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Evaluating Yoga Therapy for Irritable Bowel Syndrome

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Evaluating Yoga Therapy for Irritable Bowel Syndrome

by

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A THESIS

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Abstract

Background: Irritable bowel syndrome (IBS) is a chronic disease of the brain-gut axis. Mind-body therapies such as yoga target the central nervous system, autonomic nervous system, immune and endocrine systems involved in the brain-gut axis to improve IBS symptoms and other patient outcomes such as mental health and quality of life. Virtually delivered yoga programming has not been tested nor have the experiences of participants in these programs been explored. Further, we are unaware of the beliefs and attitudes of IBS patients and gastroenterologists towards yoga.

Objectives: This thesis had four objectives and they were to: 1) identify patients' attitudes, subjective norms, perceived behavioural control for yoga, and underlying beliefs and intentions to practice yoga; 2) identify gastroenterologists' attitudes, perceived supports, barriers and facilitators and intention to recommend a yoga program as part of routine medical care for patients with IBS; 3) explore the feasibility and efficacy of an eight-week virtual yoga program on IBS symptom severity and other patient-reported outcomes compared to an advice-only control group; and 4) explore and describe participants' experiences in a virtual yoga program, and its impact.

Methods: Using mixed-methods, cross-sectional surveys were used to answer aims 1 and 2. A randomized clinical trial answered objective 3 and semi-structured interviews answered objective 4.

Results: Patients (N=109) reported controllability, self-efficacy, and affective attitude predicted their intention to practice yoga. Gastroenterologists (N=79) reported they were ten times more likely to recommend yoga if they agreed yoga improves IBS symptoms, however, most were not recommending yoga due to lack of confidence and scientific evidence. The randomized controlled trial (N=79) found virtually delivered yoga was safe, feasible, and efficacious in improving IBS symptoms, quality of life, stress, and fatigue. The interviews revealed the participants had overwhelmingly positive experiences in the program.

Conclusions: Virtually delivered yoga programming is acceptable, safe, feasible, and efficacious in the treatment of IBS. Future research is needed to explore how virtually delivered yoga may be positioned as a therapy in the management of IBS.

Preface

While conducting the studies in this dissertation, the following manuscripts have either been *published, submitted,* or are *in preparation for submission* to a peer-reviewed journal. For each of the manuscripts, the student (and first author; Adrijana D'Silva) was responsible for study conception, rationale, and design, conducted the data collection, acquisition, analysis, and interpretation of the work, and writing of the manuscripts. This work was supervised by Dr. Maitreyi Raman and co-supervised by Dr. Deborah Marshall with committee members Dr. Yasmin Nasser and Dr. Jeff Vallance. The committee members and the co-authors reviewed the manuscripts.

We previously published a manuscript summarizing the literature on the efficacy of yoga for IBS and potential mechanisms of action. D'Silva, A., MacQueen G., Nasser, Y., Taylor, L. M., Vallance, J. K., & Raman, M. Yoga as a therapy for irritable bowel syndrome. *Digestive Diseases and Sciences.* Chapters four through seven contain a manuscript.

Chapter four: D'Silva, A., Marshall, D. A., Vallance, J. K., Nasser, Y., Taylor, L. M., Lazarescu, A., Raman, M. Gastroenterologist and patient attitudes towards yoga as a therapy for irritable bowel syndrome: An application of the theory of planned behaviour. *Submitted to Journal of the Canadian Association of Gastroenterology.*

Chapter five: D'Silva, A., Marshall, D. A., Vallance, J. K., Nasser, Y., Rajagopalan, V., MacKean, G., Raman, M. Meditation and yoga for Irritable Bowel Syndrome: Study protocol for a randomized clinical trial (MY-IBS Study). *BMJ Open.*

Chapter six: D'Silva, A., Marshall, D. A., Vallance, J. K., Nasser, Y., Rajagopalan, V., Szostakiwskyj, J. H., Raman, M. Meditation and yoga for Irritable Bowel Syndrome (MY-IBS Study): A randomