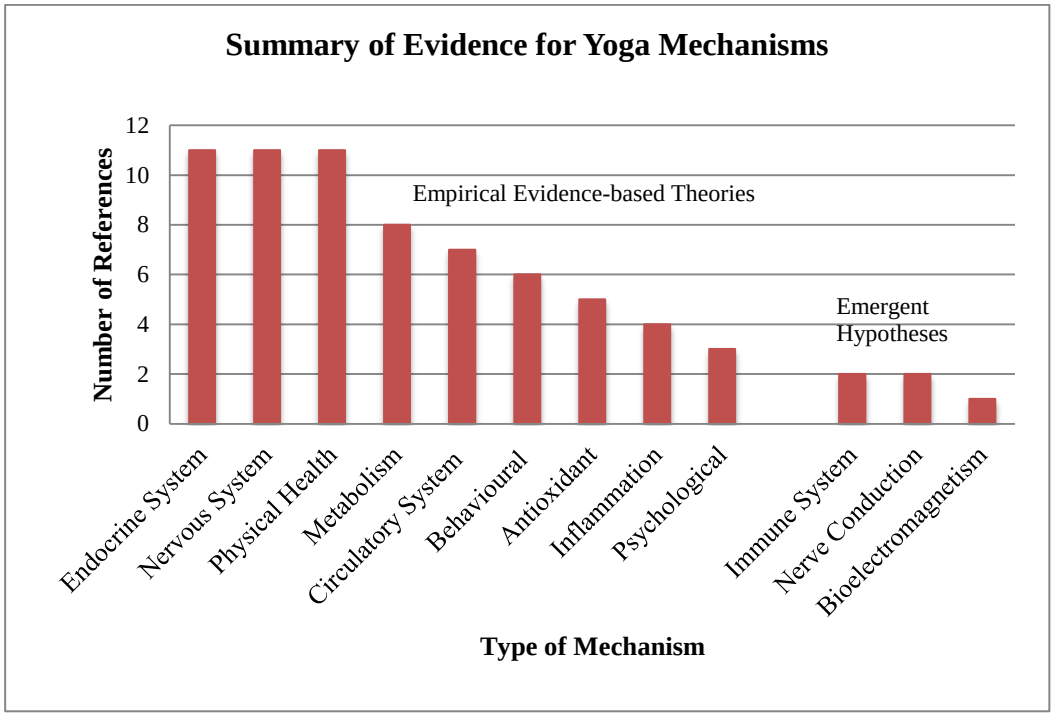


Figure 2.2. Summary of evidence for yoga mechanisms

2.4.2.3 Empirical evidence-based theories

Endocrine system

The strongest evidence in terms of quality and quantity suggested yoga has a positive impact on hormone regulation. Salivary levels of cortisol have been measured and reported to decrease in yoga reviews and clinical trials[45,47-4849,52-5354,58,61,62]. Lowering cortisol was associated with decreased perceived stress, decreased anxiety, increased feelings of wellbeing and improved pain management[45]. Enhanced serotonin production for erectile dysfunction[47], oxytocin released during visualisation techniques to regulate bone mass[56] as well as higher levels of melatonin to improve immunity and sleep quality[58,61] were identified as other potential effects of yoga.

Nervous system

Yoga has been associated with regulation of the sympathetic and parasympathetic activity in the autonomic nervous system and this mechanism was cited in several studies (n=11). Evidence suggested the respiratory effects of breathing exercises (pranayama), the visualisation and calming techniques (dhyana) as well as physical movement (asana) reduced sympathetic activation, increased levels of gamma-aminobutyric acid (GABA)[60], regulated the hypothalamic-pituitary-adrenal (HPA) axis to improve outcomes in mood disorders and provide an anxiolytic effect[48,54].

Physical health

Physical health included aspects of cardiorespiratory fitness, anthropometric characteristics and biomechanics such as balance, flexibility and strength. Exercise training effects following yoga intervention indicated positive impact in lowering resting heart rate, blood pressure (BP), decreasing oxygen consumption rate, decreasing basal metabolic rate (BMR), decreasing body mass index (BMI) and body fat mass to prevent cardiovascular disease, diabetes and obesity[46,49,51,58]. The evidence of one review also suggested yoga intervention could increase strength and balance, with demonstrative effects on decreased falls and risk of injury in a geriatric population[46].

Metabolism

The metabolic effects of yoga have also been studied for glycemic control. Evidence for improved glucose tolerance and insulin sensitivity suggested that regular asana practice may replace drug therapies for people with Type 2 diabetes[50,51]. Measureable improvements of clinical significance after yoga intervention were noted in several reviews to improve fasting plasma glucose (FPG) and postprandial plasma glucose

(PPPG) [57-5859]. Balaji et al. reported increased hepatic lipase and lipoprotein lipase levels at the cellular level, which works to improve the uptake of triglycerides by adipose tissues[45].

Circulatory system

Several theories included potential circulatory benefits of yoga. The identified effects were lowered blood pressure, enhanced cardiovagal function and slowed atherosclerosis[51], increased blood flow with the prompting of visual techniques[56] and restored baroreceptor sensitivity[60].

Behavioural/social

Enhanced sleep quality to improve psychological wellbeing was noted in two studies[58,61]. Reduced social isolation, improvement of social networks to reinforce physical activity and self-care led to improved pain management and a healthier physical and psychological response to stress[62]. One yoga treatment program within a review indicated positive results for decreased food consumption, slowed eating speed and more positive food choices to improve binge eating[66].

Antioxidant

Oxidative stress results from an imbalance in the pro-oxidant-antioxidant equilibrium and is associated with chronic diseases including cancer and diabetes[67]. Findings identified increased levels of total antioxidant status (TAS) and other naturally occurring antioxidants in human cells such as glutathione (GSH) and plasma vitamin E following yoga intervention[48,50,52]. One 3-month clinical trial with diabetic yoga practitioners achieved a 20% reduction in oxidative stress following long-term regular sessions[48].

Inflammation

The effect of yoga on inflammatory markers is a recent addition to yoga research. With a focus on pain management and effective treatment of depression, the partial role of reducing pro-inflammatory cytokines such as IL-6, interleukin-2, C-reactive protein is attributed to yoga's capacity to stimulate the vagus nerve[53]. The vagus nerve in turn decreases heart rate, blood pressure or both to improve responses to stress and which may have further effects on decreasing obesity and improving immunity[68].

Psychology and cognition

In two articles, increased feelings of satisfaction, self-confidence and self-control were linked to decreased perceived stress and increased wellbeing following yoga practice[48,54]. Another author suggested that "if yoga therapy offers an awareness of physical and mental states, benefits for pain management for back pain and cancer-related therapies including breast cancer may result," though empirical evidence to confirm this link was insufficiently robust[58].

2.4.2.4 Emergent hypotheses

As emergent hypothesis, empirical data to support these theories of yoga's effect have not been provided. Authors instead provided indirect evidence to explain how these mechanisms (n=3) might work to explain the effects of yoga.

Immunity

Two papers identified immunology for cancer treatment and stress reduction as a possible mediating factor and benefit of yoga practice[45,54]. As yoga stimulates the vagal nerve, and in turn reduces cortisol, it may be responsible for improving the health of natural killers (NK) cells in the human body[49]. This hypothesis had been

tested elsewhere in women with breast cancer[69] where results indicated both lymphocytes and NK cells were increased following massage therapy treatment. Review authors suggested the same effect could be triggered by yoga practice. Positive effects of biomarkers for an immune response were also recorded following yoga intervention[54].

Nerve Conduction

One study suggested yoga could improve nerve conduction through a 'gate theory stimulation' where chemicals are released to decrease pain and enhance sleep[49].

Bio-electromagnetism

Various health effects and biological interactions are being explored through analysis of electrical and magnetic currents within our internal, cellular structures and external, environmental surroundings (e.g. low-frequency magnetic fields)[70]. As an effective agent to optimise health, delay ageing and treat chronic illnesses, yoga's pranayama breathing and meditation may positively influence the transduction pathways via bio electromagnetism[71].

2.4.3 Discussion

2.4.3.1 Summary of findings

Evidence of yoga's biological or biomedical mechanisms has been largely explored in patients with diabetes, cardiovascular disease and mood disorders. The strongest empirical evidence for yoga's potential effect on health is published in hormonal regulation. Other prominent biomedical theories suggest yoga has a positive impact on the central nervous system and physical function. Social, cognitive and

behavioural pathways are also included as plausible mechanisms. There is further, but limited data to suggest yoga has anti-inflammatory and anti-oxidative properties.

One emerging hypothesis states that yoga can improve immunity and the immune response, which is of particular interest in cancer patients with chronically depressed immune systems[72]. The evaluation of yoga's effect on the human body appears to be in its early phase. Additional evidence is needed to determine the effect of yoga in several key areas, including: prominent theories of hormone regulation, the central nervous system, physical function, social-cognitive and behavioural changes. The degrees to which yoga might improve circulation, decrease inflammation and improve the body's immune response are other emergent areas for future research.

2.4.3.2 Strengths and limitations

The patient populations from which data have been generated include people with diabetes and those with mental health complaints or cardiovascular disease. The effects of yoga in other chronic health conditions including cancer, addiction or health behaviours remain unknown. Still, the literature review and its systematic search improve the existing evidence base for underlying mechanisms of yoga intervention.

The content of this review is limited by the quality and availability of publications in online health databases published in English and three countries: the Netherlands (Scopus), United Kingdom (Cochrane Collaboration) and United States (PubMed). If human resources and time constraints were not a limitation, a more in-depth search to include other languages (i.e. Hindi) and other sources of information may yield different results.

Clinical trials and reviews were included to increase the amount of evidence, though some low-quality studies did not include adequate randomisation and may expose results to bias or confounding variables. As the purpose of this literature review was to summarise the potential underlying mechanisms of yoga therapy for health benefit, no conclusions can be drawn regarding the accuracy of hypotheses or efficacy of treatment for outcome effects.

2.4.3.3 Results of an updated search

In an updated search (31 July 2014), 273 additional titles were identified using the title-search strategy. Of the publications issued after December 2012 and before August 2014, 11 articles of 49 reviewed abstracts were relevant to yoga's underlying mechanisms in adult health outcomes. Authors of these articles also reported the methodological quality of data as a limitation to interpreting results.

The yoga mechanisms listed in this group of articles indicated no new theories or hypotheses have emerged. Findings reiterated encouraging evidence to suggest that yoga lowers systolic and diastolic blood pressure[73-75], though some authors expressed results were inconclusive due to a risk of bias in data collection[76]. Yoga's positive effects on cardiovascular health were attributed to an increased oxygen uptake, a decrease in blood lipids such as cholesterol and triglycerides and a decreased waist circumference and waist/hip ratio[77,78]. Improved cardiac function (measured by left ventricular ejection fraction) and a reduction in heart failure biomarkers (N terminal pro B-type natriuretic peptide)[79] were also associated with yoga intervention. Systematic reviews confirmed earlier reports that yoga works to improve balance[80] and regulate hormonal abnormalities[81]. One RCT suggested yoga improved oxidative

stress and glycemic parameters in patients with diabetes[82], though results were not statistically proven and larger studies are needed to explore this relationship.

2.4.3.4 Implications for future research

The authors of existing studies suggest immune function is under-represented in yoga research[49] and these findings agree that immunology is an area for future consideration. This review adds oxidative stress, effects of behavioural, social and psychological experiences of yoga need to be better understood from a health care point of view. The internal and external validity of future studies could be improved to address concerns of bias, their limited generalisability and exposure to confounding variables. Methodological considerations of future reviews should include the implementation of high-quality randomised controlled trials (RCTs) that measure disease-specific health outcomes and related biological and clinical outcomes. Elsewhere, comprehensive lifestyle changes have been studies in changes in biomarkers associated with aging and disease[83]. An integrated analysis of yoga's biological and clinical effects may assist in understanding the potential 'active ingredients' in yoga. It would be helpful to identify the necessary components of yoga intervention to optimise its potential health and healing effect in adults.

2.5 CHAPTER SUMMARY

- Yoga includes various breathing techniques, physical postures and mind-body awareness methods that when practised, aims to improve physical and psychological wellbeing.
- The multiplicity of yoga means it is considered a complex intervention, and the Medical Research Council's framework is an appropriate guide to assist in its development in health care.
- There are multiple physiological, psychosocial and other biomedical pathways to explain yoga's positive effect on health outcomes.
- The endocrine system, central nervous system and physical function were most frequently cited as mechanisms by which yoga acts to improve health outcomes.
- Limited evidence also suggested that yoga may induce anti-inflammatory, antioxidant effects and improve biomarkers for immune responses.
- There is growing evidence to suggest how yoga might work to improve health-related outcomes, though high quality research in the area appears lacking.
- Current evidence is limited largely to people with diabetes and those with mental health disorders; additional clinical evaluation of yoga's effect in other populations including immunology and cancer is justified by evidence collected in this review.
- Further analysis of yoga intervention, its effects and its specific components for producing health effects is recommended.

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CHAPTER THREE

Bibliometric Analysis

3 BIBLIOMETRIC ANALYSIS

Features of this chapter are published in the following peer-reviewed journal:

McCall, M. C. (2014). In Search of Yoga: Research trends in a western medical database. *International Journal of Yoga, 7*(1), 4-8. doi:10.4103/0973-6131.123470

3.1 BACKGROUND

In response to the Medical Research Council's recommendation to identify the evidence base of a complex intervention[1], a descriptive summary of the available evidence serves to advance the development phase of yoga intervention. The first yoga-related title published in health care literature was authored in 1948[84]. The earliest research article available in English in a peer-reviewed journal (1964) discusses the effects of three yoga-type breathing patterns of oxygen consumption[85]. An existing bibliometric analysis identifies increasing rates of yoga publications over the past three decades, and an increase in randomised controlled trials[86]. However, the publication trends of yoga research since 2004 have not been investigated to date. In view of yoga's increasing prevalence in terms of monetary spending and class delivery in western populations (see Section 2.2), it is helpful to better understand if and how the popularity of yoga is reflected in health care publications. An updated bibliometric analysis is needed to explore the recent publication trends, to investigate associations of yoga for specified health conditions and to quantify the number of systematic reviews (SRs) or clinical guidelines for yoga.

3.2 CHAPTER AIM AND OBJECTIVES

The aim of this chapter is to explore the publication trends of yoga in health care literature available in the West. The primary objective is to collect, analyse and summarise the publication trends of yoga in peer-reviewed health care journals. The secondary objectives are to identify the type of articles published in yoga research to explore associations of yoga research with prevalent health conditions and to compare the extent of yoga research with other complementary therapies.

3.3 METHODS

A bibliometric analysis was designed to investigate publication trends of yoga research in health care (PubMed) and physiotherapy (PEDro) databases. The search was performed on 16 February 2014 and included publications listed online at http://www.ncbi.nlm.nih.gov/pubmed and http://www.pedro.org.au before 1 January 2014.

3.3.1 Search Strategy

The free-text search strategy was developed from an established list of common health topics (see Box 3.1). A list of health conditions and symptoms was compiled from the World Health Organization (WHO) list of most prevalent diseases and risk factors in the United Kingdom, Canada and the United States[87]. A list of eight comparative therapies, similar or related to yoga intervention, was also created following a literature review of physical and manual therapies. These free-text terms included: exercise therapy, manual therapy, acupuncture, massage, psychological counselling, muscle stretching, pilates and intercessory prayer.

Box 3.1 Key Term Search

yoga AND (*stress* OR *anxiety*)
yoga AND (*body mass* OR *weight* OR *obes*)*
yoga AND *cancer*
yoga AND (*cardiovascular disease* OR *congestive heart)*
yoga AND *depression*
yoga AND (*diabetes* OR *insulin)*
yoga AND (*respiratory* OR *asthma)*
yoga AND *cholesterol*
yoga AND (*hormone OR cortisol OR adrenalin)*
yoga AND *(hypertension OR blood pressure)*
yoga AND *tobacco*
yoga AND *diet*
yoga AND *alcohol*

The service offered by the National Library of Medicine (NLM), PubMed, comprises over 23 million citations for biomedical literature from MEDLINE, life science journals and online books[88]. The PubMed database is a free resource of academic citations and abstracts of research in the fields of biomedicine and health, designed to provide free access of all content archives in the English language. A free-text search [*yoga* AND *systematic review*] was employed to increase precision of systematic review titles versus the PubMed general filter for *reviews*. For health-specific annual indexes, an automated online tool of PubMed indexes was used[89].

PEDro is a Physiotherapy Evidence Database that contains over 26,000 randomised trials, SRs and clinical practice guidelines in physiotherapy[90]. It is a free online database produced by the Centre for Evidence-Based Physiotherapy at The George Institute for Global Health. An advanced search for yoga titles in PEDro used [*yoga*] as a free-text entry in the [*abstract and title*] filter. The articles were also filtered by publication date and study type using method limitations including: [*practice guideline*], [*systematic review*] or [*clinical trial*].

Search results of the PubMed and PEDro databases were recorded on a digital template in Microsoft Excel. The customised template organised data into the number of articles within each health topic category and publication date.

3.3.2 Data Analysis

First, the publication trends of yoga articles were analysed in PubMed. The annual index, article types and health-related topic data were reported quantitatively in numbers of frequency and proportions. To understand trends over time, this analysis included: time-bound categories; long-term publication trends (from 1948 up to 1 January 2014); medium-term (from 1980 to 2013); and short-term trends (from 2008 to 2013). Yoga publication trends in PEDro were also collected and analysed according to annual indexes, article types and health topics. The results are presented using descriptive and graphical presentations of the data such as histograms.

3.4 RESULTS

3.4.1 Yoga Articles Indexed in PubMed

The total number of publications listed in PubMed was 2,556. In 1950, only two yoga articles were indexed in PubMed. From 1950 to 1960 less than one yoga article was added per year for a total of seven articles registered before 1961. Fewer than ten yoga articles were indexed per year until an increase to 11 articles were registered in both years 1969 and 1970. The publication rates were consistently low ($n<30$) from 1970 to 1998 with maximum in 1975 ($n=29$) and minimum in 1983 ($n=8$). In 2000, the number of annual indexes increased from previous years to 39 new additions that year. There was another marked increase in publications from 2003 to 2004 ($n=39$ to $n=89$; 228%). The rate of publication then grew slowly from years

2006 to 2010, increasing by approximately 20 articles per year. Another surge in yoga publication was recorded when annual publications increased from 2010 (n=166) to 2011 (n=243). The number of annual yoga publications listed on PubMed has increased since 2005, reaching the highest annual amount in 2013 (n=350). See Figure 3.1 for a summary of yoga publications per annum from 1980 to 2013 in PubMed.

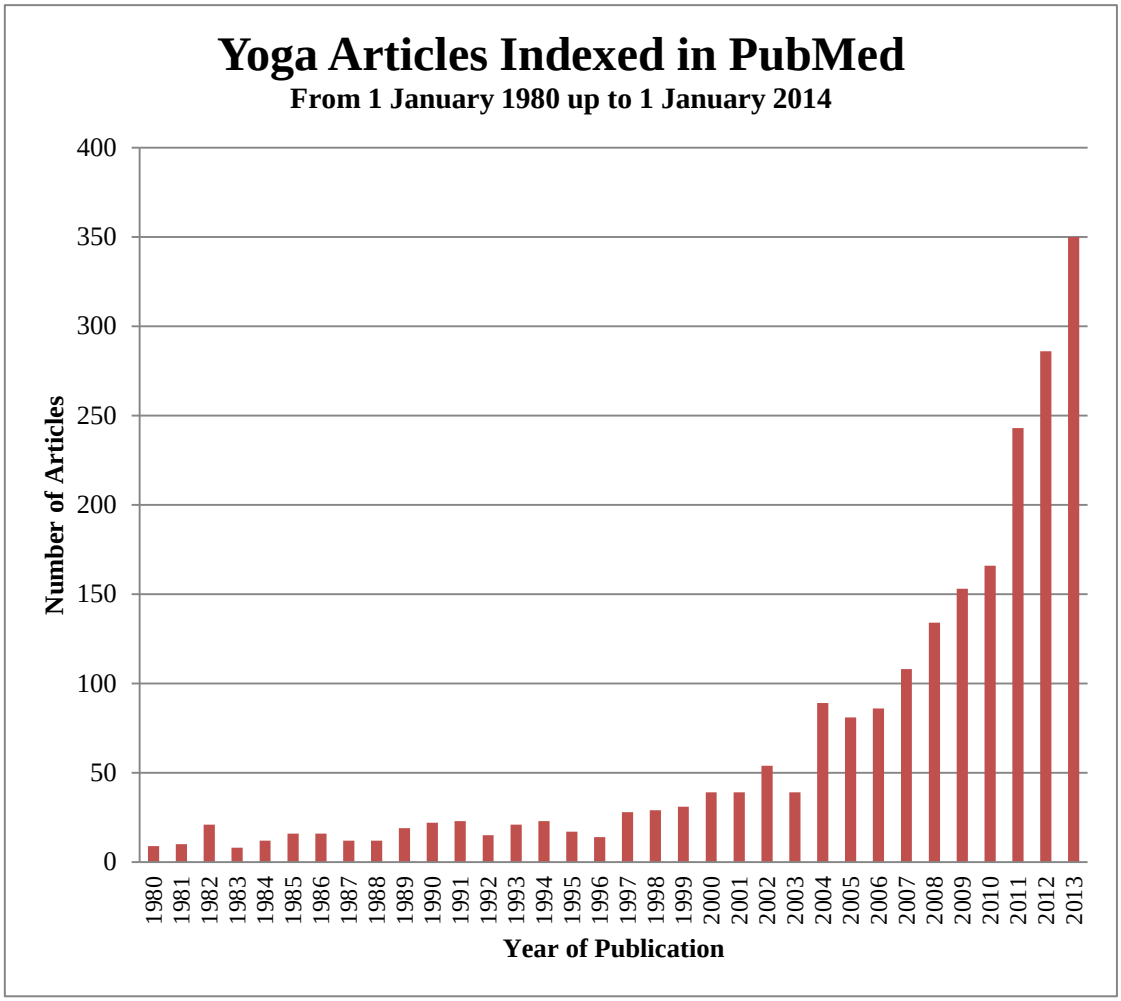


Figure 3.1. Publication trends of yoga articles in PubMed

3.4.1.1 Types of articles in PubMed

Of 2,556 indexed publications before 1 January 2014, a high proportion (30.2%) were identified as clinical trials (n=399) or SRs (n=373). A small proportion (1.8%) of articles were listed as randomised controlled trials (RCTs) (n=47). The total number of yoga articles by type of publication is illustrated in Figure 3.2.

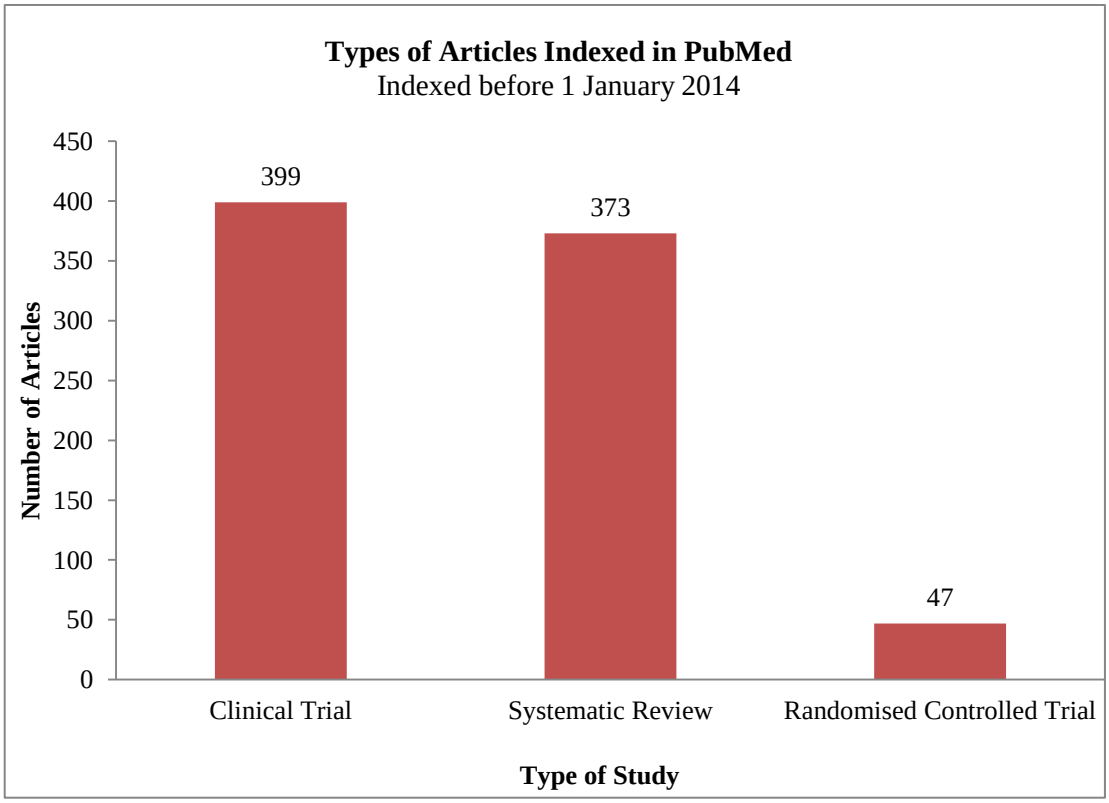


Figure 3.2. Types of yoga titles indexed in PubMed

3.4.1.2 Yoga and health topics in PubMed

The results of the key term search indicate the majority (88%) of yoga research titles (n=2,556) correlated with eight health topics: stress and anxiety (n=599), pain (n=320), depression (n=275), hypertension (n=233), body weight (n=218), cardiovascular disease (n=212), respiratory conditions (n=208) and cancer (n=189). Diabetes (n=101), diet (n=104), alcohol (n=36) and tobacco (n=10) accounted for

9.8% of the remaining literature. The results of yoga and health topics indexed before January 2014 is illustrated in Figure 3.3.

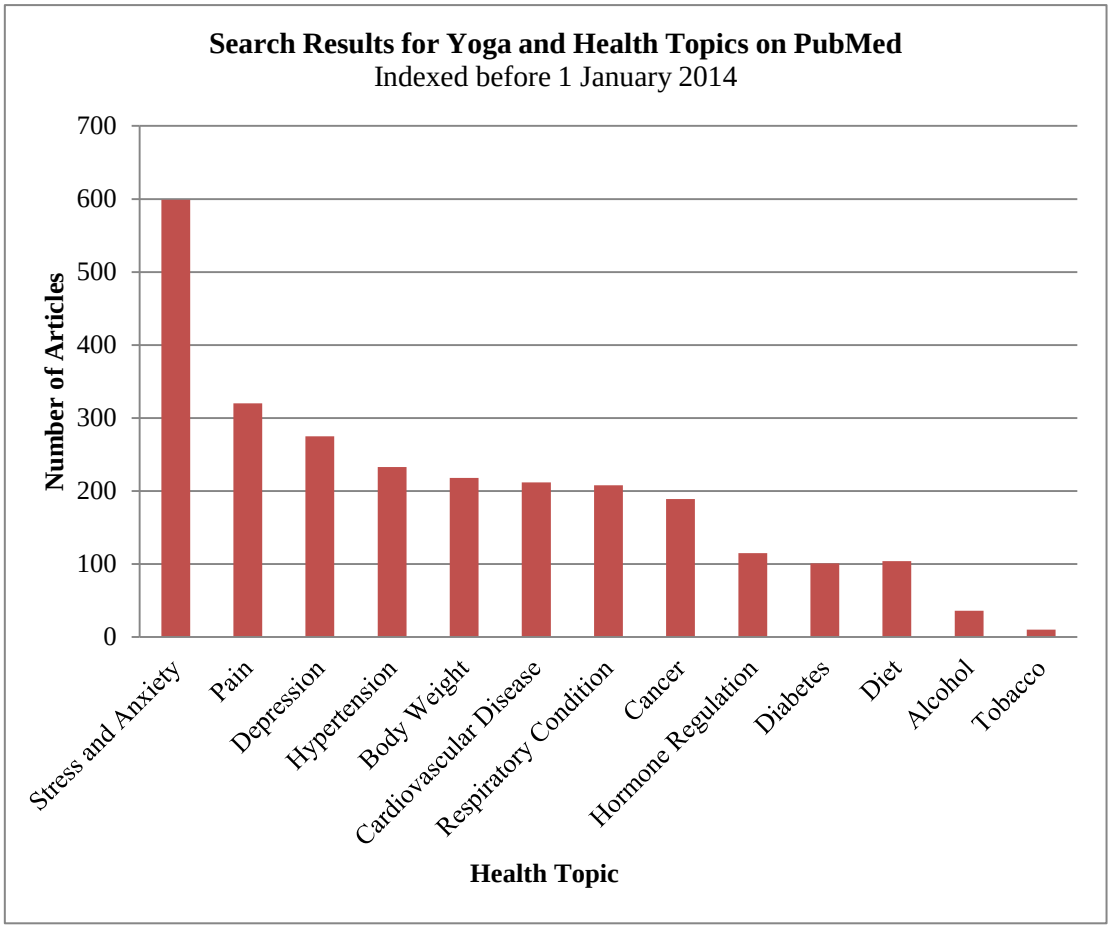


Figure 3.3. Total index of yoga titles by health topic in PubMed

From 1 January 2008 to 1 January 2014, stress and anxiety, pain, depression, cancer and cardiovascular disease were the most prevalent health topics in yoga research. In 2013, the most prevalent topics for yoga publications in PubMed were stress and anxiety (n=121), depression (n=67), pain (n=59), cancer (n=40) and hypertension (n=29). A detailed annual trend from 2013 shows the publication rate of cancer studies has increased rapidly from 2008 levels by 333%. This exponential increase was similar in depression (353%), stress and anxiety (336%) and pain

publications (327%). In the same time frame, smaller increases were recorded in diabetes (71.4%) and respiratory conditions (37.5%), while the rate of annual yoga publications associated with hormone regulation decreased by 30% from 2008 to 2013 levels. Yoga research in body weight (n=9) and cardiovascular disease (n=14) decreased by 55% and 43% respectively from 2012 to 2013 results. See Figure 3.4 for an annual trend of yoga articles indexed by health topic from 1 January 2008.

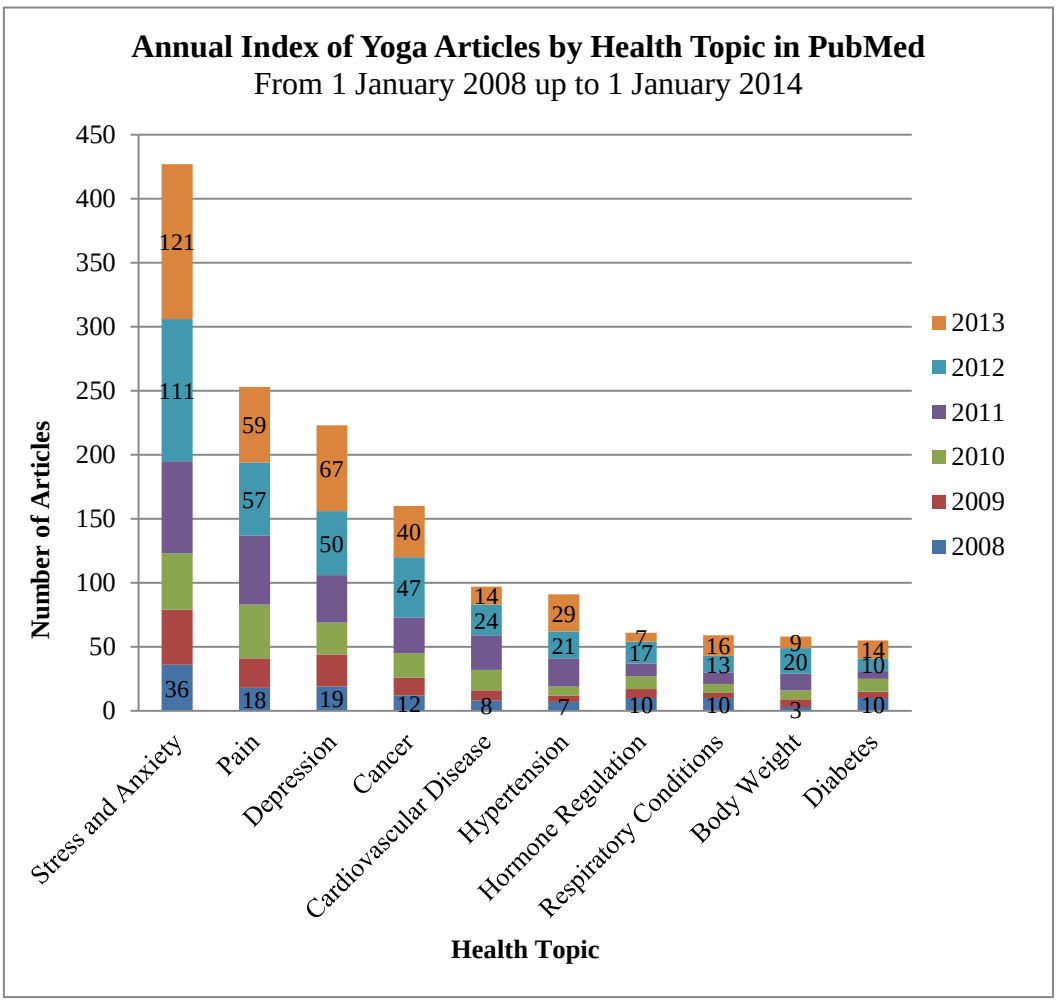


Figure 3.4. Annual index of yoga titles by health topic in PubMed

3.4.1.3 Yoga and other therapies in PubMed

In the cumulative index up to 1 January 2014, exercise therapy (n=73,462) greatly exceeded other therapeutic interventions including manual therapy (n=26,370), acupuncture (n=20,188), massage (n=11,285), psychological counselling (n=9,799), muscle stretching (n=4,015) and yoga (n=2,556). Few publications were cited for pilates and intercessory prayer (n=239). See Figure 3.5 for the summary of results for other therapies in comparison to the quantity of yoga publications indexed in PubMed.

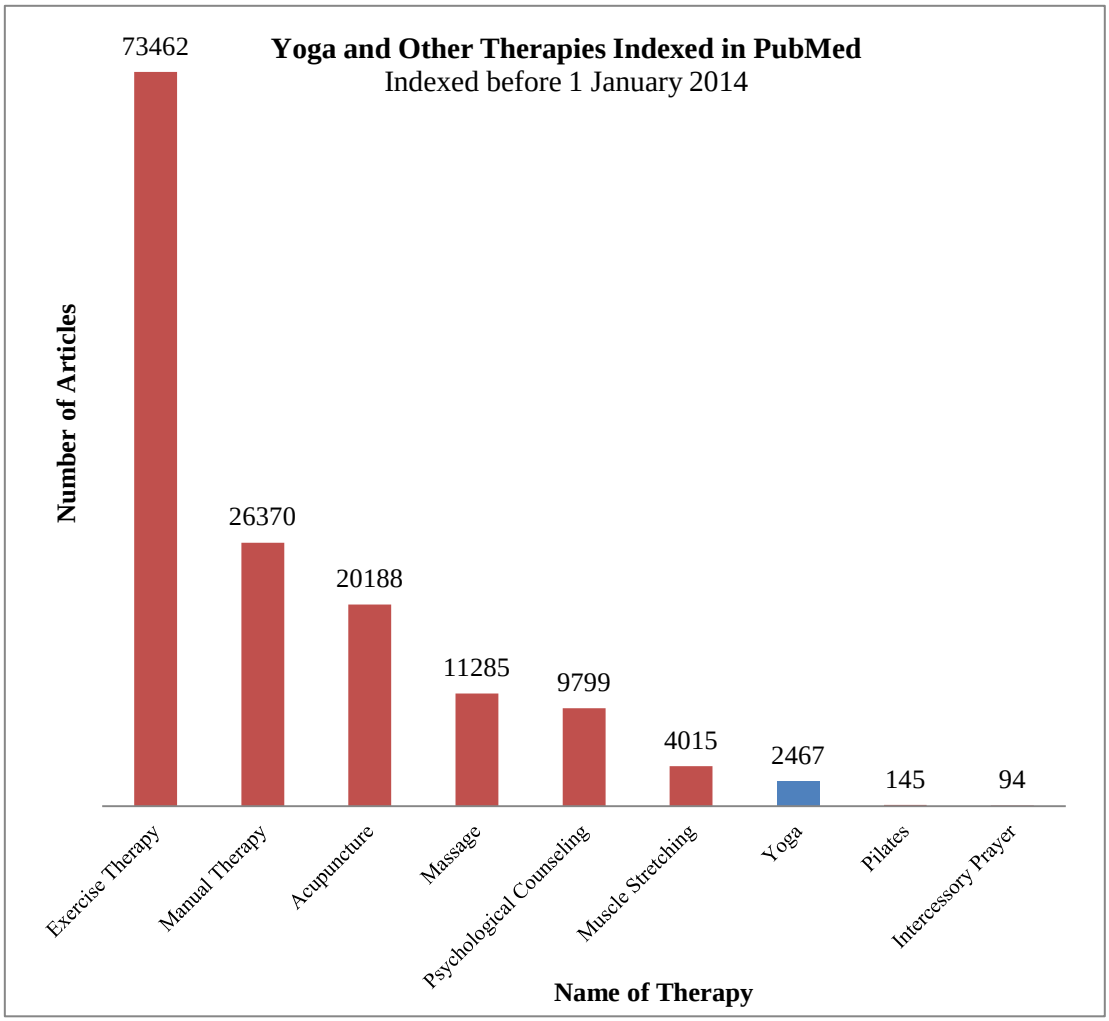


Figure 3.5. Index of yoga titles and other therapies in PubMed

In 2013, exercise therapy (n=3,906), manual therapy (n=1,469), acupuncture (n=1,373), massage (n=507) and psychological counselling (n=463) were more prevalent than yoga (n=359) in annual indexing. However, the number of yoga titles published in 2013 exceeded the number of muscle stretching publications, indicating a potential trend away from muscle stretching towards yoga. Yoga continues to exceed the number of publications in pilates (n=39) and intercessory prayer (n=4). See Figure 3.6 for the summary of 2013 publications of yoga and other therapies in PubMed.

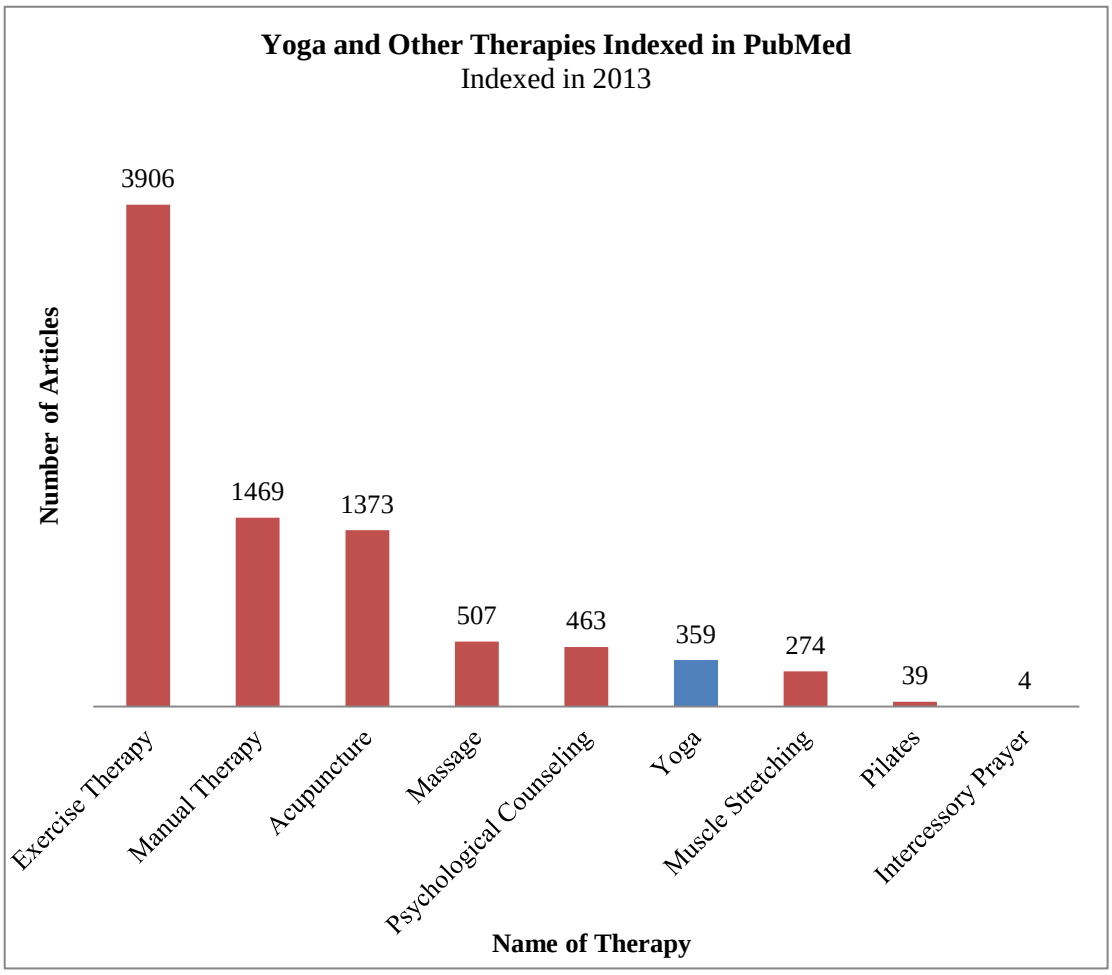


Figure 3.6. Index of yoga titles and other therapies in PubMed (2013)

3.4.2 Yoga Articles Indexed in PEDro

The total number of yoga publications catalogued in the PEDro database was 352. From 1980 to 2003, the annual publication rate of yoga research remained low (n<5). The number of annual additions over five years increased from 2003 (n=4) to 2008 (n=25) with a dip in 2009 (n=15). After 2010 (n=29), the yoga publication rate has increased steadily with a marked increase that year of 193% (29/15). Another surge in publications was recorded in 2012 (163%) with an increase from 46 to 75 records. See Figure 3.7 for annual trends of yoga publication in PEDro before 1 January 2014. Of the entire database of PEDro references (n=26,109), 1.3% of titles are related to yoga.

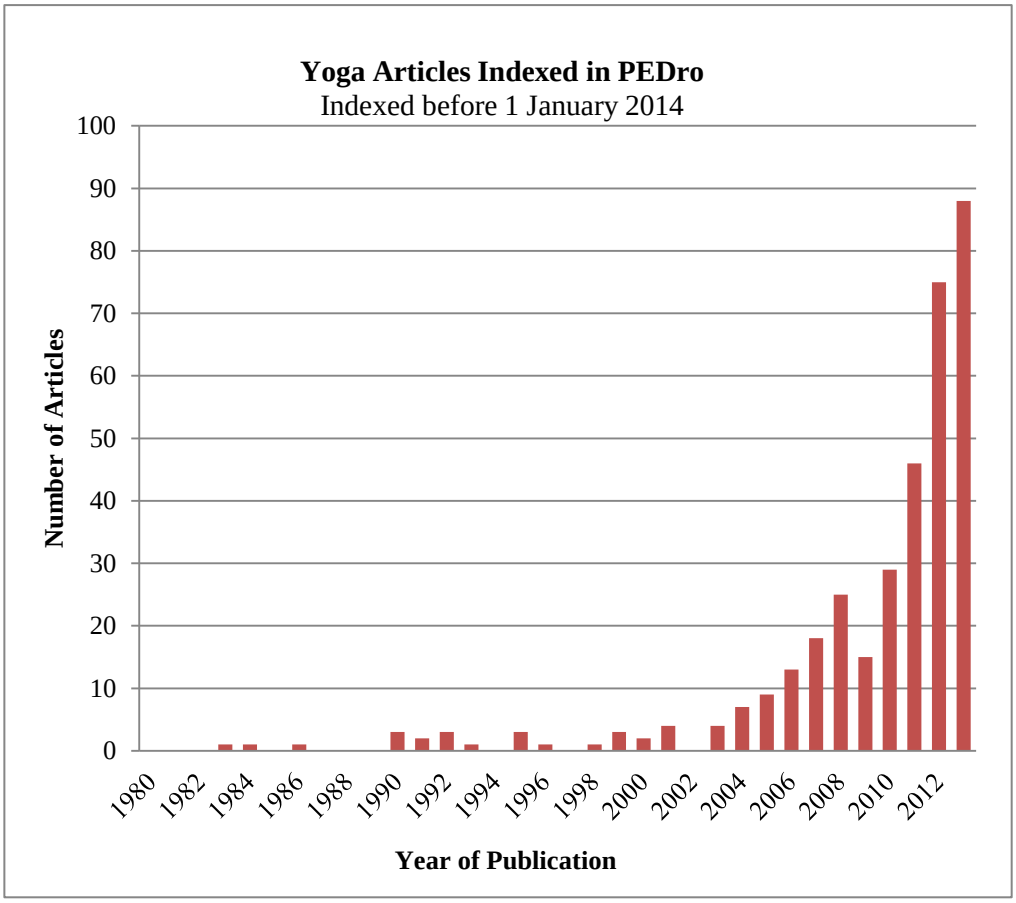


Figure 3.7. Publication trends of yoga articles in PEDro

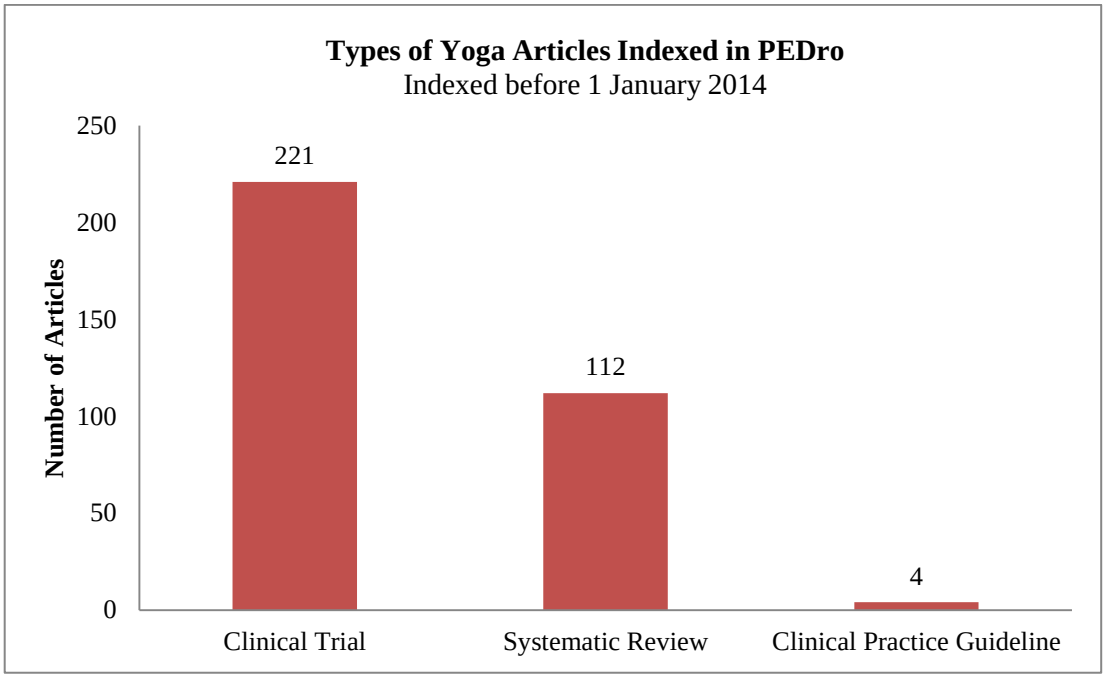


Figure 3.8. Types of yoga titles indexed in PEDro

3.4.2.1 Yoga and health topics in PEDro

The most frequently indexed health topics for yoga in the PEDro database were in pain (n=79), depression (n=73), stress and anxiety (n=65), cancer (n=48), cardiovascular disease (n=23), diabetes (n=21), respiratory conditions (n=15), body weight (n=14), hypertension (n=13) and hormone regulation (n=8). See Figure 3.9 for an overview of the annual indexes according to health topics from 1 January 2008 to 1 January 2014. The most prevalent health topics in PEDro yoga publications in 2013 were in depression (n=20), stress and anxiety (n=20), pain (n=18) and cancer (n=14). The number of cancer-associated studies in yoga surged from 2008 records (n=0) while other health topics including cardiovascular disease, diabetes and respiratory conditions remained relatively small and unchanged (n<8). See Figure 3.9 for a summary of the annual index of yoga articles by health topic in PEDro.

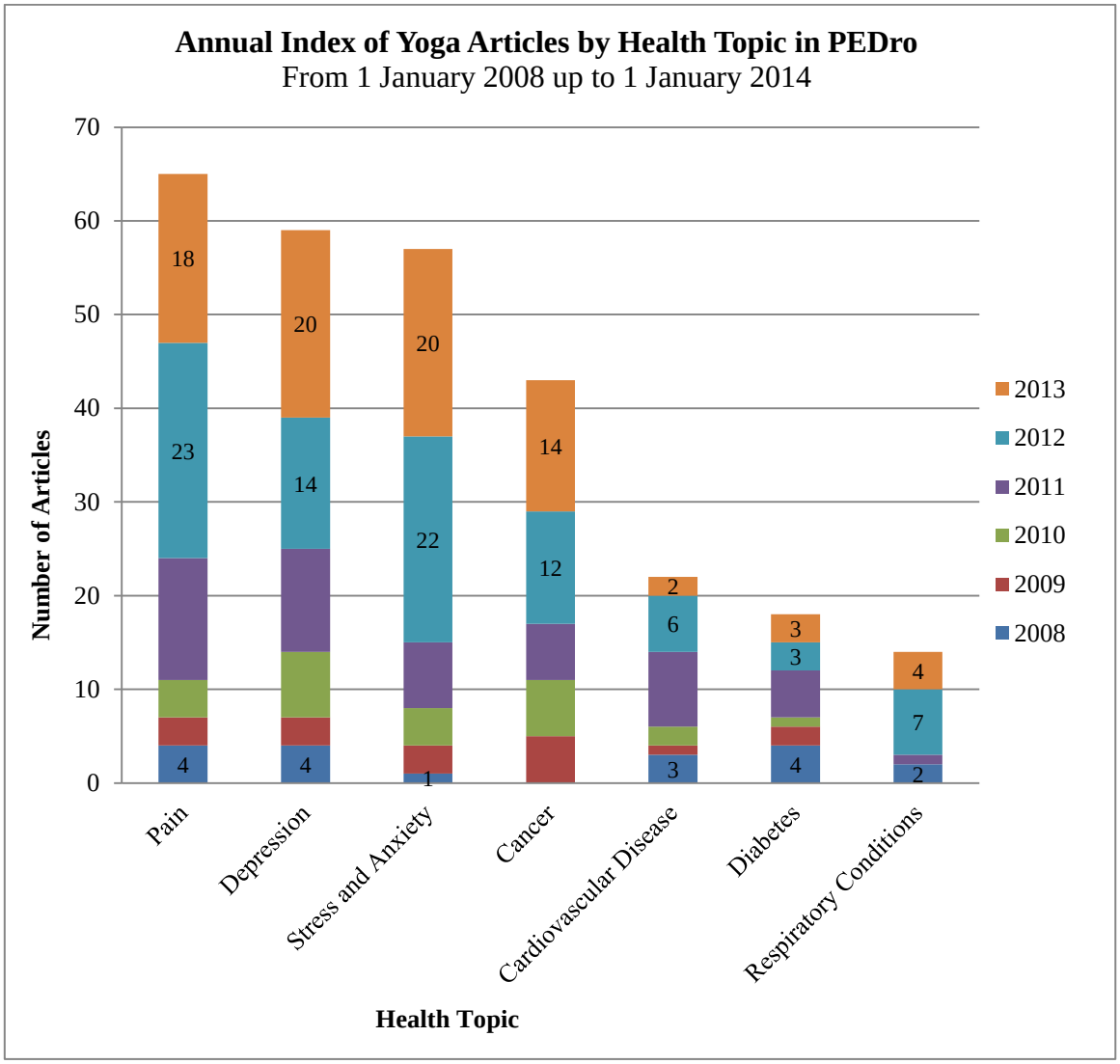


Figure 3.9. Annual index of yoga titles by selected health topic in PEDro

3.4.2.2 Yoga and other therapies in PEDro

In comparison with other therapies, acupuncture (n=2,105) and exercise therapy (n=2,043) are most commonly cited. Manual therapy (n=705) and massage (n=666) both exceed the cumulative number of references for yoga (n=354). See Figure 3.10 for a summary of articles indexed according to other complementary therapies and yoga.

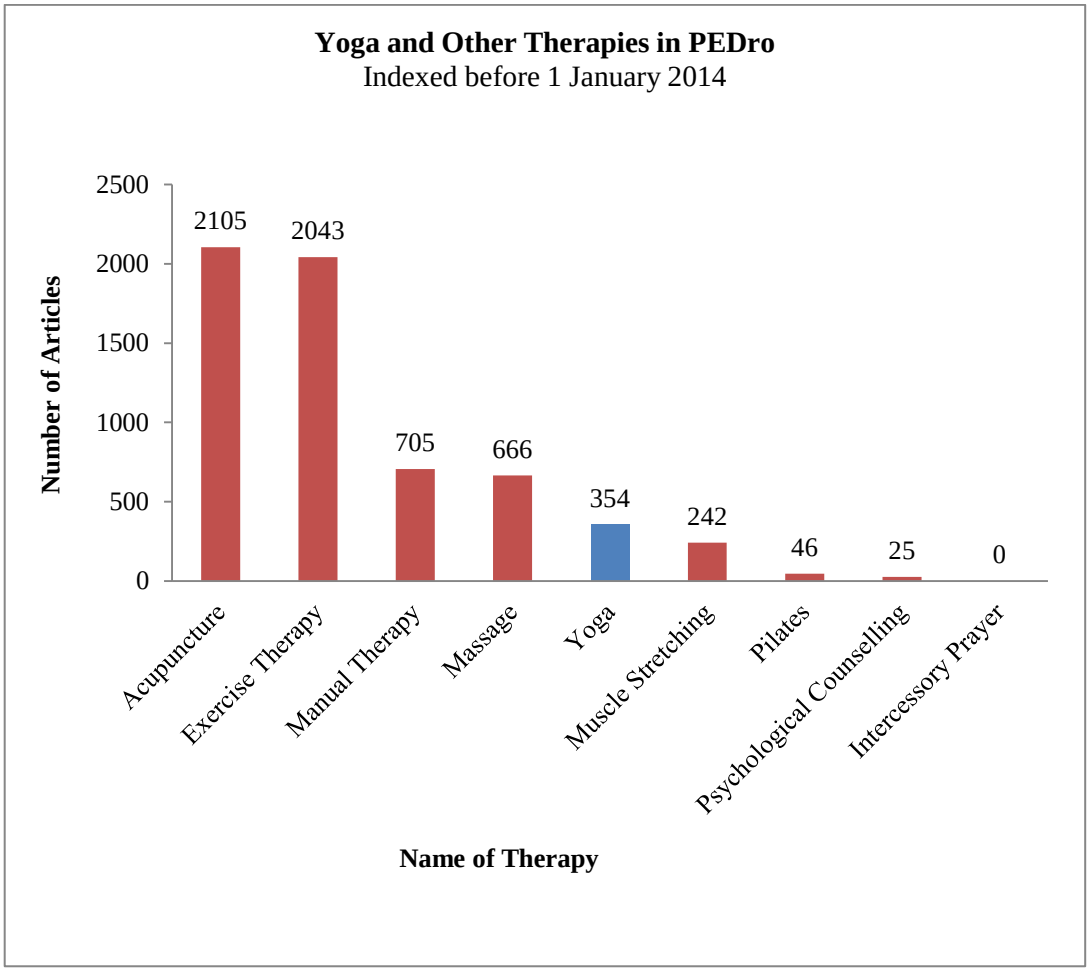


Figure 3.10. Index of yoga titles and other therapies in PEDro

In 2013, the proportion of listed yoga articles added to PEDro per year increased, as the proportion of articles associated with massage and manual therapy decreased (see Figure 3.11). Exercise therapy and acupuncture remained the most frequently cited type of therapy in PEDro in 2013. The annual publication rate for pilates appeared to have slightly increased, however like muscle stretching, both remained less prevalent than yoga titles in 2013.

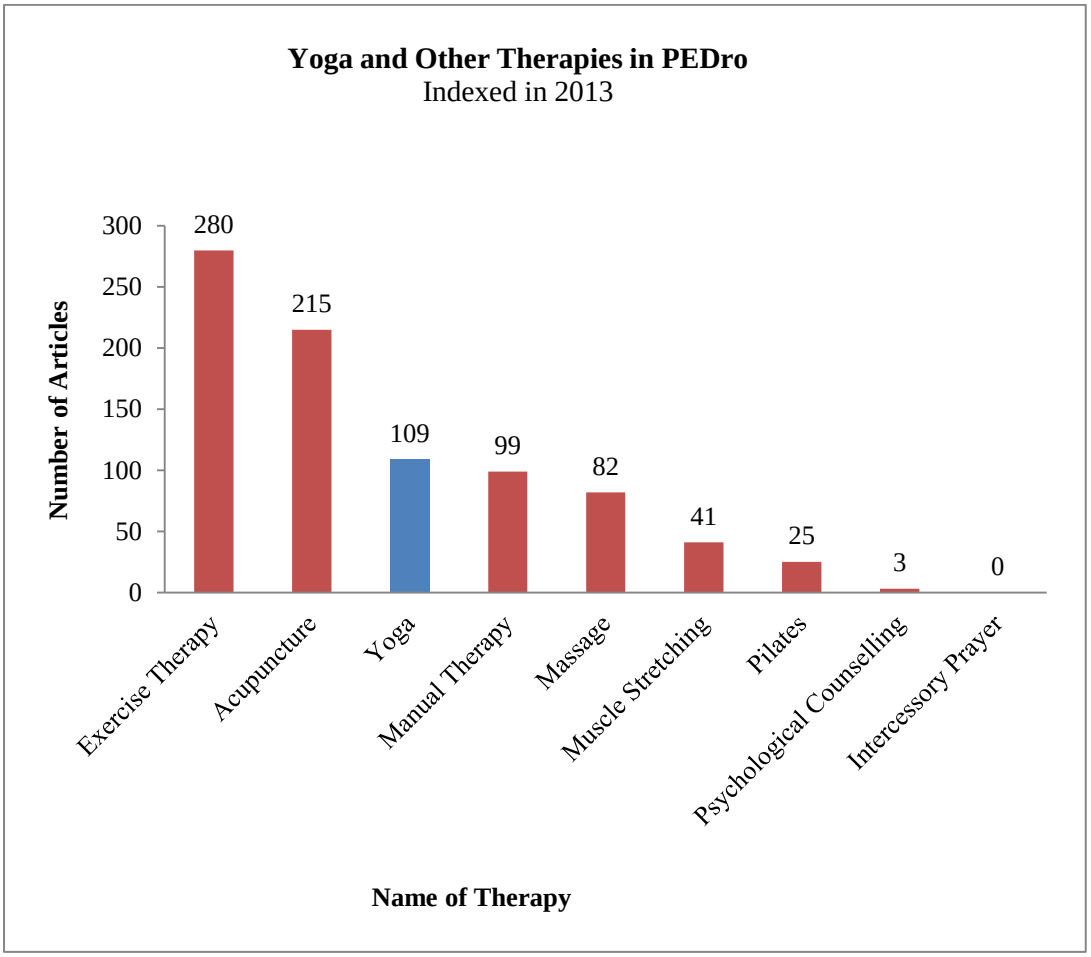


Figure 3.11. Index of yoga titles and other therapies in PEDro (2013)

3.5 DISCUSSION

3.5.1 Summary of Findings

Yoga research appeared to be increasing in both PubMed and PEDro databases since 1980. The cumulative and comparative results of both PubMed and PEDro databases indicated a strong increase in yoga publications since 2006. The greatest surge of yoga indexing in PubMed occurred in 2004 when the publication rate increased from 39 articles per year to 89 articles (228%). Yoga publications in the PEDro database increased from 2003, with a surge in 2010 from 15 to 29 articles (193%) and again in 2012 from 46 to 75 articles (163%). In relative terms (percentage of yoga titles versus

all indexed titles), 1.3% of the entire PEDro database was yoga-related publications and 0.01% of the PubMed database. This variation is partially expected due to the greater volume of publications in the PubMed database, but does indicate a potential affiliation of yoga in physiotherapy that could be further explored.

3.5.2 Summary of Yoga Articles by Type

In the PubMed database, results suggest a substantive amount of clinical trials in yoga (n=399) and SRs (n=373) have been published. However, results from PEDro indicated fewer clinical trials (n=221) and SRs (n=112). The resultant discrepancies in database results may be due to inaccuracies of study classification or differing criteria article identification. Few RCTs were reported in PubMed (n=47), which indicates a potential scarcity in high-quality studies (i.e. at low risk of bias). Clinical guidelines that include yoga for health care have been issued in three countries – United Kingdom[91], Canada[92] and the United States[93,94] in four health areas including: physical activity, mood disorders, low back pain and hypertension.

3.5.3 Summary of Health Topics in Yoga Research

Yoga research in the first 30 years of study included diverse topics such as metabolism[95], arterial blood gases[96], body composition[97,98], bronchial asthma[99] and hypertension[100]. The current evidence base of yoga research is highly associated with 10 health topics in western populations, including: stress and anxiety, depression, pain, cancer, cardiovascular disease, hypertension, diabetes and respiratory conditions, body weight and hormone regulation. The cumulative indexes of PubMed and PEDro identified stress and anxiety, pain and depression as the three most prevalent research areas in yoga. Cancer is the fourth most common condition

studied in yoga research from 2008 to 2013 in both PEDro and PubMed databases. In 2013, the number of cancer articles in PEDro (n=14) indicated a surge in interest from 2008 results (n=0). Similarly, the PubMed databases showed an increase in cancer titles from 2008 (n=12) increased by 70% in 2013 (n=40).

3.5.4 Subgroup Analysis of Other Therapies

The annual publication trends for prevalent manual therapies and other Eastern-influenced practices similar to yoga (i.e. reiki, tai chi) were extracted from PubMed for a comparative analysis with yoga research. Of the five therapies analysed (acupuncture, massage, muscle-stretching, reiki, tai chi), only acupuncture publications indicated a strong and significant increase in health care over time (see Figure 3.12). The publication trends of massage do not match trends of yoga, where the publication rate increased at a slower and more consistent rate since 1980. Annual publications in muscle stretching nearly doubled from 2005 to 2006 (n=37 to n=70) and then remained at 140 (±25) after 2008. Research titles for tai chi and reiki did not appear to increase at the same rate as yoga publications in PubMed. This is an interesting result, as tai chi[101] is similar in some regards to yoga, where mind-body awareness techniques are coupled with physical movement to enhance wellbeing.

In PubMed, research publications in exercise therapy, manual therapy, acupuncture and massage were more prominent than yoga. In 2013, there was an increase of yoga titles that exceeded the number of publications in muscle stretching. In PEDro, acupuncture was the most frequently indexed before 1 January 2014. In 2013 results, yoga research replaced manual therapy and massage to become one of the top three therapies indexed in PEDro.

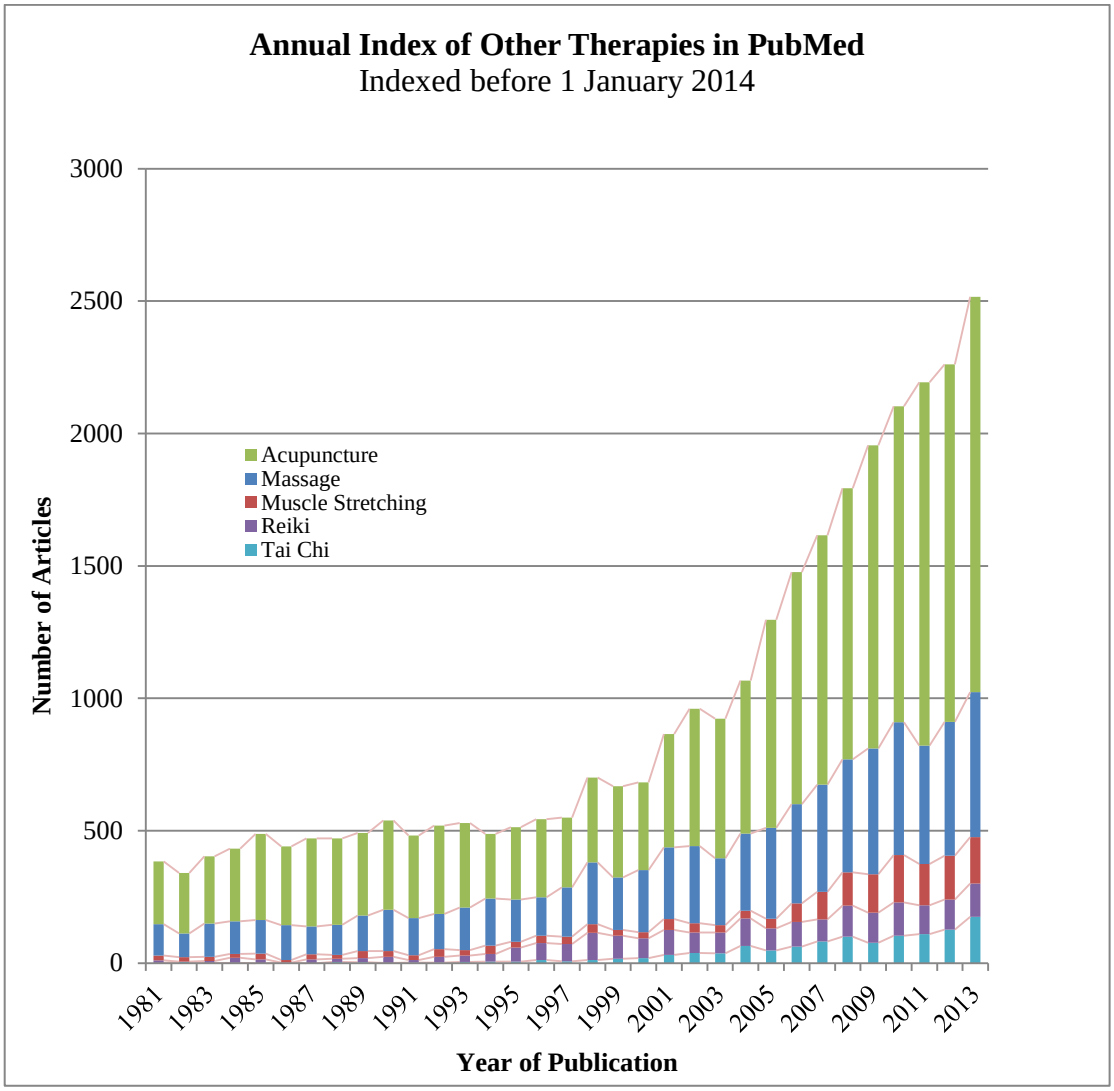


Figure 3.12. Annual index trends of five therapies in PubMed

Results of this subgroup analysis suggest that while acupuncture is more prevalent in health care research than yoga, the publication rates for yoga have experienced more sudden increases than selected manual therapies and Eastern-inspired therapies, including several surges in publication in PubMed (2004, 2011) and PEDro (2010, 2012).

3.5.5 Strengths and Limitations

The bibliometric analysis is a rudimentary but efficient method to observe the annual trends of yoga citations in a database. This analysis included only descriptive results from key term searches, so the accuracy of article content is unknown. The number of supposed SRs was very high in PubMed (n=373). However, comparatively few results for RCTs (n=47) and a similar number of clinical trials (n=399) suggest a discrepancy in the quality of available evidence and a potential misrepresentation of SRs. For pragmatic reasons, a bibliometric analysis is useful to determine the quantity of title publications, but the quality and accuracy of the results would need to be addressed through a systematic review of the literature.

3.5.5.1 Completeness of search

The selected key terms were based upon a broad search strategy developed to represent prevalent adult health conditions with limited specificity to yoga. A more yoga-sensitive or extensive list of key terms may yield different results, however, results suggest at least 88% of yoga publications corresponded to eight of the key terms for health conditions used in the search. A cross-referencing of PubMed and PEDro databases was performed to assist in the understanding of the overall trend, and minimise bias from one database in health care or physiotherapy. However, other specialty databases (i.e. AMED, CINHAL, SPORTDiscus) may yield different results, and were not consulted here due to limited time and human resources.

3.5.5.2 Search date

The original search and analysis (30 December 2012) guided the research direction of this thesis. The search results were updated and reassessed on 16 February 2014. Subsequent variations to the PubMed and PEDro databases are possible due to retroactive additions and new indexing delays (up to 2 years)[89], which further limits the potential precision of this review.

3.5.6 Recommendations

An updated or future bibliometric analysis might expand to other health topics including acute illness. Specific health outcome measures may also be included in future analyses, exploring the prevalence of outcome measures for anxiety and depression (e.g. HADS[102]), pain (e.g. McGill Pain Questionnaire[103] Visual Analogue Scales[104]) or health-related quality of life (HRQoL) measures (e.g. SF-36[105], EORTC-QLQ-C30[106]). A more in-depth search and analysis would determine the quality, strength of evidence and direction of yoga studies in adult health conditions. Given the large number of SRs identified in PubMed (n=373), an overview of SRs is recommended.

3.6 CHAPTER SUMMARY

- Yoga publication rates in PubMed and PEDro have increased over time.
- Clinical trials (n=399) and SRs (n=343) were frequently cited in yoga research, with fewer RCTs (n=43) and clinical guidelines (n=4).
- Since 2008, yoga research in cancer has increased to exceed the rate of publications for body weight, cardiovascular disease, respiratory conditions and hypertension.
- Exercise therapy, manual therapy, acupuncture and massage were all prevalent in both PubMed and PEDro databases, though when compared to other complementary therapies, yoga publications were increasing at a greater rate.
- An overview of systematic reviews is recommended to understand the quality and direction of results for yoga intervention in adult health conditions.

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CHAPTER FOUR

Overview of Systematic Reviews

4 SYSTEMATIC OVERVIEW OF REVIEWS

Features of this chapter are published in the following peer-reviewed journal:
McCall, M. C., Ward, A., Roberts, N. W., & Heneghan, C. (2013). Overview of systematic reviews: Yoga as a therapeutic intervention for adults with acute and chronic health conditions. *Evidence-Based Complementary and Alternative Medicine (eCAM)*: 945895. doi:10.1155/2013/945895

4.1 BACKGROUND

In evidence-based research methodology, "the question guides the search" where an answerable clinical question is divided into four components: population/problem, intervention, comparator/control and outcome (PICO)[107]. It is important to evaluate the evidence in acute and chronic health conditions to guide specific components of the research question. The bibliometric analysis in Chapter 3 suggests there is an extensive amount of yoga research associated with health conditions including pain, depression, anxiety, cancer and cardiovascular disease. In the past five years, yoga research in cancer appears to be increasing in proportion to other health conditions such as cardiovascular disease and its risk factors (i.e. obesity).

4.1.1 Purpose of Systematic Reviews and Overviews

In the hierarchy of evidence, the meta-analysis of homogenous data in a SR of randomised controlled trials (RCTs) is superior to all other forms of data collection to evaluate efficacy of a therapeutic intervention[108]. Research questions seeking to synthesise evidence from RCTs can be addressed by using two potential systematic methods of analysis: a SR of RCTs, or an overview of SRs[109]. The overview has many similarities to a SR with a few important differences.

First, to systematically provide a response to the research question to minimise the potential for bias, both the review and overview seek to compile existing evidence in a well-defined subject area[110]. Whereas the SR aims to evaluate evidence from primary studies in a specified population, intervention and outcome of interest, the overview cumulates evidence from more than one systematic review of different interventions for the same condition or problem; or to address different outcomes with the same intervention; or to examine different conditions or populations[110].

Second, acting as a larger umbrella of information, the overview is more efficient in collecting volumes of evidence. The key criteria of a SR and overview are as follows[111]:

1. Clearly stated set of objectives with pre-defined eligibility criteria for studies (reviews)
2. Explicit, reproducible methodology
3. Systematic search that attempts to identify all studies (reviews) that would meet the eligibility criteria
4. Assessment of the validity of the findings of the included studies (reviews), for example, through the assessment of risk of bias
5. A systematic presentation and synthesis of the characteristics and findings of the included studies (reviews)

Third, as the SR and overview build on the work of previous researchers, the quality of results in both the review and overview are dependent on the quality and availability of evidence. Methodological strategies such as grading the evidence and setting strict inclusion and exclusion criteria can increase the quality of evidence in such reviews.

4.2 CHAPTER AIM AND OBJECTIVES

The aim of this chapter is to examine the evidence base of yoga intervention for adult health conditions. The primary objective of this chapter is to collect, analyse and summarise the evidence of yoga intervention in acute and chronic health conditions. The secondary objective is to discern knowledge gaps, limitations in current evidence and epidemiological evidence to identify populations and their health conditions most likely to benefit from yoga intervention.

4.3 METHODS

The large number of systematic reviews (SRs) (n=373) indicates the need for a pragmatic overview of SRs to determine the quality and direction of yoga evidence. An overview of SRs, therefore, was selected as the preferred study design to investigate scientific evidence accumulated to determine the impact of yoga intervention in various populations, interventions, comparators and outcome measures.

4.3.1 Types of Reviews

SRs including yoga as a primary intervention to treat an adult health condition with evidence from at least one randomised controlled trial (RCT) of yoga were included. Any review addressing multiple conditions was excluded. Included reviews also satisfy the Oxman criteria as follows: state a replicable search method; adequately attempt to retrieve all relevant data; collect the data in a systematic way; analyse and present the results appropriately; consider sources of bias and the quality of evidence.

4.3.2 Types of Participants

SRs involving adult participants with a diagnosed and existing acute or chronic health condition were included. SRs of asymptomatic or otherwise healthy participants and children (less than 8 years of age) were excluded.

4.3.3 Types of Interventions

Yoga or any type of yoga intervention as defined by review authors was included. The MeSH and conventional definition of yoga (as described in Chapter 2) was used to evaluate the acceptability of authors' definitions, such that yoga intervention referred to any technique called yoga, usually including breathing techniques (pranayama), physical postures (asanas) or meditation (dhyana). Allied health or healing arts that are similar to, but did not call themselves yoga were not included. Martial arts or alternative healing modalities including karate, tai chi, qigong, reiki, massage, stretching alone, pilates, acupuncture were also not included. Talk therapies including psychological, social and cognitive behavioural modification strategies were excluded. SRs that included multiple interventions were included, if the yoga-specific data were extractable.

4.3.4 Outcomes Measures

Primary outcomes included a batch of measures commonly cited in acute and chronic disease research. The secondary outcomes included patient-reported outcomes or cost-efficiency. A list of measurable outcomes for this overview was identified following a literature review and expert consultation (CH, AW).

4.3.4.1 Primary outcomes

1. All-cause mortality
2. Direction and magnitude of disease progression
3. Surrogate markers and biomarkers that correlate with disease progression (i.e. blood pressure, resting heart rate, endocrine levels)
4. Number of clinical visits and/or hospital utilisation rates
5. Changes in medication or prescription patterns

4.3.4.2 Secondary outcomes

1. Self-reported measures of health, coping or other (e.g. quality of life)
2. Psychosocial or behavioural outcomes
3. Cost-effectiveness and related evaluations

4.3.5 Quality of Evidence

The most comprehensive assessment tool for study quality is the 'Grade of Recommendations Assessment, Development and Evaluation' (GRADE)[112]. When other measures of quality were employed in SRs, judgements to downgrade or upgrade the quality of evidence were applied based on the threat of bias due to study design and other criteria specified in the GRADE toolbox. Insufficient data were reported in instances of inadequate information to grade quality.

4.3.6 Quality of Included Reviews

The 'assessment of multiple systematic reviews' (AMSTAR) measurement tool[113] outlines 11 characteristics of high-quality systematic reviews. The AMSTAR

assessment is commonly cited in other health care areas and has been implemented to grade the quality of yoga SRs for the first time.

Box 4.1 The AMSTAR tool criteria[113]

1. Was an 'a priori' design provided?
2. Was there duplicate study selection and data extraction?
3. Was a comprehensive literature search performed?
4. Was the status of publication used as an inclusion criterion?
5. Was a list of studies (included and excluded) provided?
6. Were the characteristics of the included studies provided?
7. Was the scientific quality of the included studies assessed and documented?
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
9. Were the methods used to combine the findings of studies appropriate?
10. Was the likelihood of publication bias assessed?
11. Was the conflict of interest stated?

4.3.7 Search Method

A comprehensive electronic search of ten online health databases including MEDLINE, Cochrane Library and CINAHL was designed by combining natural language and MeSH terms for yoga as the key components with consultation of an Information Specialist (NR). See Appendix 4.A for details of the search strategy. In addition, hand-searches of relevant journals and journalistic books including *The Science of Yoga*[37] and *Yoga as Medicine*[38] were conducted. Websites of known yoga research institutes were visited and references of found reviews were searched for additional titles.

One reviewer (MM) collected and extracted the data while two other reviewers (CH, AW) randomly assessed the data collection for accuracy. Consensus through discussion or eventual consultation of a third-party resolved any discrepancies.

Missing data were considered a limitation to the overview. In reviews that included multiple interventions other than yoga, only yoga-specific data were collected.

4.3.8 Data Analysis

4.3.8.1 Selection of reviews

The first reviewer (MM) screened titles, abstracts and full articles found from electronic and other sources. A second reviewer (CH) provided supervision and random assessment of the selection process. The first reviewer (MM) extracted the data and a second reviewer (AW) independently assessed the accuracy of the data collection as registered on predefined data extraction form on an Excel spreadsheet. No discrepancies occurred and the missing data is considered a limitation to the overview.

4.3.8.2 Assessment of quality of included reviews

Two aspects of quality for the included reviews: the quality of evidence included in the reviews and the quality of the systematic reviews themselves. The first reviewer (MM) performed the quality assessments using digital templates of GRADE and AMSTAR parameters, which was verified by co-authors (CH, AW). Based on the available evidence, reviews were downgraded or upgraded by the quality of evidence based on the amount of potential bias due to study design and other criteria specified in the GRADE toolbox. Any discrepancies were resolved with discussion, and was planned to build consensus or consultation of an additional researcher if needed.

4.3.8.3 Data synthesis

The characteristics of all included reviews and the overview of reviews table summarises the data collection. As pooled results were limited within the included

systematic reviews, the summary of results includes a narrative analysis only. Where possible, the quantitative data was collected, synthesised and considered in the discussion. To manage the data, a distinction between those systematic reviews that included only yoga and reviews that used yoga with other interventions. A subgroup analysis was planned determine the effects of gender, age, ethnicity, type of health condition, type of yoga intervention, method of yoga delivery on outcomes.

4.3.8.4 Managing Heterogeneity

A certain amount of clinical diversity was anticipated and desirable for the purposes of an overview. To manage the various data, an electronic collection table was designed (Excel sheets) to include categories of participants (age, gender, health status, ethnic background, geographical location), characteristics of interventions (type of yoga, frequency, intensity, length of treatment, duration of study, follow-up), comparisons (waitlist, exercise, drug, sham yoga, lecture, massage) and health outcomes (measurement, clinical significance).

Methodological heterogeneity in overviews typically arises due to differences in research design and protocol of the systematic review[114]. Only SRs satisfying Oxman criteria (Box 4.1) were admitted for this analysis to ensure a sufficiently homogenous pool of SRs with high-quality protocols. In addition, the quality of each SR was assessed using the AMSTAR[113] tool.

Statistical heterogeneity is concerned with variations across studies that arise purely because of statistical reasons[115]. The fixed-effects and random-effects models are frequently used to investigate the amount of statistical heterogeneity, however, the volume and consistency of numerical data reporting across SRs were insufficient and considered a limitation of the overview.

4.4 RESULTS

A title search identified 2,202 potential articles, 103 abstracts were reviewed, and 41 full-text articles were assessed for eligibility; 2,034 titles were rejected because there subject was clearly not yoga-related or a review. Twenty-six SRs were included in this overview. Fifteen SRs were excluded from this overview with reasons as follows: the review did not satisfy Oxman criteria to qualify as a SR (n=8)[116-123], the review included children or healthy adults (n=6)[124-129], or the review did not report results from at least one RCT[130]. Figure 4.1 outlines the selection process in an article flow diagram.

The SRs collated evidence from 125 primary studies, of which 92 studies included only yoga interventions. Six SRs provided quantitative data with meta-analyses, seven reviews provided descriptive data with no pooled analysis, and 13 reviews contained qualitative descriptions of results. Twelve SRs included only yoga interventions. The characteristics of included reviews are summarised in Table 4.1.

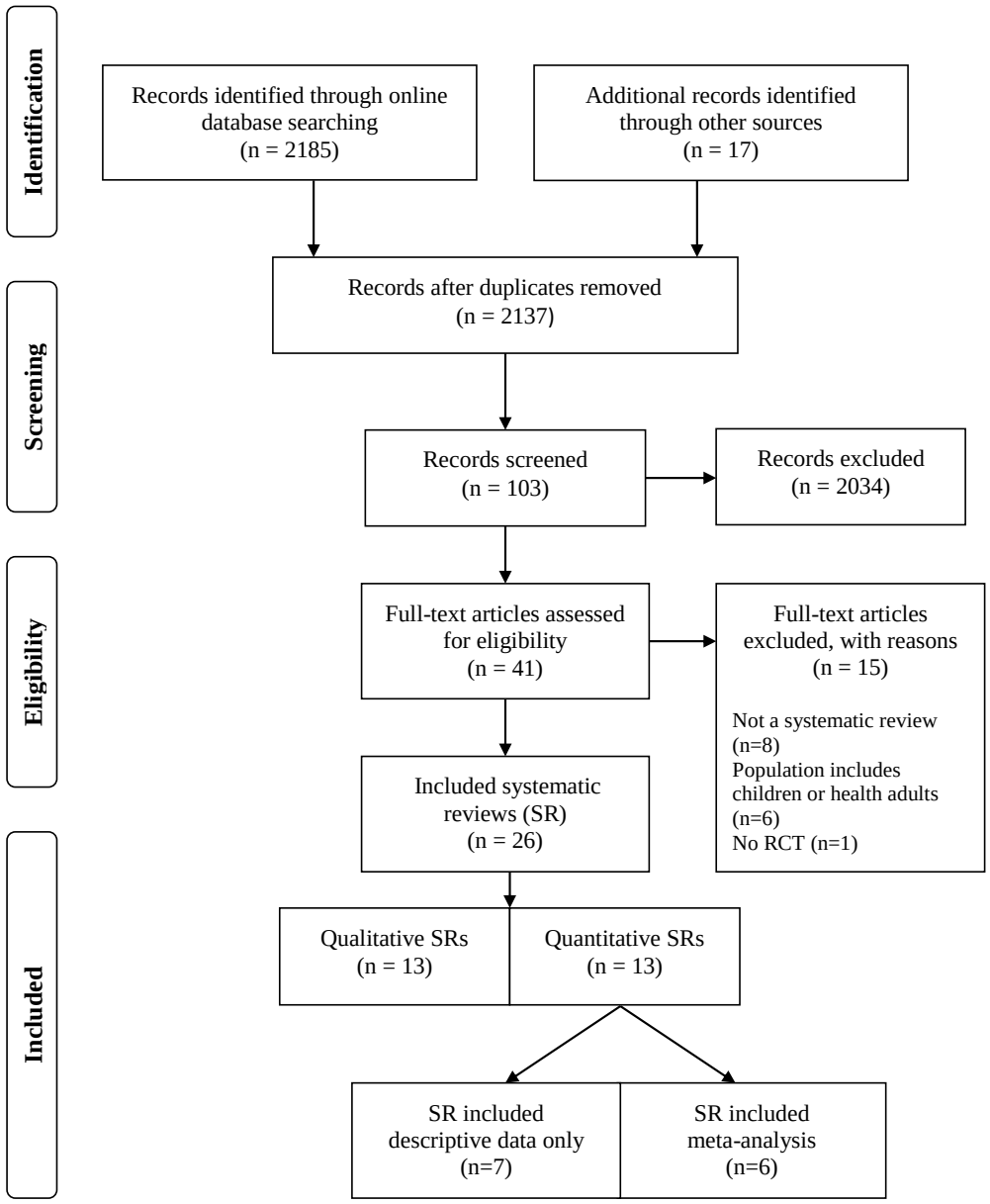


Figure 4.1. Article flow diagram for overview of systematic reviews

Table 4.1. Characteristics of included reviews

Review (first author, year)	Population			Type of yoga interventions	Type of comparisons	Outcomes
	Health condition (ICPC-2 Class)	No. of primary studies incl. in SR	No. of participants			
Aljasir 2010[131]	Type 2 diabetes (T90)	5	362	Mixed yoga and yoga with dietary and herbal intake	No data	Blood glucose levels, lipid profile, body mass index (BMI), diabetes-related complication
Anderson 2011[132]	Metabolic syndromes (T99)	2	125	Restorative yoga	Waitlist, usual care	Body mass index (BMI), waist circumference, blood pressure, insulin sensitivity, blood glucose, blood lipids (HDL,LDL), perceived stress (SF-36), food frequency
Büssing 2012[133]	Pain symptoms (A1; N1;L)	16	937	Mixed yoga (LAYT, Viniyoga, Raj and unspecified others)	Waitlist, usual care, exercise, medication, lecture	Effect size of pain using standardized measurements (i.e. VAS, MPQ, CMDQ)
Cabral 2011[134]	Psychiatric disorders (P99)	10	343	Hatha, Iyengar, Kriya, Sahaja, Integrated, Meditation and Siddha Samadhi	No data	Major psychiatric disorders (schizophrenia, depression, anxiety and PTSD)
Dickinson 2008[135]	Hypertensive (K86)	2	63	Yoga and meditation	No comparison group	Systolic and diastolic blood pressure
Gerritsen 2002[136]	Carpal tunnel syndrome (N93)	1	42	11 yoga postures	Usual care	Pain and sleep disturbance scores
Haaz 2011[137]	Arthritis (L91)	10	243	Iyngar and Kundalini yoga	Waitlist, usual care, no comparison group	Disease activity score (DAS), joint inflammation, functional ability (strength, balance, flexibility, mobility), psychosocial [arthritis impact measurement scale 2 (AIMS2), HRQL (SF-36), Beck Depression Index (BDI)], medication usage
Heiwe 2011[138]	Chronic kidney disease (U14)	1	40	Modified yoga including balancing, strengthening and breathing techniques	Exercise	Muscular strength, grip strength, blood lipids (triglyceride, total cholesterol, HDL cholesterol)

Review (first author, year)	Population			Type of yoga interventions	Type of comparisons	Outcomes
	Health condition (ICPC-2 Class)	No. of primary studies incl. in SR	No. of participants			
Innes 2008[139]	Women with menopause (X11)	7	408	Hatha, Iyengar, Sahaja, Hot, Yoga Awareness Program (Kripalu) and Integrated Approach to Yoga Therapy	Waitlist, exercise, no comparison group	Overall menopausal symptoms, vasomotor menopausal symptoms, sleep disturbance
Innes 2007[140]	Type 2 diabetes (T90)	25	1828	Various components including asana, kriya or cleansing exercises, meditation, pranayama and meditation	Waitlist, usual care, exercise, book/pamphlet	Insulin resistance (fasting glucose, post-prandial glucose, fructosamine, fasting insulin, fasting glycated hemoglobin), blood lipid profile (cholesterol, triglycerides, low/high density lipoprotein, very LDL, cholesterol/HDL ratio, LDL/HDL ratio), anthropometric measures (BMI, body weight, body composition), blood pressure (systolic/diastolic), medical usage
Kirkwood 2005[141]	Anxiety disorders (P74)	8	370	Kundalini	Sham yoga, medication, book/pamphlet, tablet placebo	Anxiety scales and checklists (YBOCS, HAS, ACL, Inst. for personality and ability testing)
Krisanaprakornkit 2006[142]	Anxiety disorders (P74)	2	76	Kundalini	Relaxation response/mindful meditation	Anxiety rating scale
Langhorst 2012[143]	Women with fibromyalgia syndrome (A99)	2	93	Yoga of Awareness Program	Waitlist, usual care	Pain, sleep, fatigue, depression (VAS), health-related quality of life (FIQ - fibromyalgia impact questionnaire)
Lee 2009[144]	Menopausal women (X2)	7	470	Iyengar, Restorative and Integrated Yoga (IAYT)	Waitlist, exercise	Psychological, somatic, vasomotor and total symptoms of menopause
Lin 2011[145]	Psychological Health (P1;P3;P29)	10	788	Hatha, Restorative, Integrated, Mind-body stress reduction, Tibetan yoga	No data	Psychological health rating (anxiety, depression, distress, stress), quality of life and physical measures (self-reported health, fatigue)
Mahendira 2009[146]	Osteoarthritis (L91)	1	n.r	Unspecified yoga	Waitlist with wrist splint	Efficacy of treatment

Review (first author, year)	Population			Type of yoga interventions	Type of comparisons	Outcomes
	Health condition (ICPC-2 Class)	No. of primary studies incl. in SR	No. of participants			
Marc 2011[147]	Anxiety in pregnant women (P73;W78)	1	34	Mindfulness interventions	Waitlist	Perceived stress (perceived stress scale), depression, anxiety, positive/negative affect, affect regulation
Morone 2007[148]	Pain symptoms (A1)	4	188	Yoga, relaxation and education	Waitlist, book/pamphlet	Pain (WOMAC, RDS, joint tenderness, visual analogue scale), physical function
Muller 2004[149]	Carpal tunnel syndrome (N93)	1	46	Unspecified yoga	Usual care (splint)	Pain and grip strength
Pilkington 2005[150]	Depression (P76)	5	183	Iyengar, Kriya, Broota's relaxation technique (BRT)	Waitlist, sham yoga, exercise, medication, electroconvulsive therapy	Depression rating scale
Posadzki 2011[151]	Pain symptoms (A1)	7	403	Hatha, Iyengar, Viniyoga and 2 others unspecified	Waitlist, usual care, exercise, book/pamphlet	Pain, disability and depression rating scales, medication usage
Ram 2003[152]	Asthmatic (R96)	3	147	Breathing exercise, meditation, postures, deep muscle relaxation, chanting	Waitlist, exercise, no data for some groups	Asthma symptoms (peak expiratory flow rates, exacerbations per week, asthma symptom scores)
Ramaratnam 2000[153]	Epileptic (N88)	2	50	Sahaja, Pranayama, Dhyana, Yama, Niyama	Sham yoga, talk therapy	Seizure frequency and duration
Slade 2007[154]	Low back pain (L33)	2	145	Iyengar, Viniyoga	Exercise, lecture, book/pamphlet	Pain and function rating scores
Smith 2011[155]	Pain/relaxation in labour (P01;W78)	2	281	Yoga program with educational activities	Usual care, exercise, music and other yoga groups	Pain intensity, satisfaction with pain relief, satisfaction with childbirth, Apgar score, use of pharmacological pain relief, length of active labour, augmentation in labour
Smith 2009[156]	Anxiety in cancer patients (P29;A79)	10	892	Hatha, Iyengar, Restorative, Yoga of Awareness, Tibetan and 4 others unspecified	Waitlist, exercise, talk therapy	Anxiety, stress, depression, fatigue, sleep quality, spiritual well-being and quality of life scales

Italics: systematic reviews including only yoga interventions

Normal: systematic reviews including yoga interventions plus other interventions; n.r = not reported

4.4.1 Quality of Included Reviews

The overall quality of SRs was high (AMSTAR average = 9.4). Fifteen of the reviews were considered very high quality (AMSTAR ≥ 10), 6 of high quality (AMSTAR 8-9.9), 5 reviews of medium quality (4-7.9 AMSTAR) and no SR scored below 4 points. See Table 4.2 for the AMSTAR ratings of included SRs. All 26 SRs scored in five of 11 methodological criteria including identification of *a priori* design, using duplicate referees for study selection and data extraction, implementing a comprehensive literature search, considering the status of publication for inclusion and the assessment and documentation of the scientific quality of evidence. Lists of excluded studies and conflicts of interest in SRs were inconsistently reported (16 SRs only). A statistical investigation to determine the likelihood of bias was poorly reported (two of 12 yoga-only SRs).

4.4.2 Quality of Evidence

The quality of evidence ranged from very poor to moderate quality. No high quality evidence was included in the reviews. SR authors implemented a diverse set of tools to evaluate evidence, including Jadad scores, CONSORT guidelines and PEDro scales. In 17 SRs the GRADE approach was applied to grade study quality, while nine reviews did not provide sufficient data to independently assess their quality of evidence (see Table 4.2).

Table 4.2. Overview of reviews: quality and outcomes summary

Review (first author, year)	Primary outcome (as stated by review author or first listed)	Quality rating of SRs (AMSTAR)	Quality of Evidence (GRADE)				Results	
			Very Low	Low	Moderate	Insufficient data to assess	Positive effect	Unclear effect
Aljasir 2010[131]	Management of type II diabetes	10		•				•
Anderson 2011[132]	Body mass index	9.5				•		•
Büssing 2012[133]	Pain (effect size)	11		•			•	
Cabral 2011[134]	Treatment for psychiatric disorder	11				•	•	
Dickinson 2008[135]	Blood Pressure	10.5	•					•
Gerritsen 2002[136]	Pain (carpal tunnel syndrome)	8.5		•				•
Haaz 2011[137]	Clinical outcomes in arthritis	6	•					•
Heiwe 2011[138]	Muscular strength	11			•			•
Innes 2007[140]	Metabolic and anthropometric measures for diabetes mellitus	9				•	•	
Innes 2008[139]	Menopausal symptoms	6.5				•	•	
Kirkwood 2005[141]	Treatment for anxiety	10		•				•
Krisanaprakornkit 2006[142]	Treatment for clinical anxiety	10.5	•					•
Langhorst 2012[143]	Pain (fibromyalgia)	10.5		•			•	
Lee 2009[144]	Menopausal symptoms	11		•				•

Review (first author, year)	Primary outcome (as stated by review author or first listed)	Quality rating of SRs (AMSTAR)	Quality of Evidence (GRADE)				Results	
			Very Low	Low	Moderate	Insufficient data to assess	Positive effect	Unclear effect
Lin 2011[145]	Quality of life for cancer patients	10		•			•	
Mahendira 2009[146]	Effectiveness of treatment for osteoarthritis	8.5				•		•
Marc. 2011[147]	Perceived stress	11		•				•
Morone 2007[148]	Pain (chronic in older adults)	9.5				•		•
Muller 2004[149]	Effectiveness of treatment for CTS	10.5		•			•	
Pilkington 2005[150]	Treatment for depression	7				•		•
Posadzki 2011[151]	Pain (low back)	10		•			•	
Ram 2003[152]	Asthma symptoms	6				•		•
Ramaratnam 2002[153]	Treatment for epilepsy	11		•				•
Slade 2007[154]	Pain (low back)	5.5				•	•	
Smith 2009[156]	Psychological functioning of patients with cancer diagnosis	10.5		•			•	
Smith 2011[155]	Pain (labour)	9		•			•	
Total (average)		9.4	3	13	1	9	11	15

Note: SRs did not report high quality evidence or negative effects

4.4.3 Participants

The total number of participants across all studies was 5,915. Six reviews did not include studies with sample sizes greater than 50 participants at baseline. The range of participants' ages was 18 to 77 years. The age, gender, ethnicity, socioeconomic and education status of participants were not consistently reported across studies, though the majority of participants were adult women.

Twelve SRs investigated only yoga interventions and included the following health conditions: anxiety (n=4), pain management (n=2), with one review each in depression, epilepsy, psychiatric disorder, diabetes, arthritis and relief of menopause symptoms. Fourteen SRs included yoga therapy in combination with other interventions and measured health outcomes in carpal tunnel syndrome (n=2), diabetes risk factors (n=2), with one review each in anxiety, asthma, chronic kidney disease, fibromyalgia, hypertension, low back pain, menopause, pain management in labour, chronic pain and osteoarthritis.

4.4.4 Characteristics of Yoga Intervention

Twenty-two SRs incorporated various types of yoga intervention, including: viniyoga, integrated yoga, raj, Iyengar, kriya, sahaja, siddha samadhi, hot yoga, water yoga and Tibetan yoga. Modified, non-descriptive or unspecified yoga interventions were identified in 12 SRs. Two SRs included only kundalini yoga intervention, and one SR included only restorative yoga or 'yoga of awareness'. See Box 4.2 for a summary of yoga interventions described in the SRs. The most frequently reported yoga interventions by type: Iyengar (n=9), hatha (n=7) restorative (n=5), kundalini (n=3) and Integrated yoga (n=3).

Box 4.2 Types of Yoga Intervention

HATHA. Traditional yoga, includes combinations of posture, breathing and meditation.
HOT. Sequence of postures performed in a heated room (35-40°C).
INTEGRATED APPROACH TO YOGA THERAPY. Posture, breathing, meditation and theory of yoga progression (kriya).
IYENGAR. Created by BKS Iyengar. Precision method of hatha using emphasis on strength, balance and use of props. Usually slow movement and holding poses.
KUNDALINI. Focuses on awakening life force located at base of spine, repetitive movements, sensory awareness with physical postures, breathing, mental and spiritual discipline.
KRIYA. Progressive, transitional yoga with techniques to accelerate spiritual development and self-realization.
RAJ. Raj or Raja practice to know higher self with focus on concentration and meditative techniques, limited physical movement.
RESTORATIVE. Gentle practice, resting in postures for deep relaxation.
SAHAJA. Seeks transformation of self with focus on energy flow, breath and meditation. Similar to kundalini.
SIDDHA SMADHI. Results-oriented yoga based on four pillars of proper nutrition, breathing, light exercise and daily meditation.
TIBETAN. Combines posture, breath and motion similar to hatha with origins in Nepal.
VINIYOGA. Adaptive yoga technique with posture, breath, chanting and meditation.
VINYASA. Flow yoga, linking postures in continuous motion, includes breath and meditation.
WATER YOGA. Physical postures in heated water to encourage greater comfort, resistance and range of motion.
YOGA OF AWARENESS. An 8-week course with gentle physical stretching, meditation and breathing techniques.

The type of delivery mechanism of yoga used in their primary studies was not reported in nine of the reviewed SRs. Instructor-led yoga was identified in a majority of cases (n=17), independent or home study (n=13), book-led yoga (n=5), audio-led yoga (n=4) and video-led yoga in one review. No review evaluated the effect of yoga by type or delivery mechanism for a specific health condition. SRs did not report on the intensity of yoga interventions in terms of cardiovascular output or caloric expenditure.

Twenty of 26 SRs reported the duration and frequency of yoga sessions. The duration of yoga sessions varied between 20 and 300 minutes. An intervention of 60

minutes in length was most prevalent. Seven reviews included yoga interventions with <3 yoga sessions per week, three reviews included only yoga interventions with ≥3 sessions per week, ten reviews included both frequencies of yoga sessions. Twenty-five of the SRs reported trial duration, and one (with two primary studies) included trials with yoga intervention of ≥ 24 weeks.

4.4.5 Comparisons

Fourteen of the 26 SRs (28 primary studies) reported a non-active waitlist comparison for yoga intervention. Other kinds of exercise are compared to yoga in 11 SRs (19 primary studies), nine SRs (16 primary studies) identified usual care, while medicinal intervention is noted in three reviews (4 primary studies). Four SRs (19 studies) did not report use of control groups or comparisons. Other comparisons reported in the reviews included disseminating reading material to participants (5 studies), sham yoga (5 studies), talk-therapy (3 studies) and lectures (2 studies).

4.4.6 Outcome Measures

The follow-up to changes in outcome measures were not reported in 18 SRs. Of the 8 SRs that reported length of time to follow-up, data were collected from primary studies with ≥ 12 weeks follow-up measures (n=4), <12 weeks follow-up (n=2), and no follow-up at all (n=2).

4.4.6.1 All-Cause mortality

Outcome results for all-cause mortality were not reported in the reviews. The absence of such data could be due to characteristics of study design including length of trials (typically three to six months) and small sample sizes (n<50). The population samples usually included middle-aged adults receiving treatment for

chronic illnesses, thus mortality may be limited in such groups, or yoga therapy may have no effect on reducing mortality.

4.4.6.2 Direction and magnitude of disease progression

Nine reviews measured the direction and magnitude of disease progression. These chronic diseases included: anxiety[141,142], depression[150], treatment of psychiatric disorder[134], clinical outcomes in arthritis[137] and osteoarthritis[146], carpal tunnel syndrome[149], epilepsy[153]and asthma[152].

4.4.6.3 Surrogate markers and correlates of disease progression

Five SRs measured surrogate markers that correlate with disease progression including blood pressure[135], body mass index[132], metabolic and anthropometric measures for diabetes mellitus[140], fasting blood glucose[131] and muscular strength[138]. Higher quality research with controlled clinical trials reported a 6.9% reduction in fasting glucose of adults with diabetes and 7.8% reduction in body weight, with reductions in systolic and diastolic blood pressures ranging from 3.9 to 13.9% and 5.8 to 15.8% for adults with diabetes or those at risk of cardiovascular disease[125]. Although an average decrease of 3/5 mmHg was found in hypertensive patients, Dickinson et al. suggested no good evidence exists to confirm yoga therapy is effective for treatment of hypertension as studies are too small to detect any effect on morbidity or mortality[135]. Study designs lacked blinding and used inadequate randomisation techniques, thus potential biases and limitations characterising most of these studies hinder interpretation of findings[131,132,137,138].

4.4.6.4 Number of clinical visits and/or hospital utilisation rates

Systematic reviews did not report changes in the number of clinical visits or hospital utilisation rates with yoga intervention. Although a number of interventions are implemented in a clinical setting (nine of 26 reviews), it is possible that primary researchers did not consider a change in this aspect of clinical care. Perhaps for reasons of limited resources or short-time horizons, this may be considered a greater priority in future studies.

4.4.6.5 Changes in medication or prescription patterns

Two SRs measured changes in medication with yoga intervention[138,151]. One author concluded that yoga may be beneficial in decreasing medication usage in diabetes[138], the second study concluded with caution that yoga may decrease medication usage in pain conditions although results were not statistically significant[151].

4.4.6.6 Self-reported measures of health

Ten SRs included self-reported measures for pain management [133,136,143,144,148,149,151,154-156], menopausal symptoms[139,144] perceived stress[147], psychological wellbeing and quality of life for cancer patients[145,156]. Seven review authors concluded positive effects[133,143,149,151,154-156]. One RCT with treatment of low-back pain showed Iyengar yoga (n=60) reduced pain intensity (64%), functional disability (77%) and pain medication usage (88%) versus the education control group with usual care[128]. The review of various pain conditions (headaches, back pain, muscle soreness, labour, arthritis) yielded a moderate effect size of yoga as measured by visual analogue scales and questionnaires (VAS, CMDQ, PPI) at SMD -0.74 [95% CI, -0.97 to -0.52; $p<0.0001$][133].

Quality of life for cancer patients in yoga groups approaches significance (p=0.06) with a SMD -0.29 [95% CI, -0.58 to 0.01] while psychological health outcomes (anxiety, depression, distress, stress) showed a pooled effect size of SMD -0.95 [95% CI, -1.63 to -0.27; p=0.006] as measured by HADS, PSS, STAI, POMS, CES-D, PANAS, IES, SCL-90-R, SOSI and the distressed mood index[145]. An earlier review (search date of April 2008) favoured yoga with concurrent treatment for anxiety and depression in adult cancer patients[156]. Effect sizes of 0.04 to 4.67 (anxiety) and 0.17 to 7.44 (depression) were reported following yoga intervention, though statistical significance and measuring tools were not reported.

Three reviews concluded neutral or unknown effects of yoga intervention for pain in carpal tunnel syndrome[136], in chronic pain of older adults[148] and for menopausal symptoms[144]. The review authors attributed a lack of scientific rigour in large-scale and long-term studies for their inconclusive results.

4.4.6.7 Psychosocial or behavioural outcomes

Systematic reviews did not report results on psychosocial or behavioural outcomes.

4.4.6.8 Cost-effectiveness and related evaluations

Systematic reviews did not report results on cost-effectiveness and related evaluations. This narrow focus could be in part due to the lack of available data in primary research studies.

4.4.7 Meta-analyses

Of the six reviews that included a meta-analysis of results, three investigated outcomes in pain[133,143,154] with one review each in psychiatric disorders[134] menopausal symptoms[144] and psychological health in cancer patients[145]. For pain studies, interventions included hatha, Iyengar, yoga of awareness, water yoga, viniyoga and unspecified yoga programs. Effects of yoga when compared to physical activity, education sessions, waiting lists, routine care and talk-therapy show positive results for yoga in pain reduction. Statistical meta-analysis of 12 primary studies suggested a moderate effect size of yoga to reduce acute pain in adult populations SMD -0.74 [95% CI, -0.97 to -0.52; p<0.0001][133]. In fibromyalgia patients, yoga improved low back pain versus education, self-care and no exercise in two primary studies: SMD -0.54 [95%CI, -0.96 to -0.11; p=0.01][143]. Results did not indicate yoga improve menopausal symptoms in two studies of low quality[144]. See Table 4.3 for an overview of reviews with pooled results.

As an adjunct therapy, Cabral et al. concluded yoga improves treatment of depression, anxiety, post-traumatic stress disorder (PTSD) and schizophrenia, with a pooled effect size of SMD -3.25 [95% CI, -5.36 to -1.14; p=.002][134]. This review also implied pranayama (breathing) techniques were most important to improve anxiety and stress-related disorders.

Table 4.3. Overview of reviews: primary outcomes (yoga meta-analyses)

Review (author, year)	Condition	Outcome		Intervention(s)	Comparison	Effect Size (95% CI)	p-value	No. of participants (studies)	Quality of Evidence (GRADE)	Heterogeneity Analysis	SR Authors' Comments
		Description	Measuring instrument(s)								
Büssing 2012[133]	Pain	Effect size of pain	VAS, MPQ, CMDQ	Hatha, Iyengar, unspecified yoga	Physical activity, educational sessions, waiting list, lecture, routine care and conversation	SMD -0.74 (-0.97, -0.52)	<0.0001	776 (12)	moderate* (low)	Chi square test 19.73, df =11 (p=0.05); I-square=44%, moderate heterogeneity detected	"methodological quality of the studies had no relevant impact on the study outcome; of note, studies with higher quality had a better pain outcome as compared with studies with low quality"
Cabral 2011[134]	Psychiatric disorder	Treatment of psychiatric disorder: depression, anxiety, PTSD and schizophrenia)	BDI, HADS, digit span test, well-being scores, stress hormone levels (cortisol and ACTH)	Integrated, Sudarshan Kriya, Hatha, Sahaj, Meditation yoga, Siddha Samadhi, Iyengar	Other treatment	SMD -3.25 (-5.36, -1.14)	0.002	343 (10)	n.r	Cochran Q test = 369.69 (p<.001) for fixed model data, heterogeneity indicated	"funnel plot and Egger regression test (P=0.007) indicate publication bias; failsafe N=212 interpreted to suggest 21.2 missing studies needed to nullify observed effect"

Review (author, year)	Condition	Outcome		Intervention(s)	Comparison	Effect Size (95% CI)	p-value	No. of participants (studies)	Quality of Evidence (GRADE)	Heterogeneity Analysis	SR Authors' Comments
		Description	Measuring instrument(s)								
Langhorst 2012[143]	Fibromyalgia syndrome	Pain	VAS	Yoga of Awareness, water yoga	Waitlist, treatment as usual	SMD -0.54 (-0.96, -0.11)	0.01	88 (2)	(low)	I-square=0%	"evidence of a short-term relief of four key domains of FMS by Yoga: pain, fatigue, depression, quality of life" No evidence of sleep improvement with yoga v. active or waitlist controls
Lee 2009[144]	Menopause	Menopausal symptoms	MENSI	Iyengar, unspecified yoga	No treatment	SMD 0.07 (-0.25, 0.39)	0.66	91 (2)	2.5/5* (low)	Chi square test 0.28, df =1 (p=0.60); I-square=0%, no heterogeneity detected	"evidence is insufficient to suggest that yoga is an effective intervention for menopause"
Lin 2011[145]	Psychological health, quality of life, physical health of cancer patients	Anxiety, Depression, Distress, Stress	HADS, PSS, STAI, SOSI, POMS, SCL-90-R, STAI, CES-D, PANAS, IES, DMI	Integrated yoga, MBSR: gentle yoga, Tibetan, unspecified yoga	Waitlist, n.r	SMD -0.95 (-1.63, -0.27)	0.006	744 (10)	5.25/10± (low)	Chi square test 33,96, df = 4 (p=0.006); I-square=88%, very high heterogeneity detected	"findings show potential benefits of yoga for people with cancer in improvements of psychological health…clinical heterogeneity to be considered when interpreting results"

Review (author, year)	Condition	Outcome		Intervention(s)	Comparison	Effect Size (95% CI)	p-value	No. of participants (studies)	Quality of Evidence (GRADE)	Heterogeneity Analysis	SR Authors' Comments
		Description	Measuring instrument(s)								
		Quality of life	SF-12, FACT_B, FACT_G, EORTC QLQ-C30	Restorative, Hatha, unspecified yoga	n.r	SMD -0.29 (-0.58, 0.01)	0.51	210 (3)	4.7/10± (low)	Chi square test 1.34, df = 2 (p=0.60); I-square=0%, no heterogeneity detected	
		Physical health	SF-12, FACT_B, FACT_G	Restorative, Hatha, Tibetan, MBSR: gentle yoga	n.r	SMD -0.16 (-0.37, -0.06)	0.15	367 (4)	5.25/10± (low)	Chi square test 3.96, df =3 (p=0.15); I-square=24%, some heterogeneity detected	
Slade 2007[154]	Chronic low back pain	Medium-term pain	n.r	Viniyoga, Iyengar	Trunk strength and aerobics, book and lectures	SMD 0.92 (0.47, 1.37)	n.r	88 (2)	7.7/10± (n.r)	n.r	"indicated significant and large effects for medium-term pain in favour of yoga"

n.r, not reported; Beck Depression Inventory (BDI); Visual Analogue Scale (VAS); Menopausal Self-inventory (MENSI); McGill pain questionnaire (MPQ); Present Pain Index (PPI); Cornell Musculoskeletal Discomfort Questionnaire (CMDQ); Hospital Anxiety and Depression Scale (HADS); Perceived Stress Scale (PSS); State of trait anxiety inventory (STAI); Symptoms of stress inventory (SOSI); Profile of mood states (POMS); Symptoms Checklist Revised (SCL-90-R); Center for Epidemiologic Studies Depression Scale (CES-D); Positive and Negative Affect Schedule (PANAS); Impact of Events Scale (IES); Distressed Mood Index (DMI); Medical Outcomes Study Short-Form Health Survey (SF-36); The 12-Item Short Form Health Survey (SF-12); Functional Assessment of Cancer Therapy-Breast (FACT_B); Functional Assessment of Cancer Therapy-General (FACT_G); European Organisation for research and Treatment of Cancer Quality of Life Questionnaire Version 3.0 (EORTC QLQ-C30); Mindfulness-based stress reduction (MBSR)

*Average Jadad score

±Average PEDro scale

4.4.8 Descriptive Data

Descriptive data (with no pooled analyses) from yoga primary studies were provided in seven reviews. Three of these reviews assessed the direction and magnitude of disease progression with yoga intervention for anxiety[141] asthma symptoms[152] and seizure frequency in people with epilepsy[153]. Heiwe et al. measured muscular strength for chronic kidney disease patients[138]. Self-reported measures of pain were included in two reviews[136,156] and perceived stress in one review[155].

Anxiety outcome measures in the quantitative studies included: Y-BOCS, HAS, IPAT, TAS, ACL, STAI and SNAQ (see Box 4.3 for a summary of instruments).

Box 4.3 Summary of Anxiety Outcome Measures

ACL: anxiety checklist
HADS: Hospital anxiety and depression scale
HAS: Hamilton anxiety scale
IPAT: Institute for personality and ability testing
POMS: Profile of mood states
PSS: Perceived stress scale (10/14 item versions)
SCL-90-R: Symptoms checklist revised
SNAQ: Snake attitude questionnaire
SOSI: Symptoms of stress inventory
STAI: State-trait anxiety inventory
TAS$^{\pm}$: Taylor's anxiety scale
Y-BOCS: Yale-Brown obsessive compulsive scale

In general, review results showed a small reduction in statistical means for yoga groups versus non-active control groups. One non-randomised controlled study (n=71) reports anxiety neurosis (HAS) decreases with yoga treatment versus placebo capsule SMD 0.89 [95% CI, 0.34 to 1.44; p=0.001]. A smaller RCT measured Y-BOCS (n=22) and reported SMD 1.10 [95% CI, -0.02 to 2.22; p=n.r]. In patients with cancer, a number of yoga interventions decrease anxiety scores (HADS, PSS, STAI SOSI, POMS, SCL-90-R). One study reported a decrease of anxiety of SMD -0.76 [95% CI, -1.34 to -0.19; p=0.009] in comparison to waitlist controls. In the two reviews that assess clinical anxiety as an outcome (n=1,087), results range from having no beneficial effect on STAI scores SMD 0.33 [95% CI, -0.31 to 0.97; p=n.r] to a significant effect size of SMD -4.78 [95% CI, -5.83 to -3.74; p=n.r] on HADS and PSS validated questionnaires. Differences in study design characteristics including type of yoga, duration of intervention and size of samples could account for these varying results but were not discussed by SR authors. Weekly Tibetan yoga showed no benefit, while integrated yoga methods including asana, pranayama and guided relaxation for 90 minutes per week show the greatest benefit in anxious participants.

For pain outcomes, 12 studies were pooled in one review that showed greater pain reduction (VAS, MPQ CMDQ) with treatment of hatha or Iyengar yoga than with physical activity, educational sessions, waiting lists, lectures, talk therapy or routine care[28]. In Smith et al., women receiving yoga reported increased satisfaction with pain relief and satisfaction with the childbirth experience with reduced pain intensity outcomes in self-reported visual analogue scales (VASTC, MCQ, VASPS) of MD -

6.12 [95% CI, -11.77 to -0.47; p=0.034] in latent phase labour versus usual care (n=66).

In asthmatic populations, one small study (n=36) reported a decrease in exacerbations (episodes per week) WMD -1.27 [95% CI, -2.26 to 0.28] following yoga breathing techniques, although results were not statistically significant. The hypothesis that yoga breathing could reduce asthmatic episodes was not confirmed and results from further randomized controlled trials were requested[152].

In one study of epileptic patients (n=20), sahaja yoga intervention (versus sham yoga) increased probability of being seizure-free following six months of treatment by 40% with OR 14.54 [95% CI, 0.67 to 316.69; p=0.089][153]. The same study showed a greater than 50% reduction of seizure duration after six months in seven of ten yoga participants versus to none in ten sham yoga participants, OR 45.00 [95% CI, 2.01 to 1006.75; p=0.016]. The review author included a second study that compared Acceptance Commitment Therapy (ACT) and yoga in seizure outcomes. Five of 10 ACT participants versus four of eight yoga participants were seizure-free after six months, with 50% or greater reduction in seizure duration in six of ten (ACT) and four of eight (yoga) groups respectively. The review authors concluded that no reliable conclusions could be drawn regarding the efficacy of yoga for treatment of epilepsy due to the small number and size of studies.

Furthermore, in a review on chronic kidney disease populations, a small yoga study (n=37) did not show any significant increase in muscular strength for yoga versus control (no exercise/placebo exercise)[138]. This review studies a special population in which yoga-related studies are limited.

4.4.9 Subgroup Analysis

The most frequently cited health outcomes in yoga research were self-reported measures in pain (7 reviews), anxiety (6 reviews) and diabetes management (3 reviews). The five reviews that measured pain outcomes after yoga intervention reported positive results. In type of yoga, Iyengar (9 reviews), hatha (7 reviews) and restorative (5 reviews) interventions led by trained instructor in a group setting (17 reviews) were most frequently implemented. Six positive effects were concluded in each of the groups of hatha and Iyengar systematic reviews. The Bussing et al. review included a subgroup analysis of duration of treatment, which indicated short-term interventions have a greater effect on pain disability SMD -1.14 [95% CI, -1.50 to -.79; p=n.r]. Sufficient data were not available to assess change in outcomes across subgroups of gender, age, setting, duration of session or intensity of yoga.

4.5 DISCUSSION

4.5.1 Summary of Findings

Yoga for treatment of acute and chronic health conditions is not likely to exacerbate symptoms in an experimental setting, although clear effect sizes and probabilities for beneficial outcomes in a specified population are not available at this time. Cumulative findings indicate hatha and restorative yoga have the highest correlation with positive outcomes for managing pain symptoms, anxiety and depression. Home study and instructor-led yoga (practised 60 minutes three times per week) suggested similar positive impacts in outcome measures. Video-led yoga has been rarely studied and appeared only in one review. The most prevalent comparisons or controls in yoga research are waitlists or another exercise. Although some yoga interventions

are reportedly implemented in clinical settings, the attitudes or referral practices of physicians for yoga intervention was not reported. Patients experiencing simultaneous health conditions that include a cluster of symptoms, including pain, anxiety or depression may experience multiple benefits from yoga intervention.

This overview adds a comprehensive and methodical examination of yoga interventions in adult populations for treatment of acute and chronic health conditions. The current evidence from SRs and primary studies lacks important information including characteristics of yoga intervention, such as type, frequency, duration and the intensity of yoga practice. The absence of detail prevents application of yoga as studied and limits the generalisability of results. Adherence rates, compliance of patients and follow-up results were also not reported in many cases and should be addressed in future research. Cost-benefit analyses or cost comparisons of treatment options were also not provided in SRs and should be considered in future research.

4.5.2 Interventions and Outcomes

Systematic reviews listed the following components for yoga intervention: breathing exercises (pranayama), physical postures (asanas), meditation (dhyana) and some yoga philosophy including sahaja (spontaneous movement), yama (personal restraint) and niyama (observance of yoga) teachings. Inconsistent reporting of changes in effect sizes of yoga by intervention type, delivery mechanism, setting, frequency or duration of sessions highlighted a serious gap in literature. SRs included yoga delivery in a clinic or hospital setting (n=9), home-based setting (n=1), and in the community (n=1). Other SRs did not explicitly define where the yoga intervention was delivered (n=15). Of 13 SRs that reported geographical location of the primary

studies, data were collected from patients in North America (n=13), Asia (n=5), and Europe (n=3).

The following 13 chronic health conditions in adult populations were included in this overview: anxiety, arthritis, asthma, carpal tunnel syndrome, diabetes, epilepsy, fibromyalgia, hypertension, kidney disease, metabolic syndrome, pain, psychological health in cancer patients and psychiatric disorders. Acute outcome measures were included for women in pregnancy, labour and menopause.

4.5.2.1 Positive effects of yoga – 11 systematic reviews

Seven of the SRs assessed pain management as a primary outcome. Of these reviews, five authors concluded positive effects of yoga[133,143,151,154,155]. Potential improvements for anxiety and quality of life in cancer patients were noted in two reviews[145,156]. Positive results for the treatment of fibromyalgia were noted in one systematic review[143]. One SR in psychiatric disorders concluded yoga may be an effective and far less toxic adjunct treatment option for severe mental illness to prevent weight gain and patients' risk for cardiovascular disease[134].

4.5.2.2 Unclear effects of yoga – 15 systematic reviews

The following outcomes were associated with unclear effects following yoga intervention: anxiety[141,142], arthritis[137,146], asthma[152], body mass index[132], diabetes management[131,140], muscular strength[138], epilepsy[153], hypertension[135] and in pain for the elderly population[148]. Conclusions for menopause and carpal tunnel syndromes were split between positive and unclear effects.

4.5.2.3 Adverse effects of yoga – 0 systematic reviews

SRs reported that yoga is safe, and no adverse effects of yoga treatment were reported. As yoga in the reviews was usually instructor-led in a clinical setting, yoga intervention delivered without a trained instructor may increase the risk of injury and other adverse events.

4.5.2.4 Size of effect

In pooled analyses, statistical data reported positive effects in five of six primary health outcomes for pain and various psychiatric disorders (depression, anxiety, PTSD, schizophrenia). Effect sizes ranged from SMD -0.54 [95% CI, -0.96 to -0.11; p=0.01] for pain in fibromyalgia patients (VAS) and SMD -3.25 [95% CI, -5.36 to -1.14; p=0.002] in various psychiatric disorders (BDI, HADS, etc.). In the first instance, water yoga and awareness of yoga versus waitlist and treatment showed benefit. Ten studies using integrated yoga, sudarshan, kriya, hatha and Iyengar techniques favoured yoga over other treatments and control groups, although the details were not reported.

Most of the SRs cited methodological weaknesses for unclear results, attributing small sample sizes and limited numbers of high-quality studies available for review. Regression analysis was used to investigate the impact of study size and quality on effect size on health outcomes (see Figure 4.2). The graphed results do not indicate consistent effect size with large or smaller studies.

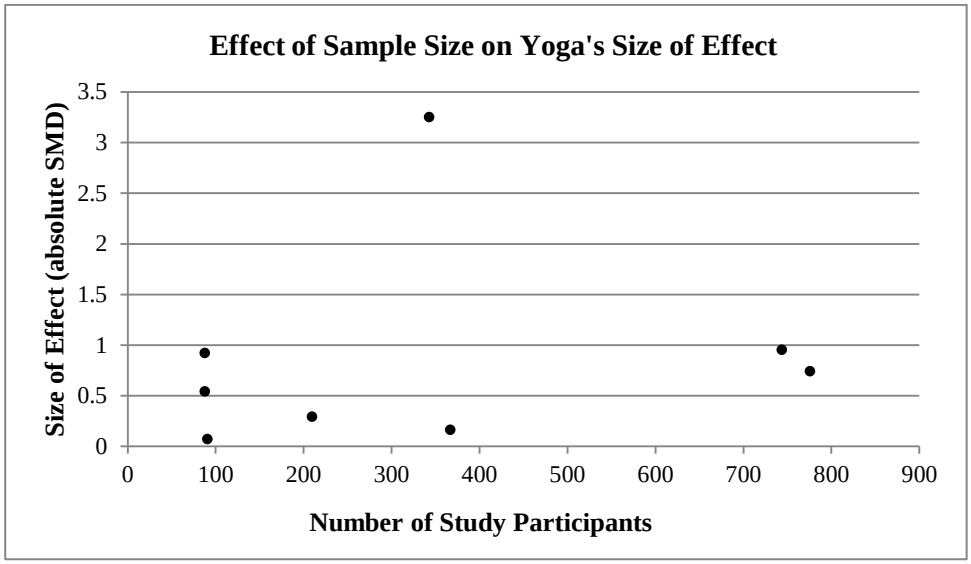


Figure 4.2. Analysis of yoga's effect on health outcomes according to sample size

4.5.3 Limitations of the Overview

The quality and quantity of evidence was a limitation to this overview. Though the quality of systematic reviews was high (9.4 AMSTAR), the quality of evidence included in reviews was generally low (GRADE). Important variables such as population statistics including gender, age, duration of interventions, comorbidities and socio-economic status were not consistently reported in SRs or their primary studies, limiting the potential for subgroup and meta-analyses. Furthermore, the descriptions of yoga interventions were insufficient to analyse which of its components are more or less effective for outcomes. Of the primary and secondary outcome measures attempted in this overview, no existing data for all-cause mortality, hospital referral rates, cost-effectiveness or psychosocial-behavioural changes were found.

In the two reviews that assessed publication bias, one funnel plot in pain outcomes[133] did not reveal publication bias, while the other review for psychiatric

disorders presented an asymmetric plot, indicating potential publication bias[134]. The other SRs did not provide results of Egger's regression, a funnel plot or critical analysis of publication bias, therefore the degree to which positive outcomes are influenced by publication bias is unknown.

As all SR reports were written in English and the majority of reviews found on electronic databases included studies from academic journals published in the west, it is possible that existing reviews have been missed. The transferability of results may be limited due to only partial descriptions of interventions such as asana, pranayama and meditative techniques. A broader definition of 'systematic review' might have increased the number of reviews included from diverse backgrounds though the imposed criteria limited the inclusion of low-quality reports. Missing data for follow-up measures, characteristics of yoga intervention and components of yoga therapy in the SRs limit the number of conclusions that can be drawn from this overview. The lack of data could be attributed to weaknesses in reporting of primary studies and not necessarily a flaw in the SR methodology.

4.5.3.1 Sources of heterogeneity

SR authors expressed concerns about the extensive variation in types of yoga intervention, the population sample, outcome measures, measuring instruments and study designs as sources of heterogeneity. As a result of this heterogeneity, SR authors considered data from independent studies in most cases (n=20). In pooled results (n=6), the amount of heterogeneity was measured (n=4) and deemed significant in three cases. Excessive heterogeneity limited the comparison across results, and future overviews or SRs may impose strict criteria on outcome measures or types of interventions to improve the chance of a more homogenous set of data.

4.5.3.2 Search date

As indicated by the bibliometric analysis in Chapter 3, the rate of yoga publications in health care is increasing rapidly. This systematic search was current as of 1 June 2012 and reviews published afterwards are excluded from a full analysis. An updated title search (31 July 2014) identified 102 potential review articles published between June 2012 and July 2014. Twenty-seven abstracts were reviewed. Three articles identified for inclusion were Cochrane Reviews seeking to determine the effectiveness for yoga for improving health-related quality of life in haematological malignancies[157], coronary heart disease[158] and primary prevention of cardiovascular disease[159]. Review authors concluded there is existing evidence to suggest yoga lowers diastolic blood pressure, HDL cholesterol and triglycerides, while current data provides little information on sleep or other health-related quality of life factors in haematological cancer. Four yoga-based Cochrane Review protocols were recently published including: yoga for schizophrenia[160], yoga treatment for chronic non-specific low-back pain[161], yoga for asthma[162] and yoga for women diagnosed with breast cancer[163]. In addition to the Cochrane titles, SRs in adult cancer[164-166], anxiety disorders[167,168], depression[169,170], asthma[162], chronic obstructive pulmonary disease[171], hypertension[172], phantom limb pain[173] and schizophrenia[174] met the criteria for inclusion within this overview. In the eligible non-Cochrane SRs (n=12), authors reported a positive impact of primary outcome measures following yoga intervention with no reported adverse effects. The conclusions of these SRs, however, remain tentative as authors stated that better quality research and larger sample sizes are needed to confirm findings.

4.5.4 Implications of Findings

The components of yoga intervention and their effect sizes on outcome measures of yoga have not been generously reported in existing literature. As supported from earlier evidence in Chapter 3, depression, pain and anxiety are frequent outcome measures following yoga intervention, and findings from this overview suggest their inverse correlation. However, this overview does not provide strong evidence to support the use of yoga intervention in populations with cardiovascular risk factors, fibromyalgia and autoimmune disease. Five SRs have indicated a positive effect for health outcomes in cancer populations. The findings in Chapter 3 and this overview suggest there are a cluster of symptoms to which yoga may provide benefit, including pain, anxiety, depression, fatigue and sleep. These combined measures affect a patient's overall health-related quality of life (HRQoL)[175]. Therefore, this outcome measure in adult cancer is an area for further research.

4.5.5 Health-Related Quality of Life

Health-related quality of life (HRQoL) includes concepts of optimal mental, physical wellbeing, personal roles (e.g. work, parent, career), social functioning, perceptions of health, fitness, life satisfaction and a patient's level of satisfaction with treatment, outcome and health status with future prospects[175]. Quality of life indicators help to answer the questions of whether the treatment leads to a life worth living, by providing a more patient-led baseline against which the effects of the intervention can be evaluated[176]. In national health care systems where budgets constrain the medical treatments and interventions available to patients, institutes focus on treatments that improve the quality and length of one's life[177]. The measurement of

HRQoL is encouraged and accepted as a primary endpoint in clinical trials of cancer patients, especially in palliative treatment[178,179].

4.5.6 Cancer Incidence and Complementary Care

There were 14.1 million new cancer cases and 32.6 million people living with cancer worldwide in 2012[180]. In addition to conventional treatment, which includes radiotherapy, hormone therapy, chemotherapy or surgery[181], cancer patients seek out complementary and alternative medicines (CAM) such as herbal remedies, vitamins/minerals, medicinal teas, spiritual therapies and relaxation techniques[182]. Adult cancer patients perceive CAM as an additive therapy to increase their body's ability to fight cancer and a means to improve physical and emotional wellbeing[183]. In Canada, 48% of patients use CAM therapy during cancer treatment – a rate 8% more than the worldwide average[184]. In response to the surge in patients seeking complementary care, oncologists are adapting behaviour to include integrative approaches, depending on their interest, knowledge and skills in supporting patients with CAM decisions[185].

The prevalence and perceptions of yoga in cancer treatment are relatively unknown at this time, though results from this evidence synthesis suggest it is an emerging field of interest. The high incidence of cancer diagnosis worldwide and frequency in which complementary therapies are accessed in adult cancer patients collectively suggest yoga intervention may provide significant impact in this population. The pursuant research question of this thesis is, therefore, includes the development of yoga intervention to improve HRQoL in adult cancer.

4.6 CHAPTER SUMMARY

- Systematic overviews are useful to evaluate the quality and direction of evidence, though the quality and quantity of available data from existing systematic reviews can limit the number and certainty of conclusions.
- Weighting the quality of evidence is an important aspect of evaluating the effects of yoga intervention, but this is not currently standard practice.
- Future articles should improve reporting of yoga interventions including its components, variation in effect sizes, patient barriers to compliance and longer-term follow-up measures (> 6 months).
- Findings of this overview support earlier claims that yoga intervention can improve depression, pain and anxiety in adult populations.
- This overview adds that yoga may improve management of pain, anxiety, fatigue, depression or other symptoms experienced by patients simultaneously.
- Sufficient research evidence and epidemiological data has been synthesised to warrant further investigation into yoga intervention and its potential efficacy for improving health-related quality of life in adult cancer patients.

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CHAPTER FIVE

Component Analysis

5 COMPONENT ANALYSIS

5.1 BACKGROUND

Findings from Chapter 3's bibliometric analysis and Chapter 4's overview of systematic reviews suggest that yoga intervention for adult cancer to improve their health-related quality of life (HRQoL) is an emerging area that warrants further study. In evidence-based terms, the synthesis of research until this point has established the 'population' and 'outcome measure' of interest for the research question. In accordance with the MRC's framework[1], the next phase in the development of such a yoga protocol for a randomised controlled trial (RCT) is the modelling of its outcomes and processes.

The modelling of yoga intervention in health care is in its early stages of development[186-189]. Based upon reviewed literature for guidelines for yoga protocols in randomised trials[36,190], there are no existing studies that provide implementation guidelines or cost-benefit analyses of yoga intervention delivery in a cancer setting. The best available guideline for yoga intervention has been developed from a systematic approach established in acupuncture research. Its author suggested the multiplicity of styles, in both yoga and acupuncture, require the "researcher to consider the type…the components to include…as well as the dose to be delivered (frequency, duration of practice and the total duration of practice). Other outlined protocol issues include the selection of instructors and monitoring fidelity to the intervention"[36]. An illustration of this existing guide has been provided for the purposes of this analysis (see Figure 5.1).

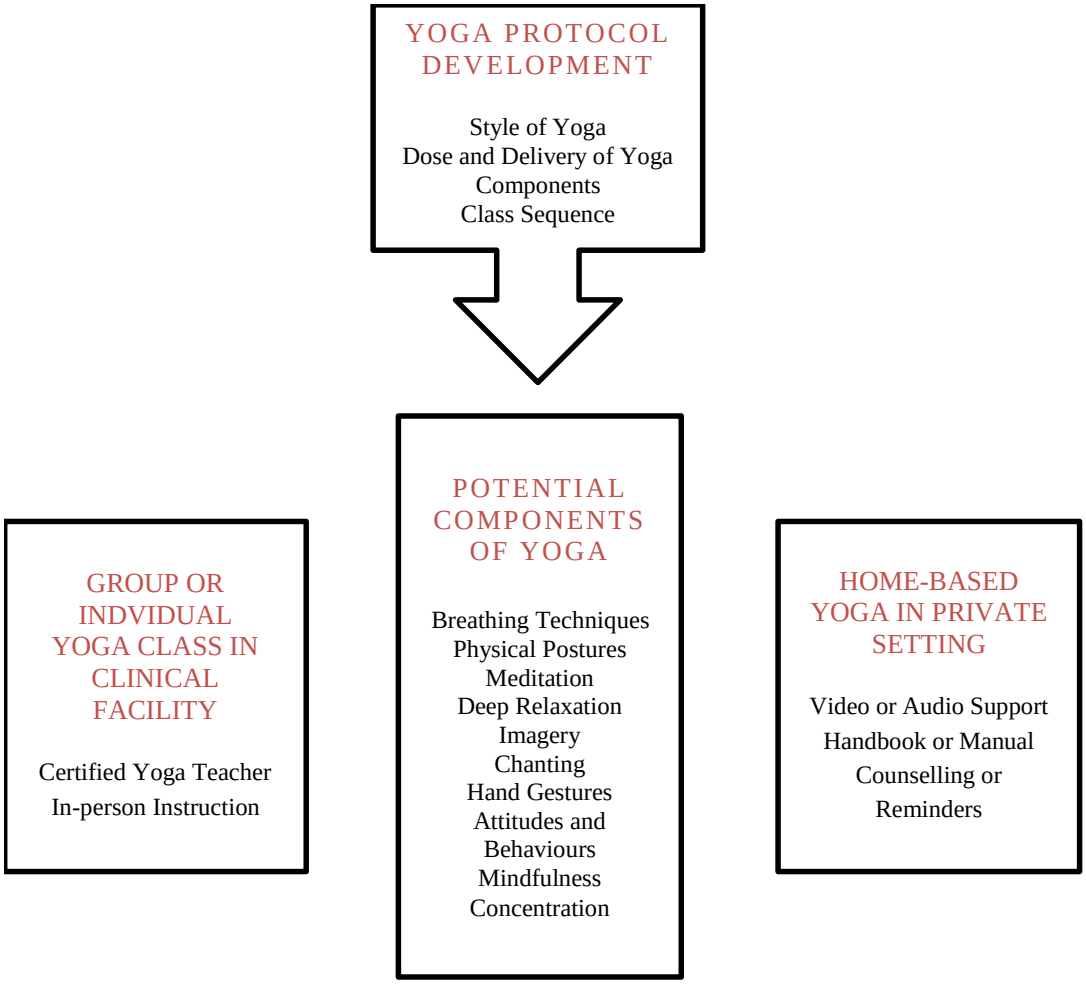


Figure 5.1. Preliminary model of yoga intervention

The strength of this current model is that it considers yoga as currently practiced in various adult health conditions including cardiovascular disease (CVD), back pain and cancer. However, the empirical data to determine the specific dose, type or duration of yoga intervention in adult cancer have not been considered to date. As such, this framework is useful to guide protocol development in general terms, but more specific information is required to construct an evidence-based model of yoga intervention for adult cancer patients.

5.2 CHAPTER AIM AND OBJECTIVES

The overall aim of this chapter is to synthesise existing evidence to develop a model of yoga intervention in adult cancer patients. The objectives of this chapter are to describe the characteristics of yoga intervention, its delivery and processes of implementation as found in other clinical trials to improve health outcomes in adult cancer.

5.3 METHODS

A component analysis of yoga intervention was performed using a systematic search for full-scale RCTs conducted in adult cancer patients. A subgroup analysis including meta-analyses of data was planned to determine the optimal conditions and characteristics of yoga intervention to improve health of adult cancer patients. Data from relevant reviews excluded for small sample sizes were considered in the discussion section only.

5.3.1 Inclusion Criteria

Studies that involved male and female adult cancer patients (18 years of age or older) undergoing conventional treatment for a cancer diagnosis were included. Any trial that adequately randomised participants ($n \geq 50$) to a yoga intervention or a comparison group were included. RCTs that reported changes in a health-related primary outcome measure (i.e. effect size, difference in means) in adult cancer patients were included. Studies that did not blind participants to group allocation were admitted due to the inherent difficulty in masking yoga intervention. Only articles published in English were included and this is considered a limitation to the analysis.

5.3.2 Exclusion Criteria

RCTs conducted in cancer survivors or healthy participants not receiving conventional treatment for adult cancer were excluded. Trials that involved other complementary or mind-therapy interventions (i.e. meditation, mindfulness-based stress reduction (MBSR), acupuncture, tai chi, reiki) were excluded to ensure a component analysis of yoga-only interventions. Non-randomised trials and small studies (n<50) were excluded as a strategy to limit susceptibility of bias and improve generalisability of results, a weakness identified from the overview in Chapter 4's analysis.

5.3.3 Search Strategy

Four online databases (Ovid MEDLINE, AMED, Embase, PsycINFO) were searched simultaneously through the Oxford Libraries Information Platform (OxLIP+). In addition, the National Database of Indian Medical Journals (IndMED)[191] was searched. Other sources of RCTs included references from systematic reviews (SRs) and bibliographies from related textbooks.

The online search was conducted using a free-text strategy (current as of 3 December 2013). Free-text terms and limitations were as follows: [(*yoga*) AND (*neoplasm* OR *cancer*) AND (*treatment*)]; limits of (age 18 years and older), (randomised controlled trial).

5.3.4 Data Analysis

The included studies were analysed for their characteristics of protocol, yoga components and effect sizes on primary outcomes measures. Their qualitative results were tabulated for frequency and descriptions of yoga interventions were transcribed verbatim from the RCT. A meta-analysis of size of effect for primary outcome measures and component subgroup analyses of yoga intervention was planned with consultation from a statistician for appropriate methods (BS). If data reporting was sufficient, a forest plot[192] would have been generated using Review Manager 5 software[193]. Data from relevant but excluded studies (i.e. non-randomised yoga interventions in small samples of cancer survivors) were retrieved for discussion purposes only, given a limited amount of data from included studies.

5.4 RESULTS

The title search yielded 2,122 results; 1,902 titles were excluded because their subject was not related to yoga in adult cancer patients. The abstracts (n=49) from selected titles were reviewed. Twenty-one full articles were retrieved for an inclusion assessment and studies were excluded with reasons (n=12) (see Figure 5.2). Nine RCTs were retrieved for the component analysis. Of the RCTs included, however, six of the authors reported data from the same population sample and yoga protocol. The apparent duplicate studies are included here for descriptive purposes (n=6), but data from one study of duplicate protocols and samples was included in the full analysis, resulting in five included studies for full consideration.

Most of the excluded RCTs had small sample sizes (n<50)[194-201] of cancer survivors[194-197,]. The studies with small sample sizes were set aside and analysed

separately. One excluded RCT administered an intervention other than yoga[204]. After an extensive online search in Oxford libraries and the journal itself, one full-text article was not found in the referenced journal[205].

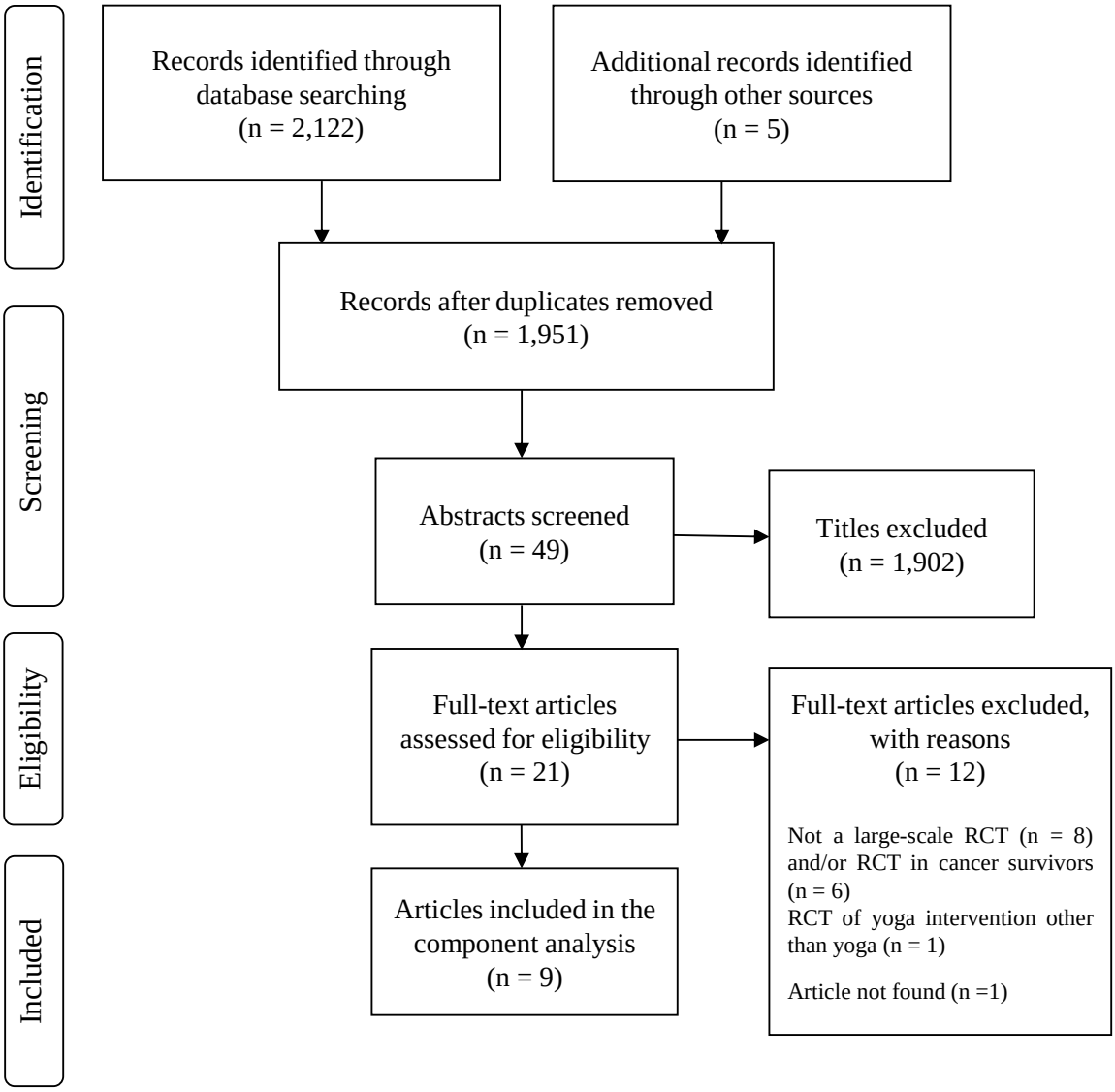


Figure 5.2. Article flow diagram for component analysis

5.4.1 Characteristics of Participants

The study participants ranged from 28 to 65 years of age. The yoga interventions were all conducted in women with breast cancer (n=9). The study participants were undergoing active conventional treatment for cancer (Stage I to IV), which included radiotherapy, chemotherapy, hormone therapy or surgery. See Table 5.1 for a summary of the patient characteristics.

5.4.2 Characteristics of Interventions

The summary of characteristics of yoga intervention according to type, components and duration are listed in Table 5.1. Integrated yoga (n=8) and hatha (n=1) were reported across the included RCTs. All interventions (n=9) included breathing techniques, physical postures and meditation. The majority of studies (n=8) also included mindfulness or mind-body awareness techniques, attitude coaching, deep relaxation and some aspect of chanting, hand gestures (mudras) or imagery as part of the intervention.

Yoga delivery across the studies included in-person instruction with a certified yoga teacher in a clinical setting. Group classes (less than six participants per session) were delivered in at least two cases, though individual sessions (n=7) and at-home practices (n=9) were most frequently reported. The tabulation of data exposed an exceptionally homogenous data set, and led to a speculation that the majority of studies (n=6) be replicate study groups. The data has been presented from all found studies, although the analysis excluded repeat authors.

Table 5.1. Summary of participants in included yoga RCTs

Author, year	Sample Size	Age (in years)			Disease Progression	Conventional Treatment
		mean	s.d	range		
Banerjee 2007[206]	58	44	1.3	n.r	Stages II, III	Chemotherapy, radiotherapy, surgery
Moadel 2007[207]	128	54.8	10	28>75	Stages I-IV	Chemotherapy, radiotherapy, surgery, hormone therapy
Raghavendra 2007[208]	62	n.r	n.r	n.r*	Stages II, III	Chemotherapy
R.Rao 2009[209]	98	n.r	n.r	n.r	Stages II, III	Chemotherapy, radiotherapy, surgery, hormone therapy
R.Rao 2008a[210]	98	49.2	9.6	40>58	Stages II, III	Undergoing surgery
R.Rao 2008b[211]	98	49.2	9.6	40>58	Stages II, III	Recovering from surgery
Vadiraja 2009a[212]	88	n.r	n.r	37.4>58.7	Stages II, III	Surgery (n=88), radiotherapy (n=16), chemotherapy (n=58)
Vadiraja 2009b[213]	88	n.r	n.r	37.4>58.7	Stages II, III	Surgery (n=88), radiotherapy (n=16), chemotherapy (n=59)
Vadiraja 2009c[214]	88	n.r	n.r	37.4>58.7	Stages II, III	Surgery (n=88), radiotherapy (n=16), chemotherapy (n=57)

*age of participants for inclusion 30>70; n.r = not reported; s.d = standard deviation; all studies included only women with breast cancer; shading indicates data included in the full analysis (i.e. excludes duplicate studies)

Table 5.2. Summary of interventions in included yoga RCTs

Author, year	Dose and Delivery				Components of Yoga Intervention						
	Duration of Total Intervention (in weeks)	Frequency of Yoga Exposure (i.e. no. of sessions per week)	Duration of Yoga Intervention per session (in minutes)	Total Estimated Time of Yoga Exposure (in hours)	Pranayama (breathing exercises)	Asana (physical postures)	Dhyana (meditation)	Pratyahara (interiorisation of the mind and/or awareness)	Attitudes and Behaviours (Yama and Niyama)	Nidra (deep relaxation)	Other
Banerjee 2007[206]	6	n.r	90	9	•	•	•	•	•	•	Chanting
Moadel 2007[207]	12	1	90	18	•	•	•				
Raghavendra 2007[208]	n.r	3 to 6	60	24	•	•	•	•	•	•	Chanting, imagery, mudras
R.Rao 2009[209]	6	1 to 2	30 to 60	6	•	•	•	•	•	•	Imagery
R.Rao 2008a[210]	n.r	1 to 3	30 to 60	1 to 10	•	•	•	•	•	•	Imagery
R.Rao 2008b[211]	n.r	1 to 3	30 to 60	1 to 10	•	•	•	•	•	•	Imagery
Vadiraja 2009a[212]	6	3	60	18 to 24	•	•	•	•	•	•	Mudras
Vadiraja 2009b[213]	6	3	60	18 to 24	•	•	•	•	•	•	Mudras
Vadiraja 2009c[214]	6	3	60	18 to 24	•	•	•	•	•	•	Mudras

Note: shading indicates data included in the full analysis (i.e. excludes duplicate studies)

The material support for home practices included distribution of audiotape or compact disc and booklets to participants. Home visits and telephone calls by trained yoga instructors were also implemented at weekly intervals to improve adherence and safety of the at-home practice (n=5). The provision of online yoga was not reported in any of the current RCTs. The specific class sequencing was not published in any of the collected RCTs. However, reference to one textbook[215] was included to guide delivery of integrated yoga. In terms of special instructions, appropriate care for surgery-associated side effects such as numbness or pain[206] was acknowledged in one study, and other reported modifications included physical posture that were done in a seated or reclined position to address the special needs of cancer patients[207,208].

The amount of yoga delivered to adult cancer patients ranged from one to 24 hours of yoga over six to 12 weeks. Studies most frequently delivered 60-minute sessions three times per week. Some interventions included as little as 30 minutes and as much as 90 minutes of yoga per session. The minimum reported exposure of yoga to study participants was for 60 minutes per week over six weeks. The maximum amount of yoga dispensed to participants was four hours per week, over six weeks of intervention.

5.4.3 Characteristics of Comparators

Eight of the RCTs included active comparisons of supportive counselling. Two of the active comparator RCTs also implemented some aspect of exercise rehabilitation (see Table 5.3). One study[207] randomised cancer patients to a yoga group or waitlist control group. The size of effect did not appear to be influenced by an active (i.e. supportive counselling) or non-active (i.e. waitlist) comparator. Sham yoga or other attempts at placebo-control groups were not reported in this set of trials.

5.4.4 Outcome Measures

The studies analysed for yoga's effect on primary outcome measures included: anxiety (n=3), quality of life (HRQoL) (n=2), nausea (n=1), post-operative outcomes (n=1), mood affect (n=1), and cortisol levels (n=1) (see Table 5.3). The instruments to measure the outcomes included STAI[216], HADS[217], FACT-G[218], RSCL[219], MANE[220], PANAS[221] and diurnal salivary cortisol levels. An excessive amount of heterogeneity reported for outcome measures prevented the pooling of results or subgroup analyses. With the exception of one study measuring HRQoL[207], authors reported yoga intervention had a consistently positive effect in adult cancer patients. No adverse effects were reported.

In one of the studies with a negative result, the FACT-G instrument was used to report the quality of life[207]. This study's results indicated a decrease of 1.3 points in the yoga group from 76.5 (±18.5) to 75.2 (±18.9), while the waitlist control group registered a greater decrease of 4.46 points in the FACT-G score over time, from 74.4 (±23.2) to 69.94 (±19.39). These findings suggest that while yoga intervention did not improve HRQoL, it may have mitigated against a further loss of HRQoL by 3.16 points (see Table 5.3).

The strongest effect size (0.84, $p<0.01$) for yoga intervention was in decreasing negative affect[213] for women in treatment for breast cancer. One further study reported a 48% improvement ($p<0.001$) in anxiety in the yoga group of breast cancer patients versus the control group. The control group's anxiety increased after receiving supportive counselling and advice to take exercise intervention[206]. Most of the studies measured outcomes after six weeks of intervention; one study collected measures after 12 weeks of intervention. RCTs did not report follow-up measures.

Table 5.3. Summary of comparators and outcome measures in included yoga

Author, year	Sample Size	Primary Outcome	Instrument	Comparison		Yoga Group				Control Group				Effect Size	% change in means	SMD	95% CI	*p*-value
				Type of Comparator	Description	Pre (mean)	s.d.	Post (mean)	s.d.	Pre (mean)	s.d.	Post (mean)	s.d.					
Banerjee 2007[206]	58	Anxiety	HADS-A	Active	Supportive counselling and advised to take exercise	8.5	1.6	4.1	1.0	8.2	1.1	10.5	1.8	n.r*	48			<0.001
Moadel 2007[207]	128	Quality of life	FACT-G	*Non-active*	Waitlist	76.5	18.5	75.2	18.9	74.4	23.2	69.94	19.39	-0.09			-8.05 to 2.63	n.r
Raghavendra 2007[208]	62	Nausea (frequency)	MANE	Active	Supportive counselling			3.6	1.6			4.5	0.9	n.r				
R.Rao 2009[209]	98	Anxiety post-chemotherapy	STAI	Active	Supportive counselling			24.1	3.1			33.1	10.5	n.r				<0.001
R.Rao 2008a[210]	98	Anxiety post-surgical intervention	STAI	Active	Supportive counselling and exercise rehabilitation			34	10.9		12	38.4	8.1	n.r		-2.79	-5.5 to 0.079	<0.01
R.Rao 2008b[211]	98	Postoperative outcomes	No. of days of drain retention	Active	Supportive counselling and exercise rehabilitation			4.7	1.6			6.44	2.5	n.r				0.001

Author, year	Sample Size	Primary Outcome	Instrument	Comparison		Yoga Group				Control Group				Effect Size	% change in means	SMD	95% CI	*p*-value
				Type of Comparator	Description	Pre (mean)	s.d.	Post (mean)	s.d.	Pre (mean)	s.d.	Post (mean)	s.d.					
Vadiraja 2009a[212]	88	Cortisol levels	Diurnal salivary cortisol levels (6 am)	Active	Supportive counselling	0.33	0.17	0.22	0.15	0.38	0.31	0.36	0.24	0.24				<0.05
Vadiraja 2009b[213]	88	Positive and negative affect	PANAS (+)	Active	Supportive counselling	24.05	7.28	27.85	7.11	21.81	7.37	23.33	8.3	0.59				<0.01
			PANAS (-)			22.15	10.6	12.91	10.39	25.22	8.82	21.85	10.86	0.84				<0.01
Vadiraja 2009c[214]	88	Quality of life	RSCL	Active	Supportive counselling									n.r**				

s.d = standard deviation; CI = confidence interval; *=study did not report results of primary outcome (48% improvement due to change in means reported); **=study did not report results of primary outcome (subscales were reported to positive effect in physical and psychological distress, fatigue, nausea, vomiting, pain, insomnia and constipation); shaded area indicates data in analysis (i.e. excluding duplicate studies)

HADS = hospital anxiety and depression scale; FACT-G = functional assessment of cancer therapy-general; MANE = morrow assessment of nausea and emesis; STAI: state anxiety inventory; PANAS = positive and negative affect schedule; RSCL = Rotterdam symptom checklist

5.4.5 Meta-Analysis

Two factors have prevented the conduct of in-depth or meta-analysis or pooling of outcome data. First, there was an excessive amount of heterogeneity of the RCTs outcome measures. Second, the sample populations in six of the included studies[209210211212213-214] appear duplicated, which eliminated essentially four studies from the analysis. A small subgroup analysis was conducted for outcome measures reported from non-duplicate studies (see Figure 5.3). The resulting differences of groups post-intervention in all reported instances indicated a positive benefit from the yoga intervention. Anxiety outcome measures in patients undergoing chemotherapy, radiation and surgical intervention (n=156)[206,209] for cancer were negatively correlated with the practice of integrated yoga for six or more hours when compared to supportive counselling. The frequency of nausea in chemotherapy patients (n=62) also decreased more following a yoga intervention than in an active control group[208]. The quality of life of cancer patients in stages I to IV (n=128) benefitted from practicing hatha yoga when compared to a waitlist control group[207].

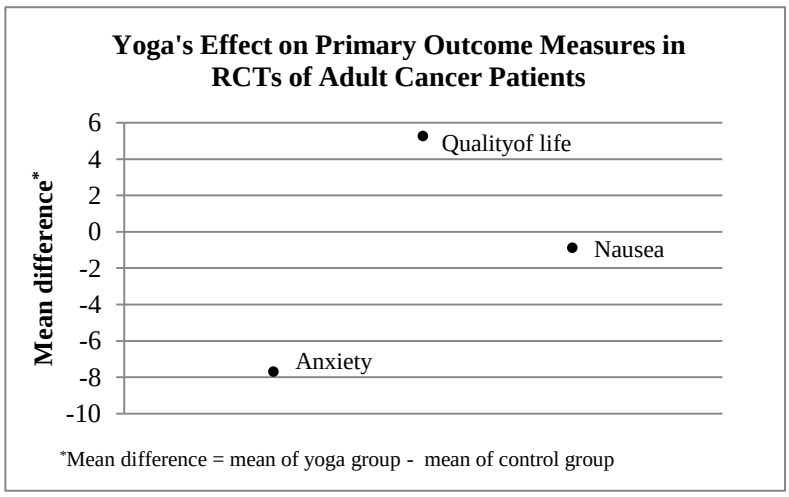


Figure 5.3. Yoga's effect on primary outcome measures in RCTs of adult cancer patients

5.5 DISCUSSION

5.5.1 Summary of Findings

Of 1,951 titles identified for inclusion after a broad free-text search across five online databases (Ovid MEDLINE, AMED, Embase, PsycINFO, IndMED), only 21 full-text articles were assessed for eligibility, and nine articles were included in the final component analysis. Of the included articles (n=9), a duplicate sample was identified in six of the studies. The included sample populations were of female patients (100%, n=434) receiving chemotherapy, radiotherapy, hormone therapy or surgical intervention for a breast cancer diagnosis.

A component analysis indicated that integrated yoga or hatha yoga delivered one to three times per week for 30 to 90 minutes can provide improvements in anxiety, frequency of nausea, mood affect, quality of life, post-operative outcomes and cortisol levels. These results were reported following six to 12 week interventions. In most instances (n=8) studies compared yoga to an active control group that included supportive counselling alone (n=8) or exercise (n=3). All of the yoga interventions conducted in a clinical setting provided in-person instruction from a certified yoga teacher. Home-based practices were encouraged through supportive material that included audiotapes, booklets and telephone or home visits from yoga instructors. The yoga classes included breathing techniques (n=9), physical postures (n=9) and meditation (n=9). All but one study also reported using mind-body awareness techniques, deep relaxation, imagery, chanting, mudras (hand gestures) and principles of yoga philosophy including ahimsa (non-harming).

Several factors arising from the data, including an excessive heterogeneity of reported outcome measures, paucity of research and poor reporting of protocols

prevented the planned meta-analysis to determine the most effective components of yoga intervention.

5.5.2 Results from Excluded Studies

Ten of the excluded studies did not meet inclusion criteria for the component analysis because of their small sample sizes (n=8), and/or their sample included cancer survivors (n=6). These studies were excluded due to their potentially insignificant or underpowered results for outcome measures in adult cancer patients receiving conventional treatment. However, due to the paucity data that were collected to model yoga intervention for tumour types in patients other than women with breast cancer, the excluded reviews (due to sample sizes or non-randomisation) were also reviewed to assess their components of intervention and protocol.

In eight smaller studies (n<50), hatha, Iyengar, pranayama (breathing only), restorative yoga, viniyoga and 'yoga in awareness' and 'yoga in daily life' were reported (see Table 5.4). The yoga dosage ranged from as little as one session (60 minutes) to seven sessions (45 minutes) per week. Two studies delivered 120-minutes yoga session once per week. The key components were similar to the larger studies and included: breathing exercise, physical postures and meditation. However, one study of male and females (n=16) tested the efficacy of pranayama-only to improve cancer-related symptoms in chemotherapy patients. These studies indicated positive direction of effects for the following primary outcomes: fatigue and menopausal symptoms in breast cancer survivors, pain in patients with metastatic breast cancer, psychological health and wellbeing of cancer survivors and quality of life in obese breast cancer survivors. Five of the excluded studies compared yoga intervention to a non-active waitlist control or standard care.

Table 5.4. Summary of populations, interventions and comparisons of excluded studies

Author, year	Sample Size	% women sample	Primary Outcome Measure and Population	Instrument	Clinical Yoga Interventions			Comparisons			Direction of Results	
					Style	Dose (sessions per week)	Components	Active	Non-Active	Description	Positive Effect	No Effect
Bower[§] 2012[194]	31	100	Fatigue in breast cancer survivors	FSI	Iyengar	90 (2)	Breathing techniques, supportive postures	•		Health education	•	
Carson 2009[195]	37	100	Menopausal symptoms in breast cancer survivors	VAS	Yoga of awareness	120 (1)	Breathing exercise, gentle yoga postures, meditation, didactic presentations, group interchange (n=5 to 10)		•	Waitlist	•	
Carson 2007[196]	21	100	Pain in patients with metastatic breast cancer	VAS	Yoga of awareness	120 (1)	Breathing exercise, gentle yoga postures, meditation, didactic presentations, group interchange (n=5 to 7)	n.r			•	
Culos Reed[§] 2006[197]	38	92	Psychological health and wellbeing of cancer survivors	EORTC,-QLQ-C30 SOSI, POMS	Hatha	75 (n.r)	Gentle stretching and strengthening exercises, relaxation, focus attention on breathing and internal sensations of the body in group classes (n=10)		•	Waitlist	•	
Dhruva[§] 2012[198]	16	87.5	Cancer-related symptoms in chemotherapy patients	PFS, GSDS, PSS, HADS, SF-12	Pranayama	60 (1)	Breathing techniques		•	Waitlist (and crossover)	•	
Kovačič[§] 2011[199]	32	100	Psychological distress in breast cancer patients following surgery	GHQ-12, RSCL, PSS	Yoga in daily life®	45 (7)	Breathing techniques, dynamic and static postures, relaxation techniques, progressive muscle relaxation, deep relaxation and meditation techniques in groups (n=3)	•		Standard physiotherapy	•	

Author, year	Sample Size	% women sample	Primary Outcome Measure and Population	Instrument	Clinical Yoga Interventions			Comparisons			Direction of Results	
					Style	Dose (sessions per week)	Components	Active	Non-Active	Description	Positive Effect	No Effect
Littman[§] 2012 Error! Bookmark not defined.	63	100	Quality of life in obese breast cancer survivors	FACT-G	Viniyoga	75 (1)	Centering exercises to promote relaxation and internal focus, seated and standing poses, guided relaxation, breathing exercises and meditation		•	Waitlist		•
Mustian[§] 2013 Error! Bookmark not defined.	410	96	Sleep quality in cancer survivors	PSQI	Yoga for cancer survivors program (YOCAS)	75 (1)	Breathing exercises, 16 gentle hatha and restorative yoga postures and meditation		•	Standard care	•	
Rosenbaum 2004[200]	398	100	Program evaluation to improve quality of life in cancer patients	Attendance rate to supportive care	Restorative yoga	n.r (2)	Restorative yoga poses likened to 'active relaxation'	n.r			•	
Ulger 2010[201]	20	100	Quality of life in breast cancer patients	NHP	Classical yoga program	60 (2)	Breathing exercises, asanas, relaxation and meditation in a supine position	n.r			•	

Dose = time per session in minutes (no. of session per week); 'components' of yoga interventions are verbatim from authors' explanation; adverse or negative effects were not reported across studies (n=0); n.r = not reported; § = randomised controlled trial

FSI = fatigue symptom inventory; VAS = visual analogue scale; EORTC-QLQ-C30 = 30-item quality of life scale; SOSI = symptoms of stress inventory; POMS = profile of mood states; PFS = Piper fatigue scale; GSDS = general sleep disturbance scale; HADS = hospital anxiety and depression scale; PSS = perceived stress scale; SF-12 = quality of life scale; GHQ-12 = general health questionnaire; RSCL = Rotterdam symptom checklist; FACT-G = functional assessment of cancer therapy-general; PSQI = Pittsburgh sleep quality index; NHP = Nottingham health profile

5.5.3 Advancing the Model of Yoga Intervention

The analysis of available RCTs indicated three fundamental components of yoga intervention: breathing techniques, physical postures, and meditation. Mind-body awareness, deep relaxation, chanting, imagery, and the practice of mudras (hand gestures) were components also identified in the current literature of yoga protocols.

In terms of style, dose and delivery of yoga, hatha-based or integrated yoga practices appear to have been safely administered to some positive effect in cancer patients. Certified yoga instructors administered group classes in all studies, varying in yoga exposure from as little as one to as many as seven times per week, for less than 30 minutes to 120 minutes per session over a minimum period of one week to a maximum study period of 12 weeks (see Box 5.1).

Box 5.1 Characteristics of yoga intervention from results of a component analysis

Type: Hatha or Integrated Yoga
Dose: 30 to 120-minute session; 1 to 7 times per week
Duration: 6 ≥12 weeks
Instructor: Certified Yoga Instructor
Required Components: Breathing Techniques, Physical Postures and Meditation
Mode of Delivery: In-person instruction in a group setting
Supportive Material: Home-based audio-video material and illustrated manual

A specific type of yoga, duration or frequency of yoga intervention did not correlate with consistently positive or non-significant results. Active (i.e. supportive counselling) or non-active comparators (i.e. waitlist) did not impact the direction of results in a consistent way. In the small studies that were excluded from the full analysis, one small study (n=16) of breast cancer patients improved HRQoL following one 60-minute of pranayama-only[198]. In a recent study, HRQoL also

improved in breast cancer patients following up to three 60-minute yoga sessions per week[222].

5.5.4 An Updated Search

The original search for relevant articles included publications on or before 1 December 2013. An updated search (5 December 2014) was performed and yielded 22 potential titles. Of these titles, one appeared to be relevant for inclusion in this component analysis[222]. The results of this study were an extension of a previous publication that was not retrievable from its online source[205]. Patients with breast cancer (stages I to III) were recruited and randomly assigned to yoga (n=53), stretching (n=56) three times a week for six weeks during radiotherapy, or waitlist control (n=54). The primary outcome measure was HRQoL (SF-36)[105]. The authors concluded the yoga group improved HRQoL and physiological changes beyond the benefits of simple stretching exercises, and these benefits appeared to have long-term durability. The yoga protocol included: up to three 60-minute classes per week; in-person instruction by a certified yoga teacher; delivery in a conference-style room located near the radiation treatment facility; flexible scheduling to accommodate patients' timetables; and an audio compact disc and written yoga program to encourage a home-based practice. The yoga components included: breathing exercises, physical postures, deep relaxation, alternate-nostril breathing and meditation.

5.5.5 Cost-efficiency of Delivering Yoga Intervention

The cost-efficiency and deliverability of a complex intervention are concerns in the development of a pragmatic RCT. However, the current evidence has not provided information on the cost or affordability of providing yoga in a clinical setting. The absence of such cost per participant data and information on the scalability of yoga for a health care setting are serious limitations in the ability to develop an adequate yoga model.

"Health research must consider social, cultural, political and economic contexts to maximize the contribution of traditional, complementary and alternative medicines to health care systems globally"[223]. As an identified gap in the current knowledge, the development of yoga intervention will need to consider two specific areas to advance completing the modelling of yoga: first, the social, cultural and personal factors of participating in yoga will need to be explored from both the patient and oncologist's perspective; and secondly, data will need to be assembled to explore the affordability, acceptability and scalability of yoga in a clinical setting. For example, in the current studies, yoga delivered has been administered in a one-on-one in-person teaching format or small groups (n<6). Modern technologies could be used to improve the scalability of yoga, and there are currently yoga-specific websites[224] with online learning platforms that could support home-based practice of yoga.

One recent pilot study in cancer survivors delivered an online stress reduction program that included yoga practice[225]. Preliminary results of this study showed participants accessed and adhered to yoga intervention via an online medium. The study authors recommended further study of this mode of delivery to improve the accessibility of yoga. In addition to this, effective yoga RCTs (n=11) used video or

audio-led yoga to support home-based practices. Hence, the provision of online visual or audio yoga might not only work to increase adherence of an at-home practice, but also decrease operational costs and limit the logistical challenges in delivering yoga in a clinical setting (i.e. adequate space, in-person instruction, scheduling).

5.5.6 Limitations of the Component Analysis

There are several limitations that impact the generalisability of this component analysis. First, there was a paucity of data in large-scale RCTs of male and female cancer patients. The bias towards female patients of breast cancer seriously limits the assumptions that could be made for other cancer populations. There is no data to report the socioeconomic status or other characteristics that may indicate a selective sample. Second, an inconsistency of reporting for outcome measures restricted the available data for pooling results. Third, six of the studies[209210211212213-214] reported findings collected from two samples of breast cancer patients. This indicated a duplication of data, especially a concern because the sample size calculation could not have been adequately powered for the numerous 'primary' outcome measures reported across the studies.

Furthermore, larger trials ($n \geq 50$) were part of the inclusion criteria, in an attempt to collect studies that were adequately powered to determine a size of effect for yoga intervention. Upon reflection, it appears that in this analysis, sample size is not a good proxy for the quality of study or its methodological rigour and therefore sample size was not an adequate filter to assist in collecting the best evidence for a component analysis. Therefore, future analyses would include clinical trials of all sizes.

This component analysis was also limited by the inclusion of studies available in English. This limitation was a result of the restricted amount of time and human resources available to conduct the analysis. A more in-depth search for studies published in Hindi or other foreign languages may improve the comprehensiveness of the study. However, to include as many studies as possible from Indian origin in the analysis, the Indian database for medical research (IndMED) was included in the search strategy.

5.5.7 Implications of Findings

A component analysis of yoga intervention for adult cancer patients has been completed with the best available evidence. Yoga protocols can be informed by the characteristics as summarised in Box 5.1, and should include components of breathing techniques (pranayama), physical postures (asanas) and meditation (dhyana). Additional aspects of yoga intervention could include mind-body awareness, deep relaxation, imagery, chanting and mudras. However, the results of this analysis are limited to two groups of breast cancer patients. The characteristics of yoga intervention and its potential outcomes in male patients, or in patients other than breast cancer, remain unclear at this time. In addition, cost implications and issues regarding access and delivery of yoga in a clinical setting have not been adequately reported in current evidence.

As a central tenet of evidence-based medicine, a patient's individual characteristics and the best available evidence (i.e. RCTs)[226] should inform decisions about efficacies of treatment[227]. While the publication rates of yoga research in health care appear to be increasing over time (see Chapter 3), the availability of high-quality evidence from RCTs of adult cancer patients is extremely limited. The results

of this component analysis reinforce the need to develop yoga intervention for a large-scale RCT in adult cancer patients. The characteristics of yoga delivery, its cost-benefits and adequate dose to improve HRQoL in cancer patients, especially in those without breast cancer remain largely unknown.

In view of the sparse quality and quantity of data available to validate a model of yoga intervention through a component analysis, data triangulation is one method to improve the completeness of the modelling process. Methodological triangulation[228,229], or the use more than one method for gathering data, is a rationale and pragmatic choice to both seek confirmation findings of this initial analysis, and facilitate a clear picture of what a yoga protocol in adult cancer should include.

In the next chapters, the modelling of yoga intervention for HRQoL in a cancer will be supplemented with data input from patient interviews (Chapter 6), oncologist surveys (Chapter 7) and yoga instructors (Chapter 8).

5.6 CHAPTER SUMMARY

- Nine yoga RCTs including three groups of breast cancer patients were included in a component analysis.
- The small samples, heterogeneity of outcome measures and lack of reporting effect sizes prevented a meta-analysis of data.
- Components highly correlated with positive effects for adult cancer patients include breathing techniques, physical postures and meditation administered by expert yoga instructors in a clinical setting, with material support (audio, video and/or booklets) to encourage a home-based practice.
- Exposure to yoga intervention ranged from 30 minutes to 120 minutes, delivered one to seven times per week (6 ≥12 weeks).
- Characteristics of yoga intervention from results of a component analysis:

Type: Hatha or Integrated Yoga
Dose: 30 to 120-minute session; 1 to 7 times per week
Duration: 6 ≥12 weeks
Instructor: Certified Yoga Instructor
Required Components: Breathing Techniques, Physical Postures and Meditation
Mode of Delivery: In-person instruction in a group setting
Supportive Material: Home-based audio-video material and illustrated manual
Comparators: Waitlist, exercise, stretching

- The evidence-based modelling of yoga intervention for health-related quality of life in adult cancer would benefit from methodological triangulation of this component analysis and data from patients, oncologists and yoga instructors

5.7 CHAPTER REFERENCES

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CHAPTER SIX

Patient Interviews

6 PATIENT INTERVIEWS

Features of this chapter are in press in the following peer-reviewed journal:

McCall, M.C., Thorne, S., Ward, A, Heneghan, C. (2015). Yoga in Adult Cancer: An exploratory, qualitative analysis of the patient experience. *Bio-Med Central.*

6.1 BACKGROUND

The component analysis of Chapter 5 was a first step to follow the Medical Research Council's guidelines to model the process and outcomes of yoga as a complex intervention in adult cancer. One recognised weakness in current evidence was the lack of study in patients with tumour types other than breast cancer. An information gap as to how other cancer patients might respond to yoga has been identified, and in particular, there is insufficient data to understand how yoga is best delivered for men and other cancer patients during conventional treatment in a clinical setting. The contextual factors including how, why and when yoga should be delivered during cancer treatment are increasingly important, but not well understood[230].

6.2 CHAPTER AIM AND OBJECTIVES

The aim of this chapter is to advance the modelling of yoga intervention in adult cancer. The research objectives of this chapter are to describe patient perception of yoga, and to explore the patient-reported benefits, barriers and characteristics of programming for yoga practice during conventional treatment.

6.3 METHODS

The in-depth semi-structured interviews were performed under naturalistic conditions with adult men and women receiving physician-supervised conventional treatment for cancer.

6.3.1 Inclusion Criteria

Adult cancer patients (18 years of age or older) using complementary therapy in parallel to conventional cancer treatment were included in the study. Domains of accepted complementary therapy included any additional therapeutic modality used to relieve the direct or indirect symptoms of cancer, such as: talk therapy, massage, acupuncture, vitamin or herbal supplementation, serious dietary modifications or yoga. Conventional treatment referred to any physician-supervised treatment for a cancer diagnosis including radiation, chemotherapy, hormone therapy, surgical intervention or active surveillance. Cancer patients who presented with co-morbidities were included unless the concurrent illnesses included serious psychoses or periods of psychotic episodes that would have posed a risk to the interviewer or validity of informed consent. All stages and any type of cancer diagnosis were included.

6.3.2 Exclusion Criteria

Patients seeking complementary care with the sole purpose to treat cancer without physician-supervised treatment were excluded. Cancer patients who were not fluent in English or French were excluded. A geographical limitation was imposed so patients who did not access treatment in Vancouver, British Columbia were also excluded.

6.3.3 Recruitment

Complementary and cancer-care centres in Vancouver, Canada were identified through an agency search online. One integrated cancer clinic was identified (InspireHealth) in Vancouver, whose administrators agreed to post advertisements and make public announcements to encourage their patients to participate in the study. In addition, complementary health care clinics (n=3) and conventional cancer clinics (n=2) agreed to post bulletins in their entrance and waiting rooms (see Appendix 6.A). Interested participants contacted the researcher via e-mail, telephone or via a web-based link and were screened for eligibility. A registration form was then e-mailed or orally communicated to participants (see Appendix 6.B) to assess participants' eligibility for the study. Eligible and ineligible participants were notified promptly or e-mailed with potential interview times.

6.3.4 Ethical Considerations

Ethical approval was provided by the University of British Columbia Behavioural Research Ethics Board (Reference: H13-01482) and the University of Oxford Tropical Research Ethics Committee (Reference: 517-13). An electronic letter of informed consent was sent to participants 48 hours before the interview meeting. Paper consent forms (see Appendix 6.C) were reviewed and signed in person at the time of interview (n=8) or audio recorded (n=2). All confidential data remain stored under lock and key (MM, AW). Participants were free to withdraw consent at any time during the study.

6.3.5 Sampling Technique

The purposive theoretical sampling technique was used to allow the researcher to maximise opportunities to compare events, incidents or happenings in a sample category[231]. This technique applied principles of maximum variation to capture and describe the central themes or principal outcomes to cut across a greater deal of participant or program variation in the population[232]. A review of patient demographic data collected in previous yoga studies from the overview of systematic reviews (Chapter 4) and a component analysis (Chapter 5) compiled a list of criteria used to construct the interview sample. These criteria were self-reported by patients at the point of eligibility screening and are listed as follows:

1. Amount of historical yoga experience
2. Disease status, including type, stage and/or location of cancer
3. Age of patient
4. Gender status
5. Occupation status
6. Highest level of education attained

6.3.6 Sample Size and Data Saturation

The recruitment end-point was defined as the moment when the interviewer could identify conceptual themes or patterns with sufficient data to address the research question. The concept of data saturation was applied to the extent that when no new patterns or concepts appeared to be expressed participants, two additional interviews were completed to verify the theoretical data saturation point. If significantly different findings were identified in the subsequent two interviews, another two interviews would have been conducted until the point at which no new or particularly

meaningful data was being collected. In addition, pragmatic parameters of data collection were established to meet time and human resource limitations, which hypothecated an allocation of 10 to 15 hours of interview time, collected from a prospective patient sample size minimum (n=8) and maximum (n=20).

6.3.7 Data Collection and Analysis

An established qualitative methodology specific to health care qualitative collection, the Interpretive Description (ID) methodology[233,234] guided the probing of individual perspectives and thematic recognition across cases. Key axioms of this inductive, naturalistic inquiry[235] are closely related to the grounded theory approach[236]. Therefore, data analysis included the generation of theories through data (rather than prior hypotheses), coding of data line by line to show action and process, and the analyst (MM, ST) sought to define categories that were later integrated into a general framework of theories[237]. The ID provided philosophical underpinnings in a health care context, and encouraged particular beliefs, such as:

1. There are multiple constructed realities that can be studied only holistically. Thus, reality is complex, contextual, constructed, and ultimately subjective.
2. The inquirer and the "object" of inquiry interact to influence one another; indeed, the knower and known are inseparable.
3. No *a priori* theory could possibly encompass the multiple realities that are likely to be encountered; rather, theory must emerge or be grounded in the data.

A reflexive journal[238] of field notes and researcher observations were used to document the reactive processes and to counter potential bias within the research process. Interpreter bias and transcription errors were minimised through audio-

recorded journaling, verbatim transcription and progressive analysis of the data over time (6 months) under supervision (CH, AW, ST). The author consistently took a larger view of 'what is happening here' and asked 'how might I be influencing this process.' Audio files were recorded on a digital memory card using the Zoom H1 Version 2.0 digital recorder and immediately deleted upon transcription to Word documents. Anonymous digital files have been encrypted and stored on a computer under password protection and a Universal Serial Bus (USB) flash drive under lock and key.

An iterative process of constant comparison methods[239] was used to develop emergent pathways to understand themes and patterns including comprehension of data to synthesise meanings to theorise relationships leading to recontexualisation of data into findings[240] during the data collection period. The interview script in the first set of interviews (n=3) was populated with open-ended questions to allow a broader spectrum of data to be collected. Over time (across interviews number four and five), the interviewer (MM) adjusted the interviewer script to streamline the data collection, to allow for more efficient and relevant collection of data (see Box 6.1 for the original set of questions and Box 6.2 for the final interview script).

Box 6.1 Original version of interview script

1. Tell me about your cancer diagnosis and treatment.
2. Why did you decide to seek complementary care for your cancer treatment? Are there other reasons?
3. I am curious about your thoughts on yoga. How do you feel about yoga?
4. Can you describe an experience in yoga, either before or now, during your cancer?
5. How often would you say you practise yoga now that you have cancer?
6. Why have you (or have not) practised yoga during your cancer treatment?
7. Tell me about your fears or concerns about doing yoga.
8. What kinds of things would have stopped you from practising yoga this week?
9. If you could imagine the perfect time and place for yoga, what would it be? What about before or after your cancer treatment? At home? In a clinic?

Box 6.2 Final version of interview script

1. Tell me about your cancer diagnosis and treatment.
2. Why did you decide to seek complementary care for your cancer treatment? Are there other reasons?
3. What complementary care therapies have you tried? What are you currently doing?
4. Have you experienced any harm or benefits from complementary therapy?
5. I am curious about your thoughts on yoga. How do you feel about yoga?
6. Why have you (or have not) practised yoga during your cancer treatment? Tell me about your fears or concerns about doing yoga.
7. What kinds of things stop you from practising yoga?
8. If your doctor recommended yoga, would you be more inclined to do it?
9. Who do you think should practise yoga and when should they do it?
10. Do you think yoga would be helpful if practised before or during a cancer treatment?
11. What kind of person might not do yoga?

Yoga-users only:

12. What are the most important parts or components of yoga for you?
13. What is it about the atmosphere or class structure of yoga that works for you?
14. Has doing yoga ever aggravated a symptom or health-related issue for you?

All interviewees:

15. Can you tell me about any emotional or spiritual impact of cancer on your life?
16. How has cancer or its treatment impacted you financially?
17. Is there anything you would like to change about your treatment plan?
18. Is there more you would like to share about your experience with cancer and its treatment?

The full data analysis was conducted one-week after the final interview was conducted. This process was facilitated by implementation of the Qualitative Analysis Guide of Leuven (QUAGOL)[241], where the material was reviewed firstly for accuracy, and then secondly for content and coding (MM). This included colour-coding and re-reading of all interview transcripts for themes and pattern recognition across cases. The codes and themes were reviewed by a second analyst (ST). The NVivo 10TM (QSR International, Doncaster, Victoria, Australia) software assisted the management of digital data.

6.4 RESULTS

The study was conducted over a six-month period from September 2013 to March 2014. Ten of 11 patient volunteers were eligible to participate in the interview study. One female participant was ineligible to participate in the study since she was no longer receiving treatment for breast cancer. The interviews took place in an integrated cancer care clinic (n=7), over the telephone (n=2) and at one patient's home. Individual interview sessions lasted between 43.4 and 103.5 minutes with an average of 75.1 minutes for women and 49.4 minutes for men interviewees. A total of 11 hours 15 minutes of interview data was analysed for themes and patterns.

6.4.1 Characteristics of Participants

Men (n=3) and women (n=7) cancer patients receiving conventional and complementary care for a current diagnosis participated in the study. Age of participants ranged from 44 to 71 years (average age of 60.1 years). Participants were retired (n=5), on disability leave (n=3), working at reduced hours (n=1) or employed full-time (n=1). The characteristics of participants are summarised in Table 6.1. Nine participants completed college or university degrees; one participant's highest academic achievement was a secondary school diploma.

All participants had practised yoga at least once in their lifetime and seven participants were currently participating in yoga during cancer treatment. Four of the seven yoga participants reported they had not practised yoga prior to receiving a cancer diagnosis. Of the seven yoga-users, men (n=2) and women (n=5) attended the same 60-minute restorative yoga class provided three times per week in a private cancer care facility.

Table 6.1. Participant characteristics

Patient	Sex	Age	Tumour Diagnosis	Stage	Current use of Complementary Therapies
1	M	71	Multiple Myeloma	n.r	Yoga, meditation, exercise
2	F	52	Breast	II/III	Yoga, massage, acupuncture, nutrition, vitamin C injections, mistletoe
3	M	56	Prostate	IV	Budwig diet, talk therapy, medical marijuana, meditation, exercise
4	F	65	Breast	II	Yoga, herbal remedies, neuro-integrative science
5	M	70	Prostate	n.r	Yoga, vitamin D, hiking
6	F	44	Breast	II	Yoga, massage, nutrition
7	F	67	Myelodysplastic Syndrome	IV	Exercise, nutrition
8	F	50	Breast	I	Yoga, talk therapy, nutrition, exercise
9	F	58	Breast	IV	Yoga, meditation, nutrition, hiking
10	F	68	Melanoma	n.r	Talk therapy, nutrition, exercise

n.r = patient unsure or did not wish to report; Budwig diet = natural foods for tumours and degenerative diseases, especially flaxseed oil and quark[242]; neuro-integrative science = neurobiology of cognitive semantics, emphasising role of nervous system

6.4.2 Thematic Analysis

Four themes emerged from the data to address the primary and secondary research objectives: patient-perceived benefits of yoga, reasons and motivations for practising yoga, hurdles and barriers to practising yoga and patient-centred advice for effective yoga program and delivery for adult cancer. See Table 6.2 for a summary of subject areas and identified patterns. This thematic summary of personal accounts from 10 cancer patients points to their perception of yoga and their ideas about possible considerations for inclusion of yoga opportunities within cancer settings.

Patient-perceived benefits included psychological and emotional wellbeing, physical wellbeing and body awareness, social cohesion and additional group support from peers. Yoga-users and patients using other complementary therapy reported a sense of personal responsibility for their health and outcomes and were seeking a non-medical approach to maximise their individual treatment.

Patients struggled to attend a yoga class due to practical considerations such as lack of time, cost, lack of personal discipline or accessibility. Interviewees suggested effective delivery of yoga in a clinical setting should include: expert in-person instruction of gentle postures, breathing techniques, and some form of meditation in a cancer-specific group. Several patients identified an ambience of calm and safety that was created by instructors, referring to the “feeling” of a yoga space as an important factor in their enjoyment and adherence to a yoga program.

Table 6.2. Thematic analysis

Theme	Category	Pattern	Supporting Statement
Patient-perceived benefits of yoga	Psychological and emotional wellbeing	Reduces my stress	"I feel more relaxed but energized at the same time. It's a really, really nice feeling….Yoga is terrific!"
		Feelings of peace and quiet	"My yoga practice has been huge, because it has allowed me, even in this kind of turmoil, to find peace."
		Helps to manage depression	"I would have worried about my mood if I hadn't found some of these complementary therapies."
		Improves sleep quality	"I sleep well and rest easily. I feel very good."
		Increases acceptance of self and world around me	"I find it very comfortable and rewarding…I just felt much calmer and more accepting."
	Physical wellbeing and body awareness	Improves strength flexibility	"I feel stronger in my body, if nothing else. I don't know if it's dealt with the fatigue so much, but it's certainly made me feel more solid."
		Helps with aches and pains	"When my body was aching, I would do yoga and it would help."
		It's like exercise, but better	"I think because it's so adaptive and gentle, it's a really beneficial way to get our bodies moving again and the environment of a yoga class is a safe place."
	Facilitates groups support and social cohesion	Comforting to be with people who have cancer	"It helped me to talk about my situation as well because, you know, you don't want to bore everyone with your diagnosis and prognosis and all of that…people here understand more of that, more of what you are going through. And it's nice to compare notes."
		A way to socialise, and meet interesting people	"The community aspect…we socialize and hike and it's nice to hear what the other people are doing…"
Reasons and motivation for practising yoga	Seeking a non-medical approach	Desire for a holistic, integrated way of thinking	"I want to pursue a more holistic approach to anything in my life."
	Maximising treatment plan	To do all I can to prolong and enjoy my life	"I think it has been an important part of my treatment. And just the feeling that you are doing everything that you can to prolong your life. And your quality of life, too."

Theme	Category	Pattern	Supporting Statement
		Creating a treatment plan that suits me	"My qualms with the conventional treatment model is right now it's off the shelf, 'oh, you've got prostate cancer? Here, do this or that', it's not customized and personalized…that's why I've chosen my own personalized treatment of different practices."
	Personal responsibility for illness and wellness		"I can't just sit back and expect someone else to make me better. Nobody can."
Hurdles and barriers to practising yoga	Logistics	Lack of time	"Time. Time. We need more of it to fit all the appointments in."
	Personal factors	Lack of discipline	"Discipline. I mean these five Tibetan rights that I could easily do every morning…but I got on it for a month or so and then slid away from that."
		I forget	"Seven o'clock on a Thursday…(I know, but) I forget."
	Finance	Free or part of a package makes it more affordable	"[Cost] is not problem here because it's part of the membership."
		Gentle and predictable class sequence	"We all get in the room and we usually throw our legs up the wall...and then she (the instructor) comes in…and she brings us back down and off we go…it's a pretty good routine…and it's yoga…a good stretch, a good workout."
Recommendations for effective yoga program and delivery	Instruction	A good teacher is important	"I think it's like anything: if you resonate with the teacher you are going to do much better. It's like any subject you ever take. If the teacher and you kind of work you are going to do well in the course."
	Supporting a home-based practice	Training needed about how to do brief sessions	"It doesn't have to be long, but it does have to be every day."

Theme	Category	Pattern	Supporting Statement
	Online or video-led yoga	Not desirable, as missing the social interaction or motivation	"The people are very, very supportive, and very interested in other people. I live alone …social contact has been really important for me."
			"You need to have somebody instructing I think. Otherwise it's very easy not to turn it on."
		Not relevant or inspiring to me	"I found doing the meditation course with the CDs as it was then, very effective. With yoga, I'm not sure…I'm not great at self-motivation with that kind of thing."
	Cancer-specific yoga	Cancer-only groups make me feel more comfortable	"That this is like our private little club of people who have cancer and you don't have cancer, you don't belong here."
		Negative experience with community-based classes	"There's other yoga places I've gone to and they say, 'go, go, go, go!' …And I don't wanna be 'go, go, go' … I need to be gentle with myself right now and I feel that's a place where I can do it."

6.4.2.1 Perceived benefits of yoga

The patients using yoga as a complementary therapy in adult cancer (n=7) reported positive benefits in terms of their physical, psychological and social wellbeing. Psychosocial benefits including management of stress, improved sleeping habits and a new ability to experience peacefulness were commonly described.

The most commonly reported benefit of yoga was its breath-related awareness of mind and body. Patients said yoga taught them about body awareness and encouraged them to accept "what is", giving them a sense of connection and calmness in their mind and body. One woman who tried yoga for the first time following her cancer diagnosis shared (F6):

> *I found the meditation quite relaxing…the breathing for relaxation really helped, too. I think you are more aware of your breath and you are more aware of all of your muscles and just the way that your body moves. I think you are just more aware…I just feel really satisfied. It makes me feel good physically and emotionally and mentally.*

Another woman (F4) explained yoga was, "very comfortable and rewarding, and I just feel much calmer and accepting" after a class. Other patient-reported benefits include: improved stress management, better sleeping habits and a new capacity to experience peacefulness. Some respondents described yoga's ability to improve physical strength and decrease stiffness and body aches associated with cancer and its treatment. One woman felt, "when my body was aching, I would do yoga and it would help (F8)". Following her weekly practice of yoga for two months said: "I certainly feel stronger in my body…more solid (F9)".

Participants also talked about the enjoyment of group dynamics in a yoga class. The yoga participants reported feeling a sense of community, of acceptance, where some likened their yoga community as important as family (M1; M5). Patients said

doing yoga in a cancer-specific group was especially helpful to create a feeling of trust and acceptance to share their fears or questions about cancer and its treatment.

6.4.2.2 Patient-reported reasons and motivation for practising yoga

The prevailing attitude of respondents was their determination to do their best and everything they could to improve their chance of survival. The perceived health locus of personal control of interviewees was high and most perceived cancer as a teacher in their life to do things better. One man with prostate cancer said for him there was a distinction between passive and active healing where (M3):

> *…surgery, radiation and chemo, are passive forms of healing, you turn yourself over to somebody to be healed, and these other forms are active healing…I'm actively involved in my own health and healing, not waiting for some saviour on the outside to make me better.*

In addition, yoga practitioners were seeking a non-medical approach to improve their symptom management of cancer and its treatment. This included holistic, integrated ways of thinking to design a personalised treatment plan. One woman with breast cancer felt that doing yoga was her way of committing to life as a person, not a patient (F6):

> *I'm someone who's not ever sick…that was my first surgery since I had my tonsils out when I was ten. I don't want to just be a medical patient.*

A first-time yoga practitioner following her breast cancer diagnosis chose yoga for its comforting, gentle approach to physical movement (F8):

> *…it's so adaptive and gentle, it's a really beneficial way to get our bodies moving again and the environment of a yoga class is a safe place. You get some personal instruction from someone who can help you if you're uncertain and you get lots of choices about you can do it this way or this way and this might work better for you.*

The customisation and personalised attention offered in yoga class appealed to participants. Patients enjoyed the non-competitive atmosphere and felt motivated by the reassurance received from expert instructors to follow their own pace of movement. Several female respondents (n=3) especially liked the language used by instructors that encouraged them to be accepting of their physical and mental states, and above all, patients welcomed the invitation to respect and listen to their bodies.

6.4.2.3 Hurdles and barriers to practising yoga

Scheduling, transportation, lack of time and competing priorities were listed as key barriers to attending regular yoga class. One man (M3) would have liked to participate in yoga at an integrated health centre but said "the parking is always a bear…and I do find it stressful…to get in my fitness classes or doctors' appointments or whatever. So while the yoga can be a de-stressor, the drive home can just sort of ruin all that!" Personal factors and financial concerns were also identified as potential limitations. A woman (F2) with two children admitted:

> *The only trouble is, honestly the time thing. I mean…the financial, too…because the extra stuff is expensive…if you have to pay the mortgage, work 9 to 5 and you have to pick Suzie up at day care and Johnny needs to go to skating and somebody's got to make dinner, where do you find time?*

Participants believed that online yoga or video-led yoga might not be an attractive alternative to in-person classes given previous experiences. A woman (F9) who has sampled the video sessions for meditations had this to say about them:

> *I've tried. Have you ever looked at those videos? They're awful … But there are all sorts of videos on YouTube but then it's…that you're not in the atmosphere either.*

Other participants (n=4) reported being more apt to come to class when they made plans with peers to socialise before or after the session. It was felt online or video yoga intervention alone would not be ideal for safety reasons and patient adherence; although patients agreed it might be useful to improve participation in a home-based practice.

According to several respondents, the yogic environment in their integrated oncology centre included a safe, quiet space with expert instructors who appreciated the concerns of cancer patients. A concern over personal treatment and stigma in public yoga classes was identified when asked about attendance in community-based classes. One cancer patient (F10) had this to say about participating in public classes:

> *I will go bald at yoga - because I'm not going to be able to wear a hat or a scarf and I don't like the wigs. I know that would make me and other people uncomfortable in a yoga class, especially say at my community centre.*

Other participants worried the instructors would not be prepared to manage their special needs in a community-based class. Furthermore, two respondents had negative experiences in private studios where they reported feeling unwelcomed or 'out of place'.

6.4.2.4 Advice for effective yoga program and delivery

A description of the ideal yoga program from patients included a 60-minute session focussing primarily on breathing techniques with a long warm-up with a variety of postures (asanas) and inclusion of savasana (supine relaxation) at the end of class. Informants noted that meditation is a challenge at first, but that it is a useful, transferable skill during treatment sessions and in daily life (M1; F6; F9). Two respondents suggested classes should be lengthened from 60 minutes to 75 minute

sessions, and administered one to three times per week (M1; F4). Participants were not able to distinguish between the most important aspects or key components of yoga practice. One male respondent (M1) said: "I don't know. I guess it's all important…it's yoga!". Other respondents (n=6) felt several components, including a balanced combination of physical postures, breathing and visualisation techniques during meditation were indicators of a 'good' yoga class.

Several patients (n=6) said they would appreciate recommendations from oncologists or health care practitioners about specific locations or types of yoga that would be suitable for their condition. Some respondents talked at length about the likability of the yoga teacher and how it was a fundamental concern to the successful delivery of a yoga class. One woman (F9) said:

> *I like a teacher who knows what they're doing. And so they can show me what I'm doing wrong. But mostly, it's important that they are personable. Approachable. And kind.*

Restorative yoga was described as the preferred type of yoga for adult cancer patients, appropriate for its ability to benefit the greatest number of participants at all stages of cancer treatment and recovery with low risk of injury. Participants in active surveillance or in the later stages of recovery enjoyed the physical challenge of yoga postures, and added that a yoga class was unique in that it allowed them to do more or less physical activity, depending on how they felt on a particular day.

Respondents overall felt their schedules were difficult to accommodate and time constraints were a major barrier in participating in yoga. The lack of time was especially challenging during early treatment periods with numerous medical visits, along with work and family commitments. A flexible and easily accessed yoga class was reportedly critical to adherence of yoga during cancer treatment.

Respondents felt a small user fee for yoga services delivered in a clinical setting was acceptable. One woman (F7) said fees to participate in yoga at her integrated cancer clinic were offered at much less than the market rate: "…fees are very low here...I think they do that intentionally…because the cancer patients aren't working and a lot of us don't have sources of income." Another woman (F9) who attended yoga in another conventional care centre said: "…it does cost money, but it is subsidised…that helps. I don't know who pays for it actually, but I think it has been an important part of my treatment." Further along in the interview, this same respondent said the yoga program in the hospital was suspended because the availability of space became an issue.

In terms of yoga ambience, it was reported that the yoga room should remain clear of electrical equipment, free of desks or chairs and be delivered in a self-contained space that is free of background noise and environmental odours. Mood lighting, hygienic space and sufficient cushioning to sit comfortably were other described features of an optimal yoga class. Generally, participants agreed yoga delivery in a conventional cancer facility would be a practical solution and could help to improve the cancer treatment experience. One woman (F8) suggested, "if the space was quiet it might be nice to have a positive experience in a building that is usually quite stressful," and others felt yoga delivered within the same building as their cancer treatment would reduce their concerns about accessibility. Some respondents thought any short meditative or pranayama-focused yoga sessions in the waiting room or during chemotherapy would be helpful to reduce stress and should be offered in conjunction with conventional therapy (F2; F6; F10).

6.5 DISCUSSION

6.5.1 Summary of Findings

This set of exploratory interviews identified four thematic areas of interest for yoga in adult cancer: patient-perceived benefits of yoga, reasons and motivations for practising yoga, hurdles and barriers to practising yoga, and advice for effective yoga delivery in adult cancer. Several men and women reported yoga reduced stress, fatigue and other negative symptoms associated with cancer treatment. As well, yoga was reported by patients as a means to encourage personal empowerment and improved awareness of physical body and self.

Adverse events or negative physical or emotional side effects of yoga were not reported in this sample. Barriers to yoga adherence from the patient perspective included lack of time, scheduling conflicts and worries about financial burden. Community-based yoga or yoga delivered online or video-based were not frequently accessed by this group of cancer patients, due to a perceived stigma by class members who do not have cancer and worries about the non-specialized instruction they might receive.

The class characteristics of an ideal yoga intervention in a conventional care centre included: flexible scheduling of one to three 60 to 75-minutes sessions per week of restorative yoga that included some aspect of breathing exercises, meditation techniques and physical postures.

Previous findings suggested yoga use in patient populations is associated with socio-demographic factors, mental health and health locus of control and not with patients' diagnosis[243]. These qualitative findings agree yoga adherence may be stronger for intrinsically motivated patients. Popular surveys and systematic reviews

also indicate adult women, especially breast cancer survivors with higher levels of education and socioeconomic status participate more in yoga[13]. Similarly in this research, the majority of women interviewees (n=7) had breast cancer (n=5) and completed tertiary education (n=7). However, contrary to what is currently known, this study adds that men enjoyed health benefits and the social aspects of practising yoga during treatment. Some men in this sample (n=2) were especially committed to yoga for its non-medical approach to reducing anxiety, improving physical fitness and improving their social and personal experience of having cancer.

The social dimension of group yoga was important to the interviewed patients, and this aspect of yoga is a potential therapeutic tool in cancer care. In previous literature, "a decrease in the level of distress through social support is also expected to lead to the improvement of immune competence"[244]. The extent to which yoga might encourage social wellbeing and improve morbidity or mortality of cancer patients is an area for future scientific investigation.

Reporting yoga-users (n=7) and CAM-users (n=10) acknowledged the relief of a non-medical environment and promotion of self-care as critical in their healing process. While patients reported an affinity for yoga (n=10), they frequently reported one or more barriers that prevent their adherence to yoga including: fatigue, lack of motivation, transportation, scheduling, lack of time and financial burden. The idea of online yoga or video-led yoga practice was not as appealing to patients as the in-person instruction, though some respondents felt online yoga might increase their adherence to a home-based practice.

6.5.2 Strengths and Limitations

The Interpretive Description (ID) methodology and its principles of thematic analysis guided this preliminary exploration of yoga in adult cancer in the context of health and complementary care. The semi-structured interviews resulted in a coherent perspective of participant based upon an inductive reasoning approach. The qualitative data gathered across ten interviews with adult patients of cancer is the first known systematic documentation of how yoga intervention is perceived by a group of patients seeking complementary care. Although the findings are important, there are some serious study limitations to be considered.

First, the sample size was limited by several factors, including: slow recruitment, a short recruitment period (six months), and practical limitations including time, financial and human resources constraints. The low response rate could be attributed to patients' lack of time, competing priorities or a lack of willingness for cancer facilities to recruit patients to document their patients' treatment stories and concerns. Future studies could improve the reach of recruitment by engaging health care providers in the recruitment, and education them on the benefits of recruiting to such a study. Furthermore, the purposive sampling technique used in this study means that particular judgements about where and who to recruit for interview were exposed to researcher bias[245]. A more random sample of patients is recommended for a larger, more generalisable study protocol.

Second, the recruitment of participants was intended to include patients from both cancer hospitals and complementary care centres, though only one participant was recruited from a cancer hospital. The other respondents (n=9) were recruited from the same integrated health clinic. This self-selection bias may have encouraged

harmonious, positive views of yoga and signalled premature theoretical data saturation because of converging themes and patterns.

Third, the maximum variation sampling technique was suboptimal in this study. Although the principles of maximum variation sampling were performed (as much as was permitted by the personal schedule of patient volunteers), the small number (n=10) and variation of the characteristics in recruited participants were limiting factors. A future study could be expanded to include a more diverse group of respondents, including culture, language, and socioeconomic status, providing a larger set of interview data to improve external validity. A larger study would also allow for a more in-depth, subgroup analyses in key areas such as *why* and *what* characteristics of yoga intervention are appropriate across different patient populations.

While the inclusion of other tumour types are better represented in this study than existing literature, this sample does capture experiences from breast cancer patients (n=5). Patients with serious physical limitations or side effects from a recent surgery did not volunteer for this study, so their attitudes or experiences of yoga are not represented here. Also as a consequence of self-selection, this sample included only middle age and older adults. Furthermore, the majority of respondents (n=9) were recruited from the same privately-funded integrated cancer care centre. A self-selection bias may have encouraged the harmonious, positive views of yoga and signalled premature theoretical data saturation because of converging themes and patterns. The experiences or opinions of patients from other cancer care hospitals, including publicly-funded institutions may differ from this sample and should be included in future research.

The concept of data saturation describes a state where no new data of importance to the study emerge, and elements of all categories are addressed[246]. This concept of data saturation often guides the researcher to determine an adequate sample size for interview studies. Previous research also suggests data saturation occurs within the first 12 interviews although basic elements for meta-themes were present as early as six interviews[247]. Other guidelines established to encourage external validity in qualitative research suggest sample sizes of at least six participants for phenomenological studies and 30-50 participants for ethnographies, grounded theory or ethnoscience studies[248]. In other maximum variation sampling methods, 12-20 participant sources are recommended for interviews[249]. Though the sample size of this study appeared to meet the minimum requirements, the data collection period and sample size of this study could have been expanded to include a more diverse group of respondents. The smaller size of this study sample was attributed to slow recruitment, limited access to local populations, along with pragmatic design limitations including a small research team and limited budget. Future studies could be designed to address the shortcomings, not least to designate a local researcher to pursue recruitment within complementary and health care agencies. A social media campaign or access to cancer support groups might also improve recruitment rates.

However, in spite of this study limitation, the small sample size in this instance was deemed acceptable for two reasons: firstly, the Interpretive Description methodology emphasises that data saturation is a theoretical endpoint and each individual story has significance, and secondly, contributions from a small number of participants are meaningful to a field of study that has little to no existing data on the

topic. Furthermore, the collected data is useful to advance the modelling of yoga in adult cancer and advances knowledge for the contextual meaning for this topic.

6.5.3 Advancing the Model of Yoga Delivery

The modelling of yoga intervention from the patient's perspective included some similarities and differences from the component analysis of Chapter 5 (see Box 6.3). Clinical trials of yoga intervention have often included 45 to 90-minutes of expert instruction in a clinical setting and provision of material support for a home-based practice[250-253]. From this sample, components of yoga intervention that are seemingly most important to include are sessions that last 60 to 75 minutes with breathing techniques, visualisation techniques and gentle physical postures led by a personable and skilled instructor. Interviewees also reported that a yoga-specific environment in a cancer-only group was important for their comfort and benefits of practice. The yoga space should encourage a feeling of calm, with provision of natural light, without chairs, tables, electrical equipment or environmental noise or odour.

Box 6.3 Characteristics of yoga intervention from the patient's perspective

Type: Restorative Yoga
Dose: 60 to 75-minute session; one to three times per week
Duration: during conventional cancer treatment
Instructor: Certified Yoga Instructor; personable and sensitive to group needs
Required Components: Breathing Techniques, Physical Postures, Meditation, Relaxation
Mode of Delivery: In-person instruction; cancer-specific group setting; yoga ambience
Supportive Material: None reported
Barriers to Adherence: Scheduling, logistics, location, fatigue, cost

Audio, video or online mediums are pragmatic approaches to improve the accessibility and scalability of yoga interventions in health care. Earlier qualitative analysis[254] and findings in this sample also suggested in-person yoga increases social

interaction and increases personal motivation to attend regular practice. However, findings from this study indicated patients avoid online yoga participation, reportedly due to the perceived loss of a yoga-inspired ambience and quality of in-person instruction. The appropriateness of online or video-led yoga is an outstanding question that needs further investigation regarding its potential benefit and acceptance with patients. Community-based yoga classes were not frequently attended by this sample of cancer patients for fear of stigma and lack of perceived instructor's awareness of their needs. Providing education or resources to identify safe, welcoming yoga classes in the community might be one solution to improving access for cancer patients. In terms of scheduling, participants have mixed views as to whether they would find time to do yoga before or after a clinic appointment, but would be willing to try doing yoga in a clinical setting. Patients acknowledged fatigue and lack of motivation as common reasons they would not be able to attend regular yoga. As shared by respondents, the cost of a regular class is potentially prohibitive and should be considered in future yoga intervention designs.

6.5.4 Implications of Findings

This set of patient interviews improved the modelling process of how yoga can be delivered in a clinical setting. Future sample populations in yoga research should endeavour to include younger adults from more diverse socioeconomic groups undergoing conventional treatment for tumour types other than breast cancer. The optimisation of yoga intervention for HRQoL in adult cancer should explore methods to decrease financial and scheduling burden of yoga for patients and health care providers.

6.6 CHAPTER SUMMARY

- Male and female adult cancer patients using complementary care as adjunct therapy in cancer treatment reported having a strong affinity towards practising yoga for its physical and psychological healing effects.
- Interviewees were motivated to participate in yoga for its non-medical approach to improving their mood, body awareness, physical stability and flexibility.
- Reported barriers to participating in yoga included: lack of time, accessibility, scheduling conflicts and potential costs associated with yoga.
- Patients preferred to practice in a cancer-specific group led by a certified, personable instructor.
- Patients most often attended a 60-minute yoga class delivered in an integrated health care setting designed with a mixture of breathing techniques, visualisation techniques and physical postures.
- Patients preferred practising in a quiet atmosphere and described the importance of a ‘yoga ambience’ that included a sense of calming space, free from outside noise, odour or disruption.
- Characteristics of yoga intervention from the patient’s perspective:

Type: Restorative Yoga
Dose: 60 to 75-minute session; one to three times per week
Duration: during conventional cancer treatment
Instructor: Certified Yoga Instructor; personable and sensitive to group needs
Required Components: Breathing Techniques, Physical Postures, Meditation, Relaxation
Mode of Delivery: In-person instruction; cancer-specific group setting; yoga ambience
Supportive Material: None reported
Barriers to Adherence: Scheduling, logistics, location, fatigue, cost

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CHAPTER SEVEN

Oncologist Surveys

7 ONCOLOGIST SURVEYS

Features of this chapter have been published in the following peer-reviewed journal:
McCall, M.C., Ward, A, Heneghan, C. (2015).Yoga in adult cancer: A pilot survey of attitudes and beliefs among oncologists. *Current Oncology, 22*(1).
doi:10.3747/co.22.2129

7.1 BACKGROUND

The World Health Organization (WHO) strategy for traditional medicines explicitly promotes the integration of complementary care into health care service delivery and for patient's self-care[255]. Nearly half of all cancer patients use traditional, complementary and alternative medicine (CAM) during treatment to help them cope with cancer and manage treatment side effects[256,257]. The extensive use complementary therapies, including herbs, mind-body techniques and traditional remedies can challenge and frustrate both health care professionals and patients, especially if there are different understandings of the role and effectiveness of an unconventional therapy during treatment[258]. The oncologist's willingness to discuss or include CAM in treatment consultations depends on their interest, knowledge and skills in supporting patients with CAM decisions[259].

In preceding Chapters 5 and 6, some features of yoga intervention were documented to advance the model of yoga intervention for health-related quality of life (HRQoL) in adult cancer. To continue the development of yoga intervention, the perspectives of oncologists, their medical opinions, perceptions and current recommendations are requisite to ensure yoga's pragmatic application in a clinical setting.

7.2 CHAPTER AIM AND OBJECTIVES

The aim of this chapter is to complete the modelling of yoga intervention as initiated by Chapter 5's component analysis and enhanced by Chapter 6's patient interviews. The primary objective of this chapter is to investigate the perceptions, patterns of use and current knowledge of yoga as a complementary therapy from the oncologist's perspective. The secondary objectives are to determine the willingness of oncologists to recommend yoga to their patients, and to identify their particular concerns, beliefs or recognised applications of yoga for adult cancer in a clinical setting.

7.3 LITERATURE REVIEW

A search for systematic reviews of oncologists' knowledge, attitude, beliefs or patterns of yoga use during conventional treatment of adult cancer was performed (current as of 1 May 2014). The search included free-text terms [*yoga* AND (*clinician* OR *oncologist*)] in five online databases (The Cochrane Library, Ovid MEDLINE, PEDro, AMED, CINAHL). The search retrieved few titles (n=10), none of which were systematic reviews describing oncologists' views or patterns of yoga use in cancer treatment.

A subsequent search was designed to identify primary studies aimed to describe the oncologists' current view and usage of yoga as a therapeutic option in adult cancer (current as of 1 May 2014). A low sensitivity search strategy was developed (MM, NR) to avoid missing potential titles including MeSH headings: [health personnel AND neoplasms AND yoga]. Free-text terms [yoga AND (clinician OR oncologist) AND (cancer OR neoplasm)] were also used and limitations for sub-disciplines of oncology or adults (18 years of age or older). Several databases were

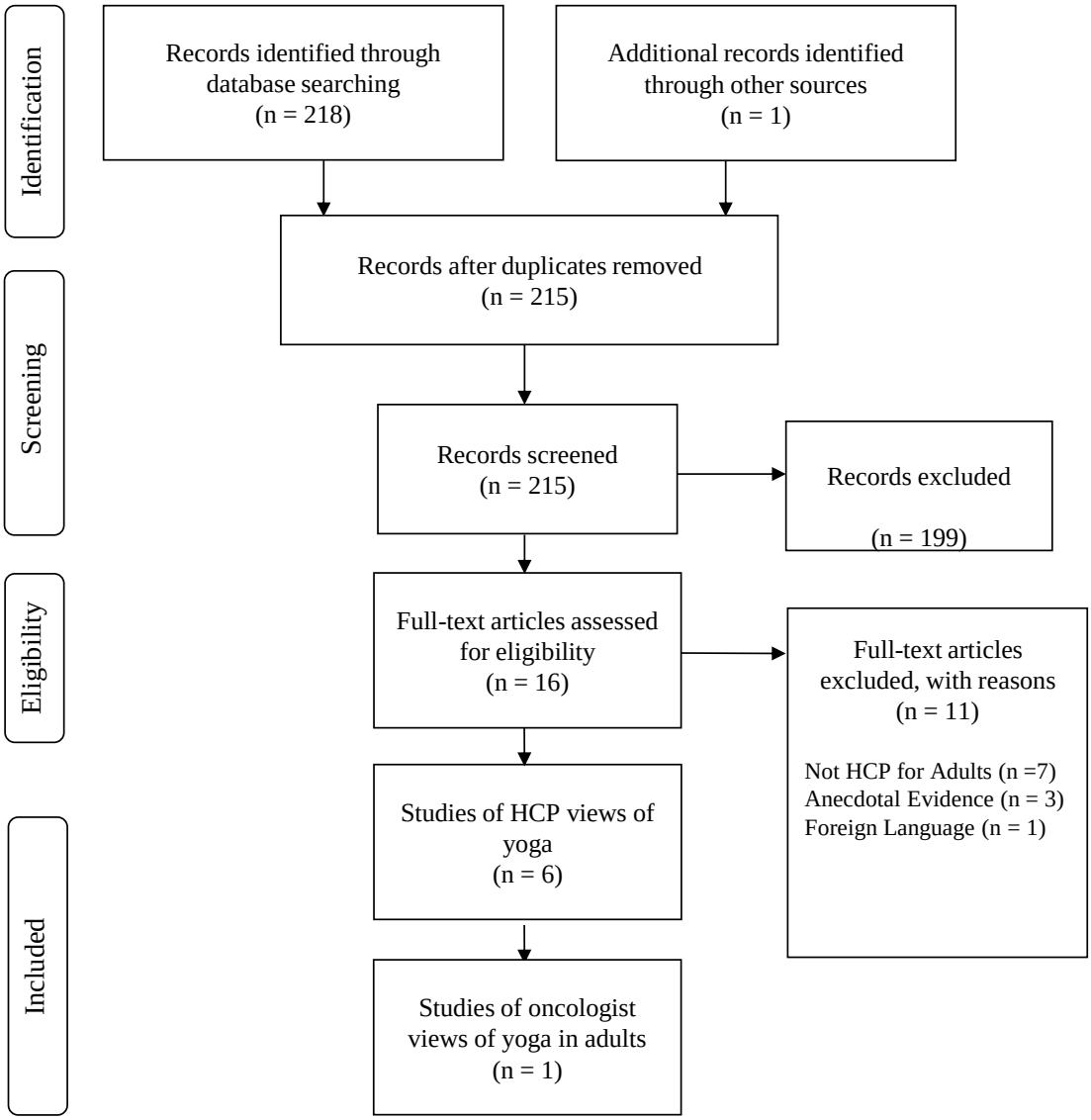
searched simultaneously via SOLO, Oxford single sign-on account using hosts: EBSCO [Ovid MEDLINE (1946 to December 2013), CINAHL and SPORTDiscus); OvidSP [AMED (Allied and Complementary Medicine 1985 to December 2013), Embase (1988 to 2013 week 50), PsycINFO (1987 to December Week 4 2013)] and PEDro searched directly from its website[90]. References within retrieved articles were also examined for relevant titles.

After duplicates were removed, 215 records were screened, 16 full-text articles reviewed, of which six studies included clinician or physician views of yoga[260-265]. One of these studies included clinician opinions for yoga practice in breast cancer survivors[260], though no documentation of oncologists' view of yoga during cancer treatment were found. See Figure 7.1 for a summary of articles included and excluded from the search.

Results of this review indicated study sizes range from small (n=8) to large (n=1,757). Of the six collected studies investigating health care practitioners (HCPs) views of yoga in adult health conditions, the studies also varied by type of participants and geographical region (see Box 7.1).

Box 7.1 Summary of Studies

Study Participants	Sample Size	Country of Origin
Health Care Personnel[260]	8	Canada
Rehabilitation Physicians[261]	36	Australia
Health Care Providers[262]	1,757	Sweden
Neurosurgeons[263]	24	United States of America
General Practitioners[264]	636	Australia
Conventional and Complementary Care Practitioners[265]	295	United Kingdom



Note: HCP=Health Care Practitioner

Figure 7.1. Article flow diagram for systematic search of yoga and oncologists' views during adult cancer treatment

In terms of yoga and its juxtaposition to CAM, authors considered yoga as one kind of CAM treatment in all instances. Five of the reviewed studies included results of various CAM treatments other than yoga. In a cross-sectional study evaluating attitudes of conventional physicians in the United Kingdom toward Indian CAM, The Telles study[265] reported 65% of conventional physicians (n=82) would prescribe yoga as a first choice of CAM treatment – ahead of acupuncture, homeopathy,

ayurveda, home remedies, massage, herbal remedies, pranic healing or reiki or Unani-Tibbs[265]. The confidence intervals and p-values of these data were not reported.

One further study investigated perceived feasibility of integrative medicine in a conventional oncology setting for breast cancer survivors with a focus on yoga therapy as CAM[260]. This study of public and community HCPs (n=8) collected data from focus groups and a self-reported survey [CAM Knowledge, Attitudes and Practice (CAM-KAP)[266] survey]. The eight HCPs included: two emergency care unit registered nurses, one each of a social worker, psychologist, radiation oncologist, medical oncologist, vocational rehabilitation therapist and registered chemotherapy nurse. Authors did not differentiate results from each occupation though reported HCPs were concerned about availability of resources, accessibility, referral guidelines and evidence to support yoga therapy in breast cancer survivors.

The results of this literature review in oncologists and HCPs delivering conventional care to adult cancer patients indicated there is no current data to ascertain their prevailing attitudes, knowledge and beliefs about yoga. In response to this paucity of research, this chapter reports the design, implementation and analysis results of an online yoga survey administered to oncologists. The oncologists' preparedness, their knowledge gaps and willingness to recommend yoga in adult patients will be examined, as well as their recommendations for its use in a clinical setting.

7.4 METHODS

A semi-structured 38-item self-reported online survey was administered to registered oncologists in the British Columbia Cancer Agency (BCCA) from 5 November 2013 to 16 December 2013.

7.4.1 Inclusion Criteria

Male and female medical, radiation and surgical oncologists licensed with the College of Physicians and Surgeons of British Columbia and the BCCA who were responsible for treatment of cancer in adults over 18 years of age were identified and recruited through the BCCA internal database. Only oncologists delivering health care in a publicly funded treatment centre, clinic or hospital were included.

7.4.2 Exclusion Criteria

Oncologists in training, or those who had been penalised for negligence or malpractice, or in some other questionable standing with the College of Physicians and Surgeons of British Columbia were excluded from eligibility. General Practitioners (GPs) or oncologists not currently treating adult patients with conventional treatment such as radiation, chemotherapy, surgery or hormone therapy were also excluded.

7.4.3 Survey Development

7.4.3.1 Content validity

The content validity assessment of the survey instrument was completed using a five-step process:[267,268]

1. Identification of full content domains: Informed by a literature review, the content of the survey was developed by the construction of a table to act as a blueprint for data collection.
2. Generation of items for all domains: All areas for cells of the table were adequately represented.
3. Assimilation of items in useable form: The items were assessed for usability, general form, reviewed and refined (reworded as necessary). The electronic template of survey-beta was transcribed onto an online agency to SurveyMonkey[269].
4. Judgement and quantification of items: Three anonymous, volunteer pediatric oncologists reviewed the content for validity and determined irrelevant items on a 4-point ordinal scale. Omitted items identified by experts were added to the list (n=5). Any irrelevant items were to be removed from the list (n=0).
5. Judgement and quantification of instrument: Three volunteer experts (SH, CS, Anon) judged the validity of the instrument and reported any errors or omissions to researchers for revision.

7.4.3.2 Face validity

Face validity was established using a general measure to test the representation, usability and functionality of the survey. The survey was piloted amongst researchers (CH, AW, SH, CS, LB, ST) and pediatric oncologists (n=3) for appearance and ease of use, collective suggestions implemented accordingly.

7.4.4 Ethical Considerations and Incentives

Ethical applications and subsequent approvals attained from the University of British Columbia (UBC) Behavioural Research Ethics Board (Reference: H13-01482) and the University of Oxford Tropical Research Ethics Committee (Reference: 517-13). An electronic letter of informed consent was administered to potential participants at the point of initial contact. Personal financial reward or any other direct incentive was not provided to participants. However, an indirect incentive (£10) of charitable money was allocated to the British Columbia Cancer Research Centre (BCCRC) upon completion of each survey.

7.4.5 Data Collection

An electronic mail invitation contained a hyperlink that initiated a three-phase study procedure. An internal database was used to send an electronic file to oncologists in British Columbia (FW) (5 November 2013). Subsequent follow-up reminders (6 November 2013; 27 November 2013) encouraged recipients to participate in the survey. The first web-based link directed potential participants to review the purpose and conditions of participating in the research. An e-signature of informed consent prompted respondents to the second web-based link that screened participants for eligibility. The third web-based link presented the survey for completion. The 38-item questionnaire comprised of five sections: A. Professional and Personal Background (24 items), B. Knowledge, Attitudes and Beliefs (5 items) C. Interest, Willingness and Clinical Practice (3 items), D. Concerns and Barriers for Cancer Patients (3 items) and E. Open Remarks (3 items) (see Appendix 7.A for Survey Template). See Table 7.1 for a summary of survey data categories that were collected for analysis. The average time to complete the survey was 15 min 47 seconds.

Table 7.1. Overview of survey data categories

Section and Question Number		Nominal		Ordinal				
		dichotomous	non-dichotomous	dichotomous	non-dichotomous	Ratio (scale)	Numerical Data	Free Text
Section A	1		•					
	2	•						
	3						•	
	4		•					
	5		•					
	6		•					
	7		•					
	8							•
	9					•		
	10	•						
	11		•					
	12					•		
	13					•		
	14		•					
	15				•			
	16		•					
	17					•		
	18					•		
	19				•			
	20		•					
	21				•			
	22		•					
	23				•			
	24				•			
Section B	25				•			
	26				•			
	27				•			
	28				•			
	29		•					
Section C	30			•				
	31			•				•
	32			•				•
Section D	33							•
	34							•
	35				•			
Section E	36							•
	37							•
	38							•

7.4.6 Data Analysis

The survey response rates and completion rates are presented in absolute and percentage values. Ordinal, nominal and ratio scale data are presented in frequency and absolute values. In some cases, nominal data were condensed from five to three categories to clarify results for the reader.

The data set from free-text of open-ended questions were initially coded into categories, analysed for recurring themes and patterns (MM), and then further verified for accuracy using an information visualisation technique, wordle[270]. Wordle is a Java applet that takes the most frequent words (of three characters or more) and organises terms by their word count in the written text[271]. The use of wordle in text analysis is a crude measure of word frequency, however it is useful as an adjunct tool to represent a cloud of text to express a general view of what has been said or discussed[272].

Sample size limitations prevented statistical analysis or any potential inference from percentage calculations and therefore confidence intervals are not included. The percentage figures are to be considered only within the context of this sample.

7.4.7 Results

7.4.7.1 Response Rate

Of 260 recipients contacted through electronic mail, 39 individuals responded to the survey. Two of 39 respondents did not provide consent and eight respondents did not advance to complete the survey without stating a reason (see Figure 7.2). One of 8 ineligible respondents stated their reason for exclusion as unlicensed to practice oncology with the College of Physicians and Surgeons of British Columbia.

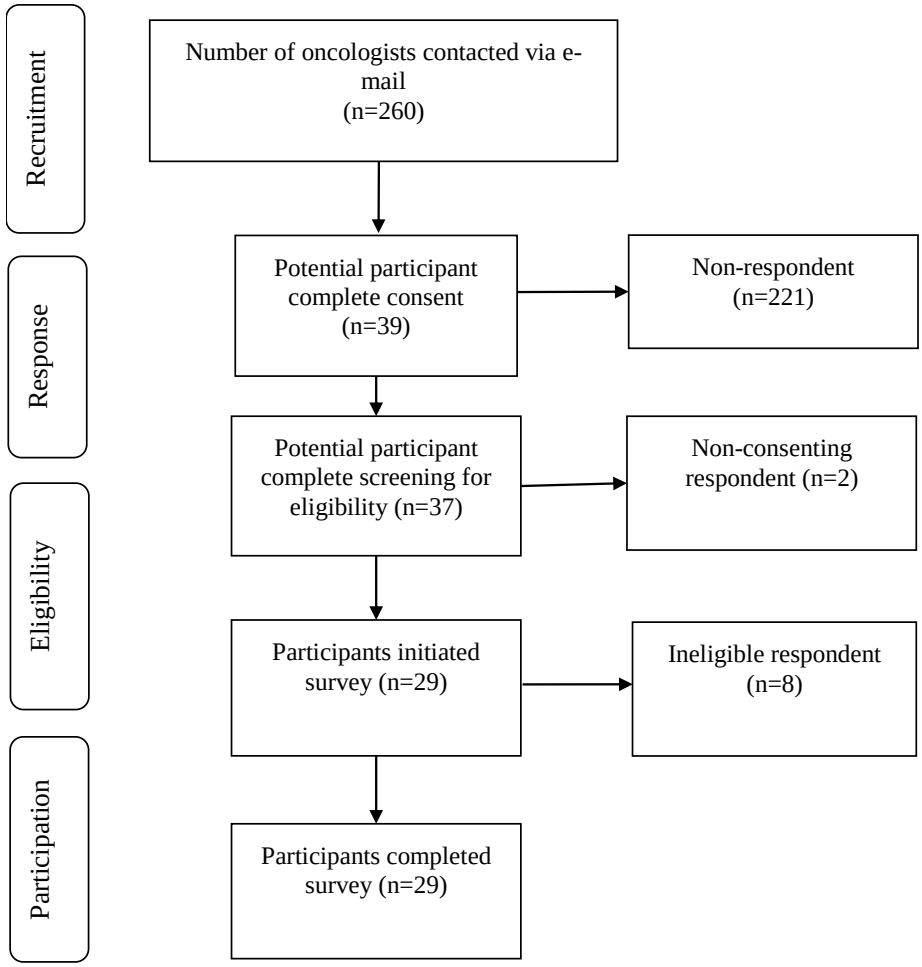


Figure 7.2. Participant flow diagram

The survey had a response rate of 15.0% (39/260) and an initiation-completion rate of 100% (29/29). Quantitative questions had a completion rate of 100% (29/29). See Appendix 7.B for a full report of quantitative and qualitative data.

7.4.8 Characteristics of Respondents

Twenty-nine oncologists participated in the study. The ratio of male to female respondents was relatively equal (15:14). The age of respondents ranged from 28 to 56 years. Reported ethnicities included: Caucasian (n=18), Chinese (n=5), Indian (n=5) and Hispanic (n=1). Religious affiliations of respondents were as follows: Christian (n=9), Hindu (n=3), Jewish (n=3) Sikh (n=1) and other non-specified or not religious (n=13). See Table 7.2 for a summary of respondents' personal information.

Table 7.2. Summary of participants' personal information

Characteristic	Description	Number
Age	< 30 years	1
	30 > 40 years	16
	40 > 50 years	5
	> 50 years	7
Gender	Male	15
	Female	14
Ethnicity	Caucasian	18
	Chinese	5
	Indian	5
	Hispanic	1
Religious Affiliation	Christian	9
	Jewish	3
	Hindu	3
	Sikh	1
	Not religious or unspecified	16
Personal Fitness Level	Poor	2
	Average	10
	Good	8
	Excellent	9

Characteristic	Description	Number
Type of Physical Activity	Walking	17
	Jogging	14
	Hiking	14
	Swimming	7
	Cycling	12
	Skiing	14
	Tennis	4
	Fitness Class/Gym	18
Frequency of Yoga Practice	never	9
	experimental (1 or 2 times)	11
	sometimes (1 per month)	4
	regularly (2 to 3 times per month)	3
	often (>1 per week)	2
Frequency of Meditation	never	13
	experimental (1 or 2 times)	10
	sometimes (1 per month)	2
	regularly (2 to 3 times per month)	2
	often (>1 per week)	2
Commitment to CAM for self	Not Committed	18
	Neutral	8
	Committed	3
Type of CAM/Activity for self	Physical Exercise	24
	Massage	22
	Acupuncture	8
	Meditation	7
	Traditional Chinese Medicine	2
	Reiki	1
	Herbs	1
	None of the above	2

CAM = complementary or alternative medicine
Note: The response rate for all questions was 100% (29/29)

The majority of oncologists (n=27) described their level of fitness as average (n=10), good (n=8) or excellent (n=9). Respondents enjoyed walking (n=17), hiking (n=14), skiing (n=14), jogging (n=14), cycling (n=12), gym-related activities (n=11) and 5 respondents identified yoga as a sporting activity they currently enjoyed to

promote physical fitness. Nine (31.0%) of respondents had never practiced yoga, 11 (38%) experimented with yoga (1 or 2 times) and remaining participants (n=18) said they practiced yoga once or more per month. Twelve respondents (41%) said they were not committed to using CAM to improve their own personal health while less than 30% (n=9) respondents said they were committed to CAM. Physical exercise (n=24) and massage (n=22) were most often reported modalities for oncologists to improve personal wellbeing. To a lesser extent, respondents also practised yoga (n=12), acupuncture (n=8) and meditation (n=7) for health purposes. No respondents reported using talk therapy, hypnosis or ayurvedic medicine.

In terms of profession, 59% (n=17) of respondents were medical oncologists, 41% (n=12) radiation oncologists and no surgical oncologists. Of eight sub-specialties reported, three specialised in breast cancer, two in genitourinary cancers, one gastrointestinal, one lymphoma and one internist. See Table 7.3 for a summary of respondents' professional practices. Twenty-two (76%) of respondents treated at least two to four new patients per week, 24% (n=7) administered care to five to ten new patients per week. The number years of practising medicine was relatively distributed: more than 25 years (n=4), ten to 25 years (n=7), five to ten years (n=6), two to five years (n=8) and practising less than two years (n=4). All respondents were employed full-time (more than 25 hours/week). Practitioners cited their treatment hospital within seven regions in British Columbia: Vancouver (n=8), Kelowna (n=6), Surrey (n=5), Victoria (n=4), Abbotsford (n=3), Nanaimo (n=1), Vernon (n=1) and West Vancouver (n=1).

Table 7.3. Summary information about respondents' professional practice

Characteristic	Description	Number
Type of Oncologist	Radiation Oncologist	12
	Medical Oncologist	17
	Surgical Oncologist	0
Years of Medical Experience	< 2 years	4
	2 to 5 years	8
	5 to 10 years	6
	10 to 25 years	7
	> 25 years	4
Amount of Work	Full Time	29
	Part Time	0
Number of New Cancer Patients	> 4 per week	13
	2 > 4 per week	22
	1 per week	1
	1 per month	0
Most Frequent Cancer Treatment	Breast	12
	Colorectal	6
	Prostate	5
	Lung	2
	Non-hodgkin Lymphoma	2
	Body of Uterus	1
Clinic Location	Vancouver	8
	Kelowna	6
	Surrey	5
	Victoria	4
	Abbotsford	3
	Vernon	1
	Nanaimo	1
	West Vancouver	1

Note: The response count for all questions was 29/29.

7.4.9 Generalisability of Results

At a 95% confidence interval (CI) of sample size (n=29) from the population sample (n=260) with 50% responding at p=.05, the margin of error (CI ±17.2). This means that if 50% respond to a question, readers could be 95% confident that the true response would be ±17.2. This calculation confirms the study was underpowered and therefore, indicates a severe limitation and the survey results are not generalisable.

7.4.10 Survey Instrument and Recommendations

Most oncologists did not submit comments or feedback on survey design (n=26). One reporting oncologist felt the questionnaire did not provide enough 'not applicable' boxes and felt some questions were vague, though specific items were not specified. Two oncologists noted that yoga is a type of exercise, neither of which should be referred to as CAM.

7.4.11 Perceptions, Patterns of Use and Current Knowledge of Yoga

In terms of practising yoga in conjunction with conventional cancer treatment, some oncologists agreed it reduces fear and anxiety of patients (n=18), improves the health-related quality of life (HRQoL) in patients (n=17), reduces depression or relating feelings of sadness (n=15) and improves fatigue (n=13) or pain (n=10) associated with cancer treatment (see Figure 7.3). The sampled population disagreed that practicing yoga decreases tumour size (n=15) or that yoga would boost the immune system in patients (n=13). In addition, most respondents disagreed that practising yoga would cause the patient to make dangerous decisions (n=19) or interfere with patient treatment in some negative way (n=19) or confuse (n=16) or harm (n=14) the patient. Clinicians are uncertain as to whether yoga would improve

patient adherence to conventional treatment (n=20). Respondents also expressed uncertainty with respect to yoga's efficacy to reduce pain symptoms (n=18), fatigue (n=15), depression or feelings of sadness (n=14). Nearly half of respondents were unsure if yoga would have any impact on cancer and its treatment (n=14). Of the 29 respondents, seven replied that yoga is not applicable (n=3) or they do not know (n=4) of any positive associations of yoga for cancer treatment.

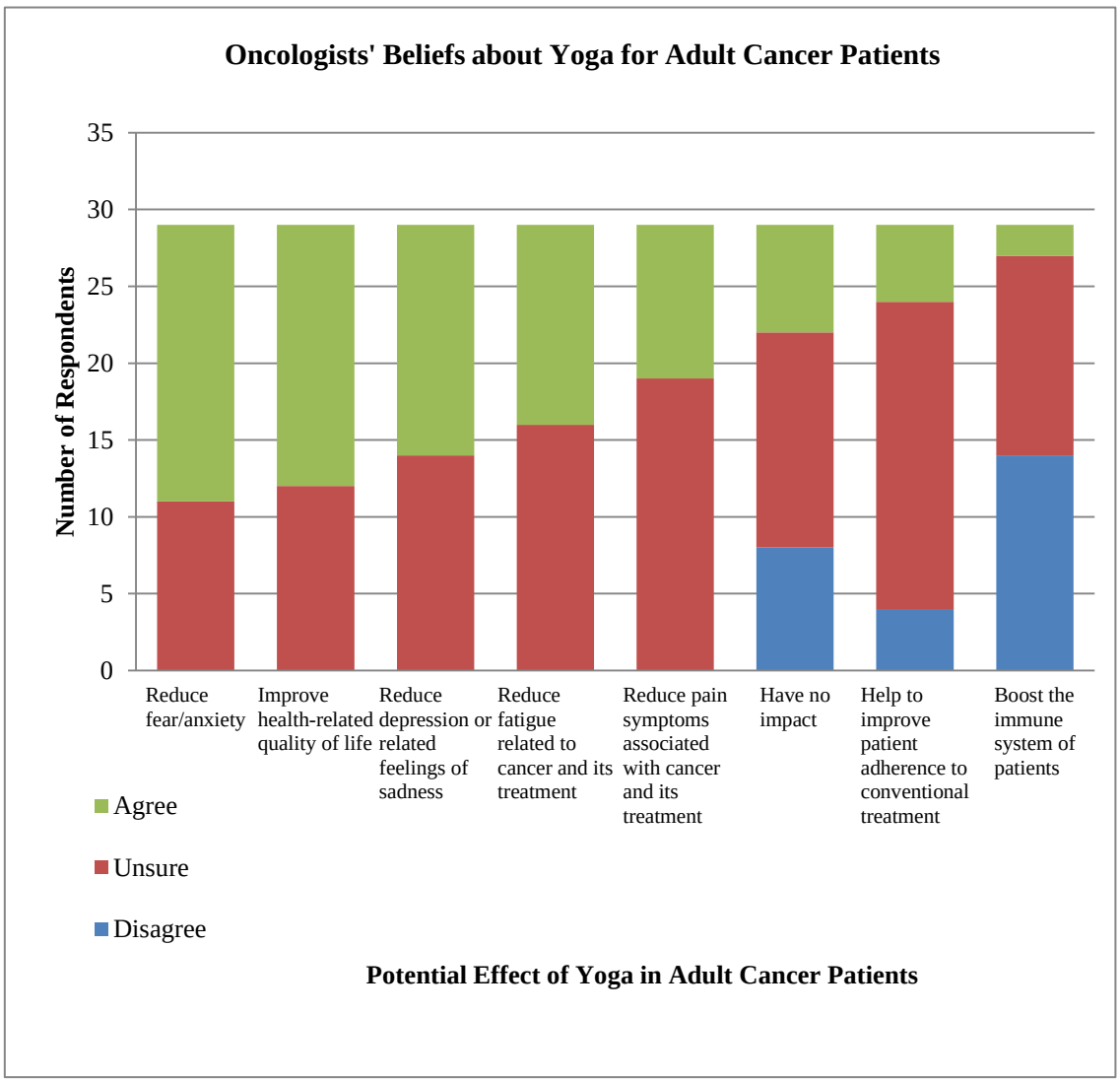


Figure 7.3. Oncologists' beliefs about yoga for cancer

100% (n=29) of responding oncologists currently suggest physical exercise to their cancer patients. Twenty-three respondents also recommend massage, acupuncture (n=14) and meditation (n=12). Eleven respondents reported having already recommended yoga use to patients to improve health-related outcomes (see Figure 7.4). Oncologists' level of reported interest for yoga (n=20) was similar to complementary therapy (n=18).

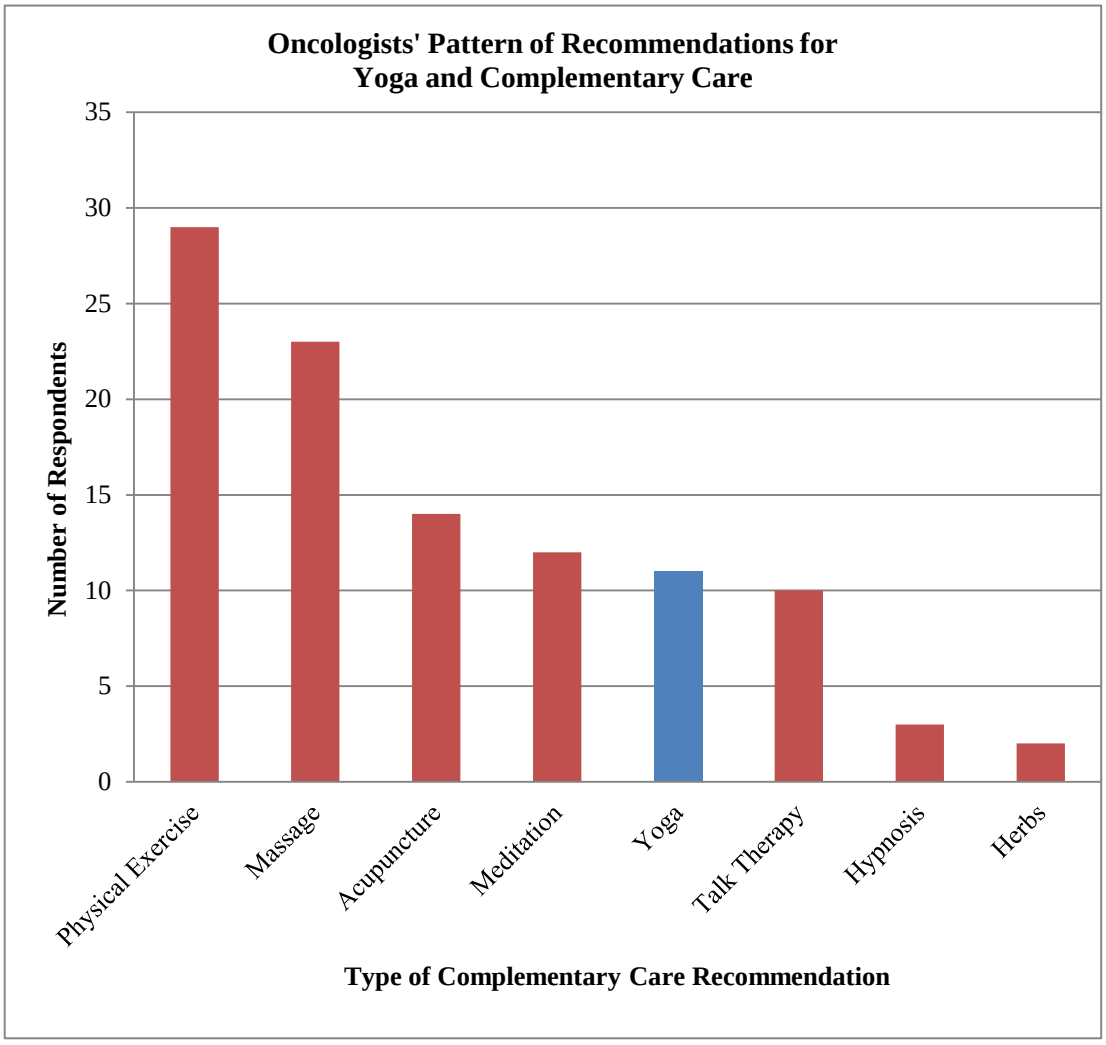


Figure 7.4. Oncologists' pattern of recommendations for yoga and complementary care

In general, respondents held a positive and curious view of yoga's application in adult cancer. Specifically, the following keywords elicited the greatest number of responses: supportive (n=19), interested (n=15), curious (n=14), hopeful (n=11), cautious (n=9), undecided (n=9), while no respondents were disapproving or convinced it is ineffective. Fourteen (48%) oncologists did not consider yoga a complementary therapy and 35% (n=10) of oncologists reported cancer patients have asked them about using yoga to improve a health-related outcome.

One oncologist said yoga could be "especially helpful for anxiety and to promote mindfulness" (male, age 40, radiation oncologist). One female oncologist (age 55) has recommended yoga for adjuvant breast cancer in anxious patients. Another oncologist recommended yoga to patients to aid in managing hot flashes and sleep disturbances (female, age 40, radiation oncologist). Several oncologists (n=5) suggested yoga's effects are comparable to exercise effects for improving endurance and physical conditioning. Another respondent (male, age 36, radiation oncologist) said: "in my opinion, all forms of exercise help with stress. Yoga is one of the best forms of exercise due to the fact that each person participates to their level (thus everyone can participate) and little harm is done to the body." Another respondent (female, age 31, medical oncologist) suggested: "if it [yoga] improved endurance and physical conditioning, patients may be able to tolerate more treatments", and therefore an important metric to include in future analysis.

One oncologist felt clinical outcomes for yoga use are uncertain and suggested immunity as an area of potential research (male, age 39, medical oncologist)

> *...we really don't have good data showing improved hard outcomes like survival, I would be careful about using the term "boosting the immune system", I regard this as a term someone uses when selling an expensive unproven product. If you think your treatment affects some immune*

parameter, explain specifically (i.e. Tcell response etc) and provide specific clinical data showing that it affects (clinical) outcomes.

In general, oncologists appeared hesitant or unlikely to suggest yoga for their patients because they don't have knowledge of yoga as a therapy (n=15) or there is lack of scientific evidence to support its use (n=11). Another respondent (female, age 50, medical oncologist) said: *"I'm not aware of research that establishes particular benefits [of yoga] but would support it being done. An interesting trial would be yoga versus any social group versus any other fitness group versus nothing, to see if the benefits are particular to exercise, particular to yoga, or particular to social interaction."* Another medical oncologist (male, age 36) "would like to see a study proving that yoga during [radiation therapy] and chemo improves stress and fatigue." The oncologists in this sample believed yoga intervention lacked scientific evidence to support its use in a clinical setting, though several oncologists would encourage further experimentation to determine its efficacy.

7.4.12 Oncologists' Beliefs and Willingness to Recommend Yoga

The themes extracted from the qualitative data from free text responses identified three themes:

1. Oncologists perceived yoga as a gentle, adaptive form of exercise.
2. Oncologists perceived yoga could benefit anxiety management in patients.
3. Oncologists reported a lack of scientific evidence or knowledge of how and where to access yoga prevented them from recommending it to patients.

A wordle pictogram summarised the qualitative data of oncologists' beliefs and attitudes towards yoga for symptom management in adult cancer (responses from question item 35; see Figure 7.5). Oncologists' report that yoga's use in oncology,

especially breast cancer, is "worth exploring" as it may improve relaxation, mindfulness and assist to reduce pain and fatigue in patients.

Within this sample of 29 oncologists, 35% (n=10) reported having recommended yoga to patients to improve physical activity, fatigue, stress, insomnia and muscle or joint stiffness. Oncologists also reported being happy to refer some patients (n=16) and willing to recommend it (n=11). Twenty-six respondents (90%) did not agree yoga is a religious practice without therapeutic value, and twenty-one respondents (72%) did not agree yoga would be a waste of time for patients. All respondents (n=29) said they would refer their patients to a clinical trial to test efficacy of yoga to improve outcomes in quality of life.

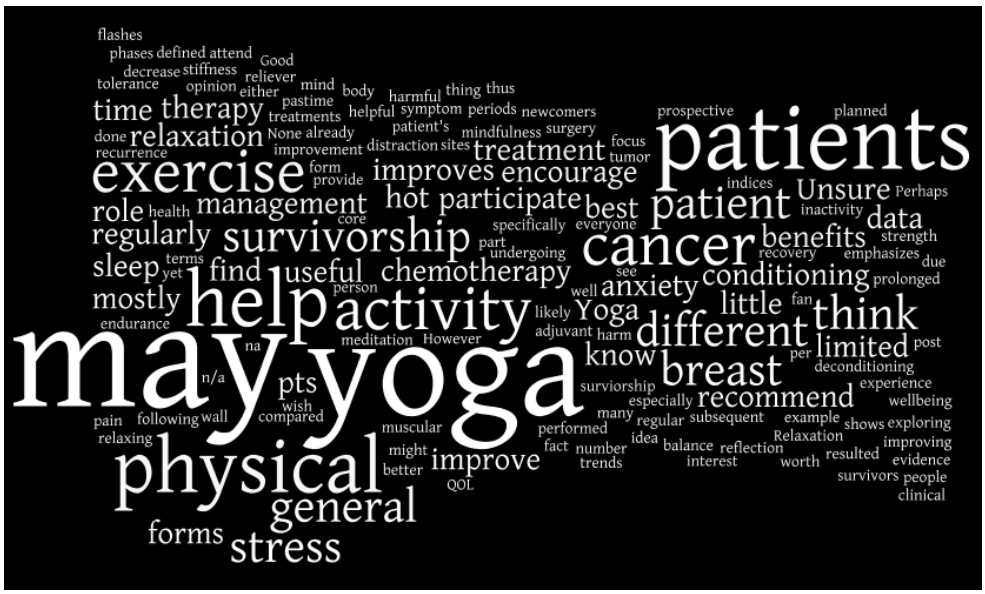


Figure 7.5. Wordle of oncologists' views of yoga

In terms of patient characteristics, the majority of respondents (n=24) believed yoga is appropriate for patients in remission and early-stage cancer or fearful or anxious patients (n=22). In addition to this, oncologists believed patients undergoing chemotherapy, radiation or surgical treatments (n=20), or late-stage cancer (n=16) and patients in palliative care (see Figure 7.6) might also find yoga beneficial. Some

oncologists indicated uncertainty as to whether yoga would be suitable for children (n=14) or patients seeking answers to spiritual questions (n=13).

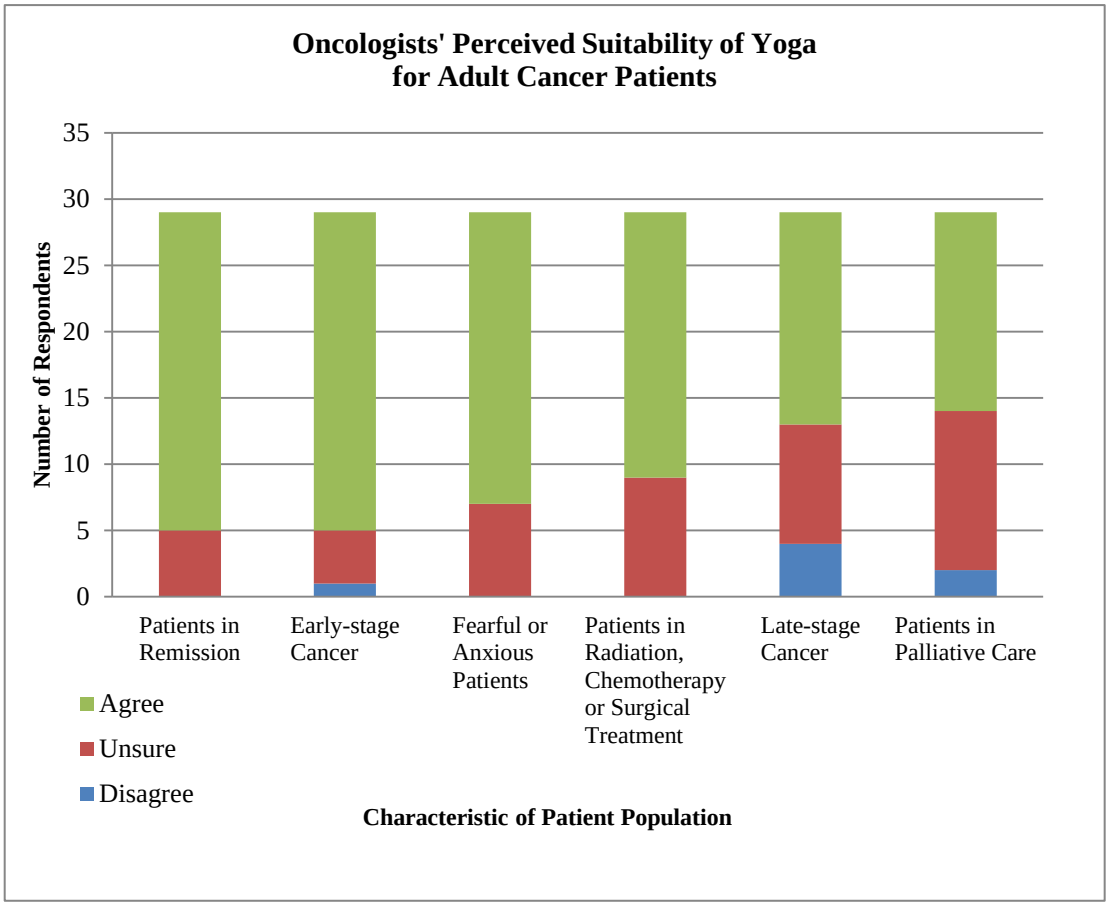


Figure 7.6. Oncologists' perceived suitability of yoga for adult cancer patients.

Oncologists were unsure or usually disagreed with the statement that yoga was not suitable for most symptoms or characteristics in adult cancer populations (see Figure 7.7). Some oncologists perceived yoga as an unsuitable intervention for those receiving surgical intervention (n=4), frail or elderly populations (n=3) or patients suffering physical pain (n=1).

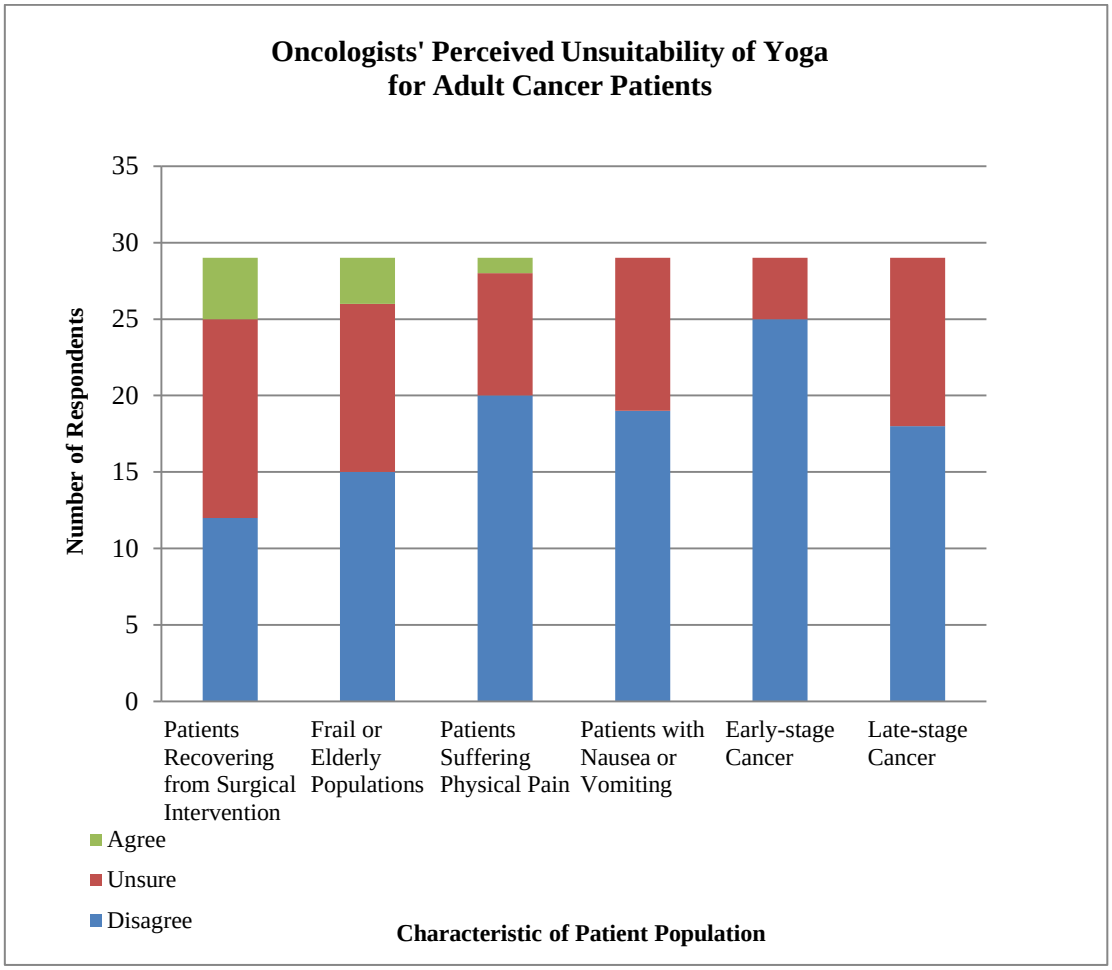


Figure 7.7. Oncologists' perceived unsuitability of yoga for adult cancer patients.

7.4.13 Oncologists' Perceived Barriers and Clinical Concerns

Oncologists identified several potential limitations and barriers to practising yoga during cancer treatment. Survey results indicated fatigue (n=28) as the most significant perceived barrier that prevents cancer patients from participating in their activities of daily living (ADLs). Patients' psychological limitations including fear, anxiety and depression were also reported in high frequency (n=25) and painful side effects from conventional treatment such as soreness in mouth, throat or extremities and nausea (n=15) are also identified as general limitations (see Figure 7.8).

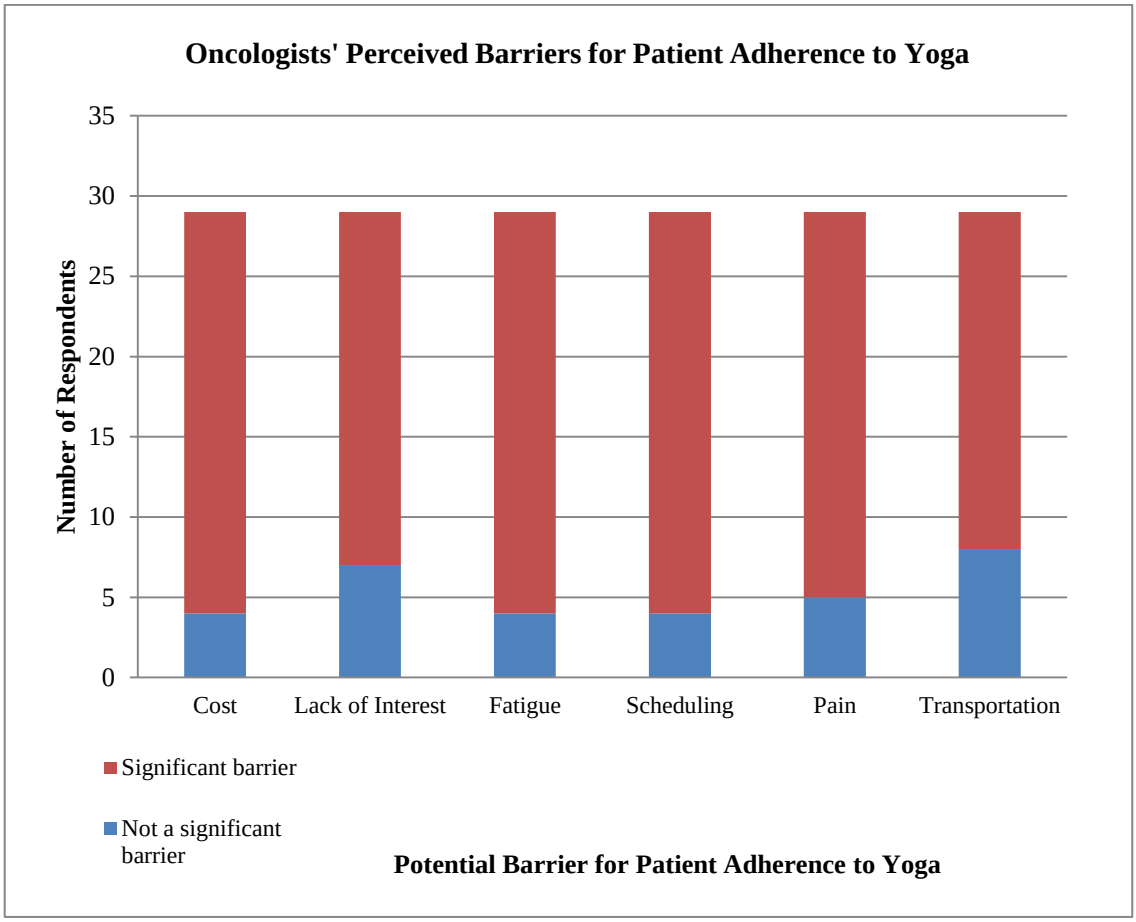


Figure 7.8. Oncologists' perceived barriers for patient adherence to yoga

The text analysis of oncologists' identified physical limitations such as fatigue, pain and nausea as serious threats to participation in activities of daily living. Psychological limitations included depression, lack of motivation, stress and anxiety about their illness and appearance. Furthermore, logistical issues such as lack of time, financial burden, scheduling issues and transportation were also revealed as potential barriers to physical activity. See Figure 7.9 for a wordle representation of question item 33, summarising the oncologists' beliefs about barriers of activity for adult cancer patients.



Figure 7.9. Oncologists' perceived barriers for patients to participate in activity

7.5 DISCUSSION

7.5.1 Summary of Findings

The existing literature is insufficient to determine the oncologist's attitude, knowledge, beliefs and patterns of yoga use in adult cancer. A pilot survey is an important first-step in tracking the acceptance and use of yoga in conventional cancer care. The quantitative and qualitative results suggest there is sufficient interest and clinical equipoise[273] to warrant research in the field of yoga intervention and potential health-related outcomes in adult cancer. Responding medical and radiation oncologists demonstrated a positive, curious attitude towards yoga. Similar to previous findings[260], the accessibility, unclear cost-benefit and lack of evidence-based guidance are significant barriers to oncologists' recommendations of yoga in adult cancer.

7.5.2 Advancing the Model of Yoga Intervention

From the responding oncologists in this survey, the modelling of yoga's processes and outcomes has been enhanced in three distinct ways (see Box 7.2). First, yoga is considered an acceptable intervention to oncologists to assist patients in improving anxiety, pain management, sleep quality; oncologists are also curious about the potential for yoga to improve adherence rates to conventional treatment and performance of immune and stress biomarkers. Second, oncologists identified significant barriers to patient adherence of yoga that would need to be adequately addressed in advance of a RCT protocol including intrinsic factors such as: anxiety, pain, fatigue, lack of motivation; and extrinsic factors such as scheduling and cost. Third, oncologists perceive yoga as an exercise technique, and request researchers consider active comparators to determine if yoga could be equivalent or superior to exercise to improve the wellbeing of patients.

Box 7.2 Components of modelling yoga intervention from the oncologist's perspective

Outcome measures: anxiety, pain, fatigue, HRQoL, biomarkers, adherence to conventional treatment, decrease in prescription medication
Comparators: exercise or other active comparator
Patient barriers: anxiety, pain, fatigue, lack of interest, cost, scheduling conflicts
Oncologist barriers to recommending yoga: lack of high-quality evidence, lack of knowledge and/or resources to provide yoga to patients

7.5.3 Deviations from Protocol

The study was designed to run for 21 days in September 2013. Due to administrative delays in BCCA and slow response rates of oncologists, the study was extended 3 weeks from 5 November to 16 December 2013. The strict deadlines reflected a decision to increase research efficiency and decrease the risk of variation of responses over time.

Initial statistical calculations were performed to consider a probability sampling technique and indicated a sample size (n=118) would be required to reach statistical significance in a population known to have a low response rate (approximately 20 to 25% from previous CAM studies conducted by LB). After internal discussion with local experts about the slow response rate, a consensus was reached (ST, LB, MM) to target a specific population using a convenient sampling approach of the BCCA database (n=260).

7.5.4 Limitations of the Survey

The 38-item online survey was initiated and completed by 29 of 260 contacted oncologists in Vancouver, British Columbia. The low response rate restricted the use of data for descriptive, preliminary analysis only. The majority of respondents (n=25) did not identify any formatting, content or areas for modification of the survey instrument. Two respondents registered complaints that ‘other’ or ‘not applicable’ boxes forced them to select responses that were not entirely indicative of their position and some questions (unspecified) appeared vague.

The instrument was modified during validation to balance the survey and its questions to avoid positive or negative suggestions where possible. Specific language to invite oncologists to ‘assist in directing funds for future research’ was used to

incentivise even non-yoga proponents to participate. The online format allowed for two minor corrections during data collection (one typo, one formatting change).

Time and budgetary constraints prevented extensive validation and reliability testing of the survey instrument; this limitation could be addressed in further studies in a larger sample to determine consistency and reliability coefficients. In addition, statistical methods should be considered to determine redundancy of questions to increase the efficiency and time to complete the survey, like a factorial analysis or application of the Rasch model which would improve instrument validity[274,275].

The sample appeared representative and equally distributed across gender, age, years of medical experience and religious groups. However, very few medical and radiation oncologists – no surgical oncologists – responded to the survey. This sample is not representative of the oncological perspectives in other geographical regions or of British Columbia itself. Suspected reasons for the low response rate include either lack of time, incentive or interest in completing a yoga survey.

7.5.4.1 Threats to internal validity

This survey was designed to pilot and collect preliminary data of oncologists' views on the application of yoga in adult cancer. The online instrument was developed in response to a limited availability of current evidence in the area and generated from questions of interest for this doctoral thesis as well as previous instruments (i.e. CAM-KAPY). For pragmatic reasons of time and limited human resources, the internal validity of the question items were not thoroughly tested. Procedures and sampling ensure the survey tool satisfied content and face validity criteria and limited test-retesting for reliability of responses was conducted (n=3). Future iterations of the survey would need to apply statistical evaluation to determine the

internal reliability and validity of questions with methodological considerations explored elsewhere[276-278].

7.5.4.2 Threats to external validity

The completion rate of this online survey was extremely low (29/260 = 15%). Statistical inferences cannot be drawn due to the margin of error [CI ± 17.2] and excessive risk of bias. The presented data are exploratory findings only. Nevertheless, the current online survey tool and data collection are sufficient to understand potential trends and methods of analysis for a similar survey. The poor response rate poses serious threats of self-selection bias and indicates follow-on surveys will need to modify their study design to improve external validity.

7.5.5 Subgroup Analysis

A recent market study reports 82% of people who practise yoga are female[279]. The exploratory findings of this survey suggest female and medical oncologists report a positive attitude towards yoga with more frequency than men and radiation oncologists (see Figure 7.10). These two subgroups also report higher rates of personal use of yoga and historical use of yoga in patient care. As demographic and professional characteristics may influence oncologists' willingness to prescribe yoga as a therapeutic option, a large-scale survey to explore this subgroup effect is needed.

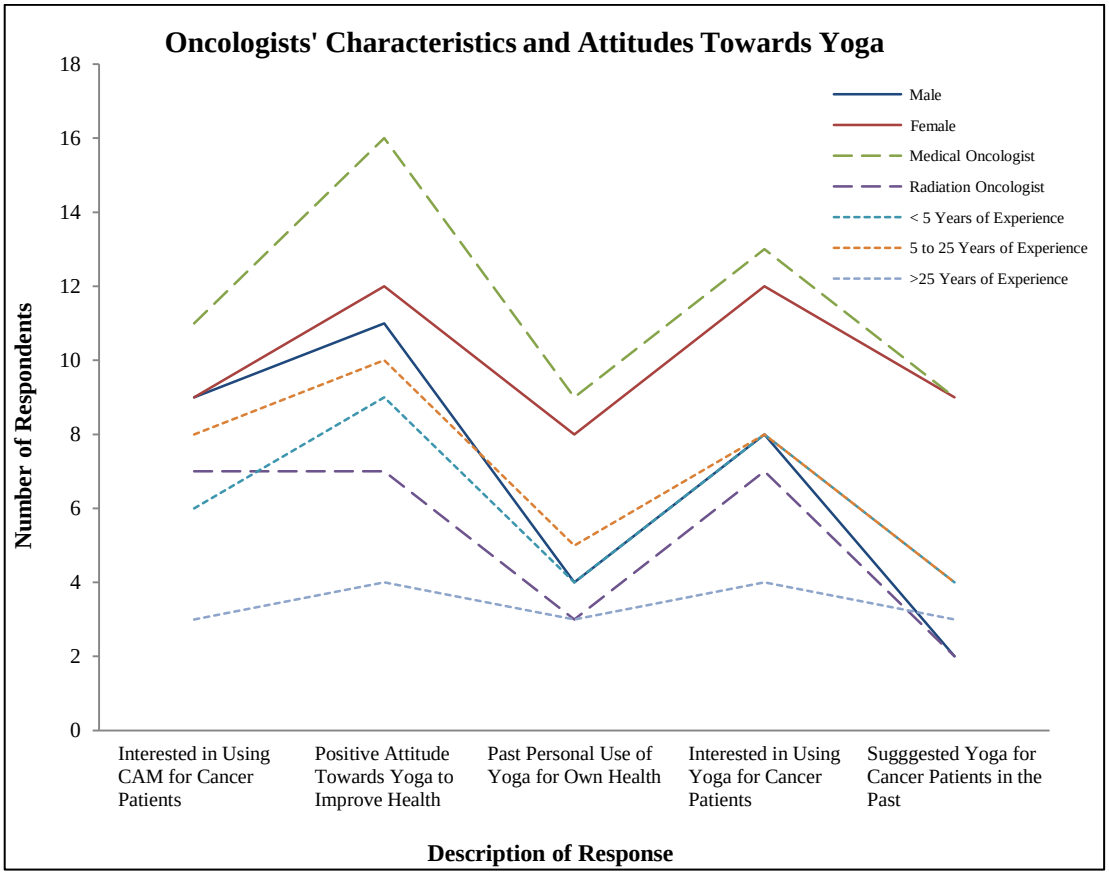


Figure 7.10. Oncologists' characteristics and their attitudes towards yoga

7.5.6 Recommendations for the Yoga Survey

In advance of future large-scale surveys of this kind, the instrument will need further internal and external validation. This process will require a more lengthy development process and improved methods of participant recruitment to increase the response rate from 15% to at least 30% and aim to meet average response rates for general practitioners (GPs) of 60%[280].

The advantage of this online survey was its scalability and efficiency of data collection. However, electronic surveys require special attention in piloting to encourage high response rates without biasing results to include only those individuals inclined to participate in internet-based communication[281]. Other web

surveys have used a sequential mixed mode approach to successfully increase response rate, where mail and paper surveys were followed by web-based contact in large-scale surveys to enhance data collection[282]. Even though web-based surveys increase participation in research[283], higher participation rates have been reported in studies that included face-to-face recruitment[284]. The results are inconclusive although, as another study showed face-to-face introduction versus a self-administered mode of survey delivery had not increased participation. Therefore, the requisites of time and cost-efficiency are appropriate determinants for choosing the online mode of data collection[285].

A meta-analysis of survey length indicated questionnaires should base decisions on content and use of data, not to limit the length to increase participation per se[286], suggesting the length of this survey (approximately 15 minutes) is not necessarily a cause for modification of its content. Other results of an experimental study on the effects of personalisation of content, the length of survey, progress indicators and survey sponsor logos in a large sample (n=2,520) indicate that of all considered factors, only personalisation significantly increases the web-based survey response rate[284]. This survey design perceived a threat of depersonalisation and addressed this potential problem by providing an introductory paragraph about the research purpose and its team. Furthermore, an internal administrator sent the invitation to oncologists associated with the BCCA database.

Limited amount of time, lack of interest or inadequate financial incentives are potential explanations for the low response rate in this study. Consultation with piloting volunteers reported this population is susceptible to “response-fatigue” where oncologists are often targeted for numerous surveys per week and offered in

excess of £100 to participate. Furthermore, a decline in survey participation has been identified as a concern in other epidemiologic studies[287], which is attributed to excessive marketing schemes including telephone and internet-based solicitations.

A systematic review of recruitment strategies of GPs reported that larger monetary and nonmonetary incentives, postal correspondence and contact from a peer or personalised packages increase participation rates ahead of random telephone or web-based surveys[280,288]. According to one RCT of response rates in GPs (n=125), even a small non-financial incentive in the form of a pen had increased response rates from 47% (in the control group) to 62%[289]. Given choice between paper and online survey methods, a group of Australian GPs completed only the paper version. These results indicate future yoga surveys to oncologists might include paper options and a small gift to increase participation.

The survey tool is inherently limited to the respondent's interpretation of the written question, which poses particular risks of assumptions made on the part of both respondent and survey author[290]. For example, as yoga has been referred to as a complementary or exercise therapy in previous research, this survey made an assumption to include language that characterised both yoga and exercise as complementary therapeutic options for adult cancer patients. Several oncologists (n=3) identified this as a mischaracterisation and did not wish to name either yoga or exercise as a complementary therapy. However, due to limitations of the survey instrument to describe people or events[291], survey data rarely captures in-depth understanding or causal relationships. Therefore, new research methods including focus groups[292] or semi-structured interviews[293] may elicit more complete data sets and provide a richer contextual understanding of oncologists' attitudes and beliefs

about yoga. These methods would also address shortcomings of one-way communication including misunderstandings, and in this instance, a potential mischaracterisation of yoga and exercise.

7.5.6.1 Yoga perceived by oncologists as exercise

Existing yoga studies tend to characterise yoga as a CAM. Though outside the scope of this study, it is evident there may be a misunderstanding of what yoga *is*, especially in terms of health care and clinician's taxonomy. According to the National Center for Complementary and Alternative Medicine (NCCAM)[294], 'complementary' generally refers to using a non-mainstream approach together with conventional medicine, usually natural or mind and body practices. The World Health Organization (WHO) defines exercise as "any bodily movement produced by skeletal muscles that requires energy expenditure."[295] While both definitions of exercise and complementary therapy appear to capture the yoga practice, the acceptability of yoga as exercise may be more established in oncology. One respondent (male, age 48, medical oncologist) disliked the characterisation of physical exercise as a complementary therapy. Other informants felt the health benefits of yoga were similar, yet potentially superior to that of exercise where "yoga is one of the best forms of exercise due to the fact that each person participates to their level (thus everyone can participate) and little harm is done to the body". Results of this study indicate some oncologists believe yoga is analogous to exercise, and should not be referred as a CAM.

7.5.7 Implications of Findings

In British Columbia, 29 medical (n=17) and radiation (n=12) oncologists responded to an online survey collecting data on their personal characteristics, professional opinions, attitudes, knowledge and patterns of yoga use in adult cancer. According to this sample, oncologists feel patients are limited in their potential activity in yoga by physical and psychological factors including excessive fatigue, pain, nausea, wound healing, anxiety and lack of motivation. These exploratory findings also suggest clinical interventions of yoga should be sensitive to the financial impact, transportation and scheduling burdens for patients, and therefore, should be added considerations for modelling optimal yoga intervention in adult cancer.

Oncologists shared outstanding clinical questions for yoga and included specific requests for an equivalency or superiority trial of yoga versus exercise or other social activity to improve anxiety, pain and fatigue during cancer treatment. Higher quality evidence is also sought by oncologists to test yoga's efficacy in improving patient adherence to conventional treatment and biological indicators of an immune response (e.g. T-cell response).

Oncologists believe that male and female patients in any conventional treatment (unless wound healing was a concern) with early to late stage of cancer would be able to participate in yoga intervention. Oncologists (n=29) said they would recruit patients to participate in a yoga trial, and believe yoga has clinical relevance in its potential to improve anxiety, health-related quality of life, pain, fatigue and mindfulness in adult cancer patients.

7.6 CHAPTER SUMMARY

- The existing literature is insufficient to describe the oncologist's perceptions, patterns of use and current knowledge of yoga as a complementary therapy to improve health-related outcomes in adult cancer.
- The delivery of this online survey is the first known study to collect data about yoga in adult cancer from the oncologist's perspective.
- A 38-item online survey was administered to oncologists in British Columbia, Canada; the response rate was extremely low (15%).
- Preliminary findings suggested oncologists believe yoga is a gentle, adaptive form of exercise that can improve health-related outcomes in cancer patients.
- 100% of survey respondents (n=29) reported willingness to refer patients to a clinical trial of yoga intervention for health-related outcomes.
- Components of modelling yoga intervention from the oncologist's perspective:

Outcome measures: anxiety, pain, fatigue, HRQoL, biomarkers, adherence to conventional treatment, changes in prescription medication
Comparators: exercise or other active comparator
Patient barriers to practising yoga: anxiety, pain, fatigue, lack of interest, cost, scheduling conflicts, wound healing
Oncologist barriers to recommending yoga: lack of high-quality evidence, lack of knowledge and/or resources to provide yoga to patients

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CHAPTER EIGHT

Feasibility Study

8 FEASIBILITY STUDY

Features of this chapter are published in the following peer-reviewed journal:

McCall, M.C., McDonald, M., Thorne, S., Ward, A, Heneghan, C. (2015). Yoga for health-related quality of life in adult cancer: a randomized controlled feasibility study. *Evidence-based Complementary and Alternative Medicine (eCAM*): 816820. doi.10.1155/2015/816820

8.1 BACKGROUND

Recently published studies continue to support yoga as a potential intervention for cancer patients, suggesting it may be effective for improving stress[296-300] and their health-related quality of life (HRQoL)[301,302]. Despite previous recommendations to include validated outcome measures of quality of life in the context of clinical trials, few studies have been conducted to measure improvement of HRQoL in adult cancer patients[303,304]. From the results of the component analysis in Chapter 5, it is clear that high-quality yoga randomised controlled trials (RCTs) are lacking, especially in populations other than female patients with breast cancer. Furthermore, evidence from Chapter 6's patient interviews and Chapter 7's oncologist surveys suggest yoga intervention can and should be tested in various tumour types. As a result of synthesising data from Chapters 5 through 7, a model of yoga intervention has been designed to optimise a framework to improve HRQOL in adult cancer patients (see Box 8.1).

Box 8.1 Framework for Yoga Intervention for HRQoL in Adult Cancer

Type: Gentle hatha, restorative yoga
Dose: 30 to 120 minute sessions
Frequency: 1 to 3 sessions per week
Components: Breathing techniques, physical postures, mediation, relaxation
Instructor: Certified and experienced instructor, sensitive to needs of cancer patients
Delivery: In-person instruction, with resources to support for home-based practice; online yoga to encourage access, scalability and affordability to patients; yoga ambience
Barriers to Address: patient fatigue, motivation, anxiety, cost, transportation and scheduling
Participants: acceptable for men and women receiving conventional treatment for any cancer diagnosis, except for those with concerns for wound healing

8.1.1 Health-Related Quality of Life

The next phase of the protocol development is to determine the most appropriate measurement tool for HRQoL in the context of a RCT. As a concept introduced in Chapter 4, HRQoL includes domains of optimal physical, mental and social wellbeing. Measures of HRQoL combine an individual's physical function, satisfaction with their role in life (e.g. work, parent, career, etc.) and a patient's satisfaction with treatment as well as health status[175]. The quality of life metrics assist health care providers and administrators to determine if treatment leads to a life worth living[305]. This multifaceted measure also seeks to provide a patient-led baseline against which the effects of an intervention can be evaluated. Health care systems work within constrained budgets and seek to both improve the quality and length of one's life[306] and measure this equation in terms of quality-adjusted life years (QALYs)[307].

8.1.1.1 Measuring Quality-adjusted Life Years

Pliskin et al.[308] first demonstrated the concept of health maximisation grounded in multi-attribute utility theory. This theory suggests decision-making for an individual patient implies three properties of preference: utility independence, constant proportional trade-offs and risk neutrality. Utility in the sense of health utility does not refer to the usefulness of the individual or of the health condition, but refers to the desirability or preference that individuals exhibit for the condition or health status[309]. Moreover, the general health index seeks to optimise total health service systems and allocation of resources to maximise overall health utility of individual patients and as a whole[310]. Quality-adjusted life years (QALYs) represent this trade-off or potential impact of health interventions on the quality and longevity of life. The number of QALYs lived by an individual in one year is measured in QALYs lived in one year = 1 * Q, $Q \leq 1$; where Q is the HRQoL weight attached to the relevant year of life[311].

8.1.1.2 Measuring Health-Related Quality of Life

Separate from QALYs, HRQoL measures do not consider longevity or life in years, but are rather useful to determine the impact of disease and medical treatment on a patient's current wellbeing. Generic tools to evaluate the impact of health on quality of life have been in development for more than 25 years. The Sickness Impact Profile (SIP), one of the earliest measurement tools, was developed by researchers at Johns Hopkins University in 1977 to provide a descriptive profile of changes in a person's behaviour due to sickness. The SF-36 was developed during the Medical Outcomes Study (MOS) to measure generic health concepts relevant to age, disease, and treatment groups[105]. HRQoL measures are subjective and usually consist of a number

(six to 100) of personal questions including parameters such as fatigue, pain, psychological state, physical ability and social function in daily activities. The strength of validity and reliability of each measurement tool varies, as well as the authorisation procedures and cost for their implementation.

Tools to measure HRQoL have been developed to assess the cancer-specific symptoms. Two frequently reported measures include the European Organization for the Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30)[106] or the Functional Assessment of Cancer Therapy (FACT)[312]. Comparative assessments suggest the collection of HRQoL parameters can be burdensome and at times stressful for patients, as they ask personal questions that can sometimes make patients uncomfortable[313].

Disease-specific tools have surged in the past decade, especially in cancer, where more than 15 measures have been identified to assess quality of life during and after treatment including cancers of the bladder, brain, breast, colorectum, central nervous system, cervix, esophagus, head and neck, kidney, gall bladder, lung, blood, skin, prostate and vulva. There are also treatment-specific (e.g. bone marrow transplant, biologic response modifiers, and neurotoxicity) and symptom specific (e.g. fatigue and lymphedema) subscales that can be added to general measures[314]. A list of identified cancer and disease-specific tools is attached for future reference (see Appendix 8.A).

8.1.1.3 Selecting a measurement tool for HRQoL in general cancer

The HRQoL measuring tool for this study was selected using a three-step process. First, a survey of existing literature identified a list of the most prevalent cancer-specific measures used in recent research as follows: EORTC-QLQ-C30[106], FACT-

G[312], FLIC[315], QOL-CA/CS[316]. Second, data collected from existing reviews, patient interviews and oncologist surveys guided the development of a list of 15 domains of HRQoL particularly important to cancer patients. Each measuring instrument was evaluated for its responsiveness to the established 15 components of HRQoL (see Table 8.1). The QOL-CA/CS tool was the only instrument that represented each domain. Third, a literature review and a pragmatic reasoning approach established a list of eight criteria to assess the appropriateness of each potential tool.

Table 8.1. Number of domains across cancer-specific measures for health-related quality of life

List of 15 domains of HRQoL (1=included; 0=not included	**Measuring Instrument**			
	EORTC-QLQ-C30	**FACT-G**	**FLIC**	**QOL-CA/CS**
Physical Function	1	1	1	1
Cognitive Function	1	0	0	1
Social Function	1	1	1	1
Family or Personal Relationship	1	1	1	1
Psychological Stress	1	1	1	1
Depression	1	1	1	1
Pain	1	1	1	1
Fatigue or Sleep	1	1	0	1
Nausea	1	1	1	1
Vomit	1	0	0	1
Appetite	1	0	0	1
Body Image or Self-Esteem	0	0	1	1
Meaning or Spiritual Well-being	0	0	0	1
Loss of Role or Identity	1	1	1	1
Perceived Health or Well-being	1	1	1	1
Other domains	Shortness of breath, digestive system, financial worries	Side effects of treatment, sex life, coping, death & dying	Afraid of future, confidence of treatment	Constipation, fertility, locus of control, fear of recurrence, fear of future tests, sexuality, isolation, financial burden
Total	**13**	**10**	**10**	**15**

The four measurement tools were graded against the established set of criteria and scored as follows: 0 for ‘not at all’, 0.5 for ‘somewhat’ and 1 point for ‘yes’, where criteria one through five were required items, six through eight were only items of preference. In particular, HRQoL tools were evaluated on their scientific proof of the validity, reliability and their minimal clinically important difference (MCID) in cancer populations. The concept of MCID helps interpreters understand the clinical impact of a treatment or intervention. It is useful in its ability to determine if a change in the measure is substantial enough to justify a change in clinical practice[317]. The QOL-CA/CS was selected over the other measures for two reasons: its ability to capture a greater number of domains in HRQoL, and its ease in analysis of results (see Table 8.2).

8.2 CHAPTER AIM AND OBJECTIVES

The aim of this chapter is to develop a pragmatic RCT of evidence-based yoga intervention to improve HRQoL in adult cancer patients. The primary objective is to perform a mixed methods feasibility study of yoga intervention to improve HRQoL in male and female adult cancer patients. This evaluation will include testing the deliverability of yoga, considering study design and data collection methods with their financial implications for a large-scale RCT. The secondary objectives include an assessment of patient adherence, as well as evaluating the acceptability and efficacy of administering three types of yoga intervention in a clinical setting.

Table 8.2. Assessment of HRQoL measuring instrument for adult cancer

	HRQoL Tool Criteria	EORTC-QLQ-C30	FACT-G	FLIC	QOL-CA/CS
1	Is it valid?	1	1	1	1
2	Is it reliable?	1	1	1	1
3	Does it include maximum number of domains for HRQoL in cancer patients?	0.5	0.5	0.5	1
4	Is it appropriate for the population of interest? (i.e. age, language, cancer)	1	1	1	1
5	Is it self-administered and easy for participants to complete?	1	1	1	1
6	*Is it free to access or download from the internet?*	0.5	0.5	0	1
7	*Is it easy to analyse results?*	0.5	1	0.5	1
8	*Is the minimal clinical difference of the instrument identified?*	1	1	0	0
Score out of 8 criteria		**6.5**	**7**	**5**	**7**

Italics = items of preference only, not required

8.3 METHODS

8.3.1 Study Design

A three-arm mixed methods feasibility trial randomised adult cancer patients to a yoga intervention over a four-week period in Vancouver, British Columbia from 7 July 2014 to 1 August 2014.

8.3.2 Ethics and Methodological Considerations

Ethical permission was received from the British Columbia Cancer Agency Research (BCCA) Ethics Board (UBC BCCA REB: reference H14-00734) and the Oxford Tropical Research Ethics Committee (OXTREC: reference 534-14).

The participants consented to the latest approved version of the informed online and written consent before any specific procedures or data collection were performed. The Participant Information Sheet (Appendix 8.B) was hand-delivered by health care professionals (HCPs) or e-mail delivered. This strategy gave patients time to consider their participation in the study, and provided them an opportunity to discuss any concerns with their HCP or family members.

For participants responding directly to the webpage, an initial participant consent was completed prior to completion of the online survey data collection. Their online consent was confirmed with an electronic ‘click’ to acknowledge agreement. The online informed consent is found here: https://www.research.net/s/Y-ACT_INFORM (see Appendix 8.C).

After the point of randomisation, participants were contacted via e-mail or telephone with reminders to attend an in-person meeting with researchers at the Vancouver-BCCA. At this initial meeting a paper copy of the previously distributed

participation information sheet and informed consent (Appendix 8.D) were reviewed with participants and co-signed with an authorised and certified researcher (TCPS 2 Core and/or GCP1). This point marked the beginning of the active intervention. In accordance to ethical standards, participants were free to withdraw consent at any time with or without providing a reason. The withdrawal of consent or willingness to participate would not have affected the patient's usual standard of care. All names and personal details remain held confidentially under password protection and encrypted files.

8.3.2.1 Sponsorship and incentives

The Vancouver-BCCA University of British Columbia (UBC) and the University of Oxford supported the design and conduct of this research. The study and its associated costs were entirely self-funded as part of this research doctorate. Participants were not offered any compensation for their participation. Recruiting oncologists and HCPs contributed their time on a volunteer basis. All yoga instructors were compensated for their teaching and administrative time.

8.3.2.2 Safety reporting and adverse events

The risks of participation in this study were minimal. As patients were undergoing current treatment for cancer, it was expected patients would be attending regular visits with their treatment physicians. Fluctuations in patient health and wellbeing during cancer treatment were expected, but if there were suspected adverse effects of the intervention (as experienced by the patient, or observed by investigators or yoga instructors), immediate reporting to investigators, their treatment physician and the local research ethical committee was recommended. This relevant contact

information was collected and provided to all study participants in advance of the trial initiation.

Participants were free to withdraw from the study. Investigators reserved the right to request a participant withdrawal from the study if their behaviour was excessively disruptive, corrupted or indicated extreme deviation from the protocol.

8.3.2.3 Data processing and management

All digital data and relevant source data were stored under password protection and encrypted files on personal laptops (MM, MMcD). Associated paper files remained under lock and key for the duration of the study. Back up files have been encrypted under password protection on a Universal Serial Bus (USB) flash drive and stored in a theft and fire-safe storage cabinet. Personal information of patients has been separated from data analysis and will remain held for five years before deletion of raw data.

Source documents were identified as original documents, data and records. These source documents included any patient record, physician notes, report forms, questionnaires, electronic mail communications or attendance records. Some source documents contained participants' identifiable details and therefore remained confidential and were accessed only when necessary by authorised members of the research team.

The study was performed in accordance with the approved protocol and its amendments. Investigators (MM, MMcD, ST, CH, AW) monitored data collection, quality of intervention, and ensured data were complete and up-to-date. Yoga instructors recorded summaries of class conduct, attendance and personal observations. An interim analysis by an independent data monitoring committee was

not considered essential due to the short study duration and non-invasive nature of the intervention.

8.3.3 Participants

Recruitment for this study included adult cancer patients planning or currently undergoing chemotherapy, radiotherapy, hormone therapy or active surveillance in a conventional care setting. Based upon the evidence from Chapters 5 through 7, the participant inclusion and exclusion criteria were defined as follows:

Inclusion criteria

1. Male and female adult cancer patients（18 years of age or older)
2. Patients receiving or planning to receive conventional treatment that includes at least one of chemotherapy, radiotherapy, hormone therapy or active surveillance within 28 days
3. Patients in any stage of cancer diagnoses of all tumour types and locations
4. Participants with internet access and willingness to participate in online communication
5. Participants with access to transportation and personal willingness to attend meetings in central Vancouver, Canada.
6. Participants fluent in the English language

Exclusion criteria

1. Patients with any physical limitation, risk of personal injury or under proscription of light to moderate physical activity
2. Patients with pre or post-surgical interventions were excluded due to potential physical limitations or safety concerns with wound healing

3. Regular or experienced practitioners of yoga were excluded and defined as those patients reporting current or historical use of regular yoga (two or more yoga sessions attended per month in past 12 months)
4. Patients undergoing medical treatment for serious psychological disturbances that might have interfered with adherence to protocol and/or ability to provide informed consent were excluded (e.g. multiple personality disorders, severe depression, obsessive-compulsive disorder)

8.3.3.1 Sample size

In previous yoga pilot studies in adult cancer (feasibility studies not found) samples ranged from n=30[318] to n=44[319]. As a feasibility study, information to predict the size of effect was not a major factor in determining the sample size. The focus of this feasibility study was to assess the deliverability of yoga in adult cancer and its sample size was determined using a cost-sensitive and pragmatic approach. The minimum and maximum sample sizes were established *a priori* to ensure substantial information on participant recruitment rates, adherence and preferences of yoga intervention. This sample size was a practical application of a fixed budget (up to £5,000) and responded to availability of space within the cancer centre to accommodate three yoga groups per week. After consultation with the clinic's administrators and yoga instructors, it was determined an existing exercise room would accommodate five to 10 yoga participants per session. Therefore, the minimum sample size (n=15) (three groups of five participants) and maximum sample size (n=30) (three groups of ten participants) were set.

If the minimum sample size was not reached before the proposed cut-off point of 30 June 2014, a tentative four-week extension period was planned. If recruitment

minimums were still not reached after this recruitment extension, the sample size would have been deemed insufficient and signalled the study design as infeasible. Amendments in eligibility criteria or recruitment strategy would then have been addressed with a subsequent proposal of amendments for ethical approval.

If maximum numbers of participants were reached, or participants registered after the cut-point, researchers (MM, MMcD) asked patients if they wished to be added to a waitlist for future trials. As well, interested patients in this category were given a list of community-based resources and programs at the Vancouver-BCCA for their interest.

8.3.3.2 Participant recruitment

Study participants were recruited from the Vancouver-BCCA in Vancouver, Canada. Posted advertisements within the Vancouver-BCCA facility and related buildings (MMcD) informed prospective participants about the study (Appendix 8.E). Interested volunteers contacted the lead researcher (MM) via e-mail, text message, telephone or completed the online registration forms directly.

Oncologists, nurses and other health care professionals (HCPs) interacting with cancer patients were invited to participate in this study as recruitment HCPs. Potential recruitment HCPs received electronic mail invites via the BCCA database (MM, MMcD) (Appendix 8.F). Volunteering health professionals contacted researchers via e-mail, telephone or text message and were mailed or hand-delivered paper brochures to offer patients during medical visits. In addition, the on-site researcher (MMcD) stored a bundle of patient brochures to deliver or advertise the study on an ad hoc basis during staff meetings, clinical workshops and word-of-mouth. In addition to this, Chapter 7's survey collected e-mails of Vancouver-based oncologists (n=8) willing to recruit patients to a yoga study. These prospective

recruiting oncologists were contacted and sent recruitment information (MM, MMcD).

8.3.3.3 Randomisation procedure

The random group allocation occurred one-week in advance of the active intervention. In response to limitations imposed by a small sample size, restricted randomisation allocation with gender stratification[320] was used to ensure equal distribution of male and female participants across three yoga intervention groups. At the point of recruitment completion, the names of participants were removed and converted into a four-digit code generated according to random initials and numbers (i.e. AZ01). The participant codes were placed in blank envelopes so researchers were made unaware of contents, identical in every way except the participant code inside and white envelopes for females and brown envelopes for males were used.

The randomisation process occurred simultaneously for all participants by an external investigator (RA) not directly involved in the design or implementation of the study. A physical shuffling of the envelopes was performed to ensure they were well mixed (RA). Envelopes were then randomly allocated to three piles designated for yoga intervention Groups A, B or C (in order from Groups C to A to allocate more participants moderate and maximum exposure). A gender-based stratification technique was employed to ensure the groups had equal distribution of male and female participants. The brown (male) envelopes were allocated first, and white (female) envelopes then followed in sequence. Envelopes were marked in ink by researcher (RA) of the yoga allocation A, B or C. The allocated bundles of envelopes were hand-delivered to the lead researcher (RA to MM). The participant codes and corresponding allocation information were then recorded on a digital template.

Participant codes remain held under password protection and encrypted on digital files. [Note: participants were recoded randomly according to group identification (i.e. A1-A5) for presentation of results]

8.3.4 Interventions

The initial framework for the yoga interventions (i.e. time, medium, component of yoga) was established by the modelling process that was completed through a component analysis, patient interviews and oncologist surveys in Chapters 5 through 7. The minimum and maximum amounts of yoga were extracted from existing studies that showed positive results in health-related outcomes (30 minutes of breathing techniques to 120 minutes of breathing techniques, physical postures and meditation). Results from patient interviews conducted in Chapter 6 and Chapter 7's oncologists' surveys were also used to optimise the scheduling and components of yoga intervention (flexible scheduling, easy to access, classes only for cancer patients, 60 to 75 minutes duration and up to three times per week).. A part and timing plot (PaT)[321] (see Figure 8.1) describes the variability components of yoga intervention across three groups and the study protocol that was designed *a priori.*

All participants were introduced to the safe conduct of yoga and invited to initiate a home practice at their discretion and were provided a personal yoga mat and instructional yoga book[322] to facilitate practice. Participants were also encouraged to contact their physician or a trained yoga teacher (e-mail and telephone information provided) with questions or concerns about the risks of doing yoga. E-mail reminders were sent to participants in Week 1. Socialising amongst all group participants was permitted though not formally structured.

Timeline	Yoga Intervention A	Yoga Intervention B	Yoga Intervention C
Randomisation			
Baseline	a	a	a
Week 1	1 2	1 2 3	1 2 3
Weeks 2 to 4		4	5
Week 5	a b	a b	a b
End of Study			
a	QOL-CA questionnaire completed by consenting participants (online or paper)		
b	Semi-structured, self-reported survey (Y-ACT) to elicit information regarding at-home yoga adherence, patient experiences, utility/dysutility of yoga, patient attitude and barriers to practising yoga (online or paper)		
1	30-minute training session of pranayama (breathing techniques) administered by a professional yoga instructor in a group setting, given own yoga mat and book to encourage home-based practice, social gathering and tea offered to encourage group discussion		
2	15-minute orientation and education session delivered by a professional yoga instructor, includes identification and list of community-based and online options to practise yoga		
3	30-minute of asana training with 15-minute orientation of free and unlimited access to online yoga classes (www.myyogaonline.com)		
4	120-minute yoga workshop, orientation and education session to include pranayama, dhyana, asana (physical postures), social gathering and tea offered to encourage group discussion		
5	3 x 60-minute yoga classes (per week) including pranayama, asana and dhyana administered by a professional yoga instructor in a group setting, social gathering and tea offered to encourage group discussion		

Figure 8.1. PaT plot of yoga interventions

The class schedules were developed in response to concerns expressed by patients about work schedules, fatigue and room availability. All yoga classes were initiated between the hours of 10am and 6:30pm. Introductory and workshop sessions were allocated two slots to allow for maximum attendance (see Appendix 8.G).

In addition to the framework provided by the modelling exercises, one 2-hour workshop session was scheduled with experienced and certified yoga instructors (n=4) and researchers (MM, MMc). The objectives of this meeting were two-fold: first, to provide yoga instructors with an overview and orientation to the study, including issues of protocol, ethic conduct and building security; second, to finalise the modelling of yoga intervention and develop standardised lesson plans for the three yoga interventions. See Appendix 8.H for the issued agenda and a sample of the blank worksheets that were used as a framework. This instructor worksheet was also used to record special requests and recommendations for home-base materials and equipment lists (i.e. yoga mats, books, candles).

The worksheets for lesson plans were completed by the group of yoga teachers (n=4) during a second follow-up meeting and through an e-mail dialogue with teachers and researchers. In-person meetings were especially difficult given the travel and work schedules of the group members. This scheduling limitation could have been addressed if there was a longer lead-time to co-ordinate agendas (i.e. 10 to 12-weeks in advance). Over a 3-week period in June, the consensus data was eventually approved by all instructors (n=4) and researchers (MM, MMc). This marked the completion of the yoga intervention modelling process for the purposes of this study, and established the standardised, evidence-based yoga intervention for the feasibility protocol.

8.3.4.1 Yoga Intervention – Group A

The minimum-exposure yoga package planned 45-minutes of contact time with a trained yoga professional. This session included a 30-minute introductory session focussing on pranayama (breathing techniques) as well as a brief introduction to available community-based and online yoga to encourage a safe home-based practice (15 minutes). Participants were invited to stay for a social discussion following the yoga class. See Table 8.3 for an overview of this low dose yoga intervention.

8.3.4.2 Yoga Intervention – Group B

The medium-exposure yoga package included components of Group A, with an additional 30-minute orientation and safety training of how to practice yoga dhyana (meditation techniques) and asana (physical postures) in week one. Participants were invited to stay and ask questions following the yoga class. A pre-paid online yoga membership to http://www.myyogaonline.com was offered for the duration of the study. In addition to this, one 120-minute workshop to further develop yoga pranayama, dhyana and asana training was administered by an expert instructor during week two or three. See Table 8.4 for an overview of this medium dose yoga intervention.

8.3.4.3 Yoga Intervention – Group C

The maximum-dose yoga package included the components of Group A, with the same 30-minute orientation and safety training of how to practice yoga dhyana (meditation techniques) and asana (physical postures) in week one. Participants were invited to stay and ask questions following the yoga class. As in Group B, a pre-paid online yoga membership to http://www.myyogaonline.com was also provided for the duration of the study. Participants were then invited to attend three 60-minute yoga

group classes led by an expert yoga instructor per week (weeks one to four). These yoga sessions were held in a clinical setting in proximity to their treatment location and delivered at no cost to the patient. See Table 8.5 for an overview of this high dose yoga intervention.

8.3.4.4 Online yoga

Despite the patients' trepidation to participate in online yoga (Chapter 6), this medium was included in Group B and Group C to test its ability to improve access, scalability and adherence to a home-based practice. Participants were offered an online membership to an existing yoga agency, MYYOGA. Members were required to enter the designated website address on a personal computer to activate a 'gift certificate' (see Appendix 8.I). Participation rates and satisfaction of using online yoga were collected in a self-report survey. To encourage the safe practice of yoga online, the following actions were taken:

1. MYYOGA online membership participants were oriented to the website and given a list of suitable classes in advance. This orientation described the components and visual cues of an appropriate class, although it did not endorse the website as being specific to cancer, nor as a replacement for in-person instruction. This was completed at the initial meeting for Group B and C by an expert yoga instructor and facilitated by investigators.
2. A supervised asana yoga class was administered by an expert yoga instructor to participants in advance and was completed at the initial meeting in Group B and C. Special attention was given to the 'feel' of postures, what is a 'good' stretch, risks of yoga and how to avoid injury.

3. Participants were invited to contact an expert yoga instructor via telephone or e-mail throughout the duration of the study with questions or concerns about specific classes or movements during their home-practice.
4. The informed consent included an explanation of how participants can opt-in and opt-out of online yoga at their own risk.

The MYYOGA online yoga platform was selected because of its Vancouver-based content that featuring local yoga instructors and was known for its affordability and the user-friendly interface. In addition, the website contains a large database of yoga classes for restorative and beginner yoga. The privacy policy and terms of use are clearly reported on their website. A written e-mail communication with the executive administrator of MYYOGA online (Co-Founder Michelle Trantina) confirmed the following conditions were satisfied *a priori*:

1. The internet servers are based in Vancouver, Canada
2. Participants could opt-out of any future mailings or contact from MYYOGA
3. Participants would be required to provide a personal e-mail address, though not required to reveal any additional personal information

Table 8.3. Summary of Group A intervention

Session Number	Section Title	Duration	Key Components	Lesson Plan Outline (i.e. how many minutes of what component?)
1	Introduction to Yoga	15 min	What is yoga? How and why practice yoga? Discuss resources and to access community-based or affordable yoga	• What is Yoga? Connection of mind & body, with others, your environment. Awareness. • Why? To create ease, balance and awareness. Calm the mind. Tool to manage symptoms & feelings. Stress management. • No one way to practice yoga. Many styles and variations. The right way is your way. Listen to your body, always, over and above any teacher. • When taking class feel free to always rest when you need it or modify postures. You are the only one who knows how your body feels. If it doesn't feel right, it's not right. • You can always talk to the teacher before class and let them know how you are feeling. Give them as little/much info as you want. This will help them to help you. • Resource list to access other yoga
1	Yoga Training	30 min	Pranayama Techniques; Satsang	• 4 minutes- Introduction and overview of class direction, check-in with students (either individually or collectively) • 4 minutes- Breath witness/awareness • 12 minutes- Pranayama • 10 minutes – Satsang, tea and group discussion NOTE: Pranayama to be done in Savasana or supported restorative, to be picked by teacher. Teacher can pick Pranayama based on the feel of the room and energy level of students. Please pick from the following list. To use: Belly breath, sectional breathing, sighing out breathing, brahmari, sitkari Not recommended: Breath holding (causes dizziness), nadi shodhana

Table 8.4. Summary of Group B intervention

Session Number	Section Title	Duration	Key Components	Lesson Plan Outline (i.e. how many minutes of what component?)
1	Introduction to Yoga and Online Membership	15 min	What is yoga? How and why practice yoga? Introduce membership to myyogaonline.com and give pamphlet for community-based resources	Similar to Group A, with addition of online yoga orientation ● Talk about 'myyogaonline' website; instruct to search on the left side of screen for Hatha or restorative yoga classes, or specific classes for anxiety, breathing, detoxification, gentle, relaxation or therapeutics. ● Emphasise that the student only does what they feel comfortable with. One of the offerings of yoga is learning to listen to your own body and then having the respect to listen to it. If it feels good, great. If it feels bad, adjust/modify or stop.
1	Yoga Training	30 min	Pranayama Techniques	Same as Group A (see Table 8.3)
1	Yoga Training	30 min	Asana Practice and Safety Training	All very gentle asana ● 10 minutes – Restorative yoga asana, floor-based ● 15 minutes – Active yoga asana, upright and on feet (muscle retention & very easy balancing) ● 10 minutes – Restorative yoga asana, floor-based ● 10 minutes – Guided meditation, dhyana
2	Yoga Workshop	120 min	Pranayama, Asana and Dhyana Techniques	● 10 minutes – Welcome, check-in ● 10 minutes – Witness/awareness & pranayama ● 20 minutes – Restorative yoga asana, floor-based ● 15 minutes – Active yoga asana, upright and on feet ● 20 minutes – Restorative yoga asana, floor-based ● 10 minutes – Guided meditation, dhyana ● 10 minutes – Satsang, tea and group discussion (25 minutes to be used at teachers discretion based on class)

Table 8.5. Summary of Group C intervention

Session Number	Section Title	Duration	Key Components	Lesson Plan Outline (i.e. how many minutes of what component?)
1	Introduction to Yoga and Online Membership	15 min	What is yoga? How and why practice yoga? Introduce membership to myyogaonline.com and give pamphlet for community-based resources	Same as Group B (see Table 8.4)
1	Yoga Training	30 min	Pranayama Techniques; Satsang	Same as Group A and B (see Table 8.3 and Table 8.4)
1	Yoga Training	30 min	Asana Practice and Safety Training	Same as Group B (see Table 8.4)
2 to 12	Yoga Training	60 min	Pranayama, Asana and Dhyana Techniques; Satsang	• 3 minutes – Welcome, check-in • 2 minutes – Seated pranayama exercise • 10 minutes – Restorative yoga asana, floor-based • 15 minutes – Active yoga asana, upright and on feet • 10 minutes – Restorative yoga asana, floor-based • 10 minutes – Guided meditation, dhyana • 10 minutes – Satsang, tea and group discussion

8.3.4.5 Recruiting yoga instructors

Prospective yoga instructors were initially contacted in one of three ways: through e-mails sent to local yoga studios (n=4) and through poster advertisements within local cafes or word of mouth from local contacts (MM, MMcD).

First-round Screening

All yoga instructors were screened for English speaking skills and yoga qualifications in the first-round which included: minimum of 10-years teaching experience, a 200-hour Registered Yoga Teacher (RYT) certificate in raja/hatha yoga or equivalent, and independent contractor insurance provision. All interested applicants (n=9) responded via e-mail and were interviewed over the telephone (n=1), Skype[323] (n=1) or in-person (n=7).

Second-round Screening

Candidates for yoga instructors were short-listed (n=5) to advance to the second round and asked to design and submit a lesson plan for one 60-minute yoga class and one 30-minute pranayama workshop. Yoga instructors were evaluated by two researchers (MM, MMcD) on their professional merit using a 5-point likert scale, as follows:

1. Applicant described a clear and comprehensive class (pranayama, dhyana and asana components)
2. Applicant indicated sensitivity to population needs including notes for variations and/or safety concerns
3. Applicant demonstrated expertise in developing yoga classes for special populations

4. Applicant expressed commitment and willingness to be available for at least 3 teaching sessions.

The study protocol recommended contractual employment of three yoga instructors, however, due to limited teacher availability and unforeseen scheduling conflicts, four instructors were employed to ensure adequate coverage and substitutions in case of unexpected absences or illness.

Contractual Agreement

The human resource department of British Columbia Cancer Agency (BCCA-HR) was consulted by investigators (MMcD) for appropriate documentation or registration procedures. Lawyer-reviewed contractual agreements with the BCCA-HR were drafted by researchers (MM, MMcD) and signed by respective parties (see Appendix 8.J).

8.3.4.6 Location

The British Columbia Cancer Research Centre (BCCRC) Cancer Foundation (675 West 10th Avenue, Vancouver, British Columbia) was asked to offer recreational space within their existing building for its proximity and affiliation with the Vancouver-BCCA (600 West 10th Avenue Vancouver, British Columbia). In the case of fire or other unexpected concern, an alternative room would have been secured in the Vancouver-BCCA treatment facility.

8.3.5 Data Collection

Participant data were collected at two designated time intervals: pre-intervention (participant registration and baseline) and post-intervention (within two weeks of intervention completion). Participant registration collected relevant personal

information on computerised digital online forms. All data were self-reported. Baseline measures included an online collection of QOL-CA/CS. Post intervention data collection included a mixed methods customised online survey (Y-ACT Survey) and QOL-CA/CS. The online report forms and surveys were developed and validated by researchers for content and face validity (MM, MMcD, CH, AW, ST). Digital files in word (.docx) were transferred and the online survey was completed through a secure webpage hosted by SurveyMonkey (MM). The agency facilitating the online data collection signed a non-disclosure agreement and agreed to rights of privacy. If online collection of data was not feasible, researchers planned to revert to paper copies and an in-person meeting with researchers (MM or MMcD).

8.3.5.1 Eligibility screening

The eligibility assessment was performed online by prospective participants at https://www.research.net/s/Y-ACT_ELIGIBILITY (see Appendix 8.K). This electronic version of the eligibility screen was initiated upon e-signing of participation information and consent forms. The inclusion and exclusion criteria were represented in dichotomous (yes or no) categorical variables. Ineligible participants were notified with an automated message as follows:

> *Thank you for contacting us to join the yoga study. The computerized eligibility survey has informed us that you are not able to participate in this study. If you feel like there has been an error, go ahead and start again, or if you wish to clarify your response please e-mail Marcy at marcy.mccall@kellogg.ox.ac.uk*

Ineligible participants progressed to an optional online registration form at: https://www.research.net/s/INELIGIBLE_REGISTER (see Appendix 8.L). Eligible participants progressed to a separate electronic form to complete registration at https://www.research.net/s/Y-ACT_REGISTER (see Appendix 8.M). This form

collected relevant personal data including health status and socio-demographic information.

8.3.5.2 Survey instruments

QOL-CA/CS

The QOL-CA/CS 41-item validated instrument that measures cancer patients' HRQoL on an 11-point scale. This questionnaire was completed online. The online version was located at https://www.research.net/s/Y-ACT_QOL-CA-CS (Appendix 8.N). See Appendix 8.O for a copy of the QOL-CA/CS tool and written authorisation for its duplication.

Y-ACT Survey

The Y-ACT Survey is a 12-item customised survey tool that included ordinal, nominal (dichotomous and non-dichotomous) and free-text data. This questionnaire was completed online. The online version was located at https://www.research.net/s/Y-ACT_SURVEY (Appendix 8.P).

Y-ACT Instructor Survey

The yoga instructors also completed an anonymous 9-item survey that included 8 open-ended responses. The online version was located at https://www.research.net/s/INSTRUCTORS_Y-ACT (see Appendix 8.Q).

8.3.6 Comparators

A waitlist or comparison group of participants who received an intervention other than yoga was not included. As the primary aim of this study was to determine the most appropriate and acceptable type of yoga intervention, it was important to maximise the amount of data generated following exposure to yoga. However, this is

limitation to the outcome analysis, as results do not include comparative data or a benchmark from a non-yoga intervention. Previous studies show yoga intervention can be successfully randomised in a controlled trial with a waitlist, exercise, talk therapy or education groups[77,301] , and a future pilot of a RCT would be sure to include a comparison group of no-yoga.

8.3.7 Data Analysis

8.3.7.1 Qualitative Analysis

Qualitative data were collected through online questionnaires administered to all participants of the study, including patients and the yoga instructors. The three directive open-ended questions asked respondents to comment on their preferences or dislikes about yoga in adult cancer, their suggested improvements to optimise the design of the yoga intervention, and their suggested improvements for aspects of the study design (i.e. recruitment methods, communication material). There was one open-ended item inviting participants to comment on any other aspect of the study that felt important to share. Individual responses were blinded and analysed for themes and patterns using an inductive reasoning approach. Data were colour-coded into categories and then assembled to establish themes and conclusions.

Open-ended responses were also compiled in a wordle[324], similar to methods in Chapter 7 (see Section 7.4.6). Free-text results collected from the Y-ACT survey and source documents included e-mail correspondences with health care administrators, administrative assistants and yoga instructors. Yoga instructors' survey responses were analysed for emerging themes and consistent recommendations for yoga delivery in the context of the study design.

8.3.7.2 Quantitative Analysis

Quantitative data from participants were also collected through online questionnaires. The individual data from participants were considered in absolute values. Averages and percentages have been used to describe group data where applicable. Financial costs of the intervention were reported in British Pound (£). An assessment of cost-efficiency across the three intervention divided the total cost of the yoga delivery (including operational expenses such as teaching fees and materials) by the total number of hours of yoga that were delivered to patients in each group (number of hours per participant). The physical space was provided free of charge by the health care facility and not considered in the expenses. Researchers' salaries and volunteers' time have been included in the financial analysis.

The quantitative analyses of the QOL-CA/CS scores have been conducted for exploratory purposes only. The feasibility design did not seek to recruit a statistically significant sample to explore the effect of yoga on QOL-CA/CS outcomes. In an adequately powered sample, an appropriate test to compare differences in two means of continuous data from two samples of parametric statistics would be to conduct a T test[325]. For the purposes of this feasibility study, the pre and post mean averages across intervention Groups A, B and C are calculated for the completed data sets. Each individual is analysed according to the group in which they were randomised. The Excel software has been used to calculate averages, standard deviation and 95% confidence intervals of the mean QOL-CA/CS and its subscale data taken from a small sample (<30) using formulas: [=AVERAGE(number1,number2,…], [=ST.DEV.S(number1, number2,…], and [=CONFIDENCE.T(0.05,SD,sample size)].

8.4 RESULTS

Quantitative analysis included statistical reporting of frequency, percentages and absolute values. The demographics and characteristics of participant data were analysed in terms of frequency and percentages. The participant recruitment rates, adherence rates and health professional referral rates were reported and compared as percentages and absolute values. The QOL-CA/CS survey was reported as a rate of completion across participants and preliminary results of the QOL-CA/CS were reported as changes in mean results from baseline to post-intervention. The Y-ACT quantitative results were analysed in frequency and percentages. Power calculations and therefore statistical inferences have not been performed because of the small sample size.

Fifteen patients volunteered for the study but were ineligible for participation for the following reasons: already an avid user of yoga (n=7), not currently receiving conventional treatment for cancer (n=4), did not provide consent (n=1), existing physical limitations (n=1) and two volunteers contacted researchers post-randomisation (n=2). Eight ineligible participants reported they had tumour diagnoses of the breast (n=3), non-Hodgkin's lymphoma (n=3), prostate (n=1) and leukemia (n=1) and the tumours were in Stage I (n=1), Stage II (n=1), Stage III (n=2) and Stage IV (n=3). Six of the reporting ineligible participants were women, two men. See Figure 8.2 for the participant flow diagram.

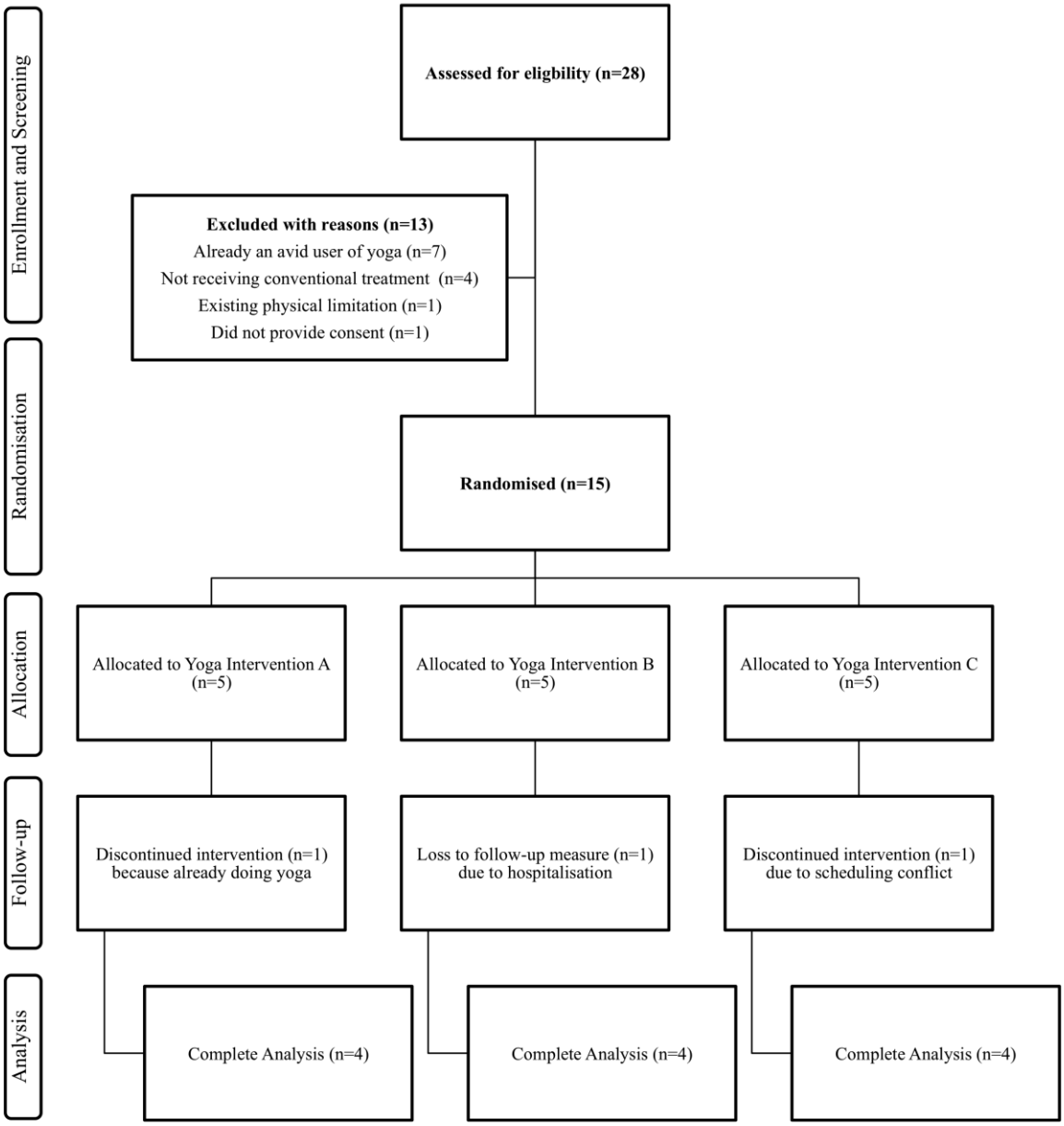


Figure 8.2. Participant flow diagram

8.4.1 Characteristics of Study Participants

Fifteen male (n=4) and female (n=11) participants were randomised into three yoga groups. Age of participants ranged from 33 to 72 years ($\overline{x}$=51 years). Working status varied from employed (n=9), retired (n=3), on disability leave (n=2) and unemployed (n=1) participants. See Table 8.6 for a summary of general characteristics of participants across groups.

All participants at the time of recruitment were receiving conventional treatment in Vancouver, Canada for a cancer diagnosis received as early as December 2009 and as recent as March 2014. The randomisation of participants was completed and resulted with relatively equal distribution across Groups A and C in participant characteristics. There was a greater distribution of breast cancer (n=3) in Group A than other groups, and on average Group C's mean age was ten years younger. A summary of cancer diagnoses of participants is provided in Table 8.7.

Table 8.6. General characteristics of participants

Participant	Age	Gender		Occupation	Registered Patient (by type of medical consultant)			
		Male	Female		Medical Oncologist	Radiation Oncologist	Surgical Oncologist	General Practitioner
A1	66	1		Industrial Safety and Health Consultant	1	1		
A2	60		1	Retired	1	1		
A3	51		1	Geologist	1	1		
A4	40		1	Self-employed	1			
A5	41		1	Quality Specialist	1		1	
Group A Total		1	4		5	3	1	0
Average	*51.6*							
B1	72	1		Retired		1		
B2	61		1	Retired	1			
B3	43		1	Massage Therapist, on medical leave	1			
B4	51		1	Not employed		1		
B5	59		1	Pharmacist		1	1	1
Group B Total		1	4		2	3	1	1
Average	*57.2*							
C1	57	1		Engineer	1			1
C2	52		1	Facilities Manager, on medical leave	1	1		1
C3	33		1	Program Manager	1	1		1
C4	45		1	Office Clerk	1		1	
C5	38	1		Internet Security Engineer	1			
Group C Total		2	3		5	2	1	3
Average	*45*							
Overall	**51.3**	**4**	**11**		**12**	**8**	**3**	**4**

Table 8.7. Summary of participants' cancer diagnoses

Participant	Tumour Type or Location	Stage of Cancer					Current Treatment				
		I	II	III	IV	Not Reported	Chemotherapy	Radiotherapy	Hormone Therapy	Active Surveillance	Post Surgery
A1	Tongue	•					•	•			
A2	Breast		•					•	•		
A3	Breast		•				•	•	•		
A4	Breast			•			•				
A5	Colorectal/Lung	•								•	
Group A Total		2	2	1	0	0	3	3	2	1	0
B1	Prostate			•				•		•	
B2	Abdomen				•				•	•	•
B3	Breast	•					•		•		
B4	Colorectal			•			•	•			
B5	Skin (forearm)					•		•			
Group B Total		1	0	2	1	1	2	3	2	2	1
C1	Prostate	•								•	
C2	Breast			•			•	•		•	
C3	Brain			•			•	•			
C4	Breast		•						•		•
C5	Leukaemia					•					
Group C Total		1	1	2	0	1	2	2	1	2	1
Overall		**4**	**3**	**5**	**1**	**2**	**7**	**8**	**5**	**5**	**2**

8.4.2 Feasibility Outcomes

The recruitment of participants in the Vancouver-BCCA commenced 15 April 2014 when posters (n=12) were posted in waiting rooms and on information boards inside the Vancouver-BCCA. E-mail invitations were sent on 21 April 2014 to oncologists in Vancouver who were identified in the earlier survey (Chapter 7) as willing to recruit patients to a yoga study (n=8). An additional e-mail describing the study and the recruitment goal was sent to all Vancouver oncologists through a centralised database on 18 June 2014.

In total, 30 Vancouver-based adult cancer patients expressed interest in the yoga study over a 12-week period from April to July 2014, 28 of whom agreed to be assessed for eligibility. For a representation of the trend of volunteer recruitment over time, see (Figure 8.3). 15 of 28 participants (54%) provided informed consent and enrolled in the Vancouver-based study at a recruitment rate of 1.5 participants per week.

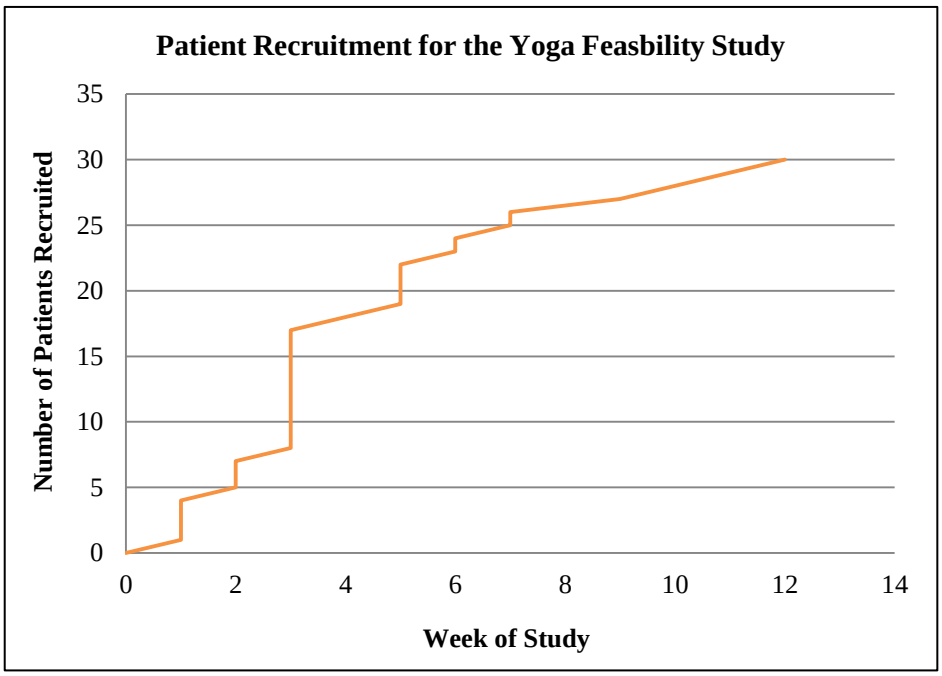


Figure 8.3. Recruitment trend for study participants

Study participants contacted researchers through e-mail (n=12), the webpage (n=12) and telephone (n=4). After the recruitment period terminated on 30 June 2014, two additional patients contacted researchers, one each by e-mail and telephone.

8.4.2.1 Deliverability of yoga Intervention in study design

The deliverability data of yoga in a clinical setting was assessed using a checklist developed *a priori* (see Table 8.8). Results indicated that administering yoga in a clinical environment was feasible and achieved 6.5/8 (81%) for performance on administrative requirements. Health administrators at the Vancouver-BCCA were receptive and encouraged the delivery of yoga in this study. In addition to prompt e-mail correspondence and effective study facilitation, the feasibility protocol was expedited and approved by UBC REB BCCA within five days of submission with no amendments.

The schedule of yoga classes at the centre was handled effectively by a receptionist and approved by a manager within 14 days. The Vancouver-BCCA human resources and legal teams organised contractual agreements in conjunction with our research team for the yoga instructors in three months. Other administrative tasks included contractual negotiations (eight to ten weeks) and securing payments for yoga instructors (four to eight weeks).

Table 8.8. Summary of feasibility outcome from researcher's perspective

Description of Feasibility Component	**Yes = 1 Partial = 0.5 No = 0**	**Researcher Comments**
Was free and suitable space readily available to deliver yoga in a clinical setting?	1	The affiliated centre across the street from the cancer treatment facility was willing and able to provide access to a conference room and their exercise room free of charge; some scheduling conflicts arose, so it is important to plan early and book the rooms; a secure and clean building, complete with a kitchenette
Was it easy to find qualified and reliable yoga instructors?	1	Word of mouth, asking patient and family counselling services at BCCA-Vancouver, e-mailed local studios
Was it easy to schedule yoga classes in a clinical setting?	1	Receptionist booked in rooms, the room is rarely used, but on a few occasions the conference room and exercise room was booked, so needed to reschedule or work with their schedule in only two instances
Was yoga delivered safely to patients?	1	No injuries or incidents associated with yoga delivery
Was providing online access for patients feasible?	1	Gift Certificates easily purchased from an existing provider; printed out to give to participants, no customisation of program
Was insurance easy to secure and/or needed?	0.5	Yoga teachers have own insurance providers; contracting with BCCA is feasible (in 8 to 10-weeks)
Was the administrative team in cancer clinics supportive and helpful?	0.5	Yes, but can be slow to respond. It is a big organization, difficult to coordinate with competing priorities.
Was the coordination of an international research team feasible?	0.5	Yes - a lot of time commitment, early and effective communication important; at least one face-to-face meeting needed to help along the rapport and commitment to the study; past relationship helped to encourage participation, though still tentative about taking on new tasks/commitments
Total Feasibility Score	**6.5/8**	

8.4.2.2 Financial considerations

The budgeted expenses for the Y-ACT feasibility study including the administrative design and delivery of four-weeks of yoga intervention for three groups (n=30) was £6,000. The projected budget allocated £200 per participant across all groups. This budget assumed investigator fees, indemnity insurance and rental of space in private or clinical settings were waived and not a direct cost of conducting the study.

The actual expense of the four-week intervention with three yoga groups (n=15) was £3,073 (see Table 8.9). The most expensive intervention was Group C's three sessions per week with pre-paid online yoga at £1,383 over four weeks, and the most inexpensive mode of delivery was Group A at £755. The overall average cost per participant across groups was £205. See Table 8.10 for a comparative summary of cost per participant across all three yoga interventions.

The cost per participant was slightly higher than budgeted in Groups A and B with an increase of £26 and £12 respectively. In general, the budget underestimated the number of administrative hours needed by the yoga instructors to design the class templates for Groups A and B. There was also an unauthorised time extension (20 minutes) was provided by yoga instructors to Group A. The online yoga expense in Groups B and C were more affordable than anticipated (£5 per month).

Table 8.9. Summary of yoga intervention expenses (in £)

Yoga Group	**Yoga Instructor Fees**		**Equipment**			**General Expenses** (prorated across groups)						**Total**	**Cost per participant**
	Teaching	Administration	Book	Yoga Mat	Online Yoga	Bolsters	Straps	Blocks	Eye Pillows	Blankets	Miscellaneous		
	(£40/hr)	(£25/hr)	18	25	5	30	8	8	8	14	3		
Group A	110	75	90	125	0	150	40	40	40	70	15	755	151
Group B	240	100	90	125	25	150	40	40	40	70	15	935	187
Group C	600	188	90	125	25	150	40	40	40	70	15	1383	277
Total	**950**	**363**	**270**	**375**	**50**	**450**	**120**	**120**	**120**	**280**	**45**	**3073**	**205**

Group A. Two one-hour introductory sessions, one of 1.75 hours duration for total of 2.75 hours of teaching fee

Group B. Two one-hour introductory sessions, two workshops of 2 hours duration for total of 6 hours of teaching fee

Group C. Three 1-hour introductory sessions, 12 classes of 1 hour duration for total of 15 hours of teaching fee

Miscellaneous expenses include refreshments, candles and other class-related props (e.g. tissue, pens)

All calculations for n=15, five participants per group at time of randomisation

Total cost and cost per participant is total cost/5, rounded to nearest whole number

Table 8.10. Comparison of estimated and actual cost per participant (in £)

Yoga Group	Cost per participant (estimated)	Cost per participant (actual)	Cost difference
Group A	125	151	26
Group B	175	187	12
Group C	300	277	(-13)
Total	**600**	**615**	**15**

Group A. Unanticipated need to extend teaching hours and session time

Group B. Online yoga expense less than anticipated, administrative time slightly more than anticipated

Group C. Online yoga expense less than anticipated

The maximum amount of yoga offered in each group was calculated and compared with the amount of yoga that was received by study participants. This calculation signals how efficient each type of intervention (Group A through C) have delivered yoga to its participants. Across all groups, ninety-nine total hours of yoga instruction were offered, of which nearly 57 hours were received by participants (n=13) for an overall delivery efficiency rating of 58%. See Table 8.11 for a summary of the delivery and amount of yoga received by participants across groups. The assessment suggests participants in Group B accessed the highest amount of yoga with the least amount of allocated teaching time (100% efficient). Group C incurred the greatest amount of operating expenses, but did not deliver yoga efficiently to its participants (45% efficient).

Table 8.11. Assessing the efficiency of yoga delivery across groups

Yoga Group	No. of yoga hours planned	No. of yoga hours delivered	No. of allocated participants	No. of actual participants	Amount of yoga offered	Actual amount of yoga received	% Efficiency in yoga delivery
Group A	.45	1.05	5	4	5.25	4.2	80%
Group B	3	3.75	5	5	18.75	18.75	100%
Group C	13.5	13.5	5	4	75	34	45%
Total *(average)*	**16.95**	**18.3**	**15**	**13**	**99**	**56.95**	***58%***

Maximum amount of yoga delivered = no. of yoga hours delivered x no of assigned participants
Actual amount of yoga received = no. of participants attending session x session duration in hours
% Efficiency in yoga delivery = amount of yoga received / amount of yoga offered

Yoga instructors and cost management

In the original protocol, three yoga teachers were to be employed to administer the yoga classes. However, due to the limited availability of two of the selected teachers, a fourth teacher was contracted. See Table 8.12 for the summary of expenses incurred per yoga teacher.

Table 8.12. Summary of teaching expenses (in £)

Teacher	No. of Hours	Teaching Fee	Administrative Fee	Total Cost
T1	3.25	130	38	168
T2	3	120	75	195
T3	11.5	460	150	610
T4	6	240	100	340
Total	**23.75**	**950**	**363**	**1313**

Teaching fee = £40 per hour
Administrative fee = £25 per hour

Administrative and lesson planning hours of yoga instructors were financially compensated (£25 per hour). The yoga instructors incurred an average administrative overhead cost of 28% of total costs. Some teachers were more cost-efficient than others in terms of time spent delivering yoga versus administration and lesson planning. For example, one teacher (T2) incurred administrative expenses 39% of the value of her teaching expenses. The other teachers (T1, T3 and T4) appeared more efficient with their time and incurred administrative fees 23%, 25% and 29% of their teaching fees. An *a priori* literature review did not identify research articles that report the administrative expense or efficiency of yoga instructors. Therefore, how this data compares to previous studies is not known.

8.4.3 Patient Dropout Rate and Adherence to Protocol

Two participants dropped out of the study before the active intervention was initiated. One of the participants randomised to Group C, a male (38 years of age) undergoing treatment for leukaemia dropped out via e-mail correspondence within 24-hours of randomisation, stating that due to work commitments he would be unable to participate in the study. The other participant was a female retired (60 years of age) receiving treatment for Stage II breast cancer. After being randomised to Group A, this participant dropped out within 36 hours because she reportedly "had misunderstood the purpose of the study" and was "already participating in regular yoga classes".

Thirteen participants completed the pre-intervention online survey and the active yoga intervention, of which 12 participants completed the QOL-CA/CS post-intervention survey (12/13 = 92% initiation-completion rate). One participant did not complete the post-intervention data collection due to a cancer-related hospitalisation for a surgical intervention.

The patient adherence to the allocated yoga intervention was measured in two ways: yoga instructors completed attendance sheets that recorded participants' signatures and participants were surveyed post-hoc to recall the number of classes of yoga they completed for the duration of the study.

8.4.3.1 Class attendance

Table 8.13 summarises the data collected from attendance sheets per yoga session. The afternoon class for Group B's workshop (Monday 2pm to 3pm) registered the highest number of attendees (n=5). There were three scheduled sessions that did not have any attendees (Group A's Introduction Alternate Friday 12pm to 1pm; Group B's Introduction Alternate Thursday 6pm to 7:15pm; Group B's Workshop Thursday 6pm to 8pm). In Group C, the sessions scheduled on Monday afternoon (2pm to 3pm) and Wednesday evening (6:30 to 7:30pm) were slightly more well attended than the Friday morning class (10am to 11am).

8.4.3.2 Self-reported yoga exposure

Participants self-reported their amount of exposure to yoga over the four-week period. In Group A, participants averaged four yoga sessions and 2.5 online yoga sessions per participant. Group B's participants averaged five yoga sessions over 28 days. In Group C, the average number of yoga sessions attended was 13, where one participant reported doing yoga 24 times. See Table 8.14 for participant-reported attendance to yoga (Y-ACT question items 3 and 5).

Table 8.13. Class attendance for yoga sessions

JULY 7 to AUGUST 1	Monday	Tuesday	Wednesday	Thursday	Friday
Start Time	**10am or 2pm**	**6pm**	**5pm or 6:30pm**	**6pm**	**10am or 12pm**
Week 1	**7**	**8**	**9**	**10**	**11**
	Group B, n=5	**Group C, n=1**	**Group A, n=4**	**Group B, n=0**	**Group A, n=0**
	Group C, n=2		**Group C, n=3**		**Group C, n=3**
Week 2	**14**	**15**	**16**	**17**	**18**
	Group C, n=3		**Group C, n=3**	**Group B, n=0**	**Group C, n=2**
Week 3	**21**	**22**	**23**	**24**	**25**
	Group B, n=5		**Group C, n=3**		**Group C, n=2**
	Group C, n=2				
Week 4	**28**	**29**	**30**	**31**	**1**
	Group C, n=3		**Group C, n=3**		**Group C, n=2**

Class attendance reported by group identification (A, B or C), n=number of participants attending

Table 8.14. Quantitative data from Y-ACT Survey

	Participant-reported amount of yoga, satisfaction and its utility										
Participant	**No. of total yoga sessions**	**No. of online yoga sessions practised**	**Amount of satisfaction participating in yoga (0=none, 10=very)**	**Amount of satisfaction doing yoga with teacher (0=none, 10=very)**	**Amount of satisfaction using online yoga**	**Felt not offered enough yoga**	**Would prefer more online yoga**	**Right amount of yoga**	**Too much yoga**	**Utility of yoga (0=none, 10=very)**	**Disutility of yoga (0=none, 10=very)**
A1	1	0	8	7	/					8	5
A3	6	4	8	8	8	1				8	0
A4	1	0	1	1	5	1				8	0
A5	8	6	10	10	9	1				10	2
Average	**4**	**2.5**	**6.8**	**6.5**	**7.3**					**8.5**	**1.8**
Group Total						***3***	***0***	***0***	***0***		
B1	4	0	8	9	0	1				8	0
B2	2	0	7	9	5	1				7	2
B3	10	0	5	10	0	1				8	4
B5	4	0	8	8	/	1				6	1
Average	**5**	**0**	**7**	**9**	**1.7**					**7.3**	**1.8**
Group Total						***4***	***0***	***0***	***0***		

	Participant-reported amount of yoga, satisfaction and its utility										
Participant	**No. of total yoga sessions**	**No. of online yoga sessions practised**	**Amount of satisfaction participating in yoga (0=none, 10=very)**	**Amount of satisfaction doing yoga with teacher (0=none, 10=very)**	**Amount of satisfaction using online yoga**	**Felt not offered enough yoga**	**Would prefer more online yoga**	**Right amount of yoga**	**Too much yoga**	**Utility of yoga (0=none, 10=very)**	**Disutility of yoga (0=none, 10=very)**
C1	10	0	9	9	/				1	8	0
C2	24	0	10	10	/	1				10	7
C3	5	0	6	7	7			1		8	2
C4	12	0	9	9	0	1				10	0
Average	**12.8**	**0**	**8.5**	**8.8**	**3.5**					**9**	**2.3**
Group Total						***2***		***1***	***1***		

/=not reported

8.4.4 Acceptability of Yoga Intervention

The aspects of acceptability and patient preferences for yoga interventions were evaluated from quantitative and qualitative data collected from three sources: patient-reported responses to a customised survey (Y-ACT), researcher field notes and customised surveys completed by yoga instructors.

8.4.4.1 Patient-reported acceptability of yoga intervention

Table 8.14 reports the participant's rating of the likeability of their yoga intervention in terms of future preferences, satisfaction and utility scores. On a scale of 1 to 10 (1 being least satisfied, 10 being most satisfied) participants were most satisfied with the amount of yoga administered in Group C (8.5). Group A and Group B had lower satisfaction in comparison: 6.8 and 7, respectively. The reported amount of satisfaction for practising yoga with an expert teacher was highest in Group B: 9/10, (90%) and Group C: 8.8/10 (88%). The reported amount of satisfaction for using online yoga was highest in Group A (7.3/10; 73%). The majority of participants in Group A and B felt they were not offered enough yoga (n=7), whereas only two participants in Group C wished for more yoga. One participant in Group C said she was offered 'the right amount of yoga' while another male participant felt he was offered 'too much yoga'. No participants requested more online yoga. Participants in Groups B and C did not use the prepaid online yoga service at all; one participant in Group A signed up and paid for her online membership to practise at-home yoga.

The highest rank in utility of yoga was scored in Group C (9/10). Group A rated yoga to be similarly high in utility (8.5), while Group B scored 1.7 points lower than Group C (7.3). The disutility score, or inconvenience and burden of doing yoga, indicated similar results across groups. On a scale of 1 to 10, (1 being least and 10

being the greatest amount of disutility) Group A scored 1.8, Group B scored 1.8 and Group C scored 2.3.

Free-text results from six open-ended questions were transcribed verbatim and filtered by yoga group and presented in three tables (Group A: Table 8.15, Group B: Table 8.16, Group C: Table 8.17). Qualitative analysis, conducted in a similar method to Chapter 6 (see Section 6.3.6) identified four emergent themes: positive patient experiences, preferences for yoga intervention, barriers to participation and recommendations for study design. All data condensed into wordle pictograms across four emergent themes (see Figure 8.4 to Figure 8.7).

Positive patient experiences

All responding participants (n=12) appreciated being involved in the study and felt participating in yoga had been a positive experience. A female participant (A5) said: "…this study gave me the opportunity to realize that practicing yoga can help me in my day to day, feeling more energized and in good spirits." One male participant (B1) said, "one session introduction was 100% satisfying…would have preferred an additional three classes." Respondents felt yoga would be helpful to restore body and mind and described it as a highly beneficial addition to their self-care. Several respondents suggested yoga should be regularly promoted and provided by their cancer centre. Online yoga in Group A was reported by one female participant as an encouraging concept, especially helpful in reducing her fear of contracting an infection in public space. Another female in Group A acknowledged online yoga for its benefits of convenience and flexibility to accommodate her schedule.

Preferences for yoga intervention

Patients across groups reported preference for the following components of yoga intervention: small class sizes, cancer-specific group, stretching, breathing practice, meditation and physical postures with core exercises and restorative poses. Participants valued the opportunity to learn yoga for the first time. Several respondents also felt the experience of spending time with other cancer patients and supportive, expert yoga instructors created an inclusive atmosphere that made it agreeable to relaxation.

Barriers to participation

Reasons for not participating in Group C's higher-dose yoga intervention differed slightly from those participants reporting from Groups A and B. Fatigue, side effects from conventional treatment, lack of motivation, cost and transportation were issues identified in Groups A and B only. Group C respondents focussed primarily on scheduling conflicts and other commitments (i.e. travel, work). One respondent in Group B (B4) was unable to participate in her yoga workshop due to excessive pain she was experiencing in association to her conventional treatment, but did attend the session scheduled for the following week.

For online yoga, reasons for not participating were less transparent, though some indicated they had problems starting (A5). One female participant (B2) believed she will try online yoga when her schedule becomes less hectic, and another (B3) said it was difficult to incorporate an online practice because her home was under renovation and she did not have enough physical space to do yoga. One male respondent (B1) felt "left out" of the online yoga and did not understand instructions to activate the online account.

Recommendations for study improvement

Several respondents (n=10) offered specific ideas on how to improve awareness and recruitment to a yoga study. Of these suggestions, the most prevalent responses included increased promotion through advertisement through oncologists, nurses, general practitioners, radiation and chemotherapy units. Word of mouth, online forums for cancer patients and providing regular classes through the BCCA were frequently suggested methods to boost participation.

As for improvement of the delivered yoga interventions, many of the respondents felt more classes should be added to Groups A and B. One woman (A3) would have preferred to start yoga just after diagnosis, before her surgery and conventional treatment proceeded. A participant (B4) who e-mailed researchers following surgery to acknowledge the value of using breathing techniques wrote: "I did it. It's very very helpful." In Group C, one respondent (C4) asked if the taught classes could be more physically challenging while another (C1) felt there were no changes needed to the yoga protocol she received. One respondent (A5) proposed scheduling a group meeting to check the progress and feelings of participants, in addition, she felt a video or more explicit guide to the online yoga resources would be useful.

Table 8.15. Qualitative results from participants in Group A

	Y-ACT Results from Open-ended Questions (Group A)					
Participant	What reasons prevented you from doing yoga in the past month?	Reasons for not using the online yoga resource	What aspects of your yoga intervention did you particularly like or dislike?	What changes would most improve your yoga session and/or sessions?	Please share any of your thoughts about being involved in this study, including any personal reflections, feelings or recommendations in the space provided below:	How could we increase awareness and participant recruitment for a yoga study like this one?
A1	Total lethargy					You presented the idea well. Slack participation was all at my end....busy with a work contract and just haven't yet made room for yoga in my regime.
A3	Fatigue and side effects from chemo		Liked the positive attitude of the instructor and meeting other people recovering or dealing with cancer.	The first class (breathing and relaxation) was perfect, but I would have like a few more scheduled classes. In a perfect world I would have liked to have started these classes after my diagnosis & before surgery & any treatment had started.	I appreciate the introduction to yoga. I have enjoyed the online yoga classes, but it will be great if BC Cancer offered yoga classes on a regular basis. I think yoga will contribute to my long term recovery.	Word of mouth through the oncologists, nurses in the radiation or chemo units, or doctors giving the initial diagnosis.
A4	Transportation, fatigue, hospitalization		Liked meeting others with cancer	Actual yoga classes for cancer patients		
A5	class schedule not matching personal schedule the first few weeks. And later I was out of town	Once I started using the online resource it was very helpful as I could do the class whenever it worked best for me and having the classes that have different duration helps fitting the class in my schedule	I liked feeling more peaceful and at the same time energized after the yoga sessions. It was great experiencing the online yoga since before this I had put off this practice because of time-availability issues.	I know we were encouraged to reach out to the team if we had any questions, but having maybe a scheduled group meeting to talk about how we are feeling or doing would be great. Also maybe having a list of recommended videos to explore in the online resource that could be used as a guide, that would be helpful.	Participating in this study gave me the opportunity to realize that practicing yoga can help me in my day to day, feeling more energized and in good spirits. Participating in this t made me feel that I am doing something for myself.	

Note: Data transcribed verbatim

Table 8.16. Qualitative results from participants of Group B

Participant	Y-ACT Results from Open-ended Questions (Group B)					
	What reasons prevented you from doing yoga in the past month?	**Reasons for not using the online yoga resource**	**What aspects of your yoga intervention did you particularly like or dislike?**	**What changes would most improve your yoga session and/or sessions?**	**Please share any of your thoughts about being involved in this study, including any personal reflections, feelings or recommendations in the space provided below:**	**How could we increase awareness and participant recruitment for a yoga study like this one?**
B1			liked it all-where is the hookup I was invited to be involved with?... has me feeling left out	One session intro was 100% satisfying---would have preferred an additional three classes	enjoyable experience from expert teachers...good for one's health and disposition. More individuals can benefit thru involvement programs. Getting started/introduced and available thru Health Departments etc via reference/introduction as beneficial/recommended.	I have contact with others similar age group 60-70 yr olds ...very keen to know more and to be involved when I shared my experience with the first class instructor
B2	having a scheduled time with an instructor. Cost could be a factor, i.e. Semperviva is cost prohibitive	I will but have been really busy planning a 5 week trip to Europe		having a schedule and more sessions with an instructor	was thrilled to participate. "love to Hate" Yoga but is critical to stretch as we get older	Offer it on a regular schedule at BCCA
B3	Fatigue, holidays, motivation		Like class size. Not very good at self motivation so did not like that there were not more actual classes.	More classes	Enjoyed the workshop. [Teacher] was an excellent instructor and I incorporated her breathing exercises into my lifestyle. On line yoga was hard for me to incorporate mainly because my house is under renovation. Getting to a computer with enough space around it to do yoga was very difficult. I could see myself using the on line yoga more when an appropriate space is finally available.	I think there needs to be someone at the oncology level who can let patients know what is available to them. Like a nurse navigator but more resource based.
B5	fatigue/weakness and lack of motivation		relaxation	more sessions available	Overall found experience positive. Good for me as I have never taken a yoga class before. Also really liked inclusive atmosphere, from instructor and from other participants. I also found that having a class where all the participants were in cancer treatment was beneficial - shared experiences/support.	put posters up in radiation waiting area-clients are usually there daily. Offer a series of classes. Offer classes outside of BCCA area - utilize local community centers (more accessible and cheaper parking)

Note: Data transcribed verbatim with the exception of removing name of yoga teacher for reasons of confidentiality [Teacher]

Table 8.17. Qualitative results from participants of Group C

	Y-ACT Results from Open-ended Questions (Group C)					
Participant	**What reasons prevented you from doing yoga in the past month?**	**Reasons for not using the online yoga resource**	**What aspects of your yoga intervention did you particularly like or dislike?**	**What changes would most improve your yoga session and/or sessions?**	**Please share any of your thoughts about being involved in this study, including any personal reflections, feelings or recommendations in the space provided below:**	**How could we increase awareness and participant recruitment for a yoga study like this one?**
C1	I couldn't make all the yoga classes at the Cancer Center, but I practise yoga at home in the evenings.		Ability to relax and meditate, and "listen" to the body	No change needed. It was a balance of some core exercise with restorative poses and meditation	I have been very pleased with my involvement in this study. It introduced the art of yoga to me, and I can see that it will be helpful for me in the future as we age and need to restore our body and mind.	Spread the word through the various cancer forums that most cancer patients are enrolled.
C2	Busy schedule especially if I am running around. I would prefer to do it first thing in the morning when I wake up because the moment I start my day without doing it, chances are I will not be able to do it at all.		I like the body scan, mindfulness relaxation technique. I also love the stretches we were doing. With me having bone aches after my chemo treatment from my waist down to my lower extremities, doing the yoga lessen the bone aches I was having and if I miss doing my yoga practice even just for one day I'm in trouble - I'm feeling those bone aches again.	Although I love the body scan but I don't want it to be too long because when I focus on what the instructor was saying during body scanning, I noticed I get the pain in between my eyebrows. I had to put something on my forehead to minimize the pain i.e., putting my wrist on my forehead just to press the area between my eyebrows, if not, by using eye pillows to take my mind off the pain.	I really do appreciate that I was selected in this study. It is very useful. I like the fact that there were different instructors. Each of them has their own style and I can choose which amongst those I learned from each session would I use in my own yoga practice and which I think would be beneficial for me.	Continuously do the advertisement around the hospital. Oncologist/GPs should encourage this.
C3	Vacations	Used site in the past but not in the last month	Small group yoga allowed for posture corrections	Offer yoga that is more physically challenging	Enjoyed the opportunity Found it relaxing and [Teacher] was great	design posters so that it is marketed as less of a study and more of an opportunity to participate in free yoga classes.
C4	I attended all sessions offered by the study		Stretches helped with digestion, pain and sleeping disorder	The public sometimes gathers outside the yoga room and is can be noisy, especially during lunchtime there is a lot of activity	Very much appreciated the opportunity. Surgery took away the tumour but yoga heals the scar and minimized the discomfort	Cancer agency could pass on this information when patints are ready to do exercise

Note: data transcribed verbatim with two exceptions: removed name of yoga teacher for reasons of confidentiality [Teacher]; formatting change of participant C4 (all capitals to lower case)

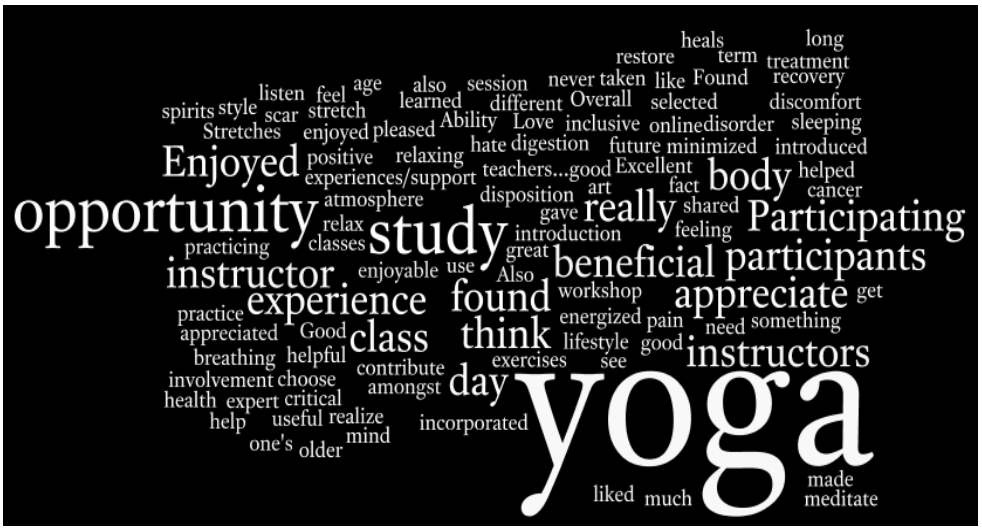


Figure 8.4. Patient-reported attitudes toward yoga intervention

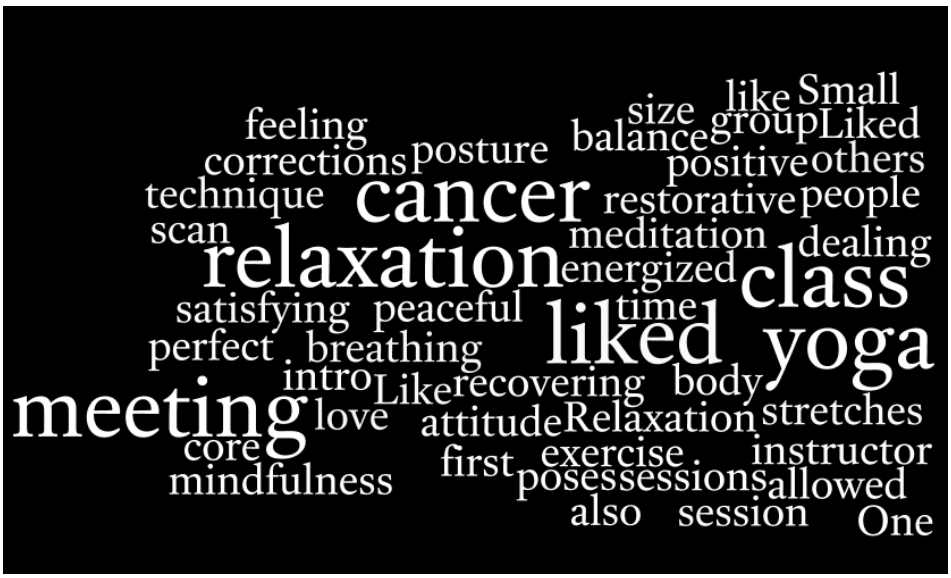


Figure 8.5. Patient-reported preferences of yoga intervention

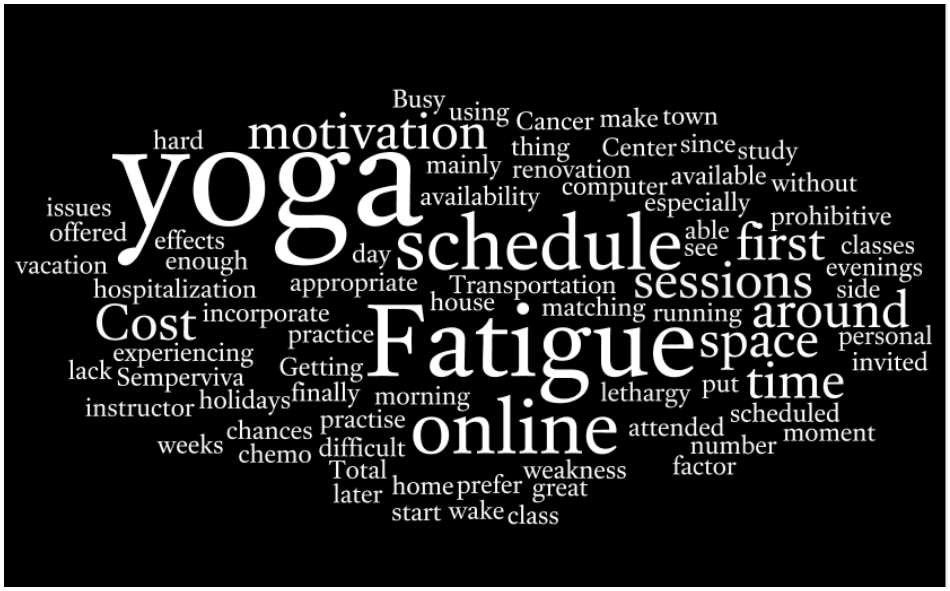


Figure 8.6. Patient-reported barriers of yoga intervention



Figure 8.7. Patient-reported recommendations for future yoga intervention

Adverse Events

No serious adverse events were reported during the conduct of the study. One participant (C2) in the follow-up questionnaire reported minor pain she experienced in between her eyebrows during the yoga body scan exercise, but found it was relieved during class by resting an eye pillow prop on her wrist or forehead. Two female participants were hospitalised for cancer-related side effects during the study. One participant (A2) experienced an unexpected complication related to conventional treatment during the intervention (Week 3) and another woman (C5) underwent surgery to remove a cancerous tumour (Week 5).

8.4.4.2 Amount of clinician and administrative support

Eight oncologists in Vancouver were contacted to assist with recruitment to this study. Nurses and health care practitioners as well as administrative staff were made aware of the study through word of mouth, posters and e-mail communication. Of the potential health care support staff that could have assisted with recruitment (n=250), only one health care administrator in the prostate tumour group registered to recruit patients through an online portal. Two of the reporting participants (n=13) identified their oncologist as the referring mechanism by which they were recruited to the study. Two participants were referred to the study by their counsellor, and one by their prostate support network. The remaining participants reported they were recruited through poster advertisements in the Vancouver-BCCA.

8.4.4.3 Attitude and experience of expert yoga instructors

The yoga instructors provided responses to eight open-ended questions. Supplementary data were collected over e-mail and written text delivered in digital files. These contributions were analysed to identify areas of strengths and

weaknesses across yoga intervention groups. Results indicated expert instructors stated a preference for the structure of Group C, over Group B and A in almost all instances. Teachers recommended all sessions should extend to 90 or 120 minutes. Table 8.18 provides a summary of instructor reports of their preferred components of yoga intervention and considerations for a future study.

Table 8.18. Instructor-informed recommendations for future yoga interventions in adult cancer

Group	To maintain	To eliminate	To provide
All Groups	Free yoga mat, book and access to online yoga for participants; investment in good props: blankets, bolsters, blocks and eye pillows for class; tea service and candles, if possible; location; small class sizes; template and class structure satisfactory	Time pressure for participants	Increase duration of introductory sessions to 120 minutes; water station; allow more time to coordinate lesson plans with other instructors; extend intervention to 12 weeks or more
A	Efficiency; pranayama techniques	60-minute time limit	Include some aspect of asana and dhyana and online support or other guidelines for a home practice
B	Comprehensive and efficient delivery of pranayama, asana, dhyana techniques	75-minute introductory session	Ideally two sessions per week
C	Frequency of yoga; flexible schedule		Increase duration of sessions to 90 minutes

In particular, yoga instructors felt Group A was too limited in scope and although it was efficient and taught key pranayama techniques, instructors would prefer to increase the duration of that session to allow for introduction of asana and dhyana. One instructor added it was impossible to teach only pranayama, as you must be in asana (comfortable physical posture) to do any breathing technique. Furthermore, the act of breathing promotes a state of relaxation (nidra) and meditation (dhyana). This

suggested that while components are different in theoretical concept, aspects of yoga merge and are perhaps difficult to extract in practice.

Group B and Group C were described as "well-rounded" frameworks that provided efficient delivery of pranayama, asana and dhyana techniques. Instructors felt Group C was superior to Group B for offering greater flexibility in scheduling and its higher frequency of exposure to yoga.

Instructors were enthusiastic and grateful for the opportunity to deliver yoga to adult cancer patients in this context. Many wished the program would continue and believed strongly the participants will have benefited in health-related outcomes, even from Group A's pranayama training.

8.4.4.4 Online and telecommunications

Eligibility screening, initial consent, participant registration, outcome measures for QOL-CA/CS and participant-reported data were completed online (100%). One modification of the online survey instrument was completed following the pre-intervention test to ensure respondents could not skip or miss questions on the QOL-CA/CS. Participants did not report grievance or confusion with the online method of data collection, and no participant requested paper-based surveys.

A Vancouver-based telephone number and voicemail was allocated for study purposes. Participants in three instances contacted researchers via e-mail citing a problem in telephone reception. Upon investigation, there was a detected failure of the telephone connection and ability to record voice messages. This technological glitch lasted two to four weeks until the communication provider was able to resolve the problem. There is no data to confirm how many participants may have attempted to call or have been lost due to this telephone malfunction.

8.4.5 Outcome in Quality of Life

Twelve participants completed the baseline and follow-up measures of QOL-CA/CS. See Table 8.19 for a summary of results of QOL-CA/CS scored at baseline and post-intervention. The average QOL-CA/CS score improved 0.23 points [95% CI ± 0.25] from baseline from mean scores 5.46/10 [95% CI ± 0.88] to 5.71/10 [95% CI ± 1.05].

The maximum improvement for one individual measure was in a participant randomised to Group A, who improved 2.24 points from 5.76 to 8.00. One other participant in Group B increased 1.08 points from 5.90 to 6.98. The maximum decline of -0.75 points was recorded in a female participant in Group A; who reported being hospitalised for cancer-related complications over the study period.

Although the incomplete data sets and small size prevent external validity and poor generalisation of results, the preliminary aggregate data across groups indicate a potential trend for small improvements of overall HRQoL following Group A and C yoga interventions.

8.4.5.1 Subscales of QOL-CA/CS in yoga groups

The QOL-CA/CS was selected in part for its superior coverage for domains specific to adult cancer patients with 15 aspects of physical wellbeing, psychological wellbeing, social concerns and spiritual wellbeing. The summary of results across the QOL-CA/CS subscales is presented in Table 8.20.

Table 8.19. Summary of QOL-CA/CS results

Participants	QOL-CA/CS Baseline	QOL-CA/CS Post-Intervention	Change in Results		Mean Difference	Approaching Clinical Significance*	Incomplete Data
			Improve	Decline			
A1	6.05	7	•		0.95	•	
A2	5.83	/			/		•
A3	4.2	4.41	•		0.21		
A4	3.51	2.76		•	-0.75	•	
A5	5.76	8	•		2.24	•	
Group A Average (SD)	4.88 (1.22)	5.54 (2.39)			0.66 (1.26)		
95% CI	2.93 to 6.83	1.73 to 9.35			-1.35 to 2.67		
B1	7.9	7.25		•	-0.65		
B2	5.9	6.98	•		1.08	•	
B3	5.13	4.73		•	-0.4		
B4	4.17	/			/		•
B5	5.58	5.29		•	-0.29		
Group B Average (SD)	6.13 (1.22)	6.06 (1.24)			-0.12 (0.78)		
95% CI	4.18 to 8.08	4.08 to 8.04			-1.36 to 1.12		
C1	6.8	6.56		•	-0.24		
C2	3.78	4.63	•		0.85	•	
C3	6.88	7.13	•		0.25		
C4	4	3.78		•	-0.22		
C5	4.1	/					•
Group C Average (SD)	5.37 (1.71)	5.53 (1.58)			0.16 (0.51)		
95% CI	2.66 to 8.08	3.01 to 8.05			-0.66 to 0.98		
Overall Average (SD)	5.46 (1.38)	5.71 (1.65)			0.25 (0.88)		
95% CI	4.58 to 6.34	4.66 to 6.76			-0.31 to 0.81		
Total			*6*	*6*		*5*	*3*

*The minimum clinical difference (MCID) score was not provided by instrument authors; based on a literature of similar scales of HRQoL, approaching clinical significance is defined here as mean difference >.75; SD = standard deviation; CI = confidence interval; overall and group analysis of complete data sets only (n=12; n=4 per group)

Table 8.20. Summary of QOL-CA/CS subscale results

Physical Wellbeing Subscale			
Participants	**Baseline**	**Post-intervention**	**Mean Difference**
Group A			
Average (SD)	5.82 (1.27)	5.19 (3.05)	-0.63 (2.66)
95% CI	3.80 to 7.84	0.34 to 9.77	-3.60 to 4.86
Group B			
Average (SD)	7.21 (2.25)	7.88 (1.76)	0.67 (0.78)
95% CI	3.64 to 10.78	5.08 to 10.68	-0.57 to 1.91
Group C			
Average (SD)	7.32 (2.59)	6.60 (2.81)	-0.72 (1.54)
95% CI	3.20 to 11.44	2.13 to 11.07	-3.18 to 1.74
Overall			
Average (SD)	6.78 (2.04)	6.55 (2.59)	-0.23 (1.76)
95% CI	5.49 to 8.07	4.90 to 8.20	-1.35 to 0.89

Psychological Wellbeing Subscale			
Participants	**Baseline**	**Post-intervention**	**Mean Difference**
Group A			
Average (SD)	4.85 (1.71)	5.73 (2.18)	0.88 (1.09)
95% CI	2.13 to 7.57	2.24 to 9.19	-2.61 to 0.85
Group B			
Average (SD)	5.97 (1.20)	5.51 (1.08)	-0.47 (0.96)
95% CI	4.07 to 7.87	3.79 to 7.23	-2.00 to 1.06
Group C			
Average (SD)	4.44 (1.74)	4.89 (1.29)	0.45 (0.45)
95% CI	1.67 to 7.21	-1.56 to 2.54	-0.27 to 1.17
Overall			
Average (SD)	5.09 (1.57)	5.37 (1.48)	0.29 (0.99)
95% CI	4.09 to 6.09	4.43 to 6.31	-0.34 to 0.92

Social Wellbeing Subscale				Spiritual Wellbeing Subscale			
Participants	**Baseline**	**Post-intervention**	**Mean Difference**	**Participants**	**Baseline**	**Post-intervention**	**Mean Difference**
Group A				Group A			
Average (SD)	4.94 (1.34)	5.29 (2.74)	0.35 (1.63)	Average (SD)	3.82 (1.18)	5.78 (1.97)	1.96 (1.15)
95% CI	2.80 to 7.08	0.93 to 9.65	-2.24 to 2.94	95% CI	1.94 to 5.70	2.65 to 8.91	0.13 to 3.79
Group B				Group B			
Average (SD)	6.29 (1.85)	6.47 (1.92)	0.19 (1.02)	Average (SD)	5.14 (1.35)	5.07 (1.56)	-.07 (1.74)
95% CI	3.35 to 9.23	3.42 to 9.52	-1.43 to 1.81	95% CI	3.00 to 7.28	2.59 to 7.55	-2.70 to 2.84
Group C				Group C			
Average (SD)	5.07 (2.06)	4.86 (1.86)	-0.21 (0.78)	Average (SD)	5.86 (1.62)	6.68 (1.78)	0.83 (0.55)
95% CI	1.79 to 8.35	1.90 to 7.82	-1.45 to 1.03	95% CI	3.28 to 8.44	3.85 to 9.51	-0.05 to 1.66
Overall				Overall			
Average (SD)	5.43 (1.73)	5.54 (2.13)	0.11 (1.11)	Average (SD)	5.18 (1.68)	5.85 (1.75)	0.67 (1.63)
95% CI	4.43 to 6.53	4.19 to 6.89	-0.59 to 0.81	95% CI	4.11 to 6.25	4.74 to 6.96	-0.42 to 1.70

Note: SD = standard deviation; CI = confidence interval; complete participant data sets only (n=12); each group (n=4)

The overall psychological, social and spiritual wellbeing patients indicate a positive trend, though the CI's indicate a high variation about the mean, and results are neither reliable nor generalisable to other patients. Of particular interest, however, it appears the physical wellbeing scores declined by 0.63 points [95% CI ± 4.23] in Group A and by 0.72 points [95% CI ± 2.46] in Group C. These results might suggest that participants receiving these yoga interventions may not have included enough physical exercise to spur a more positive result. However, Group B did show some improvement in physical wellbeing, with an increase of 0.67 [95% CI ± 1.26].

In previous studies, psychological wellbeing scores (i.e depression, anxiety) following yoga appeared to have positive results, so it is surprising that this metric has decreased following the intervention of Group B. The mean difference of psychological wellbeing of participants increased most in Group A [0.88, 95% CI ± 1.73]. Social wellbeing worsened in Group C, which is an unexpected result considering they were exposed to the most amount of yoga in a group setting. Perhaps the group socialisations of Groups A and B during the introductory sessions were more positive experiences, which could affect their perceived social wellbeing. Additional data would need to be gathered, perhaps tracking the amount of time spend socialising inside and outside of the yoga intervention to understand the context of this result.

The largest improvement in subscale results was noted in spiritual wellbeing, where Group A increased from 3.82 to 5.29 points [1.96 ± 1.83, 95% CI]. Even though Group B's spiritual wellbeing scores slightly declined from 5.14 to 5.07 [0.07

± 2.77, 95% CI], the overall group average for improved spiritual wellbeing increased from 5.18 to 5.85 [0.67 ± 1.03, 95% CI].

In comparison of subscales across groups, these preliminary results indicate that characteristics of Group A's intervention might be responsible for positive results in all aspects of HRQoL, except physical wellbeing. A negative result in physical wellbeing for Group A was expected, as these participants received pranayama training of breathing exercises only. Group C yoga intervention appeared to improve outcomes in psychological and spiritual wellbeing only. Conversely, Group B (the intervention that included free access to online yoga and 120-minutes of in-person instruction) only showed improvement in the physical and social wellbeing indexes. The sample size was much too small to account for differences in HRQoL across groups, however, this type of outcome analysis would could be repeated to understand the impact of yoga's components in a larger trial.

8.5 DISCUSSION

This study was designed to determine the feasibility of yoga intervention in the context of a clinical trial to improve HRQoL in adult cancer patients. The trial design and data collection methods were analysed for their cost efficiency, deliverability and suitability for a future, large-scale RCT. The appropriateness of yoga, patient adherence rates to protocol and preferences for three types of yoga intervention were also part of this assessment. A synthesis of the feasibility study's research questions, results and supporting evidence are summarised in Table 8.21, along with outstanding research questions for a future pilot or large-scale RCT.

Table 8.21. Synthesis of research questions and feasibility study results

Feasibility Research Question	Answer	Supporting Evidence	Outstanding Research Questions
Do adult male and female patients undergoing conventional treatment for cancer recruit to a study of yoga intervention?	yes	Male (n=4) and female patients (n=11) aged 33 to 72 years participated in the study (see Section 8.4.1).	
Is online registration, screening and data collection acceptable to patients?	yes	The feasibility was implemented successfully; qualitative and quantitative data from patients do not report concern in these areas of study design.	Does this result hold for underserviced or resource-poor settings?
Do HCPs recruit their patients to a yoga study?	no	Of 250 potential HCPs, one HCP registered to recruit patients for the study (see Section 8.4.4.2)	Are there other communication strategies that would improve dialogue and collaboration with HCPs?
Is in-clinic advertising sufficient to recruit patients to a yoga study?	somewhat	The recruitment strategy recruited 30 potential and 15 eligible participants in a 12-week period in Vancouver, Canada (see Section 8.4.1).	What are the other affordable, practical and effective ways to increase rate of recruitment?
Is it possible to recruit, employ and insure qualified yoga instructors to deliver the intervention in a clinical setting?	yes	Yoga instructors were professional, informed and qualified to finalised and implement a yoga protocol (see Section 8.4.4.3)	Does this result hold for geographical and cultural regions outside of Vancouver, Canada?
Is there administrative support and logistics that can cope with a yoga intervention study in this clinical setting?	yes	The *a priori* checklist to assess the administration and logistical aspects of a yoga trial were satisfied 6.5/8 = 81% (see Table 8.8).	
Do yoga instructors accept the standardisation and development of yoga intervention in the context of a clinical trial?	yes	The dialogue amongst yoga instructors was productive and positive. Their involvement is a time-consuming process that deserves attention in a future study.	To what extent can yoga intervention be standardised and transferable to a large-scale RCT across diverse clinical settings and populations?
Can yoga intervention be delivered safely to patients?	yes	No serious adverse events associated with yoga practice were reported	

Feasibility Research Question	Answer	Supporting Evidence	Outstanding Research Questions
Do patients adhere to yoga intervention and the study protocol?	somewhat	Two drop-out and one loss to follow up measure due to hospitalisation (see Section 8.4.3); self-reported adherence to yoga and class attendance	Is there a dose-response effect of yoga? Need to verify or control for amount of yoga practiced, to ensure accuracy of dose-response analysis.
Have the costs of implementing yoga intervention been reported?	yes	Per participant costs for a four-week intervention ranged from £151 to £277 (see Section 8.4.2.2).	
Is online yoga acceptable to patients?	somewhat	Adherence to online yoga was better in Group A, but did not encourage practice in Groups B and C (see Section 8.4.4.1).	Is online yoga feasible, and can it be utilised to improve the scalability or standardisation of yoga intervention in adult cancer?
Has the model of yoga intervention been optimised for a large-scale RCT?	no	Evidence from a component analysis, patient interviews, oncologist surveys and yoga instructors input were synthesised to develop three yoga interventions but process incomplete due to lack of generalisabilty of results; data suggests patients enjoyed yoga interventions and would like to participate regularly (see Section 8.4.4.1)	What are the core and non-core components of yoga intervention that are generalisable to an adult cancer population outside Vancouver, Canada? How much more physical yoga could patients tolerate?
Has the PICO for a future yoga RCT been established?	somewhat	P = male and female adult wellbeing during conventional treatment of adult cancer I = 50 to 90 minutes per yoga session, hatha yoga including at least breathing and socialisation, also meditation, physical postures and ambience are important, schedule Monday to Thursday in later morning or early evenings O = QOL-CA/CS, apt measure of HRQoL, includes physical, psychological, social and spiritual aspects of wellbeing	P = including post or pre surgical intervention (with medical permission)? I = what is the optimal, cost-effective and scalable yoga intervention? C = should yoga be compared to exercise or a non-active waitlist control group? O = are there other clinically important outcomes to measure, and if so, how could the same approach to selecting an outcome measure be applied (see Table 8.1, Table 8.2).

Note: HCP = health care practitioner (i.e. oncologist, nurse); RCT = randomised controlled trial; PICO = population/problem, intervention, comparator, outcome measure; HRQoL = health-related quality of life; QOL-CA/CS = quality of life measure for cancer patients and survivors

8.5.1 Summary of Findings

Yoga intervention can be safely delivered to adult cancer patients in a clinical setting. No serious adverse events were reported. The recruitment for adult cancer patients receiving conventional treatment in Vancouver, Canada for this yoga study was completed within ten weeks. The rate of recruitment for self-reported naïve or irregular users of yoga from the Vancouver-BCCA catchment area was 1.5 per week. The speed of recruitment could be enhanced with more aggressive and targeted sign posting, or communication to patients through forums and patient word-of-mouth as well as more aggressive targeting of HCPs in cancer treatment centres.

A small sample (n=15) indicated a 13% dropout rate after the point of randomisation, and one loss to follow-up (<7%) for outcome measures. All participants who attended an introductory yoga session attended follow on sessions. The adherence to online yoga was low in Group A, and extremely low to nil when it was prepaid (Groups B and C).

This feasibility study established that participant registration and outcomes measures could be completed using online surveys. The QOL-CA/CS has been adapted to an online format and participants who completed the questionnaire did not report dissatisfaction or confusion with its presentation. To ensure no missing data survey respondents should be obliged to answer each question before progressing to the next question.

In terms of cost, delivery of yoga over the four-week period indicated Group B was the most cost-efficient (number of hours provided to maximum number of patients per dollar) and Group A was least expensive (£151 per participant). The administrative support of members from the Vancouver-BCCA and its affiliated

research centre were provided at no cost to the research budget. Administrators confirmed the same exercise space would be made available for future programs, a physical space that is appropriate and provides capacity for up to 10 yoga mats, serviced with washrooms, a kitchen and a lounge area.

8.5.1.1 Acceptability of yoga intervention

Participants and teachers in this feasibility study reported positive experiences of yoga and felt it was highly beneficial across all three groups. Qualitative and quantitative findings suggest Group C had the highest utility and subsequent appeal to patients. Instructors also recommended Group C for future iterations of yoga intervention. The template of class components for Group A should closer resemble Groups B and C and include asana and dhyana techniques for 60 to 90 minutes sessions. Online access to yoga increased with a brief orientation of the service without provision of a prepaid membership.

Barriers to participating in yoga for patients are similar to the patterns revealed in Chapters 6 and 7's patient interviews and oncologists surveys, where scheduling conflicts, cost, transportation, fatigue and lack of motivation prevented participants from doing more yoga. In this sample, pre-paid online yoga was not highly utilised, though participants in Group A reported greater interest in online yoga. Delivery of yoga in a clinical setting needs to consider securing space in a quiet environment free of noise, odours, public traffic and natural daylight, if possible. In terms of timing, Monday mid-day classes and early evening classes (6:30pm) were most well attended.

8.5.1.2 Is there a dose-response effect of yoga exposure?

Preliminary results signalled positive changes in QOL-CA/CS scores following all groups of yoga intervention. In particular, subscales in psychological and spiritual wellbeing indicated improvement and to a lesser extent social concerns. The physical aspect of wellbeing decreased especially in Group A, suggesting an intervention with more physical movement might improve this aspect of wellbeing. Investigating a dose-response for yoga and HRQoL, the number of yoga hours participants reported practising was plotted against the mean difference in QOL-CA/CS from baseline to follow-up. The patient reporting participation in 24 sessions during the study (C4) improved her mean HRQoL by 0.85 points.

While no definitive results can be extrapolated from this preliminary data, future studies with a larger sample size could perform a linear regression to determine the correlation of amount of yoga exposure with changes in HRQoL (see Figure 8.8). For example, the participants reporting the least amount of exposure to yoga (A1;A4) increased QOL-CA/CS by 0.95 points and the other decreased by 0.75 mean points. Participant A1 reasoned lethargy and work commitments prevented him from participating in more yoga, though he reported “enjoyment” of the introductory session. A4 reported hospitalisation due to complications with her cancer diagnosis as the reason she did not participate in more yoga.

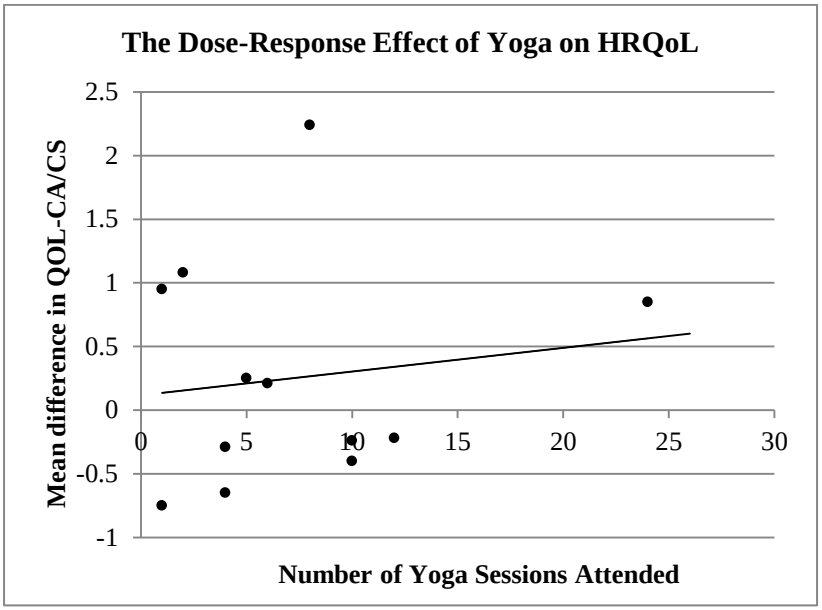


Figure 8.8. The dose-response effect of yoga on HRQoL

8.5.2 Strengths and Limitations

The feasibility protocol was conceived and designed from the University of Oxford and administered in Vancouver, Canada in collaboration with the University of British Columbia and Vancouver-BCCA. The coordination of this international research team across three organisations was successful and efficient. Several factors assisted in the smooth conduct of the study, including management in the following ways:

1. Clear leadership and roles and responsibilities outlined for research team members
2. Early and regular coordination of telephone and in-person meetings with local researcher in Vancouver-BCCA
3. Sensitive and responsive to Vancouver-BCCA's communication channels, administrative procedures and highly respectful of their physical space
4. Secured financing and established a fixed budget *a priori*
5. Effective hiring and management of yoga instructors

The study timeline allocated six weeks to receive ethical approval; an additional six weeks for participant recruitment; four weeks for intervention; two weeks for follow-up measure data collection for a total of 18-weeks of budgeted study time. The actual study timeline was completed as follows: one week for ethical approval; ten weeks for recruitment; four weeks for intervention; two weeks for follow-up measures for a total of 17-weeks. The analysis of data was performed over a six-week period.

There were three notable deviations from protocol. First, the time allocated to Group A was extended 20 minutes by the yoga instructor (to allow for questions and a longer socialisation). Second, the budgetary expenses to compensate yoga instructors and their administrative time was higher than anticipated, along with the increase from three to four yoga instructors to deliver the intervention. Third, there was an additional *ad hoc* workshop to facilitate teacher coordination and development of the yoga interventions. One workshop was planned *a priori* for the experienced and certified yoga instructors in Vancouver to build consenus and agree upon a standardised protocol for the three yoga groups. However, as deemed by the researchers and yoga instructors, agreement on the yoga protocols was not reached in the allocated 2-hour session. A second workshop meeting was held (1.25 hours) amongst only the yoga instructors conducting the trial. Online email and dialogue was maintained with the contributors and researchers until there was a consensus reached and all instructors felt the lesson plan would be optimal for adult cancer patients. In effect, the workshops may need to be a formalised as an independent research study in the future, as the potential data arising from the workshops could improve the optimisation of yoga intervention in the context of an RCT. Future studies might include other consensus building techniques or qualitative methods[326]

(i.e. mapping, Delphi method or focus groups) to enhance the agreement and potential robustness of the yoga protocol development.

In this example, there was one report of a personality conflict that occurred, and so while the researchers were present to guide the initial process, the second workshop was apparently more effective due to the absence of one particular yoga instructor. Therefore, this aspect of the feasibility study does indicate the value of capturing data from the group process and its results. Some yoga instructors were resistant to establishing too rigid of a framework, and therefore, this is an aspect of protocol development that will require a more rigorous approach in the future. Still, the resultant three yoga protocols are transparent and readily available to use as a benchmark in future studies.

In addition, the qualitative data provided by yoga instructors in Section 8.4.4.3 is at risk of bias, as teachers perceive a financial reward and personal benefit associated with an increased yoga delivery to cancer patients.

8.5.2.1 Recruitment rate

Motivating HCPs and oncologists to participate in study recruitment was unsuccessful. In the future, in-person information sessions or targeted, personalised meetings (as opposed to e-mail communication) might improve rate of HCPs involvement. In addition to these improvements, it was observed onsite at the Vancouver-BCCA that volunteer drivers are often responsible for transferring patients to and from their home to their conventional treatment at the cancer centre; additional brochures or posters could be passed to drivers of these vehicles to further assist in identifying potential study participants.

The recruitment rate was also negatively impacted by exclusion of patients who participated in yoga more than one time per month in the past 12 months. This exclusion criterion was included as an important measure to control exposure to yoga. Future iterations of a clinical trial could include current yoga-users to enhance the recruitment rate. However, depending on the aim of the future trial, replication of the study results could be problematic due to a non-standardised exposure to yoga intervention.

8.5.2.2 Randomisation procedure

The randomisation procedure in this study stratified participants according to gender. The results of this randomisation technique did not result in any serious group distortions, though Group A did have three breast cancer patients and Group C a younger age group (<10 years). This group variation was not a significant issue in this feasibility study and presumably a larger sample size (>50) in a future trial could provide sufficient data to perform subgroup analyses of variations in demographic or medical status characteristics. Future designs may also consider stratification of age, stage of cancer and type of tumour to ensure a diversified population – remembering the risks of excessive stratification are that groups lose the benefit of randomisation[327].

8.5.2.3 Patient adherence and dropout rates

The adherence to protocol varied across groups and type of yoga delivery. Participants in Groups A (n=4) and B (n=5) demonstrated 100% of in-person yoga instruction attendance, whereas participants in Group C (n=4) yielded a 65% attendance rate to its classes. The average attendance rate to instructor-led yoga in this study was 82%, slightly better in comparison to a pilot of breast cancer survivors

(n=12), where the mean number of classes attended was 78% (19/24) over a 12-week period[328]. Internet yoga was not adhered to in Groups B or C (0% participation), though two participants in Group A included online yoga as part of their four-week yoga program, although this could indicate that Group A felt they did not get enough yoga since they were administered the smallest amount.

The dropout rate after the point of randomisation was 13% (2/15). In terms of comparison across groups, Group A lost one participant because she felt there was not enough yoga involved, and she reported already doing regular yoga. Even though participants were informed about the scheduled intervention and probable time commitments at least two-weeks in advance, the other dropout participant could not continue due to work commitments that were not previously disclosed during consent. One additional participant entered the hospital for a surgical operation during Week 5 of the study and was not available to complete the two surveys. Therefore, 3/15 (20%) of randomised participants did not complete evaluation measures; a rate less than some earlier studies indicate[329] (up to 38%). However, this performance may have been enhanced by the lack of participant randomisation to a control group. An additional pilot study to randomise patients to yoga versus no-yoga may be required, or attrition rates from previous studies using a waitlist control may be more accurate for a large-scale RCT.

The exclusion criteria attempted to eliminate current yoga users and those in pre or post-surgical intervention. However, the perceived failure to screen out these ineligible participants may be a consequence of using an online self-report survey tool. It may be important to reassess the exclusion criteria viva voce or request

patients receive permission or verification from an HCP in advance of participating in the trial to reduce future errors.

8.5.2.4 Potential threats of bias

This particular study did not blind patients or the investigators for practical reasons. Patients were made aware they would receive one of the three different types of yoga intervention, but to decrease potential bias, were not given knowledge of the type or duration of yoga in other groups. The exposure and type of yoga were randomly allocated but not blinded to participants. The outcome investigator of the collected data (MM) performed the analysis of QOL-CA/CS and Y-ACT results with supervision (CH, AW). Attempts were made to reduce the threat of investigator bias in two ways: coding information during the preliminary data analysis to blind the investigator, and standardisation of the investigator script and introductory sessions. However, potential biasing of results due to personal attitude or inclination are not eliminated without adequate investigator blinding[330] and remain a threat of bias in this study.

Furthermore, as an uncontrolled trial, results have the potential to provide a distorted view of the effect of therapy[331]. Future studies should include a control group to compare the results of yoga versus another active intervention or waitlist. The self-selected group of participants who volunteered for the study may have positively biased adherence rates or overstated benefits of yoga. Data collection from yoga teachers and participants are susceptible to self-report and recall bias. The researcher's field notes are also biased to one researcher's perspective (MM), though efforts were made to include feasibility data from other researchers (MMcD), yoga instructors, and the Vancouver-BCCA/BCCRC.

The change in HRQoL was measured by QOL-CA/CS – a tool that has been tested for reliability with internal as well as external validity[316]. However, the Y-ACT survey was a customised survey evaluated for face and content validity only, and therefore may not produce the same results over time. Finally, designed as a feasibility study, the sample size is inadequate to suggest data should be inferred to other populations.

8.5.2.5 Participants

Results of this feasibility study indicated cancer patients with various tumour types do seek to participate in a yoga study to improve health-related quality of life. Patients enrolled in this study safely received three types of yoga intervention while undergoing current treatment of chemotherapy, radiotherapy, hormone therapy, active surveillance and surgical intervention for Stage I to IV cancers of the breast, prostate, brain, blood, skin, lung, colorectal, abdomen and tongue. Men and women volunteered for the study in a ratio of 1:4.

This sample of adult cancer patients indicated a moderate quality of life (QOL-CA/CS mean score of 5.3/10 pre-intervention). Inclusion criteria in future studies can refer to this index as a guide. The pre-intervention QOL-CA/CS ranged from 3.51 to 7.90, where scores of 4.0>7.0 were most prevalent in this sample (n=12; 80%). In post-intervention results, the female participant with QOL-CA/CS score of 2.76 was hospitalised during the study due to disease-related complications and was not able to continue her participation in yoga. The male participant who reported the highest baseline of QOL-CA/CS pre-intervention (7.90) dropped to 7.25 points following Group B yoga intervention. Future studies might aim to include patients with minimum scores of 4.0 points on QOL-CA/CS and maximum scores of 7.0 points. The additional QOL-CA/CS scoring criteria would

include participants who demonstrate potential to benefit in HRQoL and at the same time, demonstrate psychological or physical capacity to participate in yoga. Additional research is needed to understand if patients with very low HRQoL (i.e. less than 3.0) would be capable of adhering to yoga intervention.

8.5.2.6 Intervention

As a complex intervention, there are infinite variables of how yoga can be administered in a clinical setting. This feasibility study used mixed methods to test the viability of three types of yoga intervention. Data analyses cannot suggest one yoga group may be more effective than another, but can highlight important components and cost indicators to consider in future trials.

The one-session instructor workshop strategy achieved the following goals: to share information about the feasibility study; to outline performance expectations and reiterate the importance of following protocol; to orient instructors to the building, review safety procedures and special needs of adult cancer patients; and to facilitate group sharing, enhance communication channels and develop a supportive, team-based environment for this and future studies. However, as mentioned previously, the data collection from this meeting could have been formalised in the form of a Delphi method or other consensus building technique.

Groups B and C appeared most satisfactory for patients (7.0 and 8.5 out of 10). A one-time introductory session can increase uptake of yoga. Pranayama (breathing) techniques should be delivered in parallel to asana and dhyana (meditation) components. Group C, with regular yoga sessions of 90 minutes is highly recommended by yoga teachers. Group A intervention cost £151, Group B cost £187 and Group C cost £277 per participant. Group B was the most cost-efficient yoga

intervention and exposed participants to two in-depth training sessions of yoga (3.5 hours total over a four-week period). A resource list for community yoga classes, a yoga mat and a beginners' book about yoga[322] are highly recommended to encourage patients to practice yoga on their own, if that is the goal of the intervention.

Acceptability of online yoga

A prepaid membership was ineffective to increase participation to online yoga. Group A had the highest rate of adherence to online yoga, where two of four participants accessed online yoga to support their home practice, even though it was not an explicit or pre-paid intervention. The identified benefits of online yoga were its flexible scheduling for home practice and its decreased exposure to bacteria or germs that may threaten the health of immune-depressed patients. One participant was confused by the registration procedure for yoga online. Any future implementation of online yoga should deliver a more in-depth orientation of how to use the system and address any potential barriers, including space and technology in advance.

Scheduling and location

The facility was provided free of cost to the patients and instructors. The room was satisfactory in size (approximately 40m^2), offered sufficient space for storage of yoga equipment and provided a natural light source for calming effects. The space was amenable for its proximity to the cancer treatment facility (<10 metres), security and ease of access. However, participants (n=2) and instructors (n=2) identified lunchtime noise as a disturbance because of the yoga room's location near the kitchen area used by visitors and employees. Future studies in this location will attempt to schedule yoga away from meal times. In other hospital or clinical sites, the

availability of space may be an issue of pragmatic concern and, therefore, should be addressed as early as possible in the protocol design for yoga intervention. In addition, Thursday evening and Friday morning classes were not attended in the feasibility study. The most attended classes were in the earlier part of the week, Monday at 2pm and Wednesday at 6:30pm.

8.5.2.7 Outcome measures

The HRQoL measurement tool (QOL-CA/CS) was selected for its appropriateness and validation in adult cancer for the purposes of this study. Results from this study demonstrate the online QOL-CA/CS tool is an appropriate measurement tool for detecting changes in HRQoL of adult cancer following yoga intervention. The findings from this feasibility study indicated cancer patients mean score of 5.3 at baseline, a measure that was similar in a previous study (5.6)[332]. Domains of the QOL-CA/CS scale, especially the spiritual aspects, seem sensitive to yoga intervention in this feasibility study. In future investigations, the meaning or clinical significance[333] of a QOL-CA/CS increase by >1 point (i.e. 10% improvement) could be explored from both patient and oncologist perspectives.

The QOL-CA/CS has also been identified in two other studies[334,335], where one study concluded yoga intervention significantly improves HRQoL in cancer survivors (n=410)[334]. Even though the tool was selected using research criteria *a priori*, and results indicated it was an effective measurement tool for HRQoL, the QOL-CA/CS is sparsely reported in current literature as opposed to other measures (i.e. EORTC-QLQ-C30, SF-36). The reasons for the limited use of QOL-CA/CS may be an area to explore in future reviews.

Outcome measures to determine the potential impact of yoga on health-related behaviours (i.e. dietary changes, exercise behaviour) were not included in this feasibility study. An additional questionnaire to measure such changes, or additional biological tests to determine physiological changes, could improve understanding of the underlying effects of yoga intervention. Previous studies have measured changes in cortisol levels and blood pressure, as well as physical strength and flexibility[336,337]. Furthermore, oncologists (Chapter 7) identified potential outcome measures for a yoga RCT including: changes in patient's ability to tolerate treatment; changes in prescription drug use; changes in immune response (i.e. T-cell counts); and measureable changes of tumour response to conventional treatment.

An objective system to monitor at-home or online yoga practice (i.e. time-tracking) is desirable to verify the amount of yoga exposure received by participants, however, this was not included in this present study due to associated expenses. In a larger, longer-term study, researchers might consider additional metrics and technologies to monitor the location, type and amount of yoga that participants consumed during the course of study.

8.5.3 Implications of Findings

The results of the feasibility study can be used inform the main elements of a pragmatic, large-scale RCT. In consideration of methodological limitations identified in the study, and specific recommendations made by participants, the following adjustments to a future pilot or RCT protocol should be implemented:

1. Increase sample size and population demographic through a single or multi-site centre trial.

2. Screen patients for eligibility viva voice before randomisation or require doctor's statement to verify patient's health status.
3. Design a more aggressive, personalised recruitment strategy with health care professionals and advertising with other hospital-related support services.
4. Consider expanding or maintaining inclusion criteria for pre or post-surgical intervention patients.
5. Select a yoga intervention that is flexible and cost-efficient with at least two sessions 60>120 minutes of physical postures, breathing, meditation and opportunities for social interaction.
6. Consider environmental aspects of the clinical setting and its appropriateness to locate a yoga intervention (i.e. room location, odours, noise pollution).
7. Consider audio or video-recording of the delivered yoga intervention to improve transparency, replicability and to avoid recall bias of teacher reports.
8. Consider additional metrics and technologies to monitor the location, type and amount of yoga that participants consumed during the course of study.
9. Measure short-term and long-term changes (>6 months) of patients' HRQoL.
10. Include other clinically relevant outcome measures such as: efficacy of conventional treatment (i.e. adherence to conventional treatment; changes in prescription medication); biomarkers or surrogate markers for stress and immunity (e.g. cortisol levels, T-cells); and changes in health-related behaviour (e.g. increase in physical activity, change in dietary behaviours).
11. Blind the outcome investigator and perform at least two independent analyses of the results.

12. Decrease the absolute and relative costs of in-person yoga instruction by: increasing class sizes and the instructor-participant ratio (from 1:5 to 1:10); providing detailed lesson plans to instructors; negotiating competitive hourly rates; and establish limits on administrative expenses.
13. Consider collaboration with community-based resources to ensure participants can access safe and reliable sources for yoga post-intervention.

8.5.4 Further Recommendations for Yoga Trials

There are aspects of a full-scale RCT that have not yet been defined (see Table 8.21). One of these aspects included the detailed characteristics of a control or comparison group (i.e. active or non-active control). The selection of this comparison group (i.e. waitlist or exercise group) would have consequences on the participant adherence rates in the trial, as well as the mean difference in comparing changes in the HRQoL outcome. A sample size calculation would need to be ascertained based up adequate statistical powers given the estimation of size of effect in outcomes, and the margin of error expected across the control and experimental groups. Other outcome measures including wellbeing or biomarkers might be explored in future studies.

In terms of the yoga intervention itself, three important and outstanding questions remain: first, if and how might online yoga be included an optimal intervention construct; second, how much and what type of input should individual yoga instructors of other interventions be allowed to alter from the intervention frameworks they are provided; and third, to what extent can yoga be standardised without negatively impacting the patients perceived ‘personalised’ benefit? Research methods including focus groups, additional expert interviews with yoga instructors, or the Delphi method may assist in collecting some of this missing information.

8.6 CHAPTER SUMMARY

- Three types of yoga intervention in the context of a randomised trial were safely delivered to adult cancer patients undergoing conventional treatment.
- Male and female patients (n=15) diagnosed with tumours including breast, prostate, brain, blood, colorectal, tongue, skin and abdominal cancer volunteered and participated in the study.
- Existing recruitment methods and participant criteria suggest eligible participants from the Vancouver-BCCA catchment area would enrol in a similar yoga study at a rate of 1.5 patients per week.
- QOL-CA/CS is an appropriate measure to detect changes in HRQoL in adult cancer, and it appears particularly sensitive to detecting changes in four domains of HRQoL (physical, psychological, social and spiritual wellbeing).
- Eligibility screening, participant registration and data collection for outcomes can be completed online, though are susceptible to self-report bias, historical bias or misinterpretation; online questionnaires should be designed to prompt participants to complete missing data.
- The high exposure to yoga (Group C; £277 per participant) was preferable to patients and yoga instructors for its frequency, flexibility and complete offering of yoga's components; classes scheduled between 10am and 6:30pm Monday to Thursday had highest attendance rate in this sample of adult cancer patients.
- One session of yoga (Group A; £151 per participant) can be a positive experience for patients and might encourage self-practice or online use of yoga.
- Results of the feasibility study identified specific recommendations for the design of a more robust, evidence-based, larger-scale yoga pilot or RCT.

8.7 CHAPTER REFERENCES

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CHAPTER NINE

Discussion and Conclusion

9 DISCUSSION AND CONCLUSION

9.1 SUMMARY OF CHAPTER FINDINGS

Chapter 1 introduced this doctoral thesis in evidence-based health care and yoga. The research aim, objectives and an overview of the mixed methods were presented in a framework guided by the Medical Research Council (MRC). The outline of the thesis structure included a step-by-step approach from identifying biomedical theory, to identifying the evidence base, to modelling process and outcomes, and testing procedures of yoga delivery in the context of a randomised controlled trial (RCT) feasibility study. Secondary analyses of existing studies took the form of literature reviews, a bibliometric analysis, overview of systematic reviews and a component analysis. The secondary research evidence informed the purpose, design and implementation of three primary research studies including: patient interviews, oncologist surveys, and a mixed methods RCT feasibility study.

In Chapter 2, background information was provided to explore the meaning of yoga and its current application in health care. For the purposes of this study, yoga and yoga intervention were defined according to MeSH terminology and the traditional definition as defined by Patanjali's Yoga Sutras (Box 2.1). The biomedical theories and underlying mechanisms of how yoga might be responsible for improving health-related outcomes in adult health conditions were also explored and published in a literature review. The findings suggested yoga enhances physical strength, flexibility and improves regulation of the endocrine system and the nervous system. Yoga may also induce anti-inflammatory and anti-oxidant effects in ageing and diseased populations, though the strength of evidence in these subject areas was

limited to low-quality evidence in a small number of studies (n=3). Previous studies have not explored the extent to which cultural, socio-behavioural or environmental aspects of yoga influence health-related outcome measures.

Chapter 3 reported the design and results of bibliometric analyses in biomedical literature from PubMed (MEDLINE), life science journals and a physiotherapy evidence database (PEDro). The annual trends of yoga publication in terms of adult health conditions and type of articles were analysed. The frequency of yoga articles published for anxiety, pain and depression have been most frequently cited since 1980. Findings indicated a publication shift away from yoga intervention research in cardiovascular disease towards cancer since 2005. The title search (PubMed) identified clinical trials (n=399) and systematic reviews (n=373) and few RCTs (n=47). The title search (PEDro) identified clinical trials (n=221), systematic reviews (n=112) and clinical guidelines (n=4) for yoga in low back pain, mood and anxiety disorders, physical fitness and for lowering blood pressure. The rate of publication appeared to be increasing over time, especially in mental health and chronic diseases. The high volume of reported systematic reviews in Chapter 3 pointed to the need for an overview of systematic reviews.

Accordingly, Chapter 4 explained the design, implementation and results of an overview of systematic reviews (n=26). This study was conducted to explore the quality and direction of outcomes in yoga intervention for adults with acute and chronic health conditions. Findings suggested yoga intervention could decrease anxiety, depression and improve pain management in adult populations. A new hypothesis emerged to suggest yoga would be most beneficial for patients experiencing a cluster of health-related quality of life indices (i.e. pain, anxiety,

fatigue and depression). The overview, together with findings from Chapter 3's bibliometric analysis signalled an interest and subsequent investigation into the epidemiology of cancer. The high incidence rate of cancer worldwide (14.1 million)[180] and increased complementary-seeking behaviour of cancer patients (>40%)[184] were additional factors to establish the research aim of this thesis: the development of yoga intervention to improve HRQoL in adult cancer patients. The HRQoL metric was selected for its inclusion of physical, psychological, social and spiritual wellbeing, and its relevance to individual patients and their health status.

In Chapter 5, a background review of literature identified gaps in cost-benefit analyses and no current guidelines for developing a yoga protocol in adult cancer. As the first of a three-part phase to improve the modelling of yoga intervention, a component analysis was conducted in moderate to large-scale RCTs (n>50) of yoga in cancer patients. Results of the analysis indicated positive effects in anxiety, HRQoL, nausea, post-operative outcomes, mood affect and cortisol levels following 60 to 90 minutes of instructor-led integrate or hatha yoga delivered in a clinical setting. In all instances, home-based practices were encouraged with material support (i.e. manual or audio/video recordings), telephone reminders and house visits by a certified yoga instructor.

The essential components of yoga intervention that were identified across the RCTs included: breathing techniques, physical postures and meditation. Practice of mind-body awareness, deep relaxation, guided imagery, and chanting were also identified as frequent components of effective interventions. Despite the limited availability of evidence from high-quality studies, the component analysis initiated the modelling of yoga intervention to improve HRQoL in adult cancer patients.

Chapter 6, as a second step in modelling the processes of yoga delivery, reported the results from in-depth interviews conducted with adult cancer patients (n=10). The purpose of these interviews was to explore the patient experience and preferences for yoga intervention during conventional cancer treatment. Interviewees discussed their use of complementary care, perceived barriers and shared recommendations specific to yoga delivery in a clinical setting. The yoga patients (n=7) said they practised yoga for its calming effect, its physical strengthening, and regarded its holistic, mind-body approach to healing as critical for their wellbeing. Although not identified as a mechanism in Chapter 2, the results of patient interviews added that social and behavioural effects of yoga could have significant impact on its efficacy and adherence in a clinical setting. The conclusions of Chapter 6 outlined a new understanding of yoga's potential role in adult cancer and provided additional information to advance the modelling of a yoga intervention in adult cancer to include: restorative yoga; scheduling away from early mornings or late evening; provision at low cost to patients; variations of physical postures, breathing techniques and meditation; yoga ambience; and opportunity for participants to receive social support in a cancer-specific group.

As an additional exercise in modelling the process and outcomes of yoga intervention, Chapter 7 described a mixed methods survey of oncologists (n=29). The purpose of the study was to document perceived benefits, risks and the acceptability of yoga intervention from a clinical perspective. The responding oncologists expressed a positive attitude towards yoga, but felt there was a lack of scientific evidence to support its use in health care. Respondents agreed yoga intervention could improve health-related outcomes across all tumour groups and did not believe yoga would pose

negative side effects for patients unless wound healing was an issue. Results suggested yoga is currently recommended by a small sample of oncologists to relieve symptoms related to conventional treatment including anxiety, pain management, depression and fatigue. All respondents (n=29) said they would recruit patients to a clinical trial of yoga intervention. Some (n=3) strongly believed yoga was an intervention similar to exercise, not a complementary therapy, and further study to evaluate the utility of yoga versus exercise to improve HRQoL would be of clinical importance.

To execute the evidence-based development of yoga intervention in adult cancer, Chapter 8 considered findings from preceding chapters and results from a workshop with yoga instructors to design and implement a feasibility study of a yoga trial. Male and female patients (33 $\geq$ 72 years of age) diagnosed with breast, prostate, brain, blood, colorectal, tongue, skin and abdominal cancer tumours volunteered and safely participated in three types of yoga intervention (n=15). In general, results of the feasibility study contributed to evidence-based decisions about a prospective yoga-RCT design, characteristics of intervention, outcome measures and financial implications of delivering yoga to adult cancer patients in a clinical setting. The types of research methods, including online data collection, randomisation techniques and trial administration, were effectual and considered appropriate for use in a future study. The rate of patient recruitment (1.5 patient per week) and patient adherence rates to yoga sessions were satisfactory (from 64.6% to 100%).

Group A (minimum yoga dose) received one 50-minute in-person instruction of breathing techniques, and their home-based practice was encouraged with material support that included a yoga mat, an illustrated book, and a list of community-based resources and online classes. Group B (medium yoga dose) received one 75-minute

introductory session that included breathing techniques, physical postures and meditation; an additional 120-minute workshop within ten to 14 days of the introductory session; and home-based practice was encouraged with material support that included a yoga mat, an illustrated book, a list of community-based resources and free access to online yoga classes. Group C (maximum yoga dose) received one 75-minute introductory session that included breathing techniques, physical postures and meditation; additional 60-minute yoga classes up to three times per week; and home-based practice was encouraged with material support that included a yoga mat, an illustrated book, a list of community-based resources and free access to online yoga classes.

Patients reported highest satisfaction and utility of yoga in Group C, where yoga was offered in triweekly sessions over four weeks alongside a free online yoga membership (8.5/10 Satisfaction; 9/10 Utility). The lowest, but still positive experience in Group A (6.8/10 Satisfaction; 8.5/10 Utility) followed a 50-minute yoga session of pranayama-only training with recommendation on how to access yoga online and in the local community. The patient interviews indicated a strong preference for social time and therefore approximately 15 minutes was allocated for patients to ask questions and socialise following yoga class in all group interventions.

The cost-benefit analysis indicated Group B as the most cost-efficient mechanism to deliver yoga (100% adherence rate). Group A had lowest related cost per participant (£151) in comparison to Group B (£187) and Group C (£277). All groups (n=15) were delivered yoga intervention in a four-week period for a trial budget of £3,073. In terms of yoga's potential effects on HRQoL, Group A signalled positive

changes in three domains (psychological, social and spiritual wellbeing), Group B signalled positive changes in two domains (physical and social wellbeing), and Group C signalled positive changes in the other two domains (psychological and spiritual wellbeing).

Free access to online yoga membership did not increase the frequency of its use or amount of home-based yoga practice in Groups B and C. In comparison, the recommendation of fee-for-use online yoga to participants in Group A increased the access to online yoga and the amount of home practice in two participants. The reasons for and reasons against online yoga in adult cancer are areas for future study, and may vary depending on patient demographics including age, income and other factors including access to the Internet. Patients also expressed concern about the ability to achieve a yoga ambience in a clinical setting (i.e. environmental factors, lighting, noise, aromas, music, candles).

In summary of Chapter 8's findings, the sampled yoga instructors and patients suggest prospective yoga interventions in a clinical setting should resemble Group B or C, offering 60>120 minutes of restorative yoga sessions up to three times per week. The optimal intervention would also include adequate provision of supportive materials (i.e. equipment, illustrated book) and recommendations to access safe and appropriate yoga classes in their communities. The gaps in current information to optimise yoga intervention in the context of a RCT were identified, alongside recommendations to improve aspects of a standardised trial protocol, as well as additional outcome measures that consider both the patient and clinician perspectives.

9.2 METHODOLOGICAL STRENGTHS AND LIMITATIONS

The mixed methods research design applied to this thesis has improved the quality of evidence for yoga in adult cancer. The blending of qualitative and quantitative data has assisted to develop a yoga intervention that is responsive to the perspectives of patients, oncologists and health care administrators. The generalisability of this data is a considered limitation, in that only perspectives from a small network of oncologists and patients in Vancouver, Canada have been included. However, online data collection methods for participant registration, screening and outcome measures outlined in the yoga feasibility RCT can be scaled for future studies without additional cost. In addition, the advantages of the QOL-CA/CS survey instrument include its free distribution, straightforward analysis and breadth in terms of HRQoL domains. The patient-based surveys and other mixed methods surveys are available in online formats, to improve the potential efficiency of data collection for future studies.

The MRC's framework for developing complex interventions was applied to yoga in adult cancer for the first time. The MRC tool was selected for its acceptance in the field of evidence-based medicine as a superior framework that considers the spectrum of concerns for complex interventions in health care, including transparency and replicability[338], economic evaluation and efficiency[339], identification of emergent properties that are a feature of the system as a whole[340] and characteristics of social and personal value[341]. This methodical sequence produced a series of research studies to independently strengthen the evidence-base of yoga and collectively advance the development of yoga as a complex intervention in health care.

However, the application of the MRC framework did impose certain limitations. First, the quantity of existing evidence in yoga research, especially cost-benefit data, was inadequate to model a pre-trial economic evaluation of yoga, as recommended by the MRC guidelines[1]. This thesis attempted to model yoga intervention using a component analysis, patient interviews and oncologist surveys. These methods were gleaned from an earlier guide that suggested the key to modelling is to define the intervention's relevant components[338], using qualitative research to show how the intervention works and identifying potential barriers to behaviour change in practice[342]. An economic evaluation was included as part of the feasibility study in Chapter 8, and this data can now be used for future models of yoga intervention.

Second, the paucity of high quality research in yoga threatened the accuracy of evidence collected in the development phase. The overview of systematic reviews and component analysis sought to grade the evidence with standardised instruments to exclude low-quality studies. However, the data summarised from these reviews were susceptible to internal and external bias because data were retrieved from predominantly non-randomised clinical trials with non-blinding of outcome evaluators, inadequate control groups and small sample sizes. Furthermore, the primary studies of patient interviews and oncologist surveys were designed to enhance the understanding of yoga intervention components, its delivery and barriers in a clinical setting. The results of these studies were useful for the purposes of this study, though the above limitations restrict the internal and external validity of their results. The self-selection bias, recall bias or observer effect may have influenced the positive results arising by the interviews, surveys and the feasibility RCT.

Third, the results of this study have been gathered from a small population sample in Vancouver, Canada. As a complex intervention, yoga may have extensive variations and cultural adaptations in other populations and such views are not represented here. The public perceptions of yoga, as well as various individual factors including financial status, religious beliefs or personal motivation may influence the uptake of yoga intervention. For these reasons, a multisite, international clinical trial is needed to understand the generalisability of yoga intervention for adult cancer patients receiving conventional treatment in other cultural and geographical regions.

Fourth, the full expression of the MRC guideline and its components was a time and labour-intensive process. The conduct of a yoga RCT developed from the complex intervention framework took more than three years to define characteristics of a potential intervention and population, and to establish study methods and outcome measures. The time lag incurred additional financial burden to researchers, and presents a certain risk that some relevant information will have been missed.

However, in an updated search (15 November 2014) for high-quality yoga RCTs, research conducted in male populations or other cancers than breast cancer remain absent from the current literature. Study populations, interventions and outcome measures appeared consistent with preceding evidence of this thesis, where research is predominantly in cancer survivors or women[343-346]. One Cochrane review of yoga intervention was completed in haematological malignancies (i.e. leukemia, lymphoma, myeloma) and reported one small study of very low quality met inclusion criteria[347].

9.3 IMPLICATIONS OF THESIS

The collective findings of this doctoral thesis assist in the development and methodological underpinnings of a pilot or large-scale RCT of yoga intervention to improve HRQoL in adult cancer. In particular, the implications of this thesis and its results can be synthesised into advancement in three key areas: methodological approaches for complex interventions, guidance for the study design and improved reporting of clinical trials of yoga intervention.

9.3.1 Methodological Approach

This research adds a stepwise approach to developing yoga intervention in health care research, and offers strategic direction for clinical trials to improve HRQoL in adult cancer. In its question development, clear and answerable research questions of this thesis were identified based upon previous research findings. The selection of each independent study design included decisions based upon efficacy, appropriate research methods, as well as consideration of pragmatic limitations, such as time and cost-efficacy. In response to the paucity of quality and quantity, methodological triangulation of data across four studies (component analysis, patient interviews, oncologist surveys, feasibility study) were compiled to develop a model of yoga intervention in adult cancer.

As a result of this exploration using the MRC framework, the methodological approaches and associated research questions can now be applied in similar subject areas, where researchers seek to understand the qualitative and quantitative impact of complex interventions. See Table 9.1 for a summary of transferable research questions and methodological approaches that can be extracted to other research about complex interventions, as a result of this thesis.

Table 9.1. Sequence of thesis-derived research questions and transferable methodological approaches for complex interventions in health care

Research Question	Thesis Method	Advantages of Method	Disadvantages of Method	Optional Method(s)
Does TCI have underlying mechanisms or biological effects on health?	Literature Review	Quick, easy to conduct	Limited assessment of quality, direction and weighing of the higher quality evidence, no assessment of bias	Systematic Review
How much scientific evidence is available for TCI? Are there associations with TCI and health-related outcomes or risk factors in health?	Bibliometric Analysis	Quick, easy to conduct, generates a crude representation of quantity of existing evidence, indices of the type and topics of past published research	Lacks knowledge about quality and accuracy of data, threat of publication bias, risk of over-representation of type or high-quality evidence	Overview or Systematic Reviews of Evidence/Trials
What is the quality and direction of existing scientific evidence for TCI in health-related conditions?	Systematic Overview of Reviews	Systematic assessment of quality and direction of evidence, efficient meta-analysis of large input of data (i.e. SRs of RCTs)	Excessive heterogeneity of data (i.e. outcome measures, type of intervention) forcing unclear conclusions, susceptible to GIGO[348] (i.e. garbage in, garbage out)	Systematic Review
What does the optimal delivery of TCI look like? Is it standardised? Can it be improved for a clinical/community-based setting?	Component Analysis	Summarises the core and non-core components delivered in previous clinical trials	Paucity of data can limit results, size of effects for core and non-core components may not be well-reported	Focus Group, Delphi Method or Interviews
What are the patient/participants perspectives of TCI and its potential health related outcomes?	Patient Interviews	Provides contextual data and meaning of TCI	Risk of interpreter bias and lack of generalisable data, external validity threatened especially with small sample size, time consuming to analyse data	Survey or Focus Group
What are the HCPs perspectives of TCI and its potential health-related outcomes?	Oncologist Survey	Cost-effective method to gather and analyse a large amount of quantitative and qualitative data, increases external validity when conducted with high response rate	Internal validity can be difficult and time-consuming to determine, researcher may not be able to control response rate, also subject to recall bias and responder bias	Focus Group or Interviews
If and how might TCI be safely delivered in a clinical setting, in the context of a RCT? Is TCI cost-effective and/or scalable to reach a large population of patients? How can selected outcomes be measured?	Feasibility Study	Cost-sensitive, pragmatic method to test study design, safety and implementation of TCI, ethical to complete feasibility in advance of a larger study	Not able to generalise results to a larger sample (i.e. statistically underpowered), if no control group - may overstate adherence and deliverability	Combination of Literature Review, Focus Group, Interview, Delphi Method or RCT
Is TCI effective in improving one or more health-related outcomes?	Mixed Methods RCT	Recommended for its ability to capture qualitative and quantitative data, RCT as gold-standard for testing effectiveness of intervention	Time-consuming, expensive and requires careful administration of research protocol, added complication in analysing quantitative and qualitative outcomes	RCT, Systematic Review

TCI = the complex intervention (i.e. yoga), HCP = health care provider, RCT = randomised controlled trial

9.3.2 Study Design of Yoga Intervention

The mixed methods approach of the feasibility study allowed for extensive contextual understanding and statistical evaluation of the outcomes. This method should be carried over into a future pilot or large-scale RCT to capture qualitative data (i.e. patient-reported descriptions of benefits) as well as quantitative data (i.e. QOL-CA/CS, biomarkers) to articulate the impact of yoga intervention on HRQoL.

The designed protocol could be expanded to include observational study components, interviews or earlier written reports from patients and their yoga instructors to validate data. The cross-referencing of multiples sources (i.e. time-tracking, video recording) could also be included to limit potential threats of self-report or historical bias results. The addition of technological equipment or other data collection tools will increase the cost and logistical challenges. This will need to be considered in conjunction with a potential limitation of the number of willing participants due to additional time burden and privacy concerns.

In addition to this feasibility study, a future pilot study should include a control group (i.e. no yoga). The presence of a non-active or active control group may change the adherence rate to the clinical trial. A control group is imperative for a large-scale trial, so that the outcome measures have a true comparison of yoga's effect and seek to eliminate as many research-related biases as possible. For a summary of the outstanding research questions that could be addressed with further study and in advance of a large-scale RCT, refer to Table 8.21

9.3.2.1 Participants

As indicated by results of the feasibility study, male and female adult cancer patients undergoing conventional treatment of radiotherapy, chemotherapy, hormone therapy or active surveillance can volunteer and participate in a yoga trial. Male patients or patients in treatment for types of cancer other than breast have been historically absent from previous studies, with little or no scientific justification. Results from patient interviews and the feasibility study suggest men, especially men in active surveillance, volunteer to participate and could benefit from yoga intervention. Men and patients with other cancer types than breast cancer should be included in future RCTs.

Patients in pre or post-surgical intervention were excluded from the feasibility trial in Chapter 8 for two reasons: perceived risks to the patient, including negative impact on wound healing if required to perform physical postures; and perceived threats of increasing dropout rates or decreasing patient adherence to the yoga protocol. One female participant in the trial reported that she was unable to complete the outcome surveys because she was undergoing surgical intervention to remove a cancerous tumour. This participant e-mailed an apology post-operation to state that while she felt she was unable to complete the survey, she reported having practised the breathing techniques pre and post operatively, which she said had 'helped'.

From the results of the component analysis in Chapter 5, few yoga RCTs included only cancer patients (n=9) and fewer still include patients in acute care for surgical intervention (n=3) (see Section 5.4.1). Findings from this feasibility suggest that a pranayama-based or meditation-inspired yoga intervention may be appropriate for surgical patients or those with compromised physical capacity. Furthermore,

oncologists expressed that unless wound healing were a concern, all types of cancer patients could participate in a yoga trial. From a methodological standpoint, as one patient with operable cancer was admitted inadvertently to the feasibility study, if surgical patients are to be excluded from future trials a referral letter from a health care professional may be important to prevent participants from invalid enrolment.

Only naïve or irregular users of yoga were included in Chapter 8's feasibility RCT. This population criterion limited confounding factors and would encourage successful randomisation to a 'no-yoga' control group in future studies. However, the inclusion of current yoga-users in the study sample could yield methodological benefits such as increased recruitment rates and retention of study participants. In one instance, a patient dropped out of the feasibility study because she was randomised to Group A, and admitted she was already participating in yoga to a greater extent than was offered in her allocated intervention.

The effect size of yoga intervention to increase HRQoL components in cancer patients, including emotional and social function has been moderate in previous studies (Cohen's d=0.33 to 0.49)[329]. Existing and further literature review of data[230] can be used to calculate a sample size of adequate statistical power[349-352]. A provisional sample size calculation for a two-arm clinical superiority trial of yoga intervention has been performed using statistical software and expert consultation with a biostatistician (BS). Assuming a conservative effect size d of 0.33 (using G*Power software[353] (where $\alpha = 0.05$; $\beta = 0.20$) the statistician recommends a sample of size of 134 (67 per treatment arm), assuming a 10% dropout rate. Other software assisted to calculate a sample size estimate, found that to detect a 10% change in a mean QOL-CA/CS (i.e. 1.0 points) from 5.0 points in the control group

to 6.0 in the experimental group, assuming a continuous outcome variable, normal distribution ($SD^{\dagger}$ = 2.5, α = 0.05; β = 0.10) an adequately powered trial would include a sample of 264 (132 per treatment arm). This more conservative estimate also incorporated the $SD^{\dagger}$ of post-QOL-CA/CS scores from the feasibility study, which varied from 1.24 to 2.39 (see Table 8.19).

9.3.2.2 Intervention

This doctoral thesis adds a benchmark for cost-related issues of administering yoga in a clinical setting and establishes the evidence-base for key components. The per participant exposure and cost of in-person instruction ranged from 60 minutes to 12 hours of yoga for £151 to £277 per participant, including material supplied over a four-week period. Economies of scale with more study participants would decrease this per participant rate of yoga intervention over time.

According to results of this feasibility study and previous findings, breathing techniques, restorative physical postures and meditation are essential components in of instructor-led yoga classes for adult cancer patients. Opportunities for social interaction of cancer patients through yoga may increase HRQoL, their personal satisfaction and adherence to protocols. The scheduling of clinical-based yoga intervention should be flexible to accommodate patients' appointments and varying states of health during treatment. In addition, the physical site and location of yoga should consider proximity to the treatment centre, operational costs, level of security and its ability to create a favourable yoga environment.

In the feasibility study, free access to online yoga did not increase home-based participation in Groups B and C. Online yoga might have been more readily adopted by participants in an intervention such as Group A, where a smaller amount of in-

person yoga instruction is offered. Also, a younger population who accesses the internet more frequently might show a higher adherence rate to yoga delivered in this medium. Online yoga warrants further investigation to some extent because of these noted outstanding questions about patient adherence and safety, but also because online yoga may provide pragmatic benefits of economic efficiency and scalability in a health care setting.

In summary, while the modelling of yoga intervention in this thesis included a component analysis, patient interviews and oncologist surveys, the development of a standardised yoga intervention could have been further explored. For example, an enhanced study of yoga instructors' opinions and recommendations could have been formalised in the context of a focus group[355] or consensus building technique such as a Delphi Method[356].

9.3.2.3 Comparators

The reviewed literature of RCTs compared yoga with usual care, waitlist, physical rehabilitative exercises and counselling. Further, surveyed oncologists requested the conduct of a RCT to test efficacy of yoga when compared to exercise, as exercise is a common recommendation to improve psychological and physical outcomes in cancer patients[357]. To increase recruitment and potential adherence to protocol, the inclusion of two experimental groups (i.e. yoga versus exercise) may have greater advantages. However, the required sample size to demonstrate a statistically significant difference between control and experimental group would be lessened with a simplified yoga versus standard care, which is the comparison most prevalent in recent yoga RCTs (55.6%, n=174)[358].

9.3.2.4 Outcome Measures

Health is a composite measure of psychosocial, spiritual and physical wellbeing[359], where HRQoL outcomes carry clinical significance in oncology[333]. The HRQoL measure via the QOL-CA/CS online tool has been tested and proven to be a feasible option for future study. The most prevalent tools in the current literature were identified as the EORTC-QLC-C30[106] and FACT[312] tools and one recent study used the SF-36[105] to measure quality of life in women undergoing radiotherapy for breast cancer[296]. This particular three-arm study assigned study participants to yoga (n=53), stretching (n=56) or a waitlist control (n=54) for six weeks. The results found that yoga had a positive impact on physical components. However, the SF-36 is an imprecise measure of HRQoL (see Section 8.1.1) in terms of psychological or spiritual wellbeing.

As opposed to the SF-36 instrument, the QOL-CA/CS tool was selected for its specificity and it satisfied most aspects of the established *a priori* criteria for a yoga trial in general adult cancer population (see Table 8.2). The preliminary results of the feasibility study confirmed that the QOL-CA/CS tool was sensitive to changes in both psychological and spiritual components of HRQoL (see Table 8.20). In addition to this, the QOL-CA/CS instrument was easily adapted to an online platform and was implemented at no financial cost to researchers.

All survey tools and subjective outcome measures are at risk of historical bias and self-reporting bias[165]. In consideration of the results from the oncologist surveys and collected evidence from this research, additional outcome measures of clinical interest may also include more objective end-points such as changes in mortality and morbidity rates; patient response to conventional treatment (i.e. tumour size, wound

healing); medication or associated drug use; patient tolerance or adherence rate of conventional treatment; social or health-related behaviours (i.e. dietary intake, physical activity); and/or biomarkers for stress and immune responses (i.e. cortisol levels, T-cells). An intervention-outcome pairing test and rigorous assessment of any new measurement tool is recommended. This analysis could be similar to the evaluation process conducted for selecting the QOLC-CA/CS scale in Chapter 8 (see Tables 8.1 and 8.2).

9.3.2.5 Improving patient recruitment

Poster advertisements were somewhat effective to identify study participants. Improved strategic, in-person meetings or information sessions are recommended to engage health care professionals to recruit patients going forward. A future recruitment strategy could also apply online or creative marketing strategies, such as patient forums or volunteer patient service groups (i.e. transport services, non-profit organisations).

9.3.3 Improving Reporting of Yoga Intervention

The quality of reporting of characteristics of yoga intervention and its delivery in a clinical setting has been insufficient to perform adequate meta-analysis of trial results (see Chapter 4) or model cost-benefits of yoga intervention and its components (see Chapter 5). In a cross-sectional examination of past RCTs (n=51), the majority of published trials lacked important details describing the treatments in experimental groups[360]. Authors concluded the lack of reporting quality represented a substantial waste of time and research budget as future study designs cannot replicate or build upon study findings. An eight-point checklist has been subsequently developed to assess the quality of intervention reporting of setting, recipient, provider, procedure, materials, intensity, schedule and missing information

of study interventions[360]. This checklist could also improve the descriptive reporting and transparency of yoga interventions administered in future clinical trials. For example, the original eight-item list has been adapted here with one additional domain for cost, to target the gap in economic evaluations in the yoga literature (see Table 9.2).

The PaT tool was used to communicate the components of yoga intervention in the feasibility study. In addition to this instrument, a yoga-specific checklist could be developed to further assist the description and standardisation of yoga aspects (see Table 9.3). As an evidence-informed example, this checklist has been generated from results of this thesis' component analysis, overview of systematic reviews and feasibility study. The proposed checklist would be a useful tool to improve the quality of potential meta-analyses and useful in its reporting features to assist component analyses and dose-response investigations of yoga intervention. However, the particular focus and time constraints of this thesis did not allow for validation of this tool. A future study might consider this list as a preliminary checklist to develop with consultation across researchers and yoga experts, using qualitative methods such as focus groups[361] or the Delphi technique[362,363].

Table 9.2. Sample checklist for reporting of yoga interventions in clinical trials

Checklist for Reporting of Yoga Intervention in Randomised Controlled Trials*		
Setting	Is it clear where the intervention was delivered?	☐Yes ☐No
Recipient	Is it clear who is receiving the intervention?	☐Yes ☐No
Provider	Is it clear who delivered the intervention?	☐Yes ☐No
Procedure	Is the procedure (including the sequencing of the technique) of the intervention sufficiently clear to allow replication?	☐Yes ☐No
Materials	Are the physical or informational materials used adequately described?	☐Yes ☐No
Intensity	Is the dose/duration of individual sessions of the intervention clear?	☐Yes ☐No
Schedule	Is the schedule (interval, frequency, duration or timing) of the intervention clear?	☐Yes ☐No
Cost	Is the financial cost of the intervention or some aspect of cost-benefit analysis included?	☐Yes ☐No
Missing	Is there anything missing from the description of the intervention? If yes, what?	☐Yes ☐No

Adapted from: Schroter, S., Galsziou P., Heneghan, C. (2012). BMJ Open; 2:e001978. doi:10.1136/bmjopen-2012-001978

Table 9.3. Proposed checklist for reporting of yoga intervention in RCTs

Checklist for Yoga Intervention Components in Randomised Controlled Trials	
Setting	
Clinical or Health Care Setting	☐Yes ☐No
Community Centre or School	☐Yes ☐No
Private Studio or Residence	☐Yes ☐No
Other:	☐Yes ☐No
Components	
Breathing Techniques	☐Yes ☐No
Physical Postures	☐Yes ☐No
Meditation	☐Yes ☐No
Deep Relaxation or Yogic Sleep	☐Yes ☐No
Chanting or Mantra	☐Yes ☐No
Lecture or Yoga Philosophy Training	☐Yes ☐No
Social Opportunity or Group Discussion	☐Yes ☐No
Other:	☐Yes ☐No
Overview of Instructor-led Yoga Interventions	
Type of yoga	_____
Number of yoga classes (per week or per month)	_____
Duration of yoga class	_____
Estimated total amount of yoga exposure	_____
Other	
Support Provided for Home-based Yoga Practice	
Yoga Mat	☐Yes ☐No
Manual or Instructional Reading Material	☐Yes ☐No
Video Instruction	☐Yes ☐No
Audio Instruction	☐Yes ☐No
Online Yoga (pre-recorded)	☐Yes ☐No
Online Yoga (live, two-way communication)	☐Yes ☐No
Telephone Support and/or Reminders	☐Yes ☐No
Email Support and/or Reminders	☐Yes ☐No
Other (if yes, specify):	☐Yes ☐No

The complex and unpredictable variations that occur in yoga delivery (i.e. time spent on postures, environmental factors, instructor dialogue, special requests from patients) are inevitable. The accuracy of reporting might be improved with the inclusion of a post-intervention PaT diagram to highlight deviations from protocol (see Figure 9.1). This example from Chapter 8's feasibility study presents a colour-coded PaT. The green highlighted sections indicate the aspects of the protocol that were followed precisely. The red highlighted section indicates a deviation in protocol and includes its description. In the feasibility study, it is identified that the allocated time in Groups A's yoga session was extended to 50 minutes from the original 30-minute allocation. Such a template may improve the transparency and standardised reporting of complex intervention studies even further, ultimately improving the potential replication of yoga and its potential outcomes.

A preliminary model for yoga intervention (see Figure 5.1), and a PaT diagram (see Figure 8.1) are two examples of how evidence-based research tools can be used to improve future communication and development of yoga RCTs. Furthermore, templates of three yoga interventions have been recorded and are available for implementation in future trials (see Tables 8.3 to 8.5). The economic impact and potential utility of yoga in adult cancer treatment have been explored for the first time. The analysis of Chapter 8's feasibility study can be used to benchmark the cost and potential utility of future interventions (see Table 8.9 for economic summary; see Table 8.14 for yoga utility and satisfaction across Groups A, B and C).

Timeline	Yoga Intervention A	Yoga Intervention B	Yoga Intervention C
Randomisation			
Baseline	a	a	a
Week 1	1 2	1 2 3	1 2 3
Weeks 2 to 4		4	5
Week 5	a b	a b	a b
End of Study			
a	QOL-CA questionnaire completed by consenting participants (online or paper)		
b	Semi-structured, self-reported survey (Y-ACT) to elicit information regarding at-home yoga adherence, patient experiences, utility/dysutility of yoga, patient attitude and barriers to practising yoga (online or paper)		
1	30-minute training session of pranayama (breathing techniques) administered by a professional yoga instructor in a group setting, given own yoga mat and book to encourage home-based practice, social gathering and tea offered to encourage group discussion		
1	50-minute training session of pranayama (breathing techniques) administered by a professional yoga instructor in a group setting, given own yoga mat and book to encourage home-based practice, social gathering and tea offered to encourage group discussion		
2	15-minute orientation and education session delivered by a professional yoga instructor, includes identification and list of community-based and online options to practise yoga		
3	30-minute of asana training with 15-minute orientation of free and unlimited access to online yoga classes (www.myyogaonline.com)		
4	120-minute yoga workshop, orientation and education session to include pranayama, dhyana, asana (physical postures), social gathering and tea offered to encourage group discussion		
5	3 x 60-minute yoga classes (per week) including pranayama, asana and dhyana administered by a professional yoga instructor in a group setting, social gathering and tea offered to encourage group discussion		

Figure 9.1. Post-intervention PaT plot

9.4 ADDITIONAL CONSIDERATIONS FOR YOGA INTERVENTION AND ITS ROLE IN HEALTH CARE

According to the World Health Organization (WHO), the integration of traditional and complementary practices vary widely from country to country, and are regarded differently depending on culture, understanding and their juxtaposition to conventional medicine[364]. The results of the oncologist survey in Chapter 7 suggested that yoga intervention, from a clinician's point of view, is an exercise and should not be considered a complementary therapy. The body of evidence evaluating yoga's effect on health-related outcomes is catalogued in complementary health care journals, where yoga is frequently referred to as a complementary therapy in both popular and academic literature.

In the successful example of acupuncture, it was once considered a traditional therapy practiced only in China. Acupuncture is now covered under health insurance in 18 countries and used in over 129 countries worldwide[364]. Three salient evidence-based health care issues will need resolution if yoga, like acupuncture, is to be recognised as a complementary therapy.

First, yoga regulation should be improved, where certification, training and standardisation for its delivery are established. As outlined in Chapter 2 (see Section 2.3), yoga relies on certification through agencies to self-manage teaching quality and safety monitoring. Existing consortiums and training institutes across the United Kingdom (UK), United States and Canada are attempting to improve the certification process[365,366] and seek regulation of yoga as a therapeutic practice[367-369]. However, these efforts are largely uncoordinated and monitored by associations with potential conflicts of interest. This is a concern going forward, as health care administrators

and policymakers would need to ensure the integrity, safety and reliable delivery of yoga intervention before supporting its use.

Second, there is lack of strategic direction for yoga research in health care. For example, a high quality evidence-base of yoga research would need to be generated to satisfy requirements for the potential inclusion of yoga within the health care guidelines for lifestyle and wellbeing (i.e. NICE)[370]. To improve research capacity and efficiency, yoga researchers should seek to improve coordination across research departments, strengthen research methods and appeal to the evidence-based and cost-management principles of health care funding agencies. In the past, such types of research organisations have been implemented to improve the quality of evidence and guideline developments of complementary care modalities in the UK, including acupuncture[371,372].

Third, there is a lack of high quality evidence in yoga research. The key findings of this thesis suggest that although yoga may have the potential to improve health outcomes in adult cancer patients with very little adverse effect, the existing evidence is insufficient to explain or predict its generalisable benefit. An increase in the conduct of high quality randomised controlled trials (RCTs), exploiting evidence-based yoga protocols and pragmatic study design, are fundamental to a future direction for yoga in westernised health care systems.

Furthermore, though outside the scope of this thesis, the definition of what yoga is, or how it should be categorised going forward in health care, is an important area that impacts implementation of yoga as an intervention and should be examined in future studies.

9.5 CONCLUSION

Since the beginning of this thesis, progress for yoga intervention and its development in health care has been made. The Medical Research Council's framework has guided a strategic, pragmatic investigation of yoga as a complex intervention in health care. The evidence-base of yoga research has been strengthened, and findings suggest yoga intervention could improve the health-related quality of life (HRQoL) in adult cancer patients. The conventional health care perspectives of yoga intervention have been explored to set forth medical hypotheses of how yoga affects health-related outcomes in adult populations. An evidence synthesis of yoga research has delivered a bibliometric analysis and overview of systematic reviews.

The financial and cost-benefit analyses of yoga intervention in adult cancer had not been previously explored, and a three-part series including a component analysis, patient interviews and oncologists' surveys collectively advanced the modelling and processes to develop an evidence-based protocol of yoga in a clinical setting. A sample of patients (n=10) and oncologists (n=29) in Vancouver, Canada substantiated the perceived value and clinical importance of administering yoga to adult cancer patients.

As a result, a pragmatic, mixed methods feasibility study of yoga intervention was completed with male and female cancer patients (n=15). The findings provided new insight into the rate of patient recruitment and potential adherence of male and female cancer patients with assorted tumour types (i.e. breast, prostate, colorectal, lung, brain, blood). The cost-efficiency, efficacy and scalability of yoga intervention in a health care setting have been documented for the first time. A mixed methods yoga-RCT in adult cancer has been shown to be warranted and feasible.

Ultimately, this thesis has provided recommendations for improved research methodology of complex interventions and yoga in health care, while producing evidence-based support for the optimisation of yoga intervention in the context of a larger-scale pilot or RCT to improve HRQoL in adult cancer. In addition to the independent studies of which this thesis has been comprised, several public forums and group discussions have been conducted to share information about the research methods and their results[373-375]. In collaboration with colleagues from the University of Westminster[376] and the Minded Institute[377], an informal network of ten yoga practitioners and health care researchers has been established to advance the quality of research and coordination of efforts in the field. This interdisciplinary group meets quarterly in London, England. See Appendix 9.A as an example of the discourse led to improve strategic action and evidence-based thinking in yoga research.

Features of this thesis have been published (or are in press) in seven peer-reviewed journals[378-384]. The feasibility study is registered on ClinicalTrials.gov[385] (Identification No: NCT02309112). Results and other aspects of this thesis have been presented at conferences in the form of oral and poster presentations[386-390]. Research methods have been referenced and replicated in other studies[358], which confirms the academic relevance of this work.

In conclusion, this thesis in evidence-based health care advances knowledge in the areas of yoga and mixed methods study in health care research. The findings have both improved and exposed gaps in our current understanding of yoga and its potential role as a complex intervention in health care.

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APPENDICES

CHAPTER 4 APPENDIX

APPENDIX 4.A – SEARCH STRATEGY

A. Identification of relevant databases:

1. Cochrane Library
2. CENTRAL
3. MEDLINE
4. EMBASE
5. AMED
6. PsycINFO
7. CINAHL
8. IndMED
9. CAMQuest
10. Scopus

B. The electronic search performed in May 2012

1. Online access via SOLO [http://solo.bodleian.ox.ac.uk with SSO password]
2. Enter free text terms, MeSH descriptors and set filters.
3. Scan results for relevant titles.
4. Scan titles for relevant abstracts.
5. Scan abstract for relevant review articles.
6. Save citations with abstracts to a file and transfer to reference management database [sente].
7. Collect relevant articles in .pdf and save to file on external and internal computer hard drives under review identification label.
8. Store the external hard drive in separate location under lock and key. Two key holders.

C. Cochrane Database of Systematic Reviews (via Cochrane Library, Wiley)

1. yoga
2. yogi*
3. asana
4. pranayama
5. dhyana
6. meditation
7. 1 or 2 or 3 or 4 or 5 or 6

D. MEDLINE (1946-), EMBASE (1974-), AMED (1985-), PsycINFO (1960-) (via OVID)

1. MeSH descriptor; Meditation; Relaxation Therapy; Mind Body Medicine explode all trees
2. (yoga OR yogi* OR asana OR pranayama OR dhyana OR meditation)
3. MeSH descriptor; Meta-analysis; Review explode all trees
4. (systematic OR review OR meta-analysis)
5. 1 OR 2
6. 3 OR 4
7. 5 AND 6

E. CINAHL (via EBSCOHost)

1. limit: publication type (meta-analysis); exclude (MEDLINE results)
2. (yoga OR yogi* OR asana OR pranayama OR dhyana OR meditation)
3. (systematic OR review OR meta-analysis)
4. 1 AND 2

F. IndMED (http://indmed.nic.in); CAMQuest (http://www.cam-quest.org/en/)

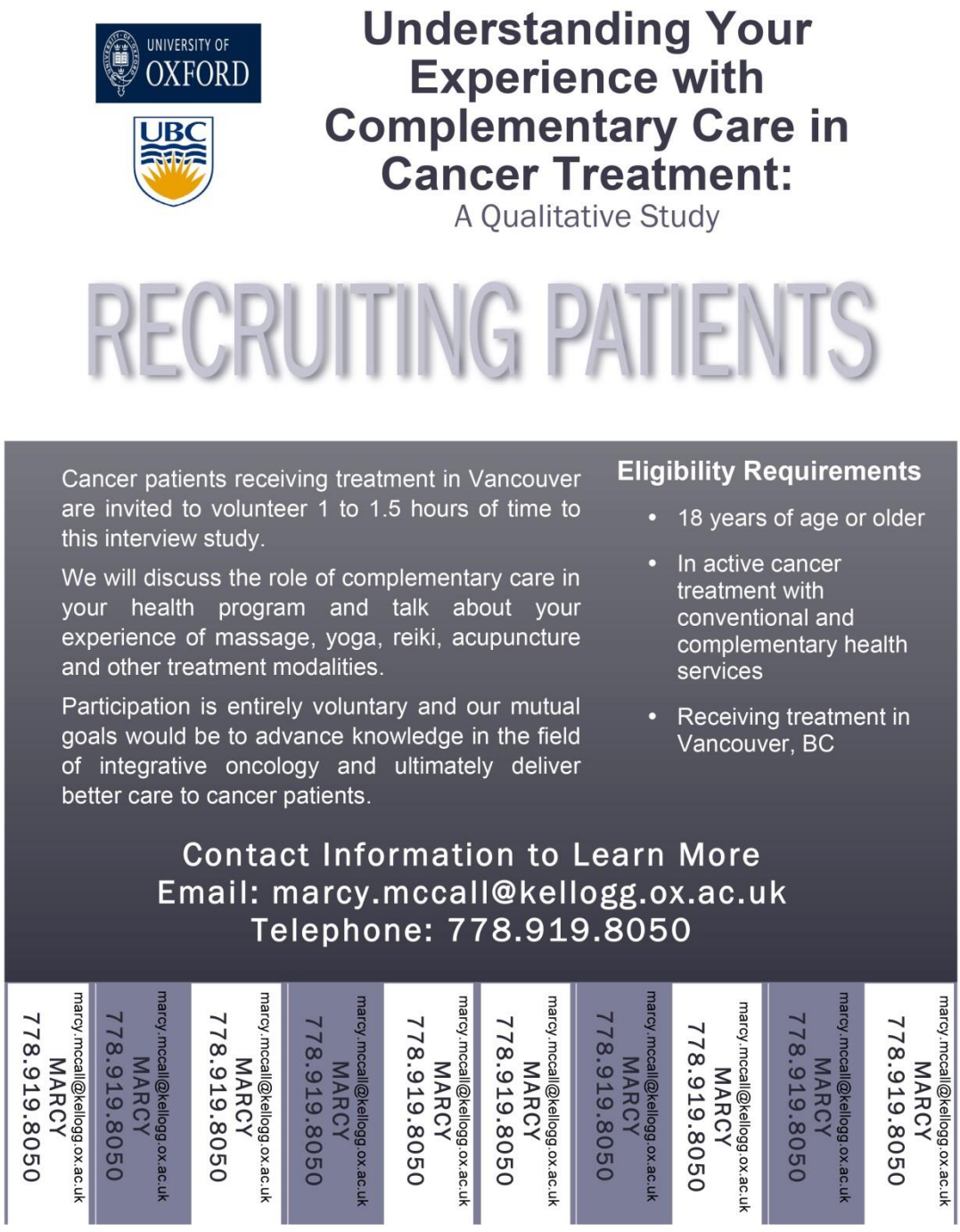
1. (yoga OR yogi* OR asana OR pranayama OR dhyana OR meditation)
2. (systematic OR review OR meta-analysis)
3. 1 AND 2

G. Scopus (via SciVerse; Elsevier)

1. limit: publication type (review)
2. (yoga OR yogi* OR asana OR pranayama OR dhyana OR meditation)
3. (systematic OR review OR meta-analysis)
4. 2 AND 3

CHAPTER 6 APPENDIX

APPENDIX 6.A – PATIENT POSTER ADVERTISEMENT



APPENDIX 6.B – PATIENT REGISTRATION FORM

Registration Form: Are you eligible for this study?

Interview Recruitment: CAM and Cancer Study

Thank you for your interest in participating in an interview study. This registration form is a confidential document that will only be viewed by Marcy McCall, Dr. Sally Thorne and other members of the research team. We are working together to explore the patient experience of using complementary and alternative medicine (CAM) alongside conventional cancer treatment.

This form collects personal information that will be used for study purposes only and held confidentially and anonymously by researchers.

1. Your Last Name, First Name and Initial

2. Your Date of Birth (day/month/year):

3. Your Mailing Address:

4. Your E-mail Address:

5. Your Contact Telephone Number:

6. Gender:

- ◯ Male
- ◯ Female

7. Current Occupation:

8. Your highest level of completed education to date:

- ◯ Highschool Diploma
- ◯ College Diploma
- ◯ University Degree (Bachelor)
- ◯ University Degree (Master)
- ◯ Doctorate

Other (please specify)

Registration Form: Are you eligible for this study?

9. Type of Cancer Diagnosis:

- ◯ prostate
- ◯ colorectal
- ◯ non-hodgkin lymphoma
- ◯ melanoma
- ◯ leukemia
- ◯ pancreas
- ◯ lung
- ◯ breast
- ◯ body of uterus
- ◯ kidney
- ◯ thyroid
- ◯ bladder

Other (please specify)

10. Location of Cancer:

11. At what stage was your cancer at the point of diagnosis?

- ◯ Stage I
- ◯ Stage II
- ◯ Stage III
- ◯ Stage IV
- ◯ Unsure

Other (please specify)

12. Are you currently receiving oncological care or conventional treatment? Check all those that apply.

- ☐ No, I am not receiving any care or treatment from an oncologists and/or doctor
- ☐ Active Surveillance
- ☐ Prescription Medication for Cancer-related Symptoms/Treatment
- ☐ Radiation Therapy
- ☐ Hormone Therapy
- ☐ Chemotherapy
- ☐ Surgical Intervention

Other (please specify)

Registration Form: Are you eligible for this study?

13. Are you receiving complementary or alternative therapy for cancer management? Check all that apply.

- ☐ Talk Therapy
- ☐ Massage
- ☐ Homeopathy
- ☐ Ayruvedic Medicine
- ☐ Yoga
- ☐ Acupuncture
- ☐ Herbal Remedies
- ☐ Nutritional Counselling
- ☐ Traditional Chinese Medicine
- ☐ No, I am not receiving any complementary or alternative treatment

Other (please specify)

14. If you are seeking complementary or alternative therapy, how regularly do you use it?

- ◯ Rarely (1 session/dose per month)
- ◯ Regularly (2 sessions/doses per month)
- ◯ Often (about 3 sessions per month)
- ◯ Frequently (more than 4 sessions per month)

Other (please specify)

15. Have you ever practiced yoga?

- ◯ No
- ◯ Yes

16. Did you practice yoga before your diagnosis?

- ◯ Yes
- ◯ No
- ◯ Not Applicable - I've never done yoga

17. How many times have you done yoga since your cancer diagnosis?

- ◯ Never
- ◯ 1-2 times
- ◯ 3-5 times
- ◯ 10-20 times
- ◯ More than 25 times

Other (please specify)

Registration Form: Are you eligible for this study?

18. Are you currently experiencing any psychological distress or psychosis that would interfere with your ability to complete an interview or provide informed consent?

- ◯ Yes
- ◯ No

19. Please be advised that we will notify you within 2 weeks if you are eligible to participate in a telephone or in-person interview. Our sincere thanks for your interest.

You are welcome to share any of your questions, comments or concerns at this time:

APPENDIX 6.C – PATIENT CONSENT FORM

Informed Consent Form for In-depth Patient Interview

University of British Columbia

In association with Kellogg College, University of Oxford

This informed consent form is for cancer patients undergoing treatment in Vancouver, British Columbia, Canada and we are inviting to participate in research interviews for the "The Role of Yoga in Complementary Care for Cancer Project."

Principal Investigator
Dr. Sally Thorne
School of Nursing, University of British Columbia

Lead Researcher
Marcy C. McCall
Department of Continuing Education, Kellogg College

Contact Information
If you have any questions, please telephone Marcy McCall (Lead Researcher) at 778.919.8050 or send an email marcy.mccall@kellogg.ox.ac.uk, or you may ask them in person during the interview. Dr. Sally Thorne (Principal Investigator) can also be contacted via email at sally.thorne@nursing.ubc.ca or telephone at 604.822.7482.

This informed consent form has two parts (4 pages):

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signature if you choose to participate)**

Part 1. Information Sheet

Introduction

My name is Marcy McCall and I am a doctoral student with the Kellogg College, University of Oxford. In collaboration with the University of British Columbia, we are conducting research to understand the use of yoga for patients undergoing cancer treatment in Vancouver, Canada. We invite you to read the information and consider becoming part of this research. Please feel free to ask questions and discuss it with anyone in which you feel comfortable before deciding to participate.

Purpose of the research

Nearly 6.6 million people will be diagnosed with cancer this year worldwide. Usual treatment options include radiation, hormone therapy, chemotherapy and surgery, though many patients feel the burdens of cancer and treatment are not fully addressed in the conventional medical setting. In your community, cancer patients seek out and spend money on supplementary care, including talk therapy, massage, yoga and acupuncture to help them cope with cancer and improve health outcomes. We want to learn about the different complementary therapies available to you and why people choose certain kinds of treatment. We want to know more

about the beliefs and attitudes towards yoga of people who do *and* don't do yoga. We want to understand the experiences of cancer patients who try yoga or other things to help them feel better.

Type of Research Intervention

This research will involve your participation in a single face-to-face interview that will take approximately one hour to complete.

Participant Selection

You are being invited to take part in this research because we feel that your experience as a patient undergoing conventional and complementary care for cancer can contribute much to our understanding and knowledge of what a patients needs to feel better.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive will continue and nothing will change. You may change your mind later and stop participating even you agreed earlier.

Procedures

We are asking you to participate in this study to learn more about your experience in complementary care for cancer treatment. If you accept, you will be asked to meet with Marcy McCall for 60 to 90 minutes. You will be asked questions about your experience in cancer treatment in general, as well as your usage of complementary therapies and your feelings about yoga intervention. The interview can take place at your home, or within a health or community centre in central Vancouver. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential and no one else except Dr. Sally Thorne and members of the research team will have access to the information documented during your interview. The entire interview will be recorded on portable audio machine, but your name will not be identified. The data on the audio machine will be transcribed within 5 days of recording, and the raw data will be stored on a secure USB file under lock and key indefinitely at the University of British Columbia and with research M.McCall. The data on the recording device will be destroyed within 24-hours of recording. All computerized files will be encrypted under password protection to keep the information private and confidential.

Duration

The research takes place over 12-weeks from June to September 2013. During that time, we will contact you to schedule one interview at your preferred location for 60 to 90 minutes.

Risks

We are asking you to share your personal experience, thoughts and beliefs about cancer care, complementary therapies and yoga. There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. We do not wish to make you feel uncomfortable and you do not have to answer a question if it is felt to be too personal.

Benefits

There will be no direct benefit to you, but your participation is likely to help us find out more about integrative oncology and about how we can improve health outcomes for cancer patients.

Reimbursements

You will not be provided any incentive or compensation to take part in the research.

Confidentiality

The research interview can be conducted in the privacy of your own home or at a designated site that you frequently visit such as your health centre. We will not be sharing information about you to anyone outside the research team. The information that we collect from this research project will be kept private. Only your initials or a pseudonym will be used in print material. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with under password protection and lock and key.

Sharing the Results

Nothing that you tell us will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you before it is made public, which will usually include publication in a peer-reviewed journal.

You can ask me more about any part of the research study, if you wish to.
Do you have any questions?

Right to Refuse or Withdraw

At any time, you may wish to withdraw from this study. You may stop participating at any time without any of your current treatment being affected. You will be given an opportunity at the end of the interview to adjust or review your responses.

Who can you contact if you have complaints or concerns about the study?

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, you may contact the Research Subject Information Line in the UBC Office of Research Services at 604-822-8598 or if long distance e-mail RSIL@ors.ubc.ca or call toll free 1-877-822-8598.

Part 2. Certificate of Consent

Statement by the participant

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and my questions (if any) have been asked and answered to my satisfaction. I consent voluntarily to be a participant in this study.

Print Name of Participant:

Signature of Participant:

Date:

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that this research intervention includes a face-to-face in-depth interview of 60 to 90 minutes. Audio recording and transcribed data will remain anonymous. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this Informed Consent Form has been provided to the participant.

Print Name of Researcher/person taking consent:

Signature of Researcher/person taking consent:

Date:

CHAPTER 7 APPENDIX

APPENDIX 7.A – ONCOLOGIST SURVEY TEMPLATE

Yoga for Cancer? An Oncologist's Perspective

Section A. Personal and Professional Background

Many patients seek out and spend money on supplementary care, including talk therapy, massage, yoga and acupuncture to help them cope with cancer without clear evidence to support their various health claims.

To improve the evidence-base and quality of care provided to patients, we want to learn more about the potential risks and/or utility of yoga from a clinician's point of view.

Thank you for your important contribution.

All personal information and your responses will remain entirely confidential.

1. Your Last Name, First Name and Initial

2. Are you male or female?

◯ Male

◯ Female

3. What is your date of birth?

MM DD YYYY

Date of Birth: ☐ / ☐ / ☐

4. Please provide your e-mail address (for related-research inquiries only):

5. What ethnicity best describes you:

☐ African American ☐ Korean ☐ Hispanic

☐ Caucasian ☐ Japanese ☐ Indian

☐ Chinese ☐ First Nation ☐ Vietnamese

Other (please specify)

Yoga for Cancer? An Oncologist's Perspective

6. Do you consider yourself Christian, Jewish, Buddhist, Muslim, Hindu, a follower of some other religion, or not religious?

- ☐ Christian
- ☐ Jewish
- ☐ Buddhist
- ☐ Muslim
- ☐ Hindu
- ☐ A follower of some other religion, unspecified
- ☐ Not religious

Other (please specify)

7. What is your current professional title?

- ◯ Medical Oncologist
- ◯ Radiation Oncologist
- ◯ Surgical Oncologist

Other (please specify)

8. What is your medical sub-specialty? (if applicable)

9. How many years have you been practicing medicine?

- ◯ less than 2 years
- ◯ 2 to 5 years
- ◯ 5 to 10 years
- ◯ 10 to 25 years
- ◯ more than 25 years

10. Do you practice medicine on a part-time or full-time basis?

- ◯ Part-Time (less than 25 hours/week)
- ◯ Full-Time (more than 25 hours/week)

11. Where is your treatment hospital and/or clinic located?

- ☐ Vancouver
- ☐ North Vancouver
- ☐ West Vancouver
- ☐ Burnaby
- ☐ Surrey
- ☐ Richmond
- ☐ Delta
- ☐ Victoria

Other:

Yoga for Cancer? An Oncologist's Perspective

12. What proportion of your patients are adults (18 years of age or older)?

- ◯ less than 5%
- ◯ 5 to 25%
- ◯ 25 to 50%
- ◯ 50 to 75%
- ◯ 75 to 99%
- ◯ 100%

Other (please specify)

13. How many new cases of cancer do you see?

- ◯ 1 per year
- ◯ 1 per month
- ◯ 1 per week
- ◯ 2 to 4 per week

Other (please specify)

Yoga for Cancer? An Oncologist's Perspective

14. What type of cancers do you most often treat?
Please rank them in order of 'most' treated at the top and 'least' treated at the bottom:

▾	prostate	☐ N/A
▾	lung	☐ N/A
▾	colorectal	☐ N/A
▾	breast	☐ N/A
▾	non-hodgkin lymphoma	☐ N/A
▾	body of uterus	☐ N/A
▾	bladder	☐ N/A
▾	melanoma	☐ N/A
▾	kidney	☐ N/A
▾	leukemia	☐ N/A
▾	thyroid	☐ N/A
▾	pancreas	☐ N/A

15. How would you describe your level of physical fitness with respect to the general population?

- ◯ very poor
- ◯ poor
- ◯ average
- ◯ good
- ◯ excellent

Yoga for Cancer? An Oncologist's Perspective

16. What kind of physical activity or sport do you currently enjoy to promote your level of fitness or well-being?

- ☐ Walking
- ☐ Jogging
- ☐ Hiking
- ☐ Swimming
- ☐ Cycling
- ☐ Skiing
- ☐ Tennis
- ☐ Fitness Classes
- ☐ Gym
- ☐ Martial Art

Other (please specify)

17. How often do you practice yoga?

- ◯ never (0 times)
- ◯ experimental (1 or 2 times in my life)
- ◯ sometimes (once per month)
- ◯ regularly (2 to 3 times per month)
- ◯ often (at least once per week)

18. How often do you partake in any meditation or mindfulness-based practices?

- ◯ never (0 times)
- ◯ experimental (1 or 2 times in my life)
- ◯ sometimes (once per month)
- ◯ regularly (2 to 3 times per month)
- ◯ often (at least once per week)

19. How would you describe your commitment to using complementary or alternative medicine (CAM) to improve your own personal health?

	Not at all committed	Somewhat committed	Neutral	Committed	Very committed
Level of commitment to CAM for your personal health	◯	◯	◯	◯	◯

Yoga for Cancer? An Oncologist's Perspective

20. In the past, what kinds of complementary therapy have you used for your own personal health?

- ☐ Massage
- ☐ Talk Therapy
- ☐ Reiki
- ☐ Acupuncture
- ☐ Herbs
- ☐ Physical Exercise
- ☐ Yoga
- ☐ Meditation
- ☐ Hypnosis
- ☐ Traditional Chinese Medicine
- ☐ Ayruvedic Medicine
- ☐ None of the above

Other (please specify)

21. How would you describe your level of interest in using complementary or alternative medicine (CAM) to improve health-related outcomes in your patients?

	Not at all interested	Not very interested	Neutral	Somewhat interested	Very interested
Level of interest in CAM for your cancer patients	◯	◯	◯	◯	◯

22. In the past, what kinds of complementary or alternative medicine have you suggested to your patients to improve their health-related outcomes?

- ☐ Massage
- ☐ Talk Therapy
- ☐ Reiki
- ☐ Acupuncture
- ☐ Herbs
- ☐ Physical Exercise
- ☐ Yoga
- ☐ Meditation
- ☐ Hypnosis
- ☐ Traditional Chinese Medicine
- ☐ Ayruvedic Medicine
- ☐ None of the above

Other (please specify)

23. In general, how would you describe your attitude towards yoga as a means to improve health or well-being?

	Very negative	Somewhat negative	Neutral	Somewhat positive	Very positive
Attitude towards yoga for health or well-being	◯	◯	◯	◯	◯

Yoga for Cancer? An Oncologist's Perspective

24. How would you describe your level of interest in using yoga to improve health-related outcomes in your cancer patients?

	Not at all interested	Not very interested	Neutral	Somewhat interested	Very interested
Level of interest in yoga for your cancer patients	◯	◯	◯	◯	◯

Section B. Knowledge, Attitudes and Beliefs about Yoga

Yoga is a complex intervention that may include physical postures, breathing techniques, meditation and psychological awareness. In cancer treatment, the use of yoga is becoming an area of research interest for various health-related outcomes.

Every oncologist has his or her own opinion about the utility of this or other complementary therapies when used alongside conventional treatment.

We are interested in knowing about your opinion and beliefs about yoga in cancer care.

Based on your current beliefs, please choose the option from the following statements that best reflects your views:

Yoga for Cancer? An Oncologist's Perspective

25. I believe the practice of yoga is best suited for...

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Healthy populations	◯	◯	◯	◯	◯
Early-stage cancer patients	◯	◯	◯	◯	◯
Later-stage cancer patients	◯	◯	◯	◯	◯
Male patients	◯	◯	◯	◯	◯
Female patients	◯	◯	◯	◯	◯
Adults	◯	◯	◯	◯	◯
Children	◯	◯	◯	◯	◯
Patients who are interested in trying it	◯	◯	◯	◯	◯
Patients who did yoga before they were diagnosed	◯	◯	◯	◯	◯
Fearful or anxious patients	◯	◯	◯	◯	◯
Patients receiving radiation, chemotherapy or surgery	◯	◯	◯	◯	◯
Patients not receiving conventional treatment	◯	◯	◯	◯	◯
Patients in palliative care	◯	◯	◯	◯	◯
Patients seeking answers to spiritual questions	◯	◯	◯	◯	◯
Patients who are experiencing stress	◯	◯	◯	◯	◯
Patients who are in remission	◯	◯	◯	◯	◯

Other (please specify)

Yoga for Cancer? An Oncologist's Perspective

26. I believe the practice of yoga is not suited for...

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Early-stage cancer patients	◯	◯	◯	◯	◯
Late-stage cancer patients	◯	◯	◯	◯	◯
Frail or elderly populations	◯	◯	◯	◯	◯
Religious followers	◯	◯	◯	◯	◯
Sedentary populations	◯	◯	◯	◯	◯
Overweight or obese populations	◯	◯	◯	◯	◯
Individuals with psychological stress or trauma	◯	◯	◯	◯	◯
Individuals suffering from physical pain	◯	◯	◯	◯	◯
Individuals who are recovering from surgical intervention	◯	◯	◯	◯	◯
Individuals who are experiencing nausea or vomiting	◯	◯	◯	◯	◯
Individuals undergoing cancer treatment	◯	◯	◯	◯	◯

Other (please specify)

Yoga for Cancer? An Oncologist's Perspective

27. I believe practicing yoga in conjunction with conventional cancer treatment will...

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
Harm the patient	◯	◯	◯	◯	◯
Have no impact	◯	◯	◯	◯	◯
Confuse the patient	◯	◯	◯	◯	◯
Interfere with patient treatment in some negative way	◯	◯	◯	◯	◯
Give a patient false hope	◯	◯	◯	◯	◯
Cause the patient to make dangerous decisions	◯	◯	◯	◯	◯
Improve health-related quality of life in patients	◯	◯	◯	◯	◯
Improve the physical health of patients	◯	◯	◯	◯	◯
Boost the immune system of patients	◯	◯	◯	◯	◯
Decrease emotional distress of patients	◯	◯	◯	◯	◯
Reduce fear and anxiety of patients	◯	◯	◯	◯	◯
Reduce pain symptoms associated with cancer and its treatment	◯	◯	◯	◯	◯
Reduce fatigue related to cancer and its treatment	◯	◯	◯	◯	◯
Reduce depression or related feelings of sadness	◯	◯	◯	◯	◯
Help to reduce tumour size	◯	◯	◯	◯	◯
Help patients cope with the experience of having cancer	◯	◯	◯	◯	◯

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Help to improve patient adherence to conventional treatment	○	○	○	○	○

Other (please specify)

28. I am unlikely or hesitant to suggest yoga for my patients because...

	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree
There is lack of scientific evidence to support its use	○	○	○	○	○
My patients would not be interested in doing yoga	○	○	○	○	○
It would be difficult for my patients to do yoga postures	○	○	○	○	○
It would cost a patient too much money	○	○	○	○	○
It would be a waste of time	○	○	○	○	○
I believe yoga is a religious practice, not a therapeutic intervention	○	○	○	○	○
I don't have knowledge about yoga as a therapy	○	○	○	○	○

Other (please specify)

Yoga for Cancer? An Oncologist's Perspective

29. Which of the following statements best describes your current attitude toward yoga as complementary therapy to improve health outcomes in adult cancer? Please check all that apply.

☐ Ambivalent	☐ Disapproving	☐ Willing to recommend it
☐ Skeptical	☐ Cautious	☐ Happy to refer some patients
☐ Curious	☐ Undecided	☐ Convinced it is not effective
☐ Doubtful	☐ Supportive	☐ Convinced it is effective
☐ Interested	☐ Hopeful	☐ None of the above

Other (please specify)

Section C. Interest, Willingness and Yoga Clinical Practice

Yoga for Cancer? An Oncologist's Perspective

30. Please indicate the response that best describes your answer to the following questions:

	No	Yes
Do you discuss complementary therapies with your patients?	◯	◯
Do you seek information on uses of complementary and alternative medicines to assist in cancer patient care?	◯	◯
Has a cancer patient ever asked you about using yoga to improve a health-related outcome?	◯	◯
To the best of your knowledge, are any of your patients doing yoga in conjunction with their conventional treatment?	◯	◯
Would you refer patients to a clinical trial of yoga for quality of life outcomes?	◯	◯
Do you consider yoga a complementary therapy?	◯	◯

31. Have you ever recommended yoga to improve a health-related outcome for a cancer patient?

◯ No

◯ Yes

If yes, please specify the symptom/condition:

Yoga for Cancer? An Oncologist's Perspective

32. In the future, do you suppose you will talk to your patients about yoga to improve their health-related outcomes?

◯ No

◯ Yes

Why or why not?

Section D. Concerns and Barriers of Yoga for Cancer Patients

33. Can you list any barriers, whether physical or psychological, that most often prevent cancer patients from participating in their activities of daily living?

34. From your experience, what can be done to overcome likely barriers presented to cancer patients who want to maintain their activities of daily living?

35. To what extent do you think the following list of items would be a concern or barrier for your cancer patients in attending a yoga class?

	Not at all	A little bit	Somewhat	Quite a bit	A tremendous amount
Physical capacity	◯	◯	◯	◯	◯
Psychological stress/instability	◯	◯	◯	◯	◯
Pain	◯	◯	◯	◯	◯
Fatigue	◯	◯	◯	◯	◯
Nausea	◯	◯	◯	◯	◯
Lack of interest	◯	◯	◯	◯	◯
Lack of perceived benefit	◯	◯	◯	◯	◯
Lack of confidence	◯	◯	◯	◯	◯
Fear of stigma in a group class	◯	◯	◯	◯	◯
Transportation	◯	◯	◯	◯	◯
Scheduling issues	◯	◯	◯	◯	◯
Cost	◯	◯	◯	◯	◯

Other (please specify)

Yoga for Cancer? An Oncologist's Perspective

Section E. Open Remarks about Yoga and this Survey

The following space is for you to explain more about your views and experience of yoga in cancer prevention or treatment.

36. Please share your thoughts on if, why and when yoga might improve symptom management of cancer treatment.

37. Please use this space to list questions, concerns or comments about yoga and its potential use during cancer treatment.

38. Please share any comments on this survey or feedback for researchers here:

APPENDIX 7.B – SURVEY DATA

Question 19. How would you describe your commitment to using complementary or alternative medicine (CAM) to improve your own personal health?

Answer Options	Not at all committed	Somewhat committed	Neutral	Committed	Very committed	Response Count
Level of commitment to CAM for your personal health	12	6	8	2	1	29
					answered question	**29**
					skipped question	**0**

Question 20. In the past, what kinds of complementary therapy have you used for your own personal health?

Answer Options	Response Count
Massage	22
Talk Therapy	0
Reiki	1
Acupuncture	8
Herbs	1
Physical Exercise	24
Yoga	12
Meditation	7
Hypnosis	0
Traditional Chinese Medicine	2
Ayurveda Medicine	0
None of the above	2
Other (please specify)	2
answered question	**29**
skipped question	**0**

Number	Other
1	I don't think of these pursuits as "therapy" when they are for healthy lifestyle, not treatment of something; I'm assuming you're not restricting your question to the context of physician dealing with illness
2	chiropractic

Question 21. How would you describe your level of interest in using complementary or alternative medicine (CAM) to improve health-related outcomes in your patients?

Answer Options	Not at all interested	Not very interested	Neutral	Somewhat interested	Very interested	Response Count
Level of interest in CAM for your cancer patients	0	4	7	15	3	29
					answered question	**29**
					skipped question	**0**

Question 23. In general, how would you describe your attitude towards yoga as a means to improve health or well-being?

Answer Options	Very negative	Somewhat negative	Neutral	Somewhat positive	Very positive	Response Count
Attitude towards yoga for health or well-being	0	0	6	11	12	29
					answered question	**29**
					skipped question	**0**

Question 24. How would you describe your level of interest in using yoga to improve health-related outcomes in your cancer patients?

Answer Options	Not at all interested	Not very interested	Neutral	Somewhat interested	Very interested	Response Count
Level of interest in yoga for your cancer patients	0	3	6	14	6	29
					answered question	**29**
					skipped question	**0**

Question 25. I believe the practice of yoga is best suited for...

Answer Options	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree	Response Count
Healthy populations	1	1	1	21	5	29
Early-stage cancer patients	0	1	4	21	3	29
Later-stage cancer patients	0	4	9	14	2	29
Male patients	0	1	5	20	3	29
Female patients	0	1	3	22	3	29
Adults	0	1	1	24	3	29
Children	0	2	14	10	3	29
Patients interested in trying it	0	0	0	19	10	29
Patients who did yoga before they were diagnosed	0	1	4	13	10	28
Fearful or anxious patients	0	0	7	17	5	29
Patients receiving radiation, chemotherapy or surgery	0	0	9	18	2	29
Patients not receiving conventional treatment	0	0	11	15	2	28
Patients in palliative care	0	2	12	14	1	29
Patients seeking answers to spiritual questions	1	2	13	11	2	29
Patients who are experiencing stress	0	0	3	19	7	29
Patients who are in remission	0	0	5	20	4	29

Answer Options	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree	Response Count
					answered question	**29**
					skipped question	**0**

Number	Other
1	Anyone who wishes to explore it as an option, if it is unlikely to cause pain or impact wound healing, essentially
2	There is no data for any of this - this is belief
3	Type of class/ difficulty depends upon situation

Question 26. I believe the practice of yoga is not suited for...

Answer Options	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree	Response Count
Early-stage cancer patients	5	20	4	0	0	29
Late-stage cancer patients	3	15	11	0	0	29
Frail or elderly populations	2	13	11	3	0	29
Religious followers	3	20	6	0	0	29
Sedentary populations	3	22	3	0	0	28
Overweight or obese populations	3	23	3	0	0	29
Individuals with psychological stress or trauma	5	21	3	0	0	29
Individuals suffering from physical pain	1	19	8	1	0	29
Individuals who are recovering from surgical intervention	1	11	13	4	0	29
Individuals who are experiencing nausea or vomiting	2	17	10	0	0	29
Individuals undergoing cancer treatment	5	20	4	0	0	29
Other (please specify)						2
					answered question	**29**
					skipped question	**0**

Number	Other
1	as above, if they are well enough to attend and participate and are interested, there's no particular diagnosis or subgroup I'd select or avoid
2	this is not science but belief

Question 27. I believe practicing yoga in conjunction with conventional cancer treatment will…

Answer Options	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree	Response Count
Harm the patient	12	14	3	0	0	29
Have no impact	0	8	14	7	0	29
Confuse the patient	4	16	9	0	0	29
Interfere with patient treatment in some negative way	7	19	3	0	0	29
Give a patient false hope	6	18	5	0	0	29
Cause the patient to make dangerous decisions	6	19	4	0	0	29
Improve health-related quality of life in patients	0	0	12	14	3	29
Improve the physical health of patients	0	0	9	17	3	29
Boost the immune system of patients	2	12	13	2	0	29
Decrease emotional distress of patients	0	0	10	16	3	29
Reduce fear and anxiety of patients	0	0	11	16	2	29
Reduce pain symptoms associated with cancer and its treatment	0	0	19	10	0	29
Reduce fatigue related to cancer and its treatment	0	0	16	12	1	29
Reduce depression or related feelings of sadness	0	0	14	13	2	29
Help to reduce tumour size	15	13	1	0	0	29
Help patients cope with the experience of having cancer	0	0	9	15	4	28
Help to improve patient adherence to conventional treatment	1	3	20	3	2	29
Other (please specify)						1
				answered question		**29**
				skipped question		**0**

Number	Other
1	"have no impact" is vague, are you talking efficacy?

Question 28. I am unlikely or hesitant to suggest yoga for my patients because...

Answer Options	Strongly Disagree	Disagree	Unsure	Agree	Strongly Agree	Response Count
There is lack of scientific evidence to support its use	2	8	8	10	1	29
My patients would not be interested in doing yoga	2	14	9	3	0	28
It would be difficult for my patients to do yoga postures	1	14	9	5	0	29
It would cost a patient too much money	1	5	12	11	0	29
It would be a waste of time	6	15	8	0	0	29
I believe yoga is a religious practice, not a therapeutic intervention	10	16	3	0	0	29
I don’t have knowledge about yoga as a therapy	3	6	5	11	4	29
Other (please specify)						3
					answered question	**29**
					skipped question	**0**

Number	Other
1	I have suggested yoga but don’t know the resources available or the cost; I relayed to patients that I’d seen the Y offering a yoga course for cancer patients, at one point, but the course seems to have been discontinued
2	Yoga might be initially expensive, but once patients are familiar with the practice, they can do it at home at no cost
3	many patients are not interested/ won’t pay

Question 29. Describe your current attitude toward yoga as complementary therapy to improve health outcomes in adult cancer

Characteristic	Number
Ambivalent	8
Skeptical	4
Curious	14
Doubtful	2
Interested	15
Disapproving	0
Cautious	9
Undecided	9
Supportive	19
Hopeful	11
Willing to recommend it	11
Happy to refer some patients	16
Convinced it is not effective	0
Convinced it is effective	3
None of the above	0
answered question	**29**
skipped question	**0**

Question 30. Willingness to refer yoga and CAM trends in clinical practice

Answer Options	No	Yes	Response Count
Do you discuss complementary therapies with your patients?	4	25	29
Do you seek information on uses of complementary and alternative medicines to assist in cancer patient care?	14	15	29
Has a cancer patient ever asked you about using yoga to improve a health-related outcome?	19	10	29
To the best of your knowledge, are any of your patients doing yoga in conjunction with their conventional treatment?	11	17	28
Would you refer patients to a clinical trial of yoga for quality of life outcomes?	0	29	29
Do you consider yoga a complementary therapy?	14	15	29
		answered question	**29**
		skipped question	**0**

Question 31. Have you ever recommended yoga to improve a health-related outcome for a cancer patient?

Answer Options	Response Percent	Response Count
No	65.5%	19
Yes	34.5%	10
If yes, please specify the symptom/condition:		9
	answered question	**29**
	skipped question	**0**

Number	Specified symptom/condition*:
1	in the context of any physical activity to help physical + psychological health
2	stiffness, feeling of weakness and isolation
3	fatigue, stress, for breast pts for arms
4	Muscle and joint stiffness
5	fatigue, stress and insomnia in pts on or completed therapy
6	arthritis type pain in pelvis
7	recommended is strong- I discuss exercise and within this- yoga. Different approaches appeal to different people. NO many free classes and not all appropriate for patients- this I can't tell what is best for the cancer patient in our community. generally yoga has mostly young, healthy participants at many "studios". and many community programs require an 8 course sign up- expensive and people are unsure what to take
8	insomnia during treatment and for hot flashes related with hormone treatment for breast cancer

Question 32. In the future, do you suppose you will talk to your patients about yoga to improve their health-related outcomes?

Answer Options	Response Percent	Response Count
No	58.6%	17
Yes	41.4%	12
Why or why not?		20
	answered question	**29**
	skipped question	**0**

Number	Why or why not?
1	needs evidence
2	as above
3	I think yoga and other physical exercise and social interaction is beneficial for humans and my patients are often looking for guidance on lifestyle, especially those who have completed curative intent therapy and who are trying to get back to regular work, energy, and positive spirit; main barrier is accessibility and cost for patients
4	I already discuss it.
5	From personal experience I am familiar with the benefits of yoga in dealing with stress, muscle tension and getting restful sleep
6	need more information
7	Not sure I have the time for this, I barely get enough time to talk to them about well proven systemic therapy
8	Does not up among the many other things that need discussing,
9	not sure about the role but could talk if there is a structured study
10	Maybe, but likely wouldn't have time
11	physical and mindfulness experience in one package
12	patients ask me about complementary health often but have never asked me about yoga
13	Uncertain value
14	Not aware of proven benefit
15	no data to support it's use over more simpler lifestyle modifications such as aerobic activity
16	Not enough info
17	I believe yoga helps patient with anxiety. I also strongly believe in physical activity for outcome improvements and quality of life during and after cancer treatment

Number	Why or why not?

18	helpful for body and mind - gives patient sense of control
19	Not sure
20	If it seems it may help a specific other issue, such as anxiety, depression, physical conditioning

Question 33. Can you list any barriers, whether physical or psychological, that most often prevent cancer patients from participating in their activities of daily living?

Open-ended Responses		**Response Count**
	answered question	**27**
	skipped question	**2**

Number	**Response Text**
1	pain, fatigue, other symptoms (ie nausea), anxiety/depression
2	fatigue, financial, travel issues/distance
3	fatigue, low self-image about appearance, nausea, fear and anxiety, sore mouth or throat, risk of infection
4	fatigue, stress, nausea, bowel issues
5	Physical pain, depression
6	Side effects from therapy, cancer-related symptoms, depression
7	Fatigue, depression, lack of motivation, loneliness
8	fatigue, pain, fear of infection
9	fatigue, pain, fear of aggrvating their symptoms
10	fatigue, pain
11	pain, energy
12	already stated
13	Fatigue, symptoms,
14	fatigue, lack of energy, so stress and negative feeling or thought
15	fatigue, pain, low mood, amotivation
16	Cost, time
17	nausea, vomiting, fatigue, pain, anxiety
18	fatigue, depression, weakness, nausea, peripheral neuropathy
19	Poor performance status
20	Pain, fatigue, depression

Open-ended Responses		Response Count
21	cachexia, pain, lack of energy, neurologic compromise, depression....	
22	treatment related side effects	
23	fatigue, time	
24	fatigue, lack of hope	
25	fatigue and patient willingness	
26	Pain fatigue	
27	fatigue, pain, depression, anxiety	

Question 34. From your experience, what can be done to overcome likely barriers presented to cancer patients who want to maintain their activities of daily living?

Open-ended Question		Response Count
	answered question	26
	skipped question	3

No.	Response Text
1	pain and symptom control, social work referral
2	ability to do from a distance, indoors
3	Not sure, as I think main issue (if you are asking about yoga, vs bathing, eating, etc) is financial
4	encourage exercise, adequate meds
5	support of both physical and psychological issues
6	manage cancer-related symptoms, supportive care to manage toxicity of therapy, home physiotherapy, exercise, psychosocial support
7	motivation by health care personnel, physical activity classes at accessible sites at centre of treatment
8	activity, emotional support
9	education, demonstrations
10	exercise
11	support and ease of access
12	integrate a schedule/ program in the community that may be partially funded and with a flexible schedule. this could be tailored to different levels of fitness. It doesn' t have to be a "cancer survivor yoga class"- most people do not want to be targetted- while others are quite happy self- identifying themselves
13	Encouragement; providing access to resouces
14	Disussion and encouragement
15	family, support, symptom management, home care
16	public support
17	treat the other symptoms, refer to counselling
18	manage treatment toxicity. this can be done with standard methods, and potentially complementary methods
19	Treat the cancer
20	Assistance for patient, modification of home to assist mobility
21	improve caloric nutrition, activity, treat the underlying cancer...
22	talk about the benefits of being active
23	support
24	clincial trial - free program for patient to try
25	Light exercise
26	increasing their activity slowly, partcipiating in manageable activities

Question 35. To what extent do you think the following list of items would be a concern or barrier for your cancer patients in attending a yoga class?

Answer Options	Not at all	A little bit	Somewhat	Quite a bit	A tremendous amount	Response Count
Physical capacity	0	7	11	11	0	29
Psychological stress/instability	5	10	11	3	0	29
Pain	0	5	14	8	2	29
Fatigue	1	3	7	14	4	29
Nausea	0	9	8	11	1	29
Lack of interest	0	7	8	8	6	29
Lack of perceived benefit	1	7	8	11	1	28
Lack of confidence	1	6	13	8	1	29
Fear of stigma in a group class	3	11	6	9	0	29
Transportation	1	7	7	12	2	29
Scheduling issues	1	3	10	13	2	29
Cost	0	4	7	10	7	28
Other (please specify)						2
					answered question	**29**
					skipped question	**0**

Number	Other
1	fear of risk of infection or impairment of wound healing; visible portacath or picc line and fear of dislodging the latter; loss of sensation in feet from some drugs, impairing balance; weight gain; body image/availability of the right prosthetic eg for breast cancer
2	allocation of limited resources including time in a palliative patient

CHAPTER 8 APPENDIX

APPENDIX 8.A – CANCER AND DISEASE-SPECIFIC MEASURES OF HRQOL

Generic Tools for Measuring Quality of Life and Symptom Management in Cancer			
Abbrev.	Full name	Author(s)	Pathology(s)
CRFDS	Cancer-Related Fatigue Distress Scale	Holley Sandra K	Neoplasms: Pathological conditions signs and symptoms
FACT-G	Functional Assessment of Cancer Therapy - General	Cella David F	
SCFS-6	Schwartz Cancer Fatigue Scale	Schwartz Anna L	
BPD	Brief Pain Diary for ambulatory patients with advanced cancer	Allard Pierre, Maunsell Elizabeth	
EORTC-QLQ-C30	EORTC Quality of Life Questionnaire	EORTC Quality of Life Group	
FLIC	Functional Living Index: Cancer	Schipper Harvey	
MAC	Mental Adjustment to Cancer Scale	Burgess C Greer S Inayat Q et al.	
QOL-CA/CS	Quality of Life Cancer Scale	Ferrell Betty R Grant Marcia Padilla Geraldine V	
SFSS	Structural-Functional Social Support Scale	Lehto Ulla-Sisko, PhD Ojanen Markku Kellokumpu-Lehtinen Pirkko	

Disease-Specific Tools for Measuring Quality of Life and Symptom Management in Cancer

Abbrev.	Full name	Author(s)	Pathology(s)
BCQ	Breast Cancer Chemotherapy Questionnaire	Levine Mark N	
EORTC QLQ-BR23	EORTC Quality of Life Questionnaire - Breast Cancer Module	EORTC Quality of Life Group	Neoplasms Skin and connective tissue diseases
IBCSG-QLC	International Breast Cancer Study Group - Quality of Life Core Form	International Breast Cancer Study Group	
EORTC QLQ-OV28	EORTC Quality of Life Questionnaire - Ovarian Cancer Module	EORTC Quality of Life Group	Neoplasms Endocrine system diseases Female genital diseases and pregnancy complications
EPIC	Expanded Prostate Cancer Index Composite	Dunn Rodney L, MS Litwin Mark S, MD, MPH Sanda Martin G, MD	
PC-QoL	Prostate Cancer Quality of Life scale	Cowen Mark E Giesler R Brian Kattan Micahel W et al.	
PROSQOLI	Prostate Cancer Specific Quality of Life Instrument	Tannock Ian	Neoplasms Male genital diseases
UCLA-PCI-SF	UCLA Prostate Cancer Index Short Form	Litwin Mark S, MD, MPH Brook Robert H, MD, ScD Fink Arlene, PhD et al.	
UCLA-PCI	UCLA Prostate Cancer Index	Litwin Mark S, MD, MPH Brook Robert H, MD, ScD Fink Arlene, PhD et al.	

Disease-Specific Tools for Measuring Quality of Life and Symptom Management in Cancer *(continued)*

FACT-Hep	Functional Assessment of Cancer Therapy - Hepatobiliary	Cella David F	Neoplasms Digestive system diseases
FACT-L	Functional Assessment of Cancer Therapy - Lung	Cella David F	
LCSS	Lung Cancer Symptom Scale	Hollen Patricia J Gralla Richard J Kris Mark G	Neoplasms Respiratory tract diseases
EORTC QLQ-HCC18	EORTC Quality of Life Questionnaire - Hepatocellular Carcinoma / Primary Liver Cancer Module	EORTC Quality of Life Group	

Tools for Measuring Quality of Life in Cancer Pediatrics

PedsQL™ Cancer Module	Pediatric Quality of Life Inventory™ Cancer Module	Varni James W, PhD	Neoplasms

Tools for Measuring Cancer Caregivers Quality of Life

CQOLC	Caregiver Quality of Life Index-Cancer	Weitzner Michael A	Neoplasms

Source: Mapi Research Trust (2013) www.proqolid.org

APPENDIX 8.B – PARTICIPANT INFORMATION SHEET

PARTICIPANT INFORMATION SHEET

THE Y-ACT STUDY

Lead Contact
Marcy C. McCall, MSc
DPhil Candidate
Kellogg College, University of Oxford
778.919.8050
marcy.mccall@kellogg.ox.ac.uk

Principal Investigator
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Patient and Family Counselling
BC Cancer Agency, Vancouver
604.877.6000 ext. 675392
melanie.mcdonald@bccancer.bc.ca

Introduction

Researchers from the BC Cancer Agency, University of British Columbia and University of Oxford are collaborating to conduct a feasibility study of how yoga could be implemented to improve the quality of life during early treatment of adult cancer. We invite you to read the information and consider becoming part of this research project. Please feel free to ask questions and discuss it with anyone in which you feel comfortable before deciding to participate.

Purpose of the Study

More than 14.1 million people will be diagnosed with cancer this year. Conventional treatment options for cancer include radiation therapy, chemotherapy, hormone therapy and surgery. The health-related quality of life (HRQoL) during treatment of adult cancer is a concern for health care providers and patients. This research seeks to understand how we could decrease symptoms including stress, fatigue, pain, social and cognitive functioning during cancer treatment using mind-body techniques. As 31.4% of patients seek complementary or alternative medicine treatment alongside usual treatment to improve these common symptoms, this study seeks to evaluate feasibility and acceptability of three variations of a complementary intervention designed to potentially improve HRQoL.

Study Design

This is a feasibility study that will collect information about your thoughts and feelings following a 4-week intervention. The study duration will not usually exceed 16 weeks from start to finish.

Participant Selection

You are invited to participate in this study because you can help us understand the health care needs and experiences of patients undergoing early treatment in adult cancer.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice to begin and/or continue participating in the study. If you choose not to participate, the health service you currently receive will not change.

Procedures

If you agree to participate, you will be asked to read and sign an online and written consent form. The first part of this study is completed over email, telephone or online surveys. If you are successful in completing the eligibility screening, you will be asked to complete a participant registration form, and you will be asked to provide initial consent to be enrolled in the study. You will be contacted within 7 days of submitting your participant registration form as to timing of next steps. In the second part of this study, you will be randomized into 1 of 3 intervention groups and invited to a meeting at the BCCA-Vancouver, where you begin the study upon signing the written informed consent.

The active intervention will last 4 weeks. This will include at least 1 to 12 approximately 60-minute in-person meetings in BCCA-Vancouver. At week 5, the third and final part of the study, you will be asked to complete an online survey. The online survey will take less than 15 minutes but is important to complete.

Confidentiality

All source documents will be held under strict privacy rules and remain confidential. We will not share information about you to anyone outside our research team. Any information about you will have a number on it instead of a name. Digital data will be stored on encrypted files and password protected. Paper files will be held under lock and key.

Incentives and Indemnity Clause

We encourage you to participate in this study to improve knowledge of how to better care for patients like you. There will be no financial compensation for your participation. In signing this consent, you acknowledge investigators are obligated to follow protocol, though not liable responsible for the repair, replacement of any form of personal indemnity.

Risks

The interventions may include some light to moderate activity. Risks to bodily harm are low, though we ask that you do not participate in any activity that feels uncomfortable. There should be no harmful psychological or social experiences as a consequent of your participation in this study. However, if you experience any adverse events as a result of your participation in this study please report them promptly to investigators, your physician and/or the UBC BCCA Research Ethics Board (BCCA REB).

Participating in Online Yoga and/or Public Yoga

Some participants may be invited to participate in online yoga or other public yoga classes. These may be profit-seeking organizations and are not to be perceived as monitored or endorsed by researchers. You may decide to opt-in or opt-out of online or public yoga classes at any time during the study. Please read any privacy policy and/or terms of use of any third-party yoga administrator in full before participating at your own risk. You may wish to consult your physician to discuss any potential physical or psychological harm in advance. Expert yoga instructors will be available to you via email or telephone throughout the study to answer your specific questions about suitable yoga.

Benefits

We are unsure about any health-related or psychosocial benefits you may experience during this study. You may experience an increase or decrease in feelings of well-being, including stress, sadness, fatigue, stiffness and pain.

Sharing Results

The results of this study are likely to be published in an academic journal. Only your data will be used to assist us in developing new knowledge. Your personal identity or identifiable information will never by published.

Right to Refuse or Withdraw

At any time you may wish to withdraw from this study with or without reasons. You may stop participating at any time without affecting your usual care. If you decide to withdraw from the study for a particular reason, we ask that you notify us by email to: marcy.mccall@kellogg.ox.ac.uk or call us at 778.919.8050 to let us know when and why you wish to stop participating in the study.

If you have complaints or concerns about the study

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, you may contact the UBC BCCA Research Ethics Board (BCCA REB) by telephone at: 604.877.6283 or email at: reb@bccancer.bc.ca. If you wish to know more about the BCCA REB consult the website at: http://www.bccancer.bc.ca/RES/REB/default.htm.

APPENDIX 8.C – ONLINE CONSENT FORM (PATIENTS)

Participant Online Consent Form

WELCOME

Thank you for your interest in participating in the Yoga, Y-ACT Study.

This informed consent form is for cancer patients undergoing treatment in or around Vancouver, British Columbia, Canada who we are inviting to participate in a feasibility study to understand the role of some mind-body techniques in adult cancer treatment.

Part One of this consent includes the Participant Information Sheet that tells you about the purpose and procedure of the study. You are welcome to share this or any of your questions or concerns with your family, friends or a health professional you trust for advice. If you have any questions about the conduct of the study at any time, you can contact Marcy McCall at 778.919.8050 or marcy.mccall@kellogg.ox.ac.uk

Part Two of this form is the online certificate of consent. Once you confirm you are aware of the study and its procedures, you will be directed towards an eligibility screening questionnaire. If you are eligible to participate, you will then advance to the participant registration form and an online survey. You will provided with a written online consent form if you are eligible and agree to participate in the study.

Thank you sincerely for your time and best wishes to you,

The Y-ACT Research Team

Participant Online Consent Form

PART ONE. PARTICIPANT INFORMATION SHEET

This Participant Information Sheet is identical to the information sheet you may have received from your health care professional or a member of our research team. Take all the time you need in reviewing it and then click to Part Two when you are ready.

Introduction

Researchers from the BC Cancer Agency, University of British Columbia and University of Oxford are collaborating to conduct a feasibility study of how yoga could be implemented to improve the quality of life during early treatment of adult cancer. We invite you to read the information and consider becoming part of this research project. Please feel free to ask questions and discuss it with anyone in which you feel comfortable before deciding to participate.

Purpose of the Study

More than 14.1 million people will be diagnosed with cancer this year. Conventional treatment options for cancer include radiation therapy, chemotherapy, hormone therapy and surgery. The health-related quality of life (HRQoL) during treatment of adult cancer is a concern for health care providers and patients. This research seeks to understand how we could decrease symptoms including stress, fatigue, pain, social and cognitive functioning during cancer treatment using mind-body techniques. As 31.4% of patients seek complementary or alternative medicine treatment alongside usual treatment to improve these common symptoms, this study seeks to evaluate feasibility and acceptability of three variations of a complementary intervention designed to potentially improve HRQoL.

Study Design

This is a feasibility study that will collect information about your thoughts and feelings following a 4-week intervention. The study duration will not usually exceed 16 weeks from start to finish.

Participant Selection

You are invited to participate in this study because you can help us understand the health care needs and experiences of patients undergoing early treatment in adult cancer.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice to begin and/or continue participating in the study. If you choose not to participate, the health service you currently receive will not change.

Procedures

If you agree to participate, you will be asked to read and sign an online and written consent form. The first part of this study is completed over email, telephone or online surveys. If you are successful in completing the eligibility screening, you will be asked to complete a participant registration form, and you will be asked to provide initial consent to be enrolled in the study. You will be contacted within 7 days of submitting your participant registration form as to timing of next steps. In the second part of this study, you will be randomized into 1 of 3 intervention groups and invited to a meeting at the BCCA-Vancouver, where you begin the study upon signing the written informed consent. The active intervention will last 4 weeks. This will include at least 1 to 12 approximately 60-minute in-person meetings in Vancouver, Canada. At week 5, the third and final part of the study, you will be asked to complete an online survey. The online survey will take less than 15 minutes but is important to complete.

Participant Online Consent Form

Confidentiality

All source documents will be held under strict privacy rules and remain confidential. We will not share information about you to anyone outside our research team. Any information about you will have a number on it instead of a name. Digital data will be stored on encrypted files and password protected. Paper files will be held under lock and key.

Incentives and Indemnity Clause

We encourage you to participate in this study to improve knowledge of how to better care for patients like you. There will be no financial compensation for your participation. In signing this consent, you acknowledge investigators are obligated to follow protocol, though not liable responsible for the repair, replacement of any form of personal indemnity.

Risks

The interventions may include some light to moderate activity. Risks to bodily harm are low, though we ask that you do not participate in any activity that feels uncomfortable. There should be no harmful psychological or social experiences as a consequent of your participation in this study. However, if you experience any adverse events as a result of your participation in this study please report them promptly to investigators, your physician and/or the UBC BCCA Research Ethics Board (BCCA REB).

Participating in Online Yoga and/or Public Yoga

Some participants may be invited to participate in online yoga or other public yoga classes. These may be profit-seeking organizations and are not to be perceived as monitored or endorsed by researchers. You may decide to opt-in or opt-out of online or public yoga classes at any time during the study. Please read any privacy policy and/or terms of use of any third-party yoga administrator in full before participating at your own risk. You may wish to consult your physician to discuss any potential physical or psychological harm in advance. Expert yoga instructors will be available to you via email or telephone throughout the study to answer your specific questions about suitable yoga.

Benefits

We are unsure about any health-related or psychosocial benefits you may experience during this study. You may experience an increase or decrease in feelings of well-being, including stress, sadness, fatigue, stiffness and pain.

Sharing Results

The results of this study are likely to be published in an academic journal. Only your data will be used to assist us in developing new knowledge. Your personal identity or identifiable information will never by published.

Right to Refuse or Withdraw

At any time you may wish to withdraw from this study with or without reasons. You may stop participating at any time without affecting your usual care. If you decide to withdraw from the study for a particular reason, we ask that you notify us by email to: marcy.mccall@kellogg.ox.ac.uk or call us at 778.919.8050 to let us know when and why you wish to stop participating in the study.

If you have complaints or concerns about the study

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, you may contact the UBC BCCA Research Ethics Board (BCCA REB) by telephone at: 604.877.6283 or email at: reb@bccancer.bc.ca. If you wish to know more about the BCCA REB consult the website at: http://www.bccancer.bc.ca/RES/REB/default.htm.

Participant Online Consent Form

PART TWO. CERTIFICATE OF CONSENT

Your participation in this study is completely voluntary and you are free to skip any question that you choose.

As researchers, we agree to respect and follow the outlined procedures and conduct the study according to the approved protocol. We acknowledge that as researchers, we are not qualified to provide counselling or other health care services. If you feel upset or aspects if this study trigger distress, talking with your qualified health care team may help.

By clicking "I AGREE" below, you are indicating you are at least 19 years old, have read and understood the participation information sheet, this consent form, and agree to participate in the online aspects of this research study. Please print a copy of this page for your records.

- [ ] I AGREE
- [ ] I DO NOT AGREE

APPENDIX 8.D – WRITTEN CONSENT FORM (PATIENTS)

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Participant Information and Consent Form

Yoga for Health-Related Quality of Life in Adult Cancer Treatment: A Feasibility Study (The Y-ACT Study)

BCCA Principal Investigator: Melanie McDonald, MSW
Patient and Family Counselling
Vancouver Center
604.877.6000 ext. 675392

Co-Investigator: Marcy McCall, MSc
Department of Continuing Education
University of Oxford
778.919.8050

For emergencies only: Call the centre nearest you and ask for your study doctor or, if he or she is not available, ask for your usual oncologist or the oncologist on-call.

Vancouver Centre	(604) 877-6000
Vancouver Island Centre	(250) 370-8000
Fraser Valley Centre	(604) 581-2211
Abbotsford Centre	(604) 851-4700
Centre for the Southern Interior	(250) 862-4000
Centre for the North (Prince George)	(250) 645-7300

For non-emergency contact numbers are noted at the end of this document under the section heading "Contacts".

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1. Invitation

You are being invited to take part in this research study because you are undergoing cancer treatment in Vancouver-BCCA.

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant you and your doctor also must take into account the requirements for the research study. These may include procedures that are not part of standard practice or are not yet proven. This consent form describes procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. Who is conducting this study?

This study is being conducted by researchers at the University of Oxford, the University of British Columbia and the Vancouver-BCCA.

This study is not receiving funds from an external agency or sponsor. Neither the BC Cancer Agency nor any of the investigators or staff conducting this study will receive any personal payments for conducting this study.

The investigators are not receiving compensation for their participation in this research study and have no potential financial gains that are dependent on the study, or its related results.

4. Background

More than 14.1 million people will be diagnosed with cancer this year. Conventional treatment options for cancer include radiation therapy, chemotherapy, hormone therapy and surgery. The health-related quality of life (HRQoL) during treatment of adult cancer is a concern for health care providers and patients. Researchers are seeking to understand how we could decrease symptoms including stress, fatigue, pain, social and cognitive functioning during cancer treatment using mind-body techniques. As 31.4% of patients seek complementary or alternative medicine treatment alongside usual treatment to improve these common symptoms, it is important for us to know more about how we can support patients in a clinical setting.

5. What is the purpose of the study?

This study seeks to evaluate feasibility and acceptability of three variations of yoga intervention designed to potentially improve cancer patient's health-related quality of life.

A "pilot study" or "feasibility study" is done to test the study plan and to find out whether enough participants will join a larger study and accept the study procedures. This type of study involves a small number of participants and so it is not expected to prove safety or effectiveness. The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Participation in a pilot study does not mean that you will be eligible to participate in a future larger study. Knowledge gained from pilot or feasibility studies may be used to develop future studies that may benefit others.

6. Who can participate in this study?

You may be able to participate in this study if:

- You are a male or female adult cancer patient 19 years of age or older
- You receive or plan to receive conventional treatment that includes at least one of chemotherapy, radiotherapy, hormone therapy or active surveillance within 28 days
- You are a patient in stage I, II, III and IV cancer diagnoses of all tumour types and locations
- You are a new, novice, experimental or irregular practitioner of yoga
- You have access and willingness to participate in internet communication including an electronic mail account and completion of online data collection forms
- You have access to transportation and willingness to attend meetings in central Vancouver, Canada.
- You are fluent in English language

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7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You have any physical limitations, risk of personal injury or restrictions from participating in light to moderate physical activity
- You are pre or post surgical intervention
- You currently regularly practice yoga (>2 session per month in past 12 months)
- You are undergoing medical treatment for serious psychological disturbances that may interfere with adherence to protocol and/or ability to provide informed consent are excluded (multiple personality disorders, severe depression, obsessive-compulsive disorder)

8. What does the study involve?

Design of the study

This is a feasibility study that will collect information about your thoughts, feelings and experience after yoga intervention. If you agree to participate in the study, you will be randomly allocated into one of three yoga groups that will be delivered a variation of type and amount of yoga training. The intervention will not last longer than 4 weeks, and the entire study should be completed within 16 weeks.

Participant Selection

You are invited to participate in this study because you can help us understand the health care needs and experiences of patients undergoing early treatment in adult cancer. You will be screened for your eligibility to participate this study with an online questionnaire or telephone call with researchers. If you are eligible to participate, you will be asked to give a verbal or online initial consent.

Randomization

Everyone who enters the study will have the same chance to be selected into each of the three yoga groups. The selection will be purely random, equivalent to the flipping of a coin. There will be no participant who receives nothing, unless you are waitlisted because the study is full.

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Research Procedures

The first part of this study can be completed over email, telephone or online. This will include a survey that will take approximately 15 minutes to complete.

Then you will be randomly allocated to join one of three possible intervention groups and invited to attend an introductory yoga session. When you arrive at the introductory session, you will be given an opportunity to ask questions about the study, your role and then if you decide to participate, you will be asked to read and sign a written consent form (this form).

The second part of the study, the active intervention will then commence and last 4 weeks. This will include at least one, maximum 12 of approximately 60-minute in-person meetings at Vancouver-BCCA. The yoga sessions may include some breathing training, physical postures and/or meditation techniques.

At week 5, the third and final part of the study, you will be asked to complete two surveys. These surveys may also be completed online or in paper form and will take less than 15 minutes each, but are very important to complete. You do not have to answer any questions that you make you feel uncomfortable.

If you agree to take part in this study, the procedures and visits you can expect will include the following:

- 1 to 12 approximately 60-minute visits of yoga training
- The sessions will include either breathing training, physical postures and/or meditation
- Attendance in group and at-home yoga will be encouraged

Participating in Online Yoga and/or Public Yoga

Some participants may be invited to participate in online yoga or other public yoga classes. These may be profit-seeking organizations and are not to be perceived as monitored or endorsed by researchers. You may decide to opt-in or opt-out of online or public yoga classes at any time during the study. Please read any privacy policy and/or terms of use of any third-party yoga administrator in full before participating at your own risk. You may wish to consult your physician to discuss any potential physical or psychological harm in advance. Expert yoga instructors will be available to you via email or telephone throughout the study to answer your specific questions about suitable yoga.

Expected Follow-up

If you are not able to complete the study, investigators may contact you by email or telephone to understand reasons you were unable to continue with the program. If and when you complete the study and final set of two surveys, you will no longer be expected to visit or remain in contact with the investigators.

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9. What are my responsibilities?

- If you have questions regarding your physical or psychological ability to participate in this study, please consult your medical doctor or your oncologist with any questions in advance
- If you agree to participate, we ask that you mind the recommendations provided to you by an expert yoga instructor, and follow the study protocol to the best of your ability

10. What are the possible harms and discomforts?

The interventions may include some light to moderate activity. Risks to bodily harm are low, though we ask that you do not participate in any activity that feels uncomfortable. There should be no harmful psychological or social experiences as a consequent of your participation in this study. However, if you experience any adverse events as a result of your participation in this study please report them promptly to investigators, your physician and/or the UBC BCCA Research Ethics Board (BCCA REB).

11. What are the potential benefits of participating?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.

We hope that the information learned from this study can be used in the future to benefit other people with a similar disease.

12. What are the alternatives to the study treatment?

This study does not replace or intend to replace any form of standard treatment. The interventions in this study are meant to complement your current treatment plan. Please continue with your standard care as usual throughout the duration of this study.

13. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis.

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14. Can I be asked to leave the study?

If you are not able to follow the requirements of the study or for any other reason, the investigators may withdraw you from the study. Your treatment with the Vancouver-BCCA would continue as usual. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

15. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the study investigators.

16. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the investigators, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided as usual.

BC Cancer Agency
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In case of a serious medical event, please report to an emergency room and inform them that you are participating in a research study and that the following person can then be contacted for further information: Marcy McCall at telephone number: 778.919.8050

17. What will the study cost me?

All research-related and specified yoga interventions you will receive during your participation in this study will be provided at no cost to you. There will no reimbursement for study related expenses such as parking or your personal travel expenses.

18. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Marcy McCall at 778.919.8050.

In the event of a research related injury, please speak to your doctor. Or, you can speak the BCCA principal investigator, Melanie McDonald at 604.877.6000 ext. 675392.

Or, you can speak to the Head of Patient and Family Counselling Program of the BC Cancer Agency. That person can be reached at 604-877-6000, Local 672194.

19. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

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20. After the study is finished

As a feasibility test, we are not seeking efficacy of yoga intervention. This means no changes or decisions will be made with respect to standard care and you will not usually be offered yoga after your participation in the study is completed.

When the study is finished, the results will usually be prepared for publication in a peer-reviewed academic journal. In addition to this, we would be happy to provide you with a summary of findings. If you wish to be emailed this summary, please check the box below and provide your preferred mailing address.

☐ Yes, I want the investigators to share a summary of findings with me at this email address:

_____

Participant Initials: _____

☐ No, I do not want the investigators to share a summary of findings with me.

Participant Initials: _____

Future Contact

When you complete the study, the investigators will not contact you again. If you wish to be considered for participation in another study, please check the appropriate box and initial.

☐ Yes, I would like the investigators to contact me in the future for a larger or similar intervention. You can telephone or email me at this address:

_____

Participant Initials: _____

☐ No, I do not want the investigators to contact me for future studies.

Participant Initials: _____

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21. Signatures

PARTICIPANT COPY

Statement by the participant
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and my questions (if any) have been asked and answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I will be randomly allocated one of three yoga interventions. I am aware of the potential risks, benefits, and I understand my role in this research study.

Name of Participant:

Signature of Participant:

Date:

Statement by the researcher/person taking consent
I have accurately communicated the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that this research intervention includes a minimum of 1 and maximum of 12 60-minute meetings over a 4-week period. I confirm that the participant was given contact details to direct any questions about the study, and any questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this Informed Consent Form is provided to the participant in advance of yoga intervention.

Name of Researcher:

Signature of Researcher:

Date:

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RESEARCHER COPY

Statement by the participant
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and my questions (if any) have been asked and answered to my satisfaction. I consent voluntarily to be a participant in this study and understand that I will be randomly allocated one of three yoga interventions. I am aware of the potential risks, benefits, and I understand my role in this research study.

Name of Participant:

Signature of Participant:

Date:

Statement by the researcher/person taking consent
I have accurately communicated the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that this research intervention includes a minimum of 1 and maximum of 12 60-minute meetings over a 4-week period. I confirm that the participant was given contact details to direct any questions about the study, and any questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this Informed Consent Form is provided to the participant in advance of yoga intervention.

Name of Researcher:

Signature of Researcher:

Date:

BC Cancer Agency
CARE & RESEARCH
An agency of the Provincial Health Services Authority

CONTACTS

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions about the study, please speak to your doctor, or you can speak to the principal investigator for the study who is noted on the first page of this document.

You can also speak to the **Head of Patient and Family Counselling Program of the BC Cancer Agency**. That person can be reached at 604-877-6000, Local 672194

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A SUBJECT?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598).

APPENDIX 8.E – POSTER ADVERTISEMENT TO PATIENTS



APPENDIX 8.F – E-MAIL INVITE TO HEALTH CARE PRACTITIONERS

RECRUITING CANCER PATIENTS FOR YOGA

THE YOGA (Y-ACT) STUDY

April 2014

We hope this note finds you well. As a result of your participation in a recent oncologist survey implemented by our research team, we are now conducting a feasibility study designed to improve quality of life in treatment of adult cancer. Your patients will be introduced to yoga in a clinical setting, designed specifically to mind their safety, improve their mood, sleep quality and health-related quality of life.

About the Study

The study is a collaboration of Evidence-Based Health Care researchers from the University of Oxford, University of British Columbia and the BCCA.

The purpose of this research study is to determine the feasibility of three types of yoga interventions to improve the quality of life in early cancer treatment. This is a non-invasive low-risk study that will offer varying amounts and types of yoga, free delivery to patients over a 4-week period. The results will determine the feasibility and acceptability of yoga intervention for potential use in a randomized controlled trial (RCT).

How to Participate

We ask that you consider distributing information to patients during clinical visits to patients 19 years of age or older, currently or planning to undergo chemotherapy, radiotherapy, hormone therapy or active surveillance for a cancer diagnosis and demonstrate physical capacity to participate in low to moderate physical activity.

How to Distribute Information to Your Patients

You can choose to receive Patient Information Brochures that would be deliverable to your patients in one of the following ways:

- Link to https://www.research.net/s/Y-ACT_RECRUIT to register as a recruiting HCP and we will deliver the information packets to your office
- Print (and reprint) copies of the attached brochure and distribute as frequently as possible to patients you receive within Vancouver-BCCA
- Email marcy.mccall@kellogg.ox.ac.uk with your name and postal address
- Telephone or text Marcy at 778.919.8050 with your name and postal address

Both your time and commitment are very much appreciated.

Sincere regards,



Marcy McCall, Lead Contact
marcy.mccall@kellogg.ox.ac.uk

Group A Yoga Schedule

Week of Study	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2	3	4	5
Week 1	7	8	9	10	11	12
			INTRO (60 min) 5pm to 6pm		INTRO ALTERNATE (60 min) 12pm to 1pm	
Week 2	14	15	16	17	18	19
Week 3	21	22	23	24	25	26
Week 4	28	29	30	31	1st of August	

Instructor Identification

	JW
	CR
	DS
	RB

Group B Yoga Schedule

Week of Study	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2	3	4	5
Week 1	7	8	9	10	11	12
	INTRO (75 min) 10am to 11:15am			INTRO ALTERNATE (75 min) 6pm to 7:15pm		
Week 2	14	15	16	17	18	19
				WORKSHOP 6pm to 8pm		
Week 3	21	22	23	24	25	26
	WORKSHOP ALTERNATE 11am to 1pm					
Week 4	28	29	30	31	1	

Instructor Identification

- JW
- CR
- DS
- RB

Group C Yoga Schedule

Week of Study	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1	2	3	4	5
Week 1	7	8	9	10	11	12
	INTRO (75 min) 2pm to 3:15pm	INTRO ALTERNATE 6pm to 7:15pm	CLASS (60 min) 6:30pm to 7:30pm		CLASS (60 min) 10am to 11am	
Week 2	14	15	16	17	18	19
	CLASS (60 min) 2pm to 3pm		CLASS (60 min) 6:30pm to 7:30pm		CLASS (60 min) 10am to 11am	
Week 3	21	22	23	24	25	26
	CLASS (60 min) 2pm to 3pm		CLASS (60 min) 6:30pm to 7:30pm		CLASS (60 min) 10am to 11am	
Week 4	28	29	30	31	1	
	CLASS (60 min) 2pm to 3pm		CLASS (60 min) 6:30pm to 7:30pm		CLASS (60 min) 10am to 11am	

Instructor Identification

- JW
- CR
- DS
- RB

APPENDIX 8.H – YOGA WORKSHOP AGENDA & INTERVENTION WORKSHEETS

Teacher Initiation Session and Workshop for the Yoga Study
AGENDA
Friday, June 13th at BC Cancer Research Centre from 2pm to 4pm

Dorothy Lam Conference Line: 604.675.8236 (mobile: 604.812.2939 as alternate)
Help Desk at BCCRC x8181 Housekeeping x7853
Security x2990 (604.875.2999) bccavcc@paladinsecurity.com
Meeting Chairs: Melanie McDonald and Marcy McCall MacBain

Welcome – Dorothy Lam Boardroom (15 minutes)

1. Introduction of the Study and Purpose of Meeting (Marcy)
   - Genesis of research and collaboration
   - Feasibility study design and purpose
   - Goals of the meeting and distribute worksheets
2. Introduction of Yoga Instructors (Marcy and others)
   - Name, experience and interest in the study
   - Administrative papers: submission of certifications and schedules
3. Introduction of BCCA and Role in Cancer Care (Melanie)
   - Mission and aim of BCCA
   - Personal remarks
   - Overview of patient experiences and symptom management

The Facility and Yoga Room Orientation (15 minutes)

4. Tour of the Building and Key Areas (Melanie)
   - Entry and exit procedures
   - Yoga room – layout, maximum capacity, fire exit and safety procedures, equipment list
   - Dorothy Lam Boardroom – study protocol and ethics

The Yoga Workshop (1.5 hours)

5. Yoga Intervention Workshop
   - Review worksheets and framework of yoga intervention
   - Identify key components for Groups A, B and C
   - Brainstorm considerations, ideas and themes for each class
   - Reach agreement and develop lesson plans (must provide teacher-approved copy of protocols and list of materials needed to Marcy: marcy.mccall@kellogg.ox.ac.uk)

Closing Comments

- Yoga Teachers
- Researchers (Melanie and Marcy)
- Follow-up and Questions
- Thank you

FRAMEWORK & MATERIAL LIST: To be designed, completed and agreed upon by all participating Yoga Instructors

GROUP A – LOW DOSE

Session Number	Section Title	Duration	Key Components	Lesson Plan Outline (ie how many minutes of what component?)
1	Introduction to Yoga	15 min	What is yoga? How and why practice yoga? Discuss resources and to access community-based or affordable yoga	
1	Yoga Training	30 min	Pranayama Techniques; Satsang	

FRAMEWORK & MATERIAL LIST: To be designed, completed and agreed upon by all participating Yoga Instructors

GROUP B – MEDIUM DOSE

Session Number	Section Title	Duration	Key Components	Lesson Plan Outline (ie how many minutes of what component?)
1	Introduction to Yoga and Online Membership	15 min	What is yoga? How and why practice yoga? Introduce membership to myyogaonline.com and give pamphlet for community-based resources	(SIMILAR WITH ADDITION OF MYYOGAONLINE ORIENTATION)
1	Yoga Training	30 min	Pranayama Techniques	(SAME AS GROUP A)
1	Yoga Training	30 min	Asana Practice and Safety Training	
2	Yoga Workshop	120 min	Pranayama, Asana and Dhyana Techniques	

FRAMEWORK & MATERIAL LIST: To be designed, completed and agreed upon by all participating Yoga Instructors

GROUP C – HIGH DOSE

Session Number	Section Title	Duration	Key Components	Lesson Plan Outline (ie how many minutes of what component?)
1	Introduction to Yoga and Online Membership	15 min	What is yoga? How and why practice yoga? Introduce membership to myyogaonline.com and give pamphlet for community-based resources	(SAME AS GROUP B)
1	Yoga Training	30 min	Pranayama Techniques; Satsang	(SAME AS GROUP A)
1	Yoga Training	30 min	Asana Practice and Safety Training	(SAME AS GROUP B)
2 to 12	Yoga Training	60 min	Pranayama, Asana and Dhyana Techniques; Satsang	

FRAMEWORK & MATERIAL LIST: To be designed, completed and agreed upon by all participating Yoga Instructors

EQUIPMENT LIST FOR PARTICIPANTS:

1. Type of Yoga Mat – Kind and Colour:

2. Type of Book – Author and Title:

3. List of Resources – name centres, classes, teachers and resources for yoga in Greater Vancouver

Name	Location	Contact Information	Description
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

FRAMEWORK & MATERIAL LIST: To be designed, completed and agreed upon by all participating Yoga Instructors

EQUIPMENT LIST FOR YOGA ROOM:

1. Type of Yoga Bolsters – Kind and Colour:

2. Type of Yoga Blankets – Kind and Colour:

3. Type of Yoga Blocks – Kind and Colour:

4. Other Equipment:

MISCELLANEOUS NOTES AND/OR SPECIAL REQUESTS:

APPENDIX 8.I– MYYOGA GIFT CERTIFICATE

Your Online Yoga Gift Certificate



TO ACTIVATE YOUR MEMBERSHIP, CLICK ON
http://www.myyogaonline.com/join/634e74297c
If necessary, enter code: 634e74297c

Please be sure to adjust your privacy settings if you do not wish to receive advertisements or share personal information with this organization.
Access to your account will expire 1-month after registration.
Enjoy and practise yoga safely, in private and at your convenience!

If you have any questions or concerns on accessing your membership, call or email My Yoga Online at

1.888.488.3877 or support@myyogaonline.com

APPENDIX 8.J – YOGA INSTRUCTOR CONTRACT

INDEPENDENT CONTRACTOR AGREEMENT

AN EXPERT YOGA TEACHER FOR RESEARCH PURPOSES

This agreement (the "Agreement") is made and entered into as of July 1, 2014 (DATE OF AGREEMENT] (the "Effective Date") between the Vancouver-British Columbia Cancer Agency Branch (the "Vancouver-BCCA"), its affiliates (the "Researchers") and [NAME OF CONTRACTOR] (the "Contractor") (collectively, the "Parties").

WHEREAS Vancouver-BCCA and the Researchers are conducting a feasibility study of the adherence and appropriateness of yoga intervention in adult cancer.

WHEREAS Vancouver-BCCA and the Researchers wish to engage the Contractor to provide yoga instruction to patients of Vancouver-BCCA for the purposes of this study; and

WHEREAS, the Vancouver-BCCA, Researchers and Contractor desire to enter into an agreement which will describe the duties as to all services to be performed by the Contractor and compensation for those services.

NOW, THEREFORE, in consideration of the agreements contained herein, the Parties hereto agree as follows:

Beginning on the Effective Date and remaining in effect for the one year from the Effective Date, the Contractor will provide the following services on the terms and conditions specified herein, without limitation:

1.0 **Services**

The Services to be performed by the Contractor are as follows:

1.1 To design yoga classes for study participants, as stipulated by Vancouver-BCCA and the Researchers, receiving treatment at the Vancouver-BCCA (the "Participants").

1.2 To design yoga classes that are appropriately tailored to the needs of the Participant group and are delivered to a standard of safety expected of a professional expert yoga instructor in British Columbia with qualifications equivalent or greater than the 200-hour Registered Yoga Teacher certificate.

1.3 To organize, implement and coordinate delivery of yoga education, orientation and online safety training to Participants by providing the Participants with general information on how and where to access yoga and an introduction to online yoga, which shall include what to expect and how to access safe and appropriate online yoga, plus an online yoga membership.

1.4 To deliver up to 13 punctual, safe and appropriate yoga classes to Participants, which shall take place between July, 2014 and August 10, 2014 and shall include physical postures and breathing and meditation techniques, and to track attendance of Participants.

1.5 To provide to Vancouver-BCCA and the Researchers upon request, information regarding logistic and operational aspects of the study including but not limited to acceptability of the designated space to conduct yoga class, timing and content of the class, and attendance of Participants.

1.6 To work in a collaborative and professional manner with the Parties.

2.0 **Compensation**

2.1 The work performed by the Contractor shall be performed at the rate set forth as follows: $50 CAD/hour for administrative planning (to maximum of 10 hours), $75 CAD/hour for class time (to maximum of 15 hours).

2.2 If the Parties, perceive the required hours should exceed the maximum amounts outlined in Article 2.1, the Contractor will, in collaboration with the other Parties, submit a written request to Vancouver-BCCA and the Researchers for additional allocation of hours. Additional hours will need to be pre-approved by Vancouver-BCCA and the lead investigator (M.McCall) in advance. Upon completion of Services, the total invoice will be submitted to Vancouver-BCCA by the Contractor and co-signed by the Researchers. The full amount will be processed by Vancouver-BCCA within two-weeks of receipt of an invoice addressed and emailed to "The Y-ACT Study": marcy.mccall@kellogg.ox.ac.uk.

2.3 The Contractor will not circumvent Vancouver-BCCA or the Researchers to directly solicit business from the Participants of the study.

2.4 The Contractor will provide equipment necessary to carry out the Services herein described to the safety standard stipulated in Article 1.2.

3.0 **Obligations of Vancouver-BCCA and the Researchers**

3.1 Vancouver – BCCA shall provide at no charge to the Contractor, designated physical space within Vancouver-BCCA for the safe provision of the agreed upon Services.

4.0 **Term of the Agreement**

4.1 The Term of this Agreement shall be from July 1, 2014 to July 1, 2015.

5.0 **Governing Law**

5.1 This agreement shall be governed by the laws of British Columbia applicable to contracts made and performed therein.

6.0 **Contractor's Management Responsibilities**

6.1 The Contractor shall demonstrate to Vancouver-BCCA and the Researchers that he/she has complied with the requirements of the *Criminal Records Review Act* ("CRRA"). The Contractor will not provide the Services herein described until the results of a criminal records check under the CRRA has been received.

6.2 It is the express mutual understanding and intention of the Parties that the Contractor is not an employee of Vancouver-BCCA and nothing in the Agreement shall be considered, interpreted, understood or implied contrary to that mutual intention and understanding.

6.3 The Contractor must pay any and all payments and / or deductions required to be paid by him/ her, including those required for income

tax, Employment Insurance premiums, Workers Compensation premiums, Canada Pension Plan premiums or contributions, and any other statutory payments or assessments of any nature or kind whatsoever that he / she is required to pay to any government (whether Federal, provincial or municipal) or to any body, agency, or authority of any government in respect of any money paid to the Contractor pursuant to this Contract.

6.4 The Contractor will comply with all requirements of the *Workers Compensation Act (British Columbia)* and obtain and maintain the necessary coverage for the Contractor (and any of its employees) and shall provide a WCB clearance letter indicating all assessments have been paid. The Contractor will comply with all applicable laws including without limitation the *Workers Compensation Act (British Columbia)* and the *Occupational Health and Safety Regulations*, as amended from time to time.

6.5 The Contractor will maintain liability insurance coverage in amounts and in a form satisfactory to Vancouver-BCCA and provide evidence of coverage to Vancouver-BCCA upon request.

6.6 It is agreed that Vancouver-BCCA has the right to suspend access without advance notice at times when special restrictions are in place for clinical or infection control reasons.

6.7 The Contractor will not use Vancouver-BCCA in any advertising without prior knowledge and written approval of Vancouver-BCCA.

7.0 **Confidentiality and Protection of Personal Information**

7.1 The Parties acknowledge that the Contractor is not, by virture of the services provided, expected to, and is not entitled to have access to "Personal Information" as defined in the *BC Freedom of Information and Protection of Privacy Act*, with the exception of personal information that may be voluntarily provided to the Contractor by the Participants in accessing the services provided under this Agreement. Where the Contractor inadvertently or otherwise obtains access to any Personal Information, the Contractor shall comply with the provisions of Appendix A and any other requirements that may be established from time to time by the PHSA or pursuant to applicable laws.

7.2 The Contractor shall not disclose any Vancouver-BCCA confidential information, including study results or sensitive data, any materials or intellectual property of the research study for any purpose other than the performance of the Services.

7.3 By agreeing to provide the Services herein described, the Contractor confirms that he / she is competent and properly qualified to perform the Services to the service standards outlined in Article 1.2 of the Agreement. The Contractor will provide BCCA with documentation proving that she has met the required qualifications prior to July 1, 2014.

7.4 The Contractor will adhere to all existing and future Vancouver – BCCA policies relating to security, protection service, fire and safety, infection control, site orientation and other policies relating to the health and safety of the Participants. Vancouver-BCCA will make available the necessary policies for the Contractor.

8.0 **Indemnification.**

8.1 The Contractor agrees to indemnify and save harmless the Vancouver-BCCA, Researchers and its affiliates and its respective officers, managers, directors, agents and employees from any and all claims, demands, losses, causes of action, damage, lawsuits, judgments, including any administrative or associated fees and costs arising out of or relating to the Contractor's services under this Agreement.

9.0 **Early Termination of Agreement.**

9.1 This agreement is an acknowledgement of the Contractor's willingness and capacity to perform adequate Services as described herein. Should the Parties feel the Services are no longer required or that the pre-agreed standard of quality and safety required is or cannot be met, the agreement can be terminated with a written notification of any party at any time without notice. No additional payment or compensation will be made beyond the last contribution of work.

10.0 **Termination of Agreement**

10.1 Upon the expiration or earlier termination of the Agreement, the Contractor shall promptly return to Vancouver-BCCA and its Researchers all records in the Contractor's possession pursuant to the agreement, whether created by the Contractor or by others, constituting or based upon Personal Information and shall confirm that delivery in writing.

Signatures

Name of Authorized Vancouver-BCCA Investigator	Signature	Date
Name of Authorized Representative of Researchers	Signature	Date
Name of Yoga Instructor	Signature	Date

APPENDIX A
PRIVACY SCHEDULE

Purpose

1. The purpose of this Schedule is to:
   (a) enable the Public Body to comply with its statutory obligations under the Act with respect to Personal Information; and
   (b) ensure that, as a service provider, the Supplier is aware of and complies with its statutory obligations under the Act with respect to Personal Information.

Definitions

2. In this Schedule,
   (a) "**Access**" means disclosure of Personal Information by the provision of access;

   (b) "**Act**" means the *Freedom of Information and Protection of Privacy Act* (British Columbia), as amended from time to time;

   (c) "**Contact Information**" means information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual;

   (d) "**Supplier"** means the Contractor named in the Independent Contractor Agreement;

   (e) **"Public Body"** means the British Columbia Cancer Agency – Vancouver Centre;

   (f) "**Personal Information** means recorded information about an identifiable individual, other than Contact Information, collected or created by the Supplier as a result of the Contract or any previous contract between the Public Body and the Supplier dealing with the same subject matter as the Contract.

Collection of Personal Information

3. Unless the Agreement otherwise specifies or Public Body otherwise directs in writing, the Supplier may only collect or create Personal Information that is necessary for the performance of the Supplier's obligations, or the exercise of the Supplier's rights, under the Agreement.

4. Unless the Agreement otherwise specifies or Public Body otherwise directs in writing, the Supplier must collect Personal Information directly from the individual the information is about.

5. Unless the Agreement otherwise specifies or Public Body otherwise directs in writing, the Supplier must tell an individual from whom the Supplier collects Personal Information:

   (a) the purpose for collecting it;

   (b) the legal authority for collecting it; and

(c) the title, business address and business telephone number of the person designated by Public Body to answer questions about the Supplier's collection of Personal Information.

Accuracy of Personal Information

6. The Supplier must make every reasonable effort to ensure the accuracy and completeness of any Personal Information to be used by the Supplier or Public Body to make a decision that directly affects the individual the information is about.

Correction of Personal Information

7. Within 5 Business Days of receiving a written direction from Public Body to correct or annotate any Personal Information, the Supplier must correct or annotate the information in accordance with the direction.

8. When issuing a written direction under section 7, Public Body must advise the Supplier of the date the correction request to which the direction relates was received by Public Body in order that the Supplier may comply with section 9.

9. Within 5 business days of correcting or annotating any Personal Information under section 7, the Supplier must provide the corrected or annotated information to any party to whom, within one year prior to the date the correction request was made to Public Body, the Supplier disclosed the information being corrected or annotated.

10. If the Supplier receives a request for correction of Personal Information from a person other than Public Body, the Supplier must promptly advise the person to make the request to Public Body and, if Public Body has advised the Supplier of the name or title and Contact Information of an official of Public Body to whom such requests are to be made, the Supplier must also promptly provide that official's name or title and Contact Information to the person making the request.

Protection of Personal Information

11. The Supplier must protect Personal Information by making reasonable security arrangements against such risks as unauthorized Access, collection, use, disclosure or disposal, including any expressly set out in the Contract.

Employee Access

12. The Supplier will provide a list of employees that will have Access to Personal Information. Each of the specified employees will execute a confidentiality agreement. Approval of the Public Body must be obtained before any employee of the Supplier Accesses Personal Information. Employees who have not obtained approval from the Public Body must not Access Personal Information.

Storage and Access to Personal Information

13. Unless the Public Body otherwise directs in writing, the Supplier must not store Personal Information outside Canada, Access Personal Information from outside Canada, or permit Access to Personal Information from outside Canada. No services that require Access to Personal Information shall be provided or performed by the Supplier in any location outside of Canada.

Use of Personal Information

14. Unless the Public Body otherwise directs in writing, the Supplier may only Access Personal Information if that Access is for the performance of the Supplier's obligations, or the exercise of the Supplier's rights, under the Contract and for no other reason whatsoever.

Disclosure of Personal Information

15. Unless the Public Body otherwise directs in writing, the Supplier may only disclose Personal Information inside Canada to any person other than the Public Body if the disclosure is for the performance of the Supplier's obligations, or the exercise of the Supplier's rights, under the Contract.

16. Unless the Contract otherwise specifies or the Public Body otherwise directs in writing, the Supplier must not disclose Personal Information outside Canada.

Requests for Access to Personal Information

17. If the Supplier receives a request for Access to Personal Information from a person other than the Public Body, the Supplier must promptly advise the person to make the request to the Public Body unless the Agreement expressly requires the Supplier to provide such Access and, if the Public Body has advised the Supplier of the name or title and Contact Information of an official of the Public Body to whom such requests are to be made, the Supplier must also promptly provide that official's name or title and Contact Information to the person making the request.

Notice of foreign demands for disclosure

18. In addition to any obligation the Supplier may have to provide the notification contemplated by section 30.2 of the Act, if in relation to Personal Information in the custody or under the control of the Supplier, the Supplier:

(a) receives a foreign demand for disclosure;

(b) receives a request to disclose, produce or provide Access that the Supplier knows or has reason to suspect is for the purpose of responding to a foreign demand for disclosure; or

(c) has reason to suspect that an unauthorized disclosure of Personal Information has occurred in response to a foreign demand for disclosure.

the Supplier must immediately notify Public Body and, in so doing, provide the information described in section 30.2(3) of the Act. In this section, the phrases "foreign demand for disclosure" and "unauthorized disclosure of Personal Information" will bear the same meanings as in section 30.2 of the Act.

Notice of unauthorized disclosure

19. In addition to any obligation the Supplier may have to provide the notification contemplated by section 30.5 of the Act, if the Supplier knows that there has been an unauthorized disclosure of Personal Information in the custody or under the control of the Supplier, the Supplier must immediately notify Public Body. In this section, the phrase "unauthorized disclosure of Personal Information" will bear the same meaning as in section 30.5 of the Act.

Notice of non-compliance

20. If for any reason the Supplier does not comply, or anticipates that it will be unable to comply, with a provision in this Schedule in any respect, the Supplier must promptly notify the Public Body of the particulars of the non-compliance or anticipated non-compliance and what steps it proposes to take to address, or prevent recurrence of, the non-compliance or anticipated non-compliance.

Inspection of Personal Information

21. In addition to any other rights of inspection the Public Body may have under the Contract or under statute, the Public Body may, at any reasonable time and on reasonable notice to the Supplier, enter on the Supplier's premises to inspect any Personal Information in the possession of the Supplier or any of the Supplier's information management policies or practices relevant to its management of Personal Information or its compliance with this Schedule and the Supplier must permit, and provide reasonable assistance to, any such inspection.

Audit

22. The Supplier shall permit the Public Body and/or its representatives and agents to conduct periodic audits of records related to performance by the Supplier, its employees, agents, representatives, associates and any Subcontractors, if any, of the Supplier's obligations under this Schedule.

23. The Supplier will at all times maintain and make available to the Public Body an "Audit Log" of Access to Personal Information. The Audit Log will list who, when and for what reason Personal Information was Accessed.

Compliance with the Act and directions

24. The Supplier must in relation to Personal Information comply with:

    (a) the requirements of the Act applicable to the Supplier as a service provider, including any applicable order of the commissioner under the Act; and

    (b) any direction given by the Public Body under this Schedule.

25. The Supplier acknowledges that it is familiar with the requirements of the Act governing Personal Information that are applicable to it as a service provider.

Termination of Agreement

26. In addition to any other rights of termination which the Public Body may have under the Contract or otherwise at law, the Public Body may, subject to any provisions in the Contract establishing mandatory cure periods for defaults by the Supplier, terminate the Contract by giving written notice of such termination to the Supplier, upon any failure of the Supplier to comply with this Schedule in a material respect.

Interpretation

27. In this Schedule, references to sections by number are to sections of this Schedule unless otherwise specified in this Schedule.

28. Any reference to the “Supplier” in this Schedule includes any Subcontractor retained by the Supplier to perform obligations under the Contract and the Supplier must ensure that any such Subcontractors comply with this Schedule.

29. The obligations of the Supplier in this Schedule will survive the termination of the Contract.

30. If a provision of the Contract (including any direction given by the Public Body under this Schedule) conflicts with a requirement of the Act or an applicable order of the commissioner under the Act, the conflicting provision of the Contract (or direction) will be inoperative to the extent of the conflict.

31. The Supplier must comply with the provisions of this Schedule despite any conflicting provision of the Contract or the law of any jurisdiction outside Canada.

APPENDIX 8.K – PARTICIPANT ELIGIBILITY SCREENING FORM

Participant Eligibility Screening Form

WELCOME

Thank you for your interest in the Yoga, Y-ACT Study.

There are a few questions we would like to ask to assess your eligibility for this study. If in the end you are not eligible to participate, you are welcome to leave your name and contact information for future considerations.

Your time and commitment to health care research is appreciated.

With warm regards,

The Y-ACT Research Team

If you wish to leave your name and contact information, please do so in the space provided below:

PARTICIPANT ELIGIBILITY ASSESSMENT

We would like to ask you a few questions to determine your eligibility for this study.

The purpose of this assessment is to ensure your health and safety as a participant in a pre-approved protocol. Please answer the questions as truthfully as possible and leave comments or clarification as you feel necessary.

Are you currently 19 years of age or older?

- ☐ Yes
- ☐ No

Are you fluent in English?

- ☐ Yes
- ☐ No

Participant Eligibility Screening Form

Do you have access and the willingness to communicate over the internet with a personal email account?

- [ ] Yes
- [ ] No

Comment (if any)

Are you currently undergoing conventional treatment for a cancer diagnosis? This could include one or more of the following: active surveillance (or other monitoring), chemotherapy, radiotherapy, hormone therapy.

- [ ] Yes
- [ ] No

Other (please specify)

Do you have access to transportation and the willingness to attend meetings in Vancouver, Canada?

- [ ] Yes
- [ ] No

Comment (if any)

Are you pre or post a surgical intervention that would interfere with your ability to participate in light to moderate physical activity?

- [ ] Yes
- [ ] No

Comment (if any)

Participant Eligibility Screening Form

Have you regularly practised yoga (more than one time per month) within the past 12 months?

- [ ] Yes
- [ ] No

Comment (if any)

Are you currently experiencing serious physical limitations, personal injury or under any medical advice not to participate in low to moderate physical activity?

- [ ] Yes
- [ ] No

Comment (if any)

Are you currently experiencing serious psychological disturbances that require medical attention and may prohibit your ability to adhere to the study protocol or ability to provide informed consent?

- [ ] Yes
- [ ] No

Comment (if any)

APPENDIX 8.L – INELIGIBLE PARTICIPANT REGISTRATION FORM

Ineligible Participant Registration Form

Welcome to the Information Page

Thank you for contacting us regarding the yoga study.

The computerized eligibility survey has informed us that you are not able to participate in this study.

If you feel like there has been an error, please try again, or if you wish to clarify your response, please email Marcy at marcy.mccall@kellogg.ox.ac.uk

If you are not eligible to participate in this study, we ask that you consider sharing information about your health status and current treatment. This helps us to understood who would be interested in the yoga study, and we can let you know if there are future studies for which you might be eligible. All of the information you share will be held confidentially and not shared with anyone else but this research team.

Thank you, and we wish you all the best for good health,

Marcy and the Y-ACT Research Team

Last name, First name

Age

Gender

☐ Male

☐ Female

Occupation

Your E-mail Address (for correspondence during this study)

Your Telephone Number (for correspondence during this study)

Home Telephone

Mobile Telephone

Your Mailing Address

Ineligible Participant Registration Form

Please tell us about the health care professional(s) responsible for your conventional cancer treatment. Check the box that applies and fill in the space below.

- ☐ Medical Oncologist
- ☐ Radiation Oncologist
- ☐ Surgical Oncologist
- ☐ General Practitioner

Name of Doctor (or other)

Name of Treatment Hospital or Clinic where you are receiving conventional treatment

When were you diagnosed with the cancer for which you are currently being treated?

DD MM YYYY

Date of Diagnosis ☐ / ☐ / ☐

Type or Location of Cancer for which you are being treated

What is your stage of diagnosis?

- ☐ Stage I
- ☐ Stage II
- ☐ Stage III
- ☐ Stage IV

What is your current treatment plan? (check all that apply)

- ☐ Chemotherapy
- ☐ Radiotherapy
- ☐ Hormone Therapy
- ☐ Active Surveillance

Other (please specify)

APPENDIX 8.M – ELIGIBLE PARTICIPANT REGISTRATION FORM

Participant Registration Form

WELCOME

Congratulations, you are eligible to participate in the Yoga, Y-ACT Study!

We would like to collect some personal information at this time, to help us know more about you and your current health status. When your registration is complete, you will be enrolled in the study and asked to complete an online survey.

We look forward to meeting you soon,

The Y-ACT Research Team

Last name, First name

Age

Gender

☐ Male

☐ Female

Occupation

Your E-mail Address (for correspondence during this study)

Your Telephone Number (for correspondence during this study)

Home Telephone

Mobile Telephone

Your Mailing Address

Participant Registration Form

Please tell us about the health care professional(s) responsible for your conventional cancer treatment. Check the box that applies and fill in the space below.

- ☐ Medical Oncologist
- ☐ Radiation Oncologist
- ☐ Surgical Oncologist
- ☐ General Practitioner

Name of Doctor (or other)

Name of Treatment Hospital or Clinic where you are receiving conventional treatment

When were you diagnosed with the cancer for which you are currently being treated?

DD MM YYYY

Date of Diagnosis ☐ / ☐ / ☐

Type or Location of Cancer for which you are being treated

What is your stage of diagnosis?

- ☐ Stage I
- ☐ Stage II
- ☐ Stage III
- ☐ Stage IV

What is your current treatment plan? (check all that apply)

- ☐ Chemotherapy
- ☐ Radiotherapy
- ☐ Hormone Therapy
- ☐ Active Surveillance

Other (please specify)

APPENDIX 8.N – ONLINE QOL-CA/CS SURVEY

The QOL-CA/CS Survey

Name of Respondent

1. What is your last name, first name and initial?

Directions

We are interested in knowing how your experience of having cancer affects your Quality of Life. Please answer all of the following questions based on your life at this time.

Please select the number from 0 to 10 that best describes your experiences.

Physical Well Being

To what extent are the following a problem for you:

2. Fatigue

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

3. Appetite changes

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

4. Aches or pain

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

5. Sleep changes

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

6. Constipation

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

The QOL-CA/CS Survey

7. Nausea

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

8. Menstrual changes or fertility

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

9. Rate your overall physical health

extremely poor (0)	1	2	3	4	5	6	7	8	9	excellent (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

Psychological Well Being Items

10. How difficult is it for you to cope today as a result of your disease and treatment?

not at all difficult (0)	1	2	3	4	5	6	7	8	9	very difficult (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

11. How good is your quality of life?

extremely poor (0)	1	2	3	4	5	6	7	8	9	excellent (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

12. How much happiness do you feel?

none at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

13. Do you feel like you are in control of things in your life?

not at all (0)	1	2	3	4	5	6	7	8	9	completely (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

14. How satisfying is your life?

not at all (0)	1	2	3	4	5	6	7	8	9	completely (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

The QOL-CA/CS Survey

15. How is your present ability to concentrate or to remember things?

extremely poor (0)	1	2	3	4	5	6	7	8	9	excellent (10)
○	○	○	○	○	○	○	○	○	○	○

16. How useful do you feel?

not at all (0)	1	2	3	4	5	6	7	8	9	extremely (10)
○	○	○	○	○	○	○	○	○	○	○

17. Has your illness or treatment caused changes in your appearance?

not at all (0)	1	2	3	4	5	6	7	8	9	extremely (10)
○	○	○	○	○	○	○	○	○	○	○

18. Has your illness or treatment caused changes in your self concept (the way you see yourself)?

not at all (0)	1	2	3	4	5	6	7	8	9	extremely (10)
○	○	○	○	○	○	○	○	○	○	○

How distressing were the following aspects of your illness and treatment?

19. Initial diagnosis

not at all distressing (0)	1	2	3	4	5	6	7	8	9	very distressing (10)
○	○	○	○	○	○	○	○	○	○	○

20. Cancer treatments (i.e. chemotherapy, radiation, or surgery)

not at all distressing (0)	1	2	3	4	5	6	7	8	9	very distressing (10)
○	○	○	○	○	○	○	○	○	○	○

21. Time since my treatment was completed

not at all distressing (0)	1	2	3	4	5	6	7	8	9	very distressing (10)
○	○	○	○	○	○	○	○	○	○	○

22. How much anxiety do you have?

none at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
○	○	○	○	○	○	○	○	○	○	○

The QOL-CA/CS Survey

23. How much depression do you have?

none at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

To what extent are you fearful of:

24. Future diagnostic tests

no fear (0)	1	2	3	4	5	6	7	8	9	extreme fear (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

25. A second cancer

no fear (0)	1	2	3	4	5	6	7	8	9	extreme fear (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

26. Recurrence of your cancer

no fear (0)	1	2	3	4	5	6	7	8	9	extreme fear (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

27. Spreading (metastasis) of your cancer

no fear (0)	1	2	3	4	5	6	7	8	9	extreme fear (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

Social Concerns

28. How distressing has illness been for your family?

not at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

29. Is the amount of support you receive from others sufficient to meet your needs?

not at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

30. Is your continuing health care interfering with your personal relationships?

not at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

The QOL-CA/CS Survey

31. Is your sexuality impacted by your illness?

not at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

32. To what degree has your illness and treatment interfered with your employment?

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

33. To what degree has your illness and treatment interfered with your activities at home?

no problem (0)	1	2	3	4	5	6	7	8	9	severe problem (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

34. How much isolation do you feel is caused by your illness or treatment?

none (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

35. How much financial burden have you incurred as a result of your illness or treatment?

none (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

Spiritual Well Being

36. How important to you is your participation in religious activities such as praying, going to church?

not at all important (0)	1	2	3	4	5	6	7	8	9	very important (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

37. How important to you are other spiritual activities such as meditation?

not at all important (0)	1	2	3	4	5	6	7	8	9	very important (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

The QOL-CA/CS Survey

38. How much has your spiritual life changed as a result of cancer diagnosis?

less important (0)	1	2	3	4	5	6	7	8	9	more important (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

39. How much uncertainty do you feel about your future?

not at all uncertain (0)	1	2	3	4	5	6	7	8	9	very uncertain (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

40. To what extent has your illness made positive changes in your life?

none at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

41. Do you sense a purpose/mission for your life or a reason for being alive?

none at all (0)	1	2	3	4	5	6	7	8	9	a great deal (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

42. How hopeful do you feel?

not at all hopeful (0)	1	2	3	4	5	6	7	8	9	very hopeful (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

Thank you for your responses. The first of two required surveys are complete.

You will now be transferred automatically to the Yoga (Y-ACT) Study survey at https://www.research.net/s/Y-ACT_SURVEY

Thank you,

Marcy and The Y-ACT Research Team

APPENDIX 8.O – QOL-CA/CS SCALE AND AUTHORISATION



NATIONAL MEDICAL CENTER AND
BECKMAN RESEARCH INSTITUTE

Quality of Life Patient/Cancer Survivor Version

Dear Colleague:

The Quality of Life Instrument (CANCER PATIENT/CANCER SURVIVOR VERSION) is a forty one-item ordinal scale that measures the Quality of Life of a cancer patient. This tool can be useful in clinical practice as well as for research. This instrument can be administered by mail or in person. The instrument originated in our pain research and has been recently adapted for use in long term cancer survivors. A Hispanic version of this questionnaire is also included.

Directions: The patient is asked to read each question and decide if he/she agrees with the statement or disagrees. The patient is then asked to circle a number to indicate the degree to which he/she agrees or disagrees with the statement according to the word anchors on each end of the scale.

The scoring should be based on a scale of 0 = worst outcome to 10 = best outcome. Several items have reverse anchors and therefore when you code the items you will need to reverse the scores of those items. For example, if a subject circles "3" on such an item, (10-3 = 7) thus you would record a score of 7. The items to be reversed are: 1-7, 9, 16-27, & 29-34 and 38. Subscales can be created for analysis purposes by adding all of the items within a subscale and creating a mean score.

You are welcome to use this instrument in your research/clinical practice to gain information about Quality of Life of patients. You have permission to duplicate this tool.

The QOL instrument is based on previous versions of the QOL instrument by researchers at the City of Hope National Medical Center (Grant, Padilla, and Ferrell). This instrument was revised in cancer survivorship studies and includes 41 items representing the four domains of quality of life including physical well being, psychological well being, social well being and spiritual well being. A study was conducted in 1995 to evaluate the psychometrics of this revised instrument as a mail survey to the membership of the National Coalition for Cancer Survivorship. This survey included a Demographic tool, the QOL tool and the FACT-G tool developed by Cella. Psychometric analysis was performed on 686 respondents including measures of reliability and validity. Two measures of reliability included re-test and internal consistency. In order to perform test re-test reliability, a randomly selected sample of 150 subjects who completed the initial QOL survey were asked to repeat this tool approximately two weeks later. 110 of the 150 subjects responded for an overall response of 73%. Of the 110 respondents, only those with complete data sets on all variables were used (N=70). The overall QOL-CS tool test re-test reliability was .89 with subscales of physical r=.88, psychological r=.88, social r=.81, spiritual r=.90. The second measure of reliability was

computation of internal consistency using Cronbach's alpha co-efficient as a measure of agreement between items and subscales. Analysis revealed an overall r=.93. Subscale alphas ranged from r=.71 for spiritual well being, r=.77 for physical, r=.81 for social, and r=.89 for psychological. Several measures of validity were used to determine the extent to which the instrument measured the concept of QOL in cancer survivors. The first method of content validity was based on a panel of QOL researchers and nurses with expertise in oncology. The second measure used stepwide multiple regression to determine factors most predictive of overall QOL in cancer survivors. Seventeen variables were found to be statistically significant accounting for 91% of the variance in overall QOL. Variables accounting for the greatest percentage were control, aches and pain, uncertainty, satisfaction, future, appearance and fatigue. The fourth measure of validity used Pearson's correlations to estimate the relationships between the subscales of the QOL-CS and the subscales of the established FACT-G tool. There was moderate to strong correlation between associated scales including QOL-CS Physical to FACT Physical (r=.74), QOL-CS Psych to FACT Emotional (r=.65), QOL Social to FACT Social (r=.44). The overall QOL-CS correlation with the FACT-G was .78. Additional measures of validity included correlations of individual items of the QOL-CS tool, Factor Analysis, and Construct Validity discriminating known groups of cancer survivors. This psychometric data is reported in reference #1 and 2.

Good luck with your research!!





Betty R. Ferrell, RN, PhD, FAAN
Research Scientist

Marcia Grant, DNSc, FAAN
Research Scientist
Director Nursing Research & Education

City of Hope National Medical Center
1500 E. Duarte Road
Duarte, CA 91010

References from City of Hope Cancer Survivorship Studies:

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3. Ferrell BR. "The Quality of Lives: 1,525 Voices of Cancer." Oncology Nursing Forum, 1996; 23(6):907-916.

4. Ferrell BR, Dow KH. "Portraits of Cancer Survivorship: A Glimpse through the Lens of Survivors' Eyes." Cancer Practice, 1996; 4(2):76-80.

5. Ferrell B, Hassey-Dow K. "Quality of Life Among Long-Term Cancer Survivors." Oncology, 1997; 11(4):565-576.

6. Juarez G, Ferrell BR, Borneman T. "Perceptions of Quality of Life in Hispanic Patients with Cancer." Cancer Practice, 1998; 6(6):318-324.

7. Hassey-Dow K, Ferrell B, Haberman M. "The Meaning of QOL in Cancer Survivors." Oncology Nursing Forum, 1999; 26(3):519-528.

8. Hassey-Dow K, Ferrell BR, Haberman MR, & Eaton L. "The meaning of quality of life in cancer survivorship." Oncology Nursing Forum, 1999; 26(3):519-528.

9. Ferrell B, Virani R, Smith S, Juarez G. "The Role of Oncology Nursing to Ensure Quality Care for Cancer Survivors: A Report Commissioned by the National Cancer Policy Board and Institute of Medicine." Oncology Nursing Forum, 2003; 30(1):E1-11 (online exclusive).

Note: Additional references from City of Hope Breast Cancer and Ovarian Cancer survivorship studies are listed under those headings.

Quality of Life Scale/CANCER PATIENT/CANCER SURVIVOR

Directions: We are interested in knowing how your experience of having cancer affects your Quality of Life. Please answer all of the following questions based on your life **at this time**.

Please circle the number from 0 - 10 that best describe your experiences:

Physical Well Being

To what extent are the following a problem for you:

1. **Fatigue**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

2. **Appetite changes**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

3. **Aches or pain**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

4. **Sleep changes**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

5. **Constipation**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

6. **Nausea**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

7. **Menstrual changes or fertility**

no problem	0	1	2	3	4	5	6	7	8	9	10	**severe problem**

8. Rate your **overall physical health**

extremely poor	0	1	2	3	4	5	6	7	8	9	10	**excellent**

Psychological Well Being Items

9. How difficult is it for you to **cope** today as a result of your disease and treatment?

not at all difficult	0	1	2	3	4	5	6	7	8	9	10	**very difficult**

10. How good is your **quality of life**?

extremely poor	0	1	2	3	4	5	6	7	8	9	10	**excellent**

11. How much **happiness** do you feel?

none at all	0	1	2	3	4	5	6	7	8	9	10	**a great deal**

12. Do you feel like you are **in control** of things in your life?

not at all	0	1	2	3	4	5	6	7	8	9	10	**completely**

13. How **satisfying** is your life?

not at all	0	1	2	3	4	5	6	7	8	9	10	**completely**

14. How is your present ability to **concentrate or to remember** things?

extremely poor	0	1	2	3	4	5	6	7	8	9	10	**excellent**

15. How **useful** do you feel?

not at all	0	1	2	3	4	5	6	7	8	9	10	**extremely**

16. Has your illness or treatment caused changes in your **appearance**?

not at all	0	1	2	3	4	5	6	7	8	9	10	**extremely**

17. Has your illness or treatment caused changes in your **self concept** (the way you see yourself)?

not at all	0	1	2	3	4	5	6	7	8	9	10	**extremely**

How distressing were the following aspects of your illness and treatment?

18. **Initial diagnosis**

not at all distressing	0	1	2	3	4	5	6	7	8	9	10	**very distressing**

19. **Cancer treatments** (i.e. chemotherapy, radiation, or surgery)

not at all distressing	0	1	2	3	4	5	6	7	8	9	10	**very distressing**

20. **Time since my treatment** was completed

not at all distressing	0	1	2	3	4	5	6	7	8	9	10	**very distressing**

21. How much **anxiety** do you have?

none at all	0	1	2	3	4	5	6	7	8	9	10	**a great deal**

22. How much **depression** do you have?

none at all	0	1	2	3	4	5	6	7	8	9	10	**a great deal**

To what extent are you <u>fearful</u> of:

23. **Future diagnostic tests**

no fear	0	1	2	3	4	5	6	7	8	9	10	**extreme fear**

24. **A second cancer**

no fear	0	1	2	3	4	5	6	7	8	9	10	**extreme fear**

25. **Recurrence** of your cancer

no fear	0	1	2	3	4	5	6	7	8	9	10	**extreme fear**

26. **Spreading (metastasis)** of your cancer

no fear	0	1	2	3	4	5	6	7	8	9	10	**extreme fear**

Social Concerns

27. How distressing has illness been for your **family**?

not at all 0 1 2 3 4 5 6 7 8 9 10 **a great deal**

28. Is the amount of **support** you receive from others sufficient to meet your needs?

not at all 0 1 2 3 4 5 6 7 8 9 10 **a great deal**

29. Is your continuing health care interfering with your **personal relationships**?

not at all 0 1 2 3 4 5 6 7 8 9 10 **a great deal**

30. Is your **sexuality** impacted by your illness?

not at all 0 1 2 3 4 5 6 7 8 9 10 **a great deal**

31. To what degree has your illness and treatment interfered with your **employment**?

no problem 0 1 2 3 4 5 6 7 8 9 10 **severe problem**

32. To what degree has your illness and treatment interfered with your **activities at home**?

no problem 0 1 2 3 4 5 6 7 8 9 10 **severe problem**

33. How much **isolation** do you feel is caused by your illness or treatment?

none 0 1 2 3 4 5 6 7 8 9 10 **a great deal**

34. How much **financial burden** have you incurred as a result of your illness and treatment?

none 0 1 2 3 4 5 6 7 8 9 10 **a great deal**

Spiritual Well Being

35. How important to you is your participation in **religious activities** such as praying, going to church?

not at all important	0	1	2	3	4	5	6	7	8	9	10	**very important**

36. How important to you are other **spiritual activities** such as meditation?

not at all important	0	1	2	3	4	5	6	7	8	9	10	**very important**

37. How much has your **spiritual life** changed as a result of cancer diagnosis?

less important	0	1	2	3	4	5	6	7	8	9	10	**more important**

38. How much **uncertainty** do you feel about your future?

not at all uncertain	0	1	2	3	4	5	6	7	8	9	10	**very uncertain**

39. To what extent has your illness made **positive changes** in your life?

none at all	0	1	2	3	4	5	6	7	8	9	10	**a great deal**

40. Do you sense a **purpose/mission** for your life or a reason for being alive?

none at all	0	1	2	3	4	5	6	7	8	9	10	**a great deal**

41. How **hopeful** do you feel?

not at all hopeful	0	1	2	3	4	5	6	7	8	9	10	**very hopeful**

APPENDIX 8.P – Y-ACT PATIENT SURVEY

The Yoga (Y-ACT) Survey

Name of Respondent

1. What is your last name, first name and initial?

Instructions

This is a short-form survey with questions asking about your experience of yoga and the study in the past month. It should take you about 10 minutes to complete.

There are no right or wrong answers, please do answer as honestly as you can and we assure you that all responses are entirely confidential.

2. Did you attend at least one yoga class or workshop in the past 28 days?

- ☐ Yes
- ☐ No

Comment (if any)

3. How many times did you practise yoga this past month?

☐ 0	☐ 9	☐ 18
☐ 1	☐ 10	☐ 19
☐ 2	☐ 11	☐ 20
☐ 3	☐ 12	☐ 21
☐ 4	☐ 13	☐ 22
☐ 5	☐ 14	☐ 23
☐ 6	☐ 15	☐ 24
☐ 7	☐ 16	☐ 25
☐ 8	☐ 17	☐ > 25

Comments

4. What reasons prevented you from doing yoga in the past month?

The Yoga (Y-ACT) Survey

5. How many times did you practise ONLINE yoga this month?

☐ 0	☐ 9	☐ 18
☐ 1	☐ 10	☐ 19
☐ 2	☐ 11	☐ 20
☐ 3	☐ 12	☐ 21
☐ 4	☐ 13	☐ 22
☐ 5	☐ 14	☐ 23
☐ 6	☐ 15	☐ 24
☐ 7	☐ 16	☐ 25
☐ 8	☐ 17	☐ >25

Comments

6. On a scale from 0 to 10, 0 being not satisfying at all, 10 being very satisfying, how satisfying was your experience in participating in this yoga intervention?

not satisfying (0)	1	2	3	4	5	6	7	8	9	very satisfying (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

7. On a scale from 0 to 10, 0 being not at all, 10 being very much, how satisfying was your experience of doing yoga with a group and expert instructor?

not satisfying (0)	1	2	3	4	5	6	7	8	9	very satisfying (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

8. On a scale from 0 to 10, 0 being not at all, 10 being very much, how satisfying was your experience in doing ONLINE yoga?

not satisfying (0)	1	2	3	4	5	6	7	8	9	very satisfying (10)
◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯

The Yoga (Y-ACT) Survey

9. Of the amount and type of yoga instruction you received during this study, do you feel it was (check all that apply):

- ☐ Not enough, you would have liked more in-person instruction
- ☐ Not enough, you would have preferred more time for online yoga
- ☐ Just about right
- ☐ Too much, you had difficulty attending the yoga session/s that were offered
- ☐ Additional comments

10. What aspects of your yoga intervention did you particularly like or dislike?

11. What changes would most improve your yoga session and/or sessions?

12. On a scale of 0 to 10, 0 being not all and 10 being very much, how do you rate the utility of practising yoga? Utility refers to the amount of benefit, usefulness or ability for yoga to satisfy your needs.

no utility (0)	1	2	3	4	5	6	7	8	9	very much utility (10)
○	○	○	○	○	○	○	○	○	○	○

13. On a scale of 0 to 10, 0 being not at all, 10 being very much, how do you rate the 'disutility' of practising yoga? Disutility means the negative, adverse or harmful effects of an activity. This includes any burden or inconvenience experienced by you, such as monetary cost, time, stress or other negative physical or mental consequences of participating in yoga.

no disutility (0)	1	2	3	4	5	6	7	8	9	very much disutility (10)
○	○	○	○	○	○	○	○	○	○	○

About the Yoga Study and Recruitment

The Yoga (Y-ACT) Survey

14. Please share any of your thoughts about being involved in this study, including any personal reflections, feelings or recommendations in the space provided below:

15. How did you find out about participating in this study?

- [ ] Oncologist Referral
- [ ] GP Referral
- [ ] Nurse Referral
- [ ] Friend Referral
- [ ] Advertisement/Poster

Other (please specify)

16. How could we increase awareness and participant recruitment for a yoga study like this one?

Thank you very much for your thoughtful responses.

This marks the end of the survey and your participation in this study is now complete.

We wish you all the very best in your journey,

Marcy and The Y-ACT Research Team

The Y-ACT Study: Yoga Instructor Summary

This is a short-form questionnaire to aid in the collection of your thoughts, your personal experience and recommendations with regards to teaching in the Y-ACT study.

Kindly send your lesson plans with your comments and any 'deviations' from the established framework to me in a separate file.

In gratitude for your commitment to the participants and this study,

Sincerely,

Marcy

1. If you instructed an introductory session for Group A, what were the strengths and weaknesses of this intervention from your perspective? You may wish to comment on timing, content, focus and risks or benefits to participants.

2. If you instructed an introductory session for Group B or C, which included the free gift certificate to online yoga, what were the strengths and weaknesses of this intervention from your perspective? You may wish to comment on timing, content, focus and risks or benefits to participants.

3. If you instructed a workshop session for Group B, (the 2-hour session), what were the strengths and weaknesses of this intervention from your perspective? You may wish to comment on timing, content, focus and risks or benefits to participants.

4. If you instructed one or more yoga classes for Group C, (the 60-minute sessions offered Monday, Wednesday and Fridays), what were the strengths and weaknesses of this intervention from your perspective? You may wish to comment on timing, content, focus and risks or benefits to participants.

APPENDIX 8.Q – Y-ACT INSTRUCTOR SURVEY

The Y-ACT Study: Yoga Instructor Summary

5. Please rank the following Interventions in order of preference (1=most preferred, 3=least preferred). Consider this in terms of potential benefit, adherence and/or acceptability to adult cancer patients, and feasibility of intervention (i.e. convenience, cost-effective, etc).

[ ]	Group A: 1 Introductory session (approx. 60-minutes), Pranayama-focus, Yoga Education and Community Referrals
[ ]	Group B: 1 Introductory session (approx. 75-minutes), Pranayama, Asana, Dhyana, Yoga Education and Community Referrals, 1-month of Free Online Yoga + 1 Yoga Workshop (approx. 2 hours)
[ ]	Group C: 1 Introductory session (approx. 75-minutes), Pranayama, Asana, Dhyana, Yoga Education and Community Referrals, 1-month of Free Online Yoga + 3 Yoga Classes per week (approx. 60-minutes) for 4 weeks

6. In terms of appropriateness and acceptability, how would you describe the ideal yoga intervention for patients undergoing cancer treatment in Vancouver?

7. If you were asked to improve aspects of the yoga study design, including recruitment, communication, location, characteristics and contents of the intervention, what would you recommend to future researchers?

8. What aspects of this yoga study were commendable and should be included in any future studies?

9. Open Remarks. In the space below, kindly share any thoughts or feelings about the study, your participation, and/or yoga as an intervention to improve health outcomes in adult cancer.

That's it!

Thank you for your contribution.

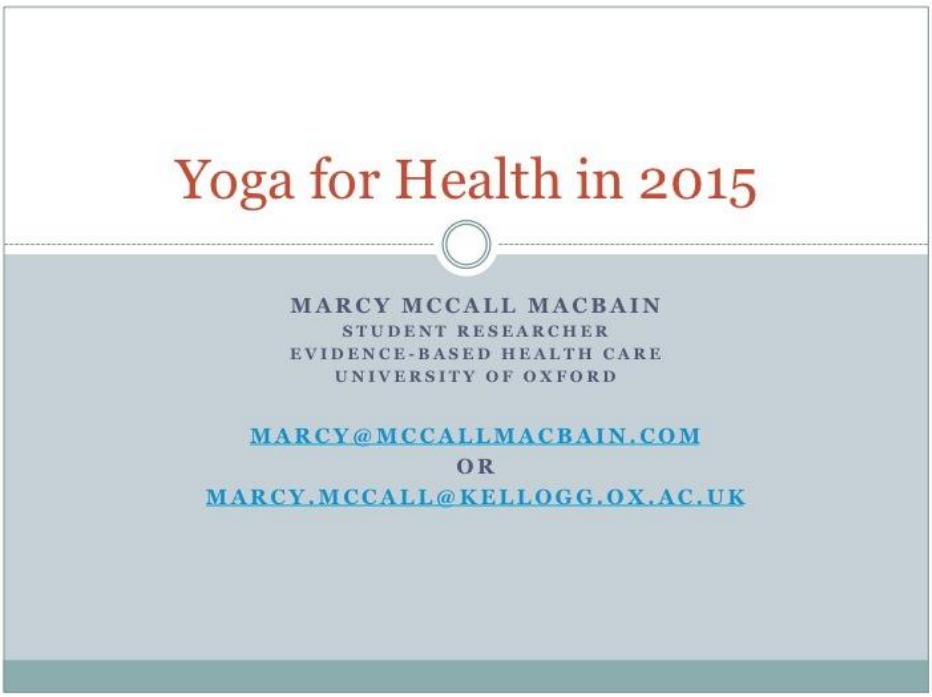
Please don't hesitate to contact me at marcy.mccall@kellogg.ox.ac.uk with any further comments or suggestions.

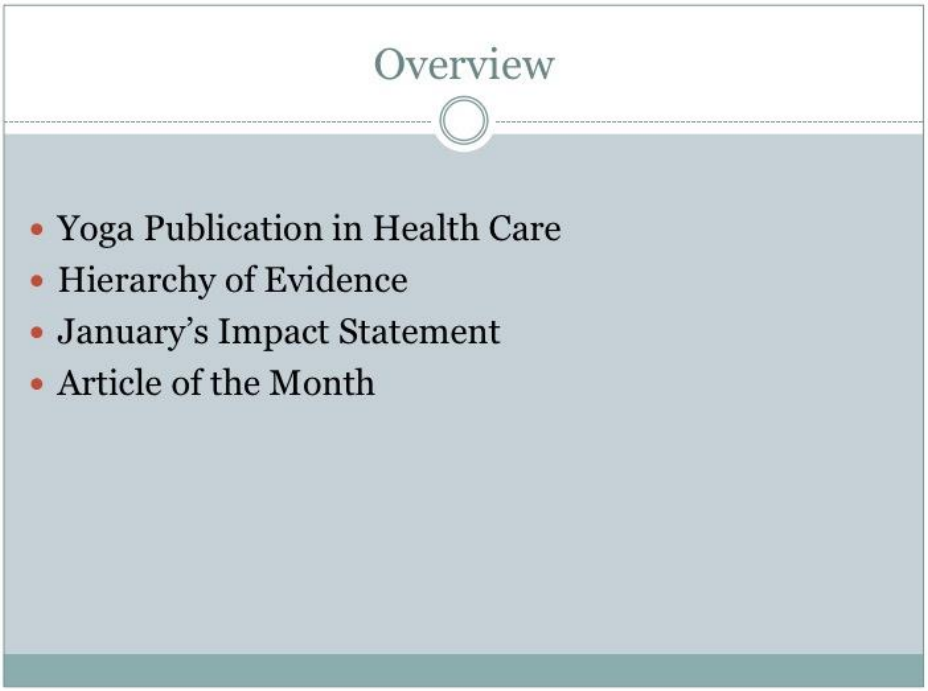
Keep in touch,

Marcy

CHAPTER 9 APPENDIX

APPENDIX 9.A – YOGA RESEARCH LECTURE





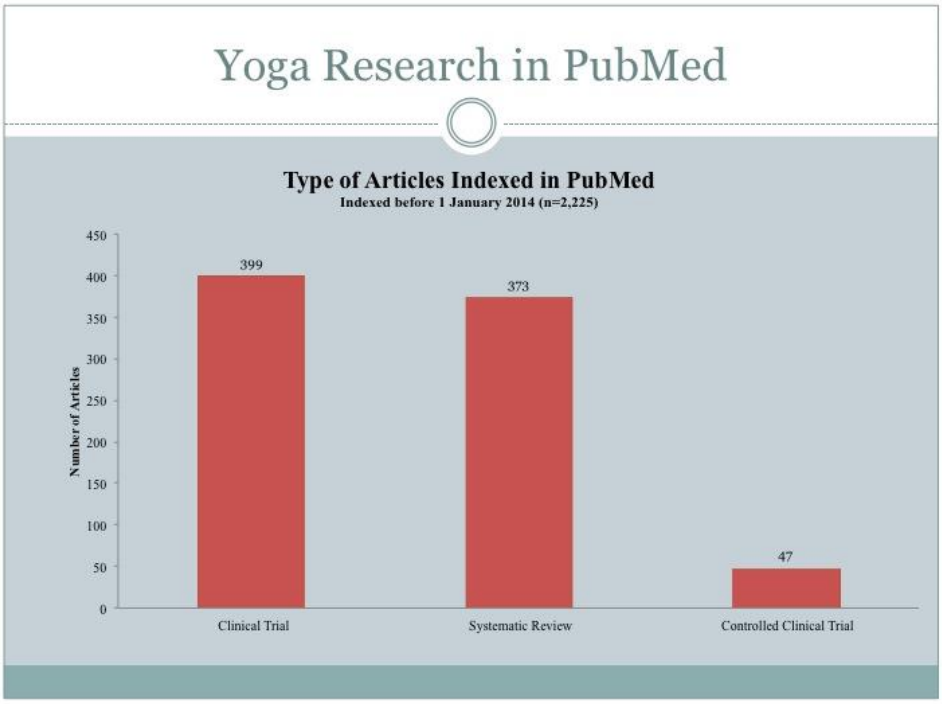
Publication Trends of Yoga

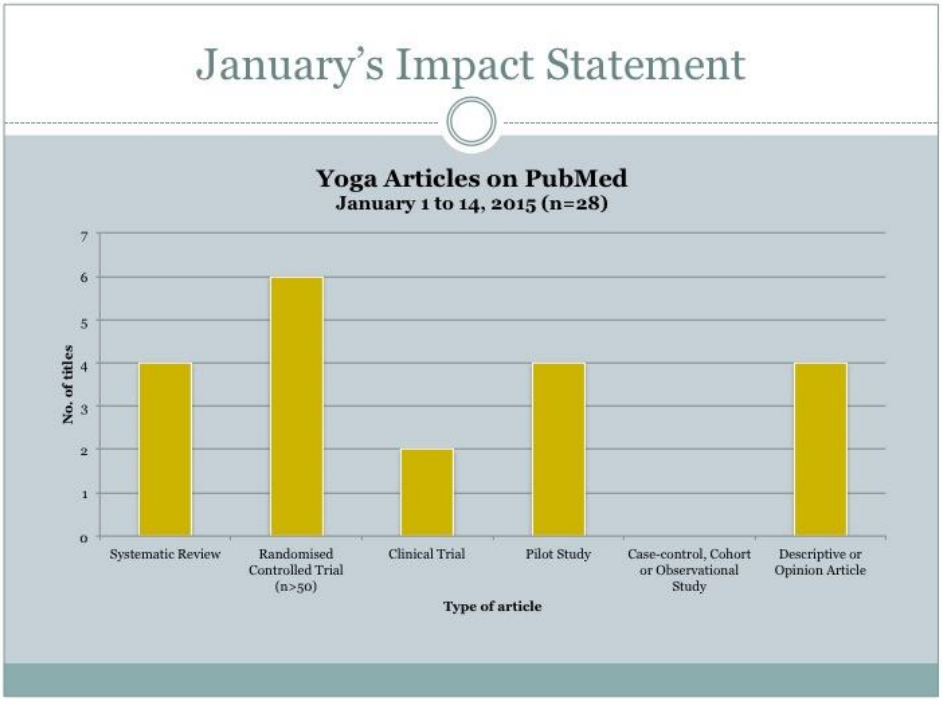


Hierarchy of Evidence



More information at:
http://www.cebm.net/ocebm-levels-of-evidence/


Yoga Research in PubMed
Type of Articles Indexed in PubMed
Indexed before 1 January 2014 (n=2,225)
Number of Articles
450
400
350
300
250
200
150
100
50
0
399
373
47
Clinical Trial
Systematic Review
Controlled Clinical Trial

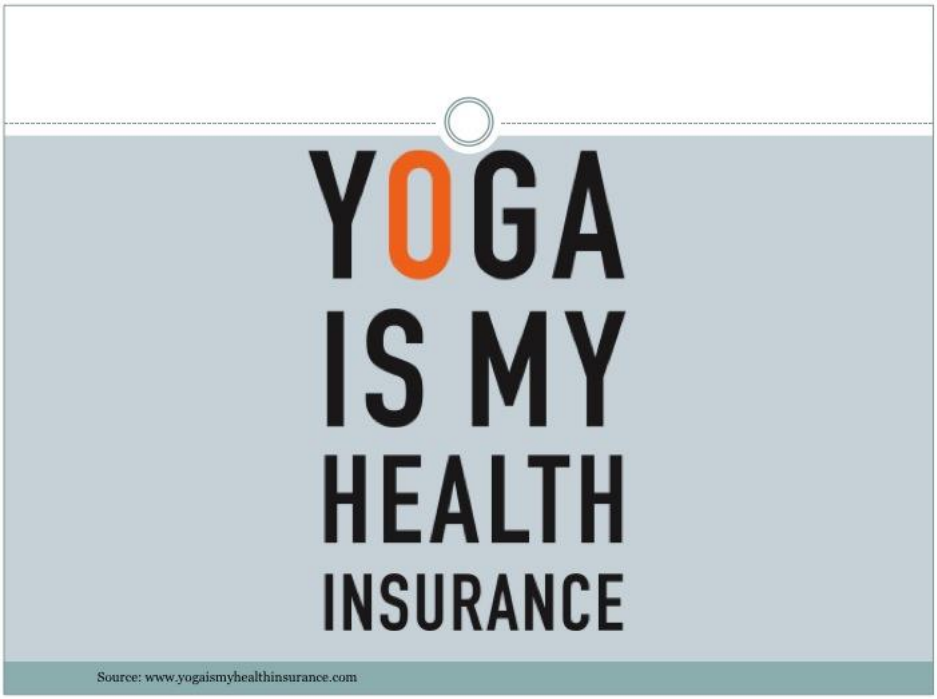

January's Impact Statement
Yoga Articles on PubMed
January 1 to 14, 2015 (n=28)
No. of titles
7
6
5
4
3
2
1
0
Systematic Review
Randomised Controlled Trial (n>50)
Clinical Trial
Pilot Study
Case-control, Cohort or Observational Study
Descriptive or Opinion Article
Type of article

Article of the Month

- Could yoga practice improve treatment-related side effects and quality of life for women with breast cancer? A systematic review and meta-analysis
  - Pan Y, Yang K, Wang Y, Zhang L, Liang H in the Asia-Pacific Journal of Clinical Oncology (2015)

Results of Pan et al. 2015

- 16 RCTs with 930 participants
- Significant difference in overall HRQoL, depression, anxiety and gastrointestinal symptoms when compared with active and waitlist control groups
- Duration of yoga and type of control group explained some heterogeneity; one subgroup analysis showed benefit of anxiety only after 3 months of intervention
- Only the waitlist control group showed effect of yoga on physical wellbeing



Avenues & Opportunities for 2015

- Research collaborations to increase the hierarchy of yoga evidence and the dissemination of results
- Isolate areas of interest based upon biomedical theory and epidemiological evidence
- Yoga is most likely to help (x) + greatest need in the population (y) + funding = STRATEGIC ACTION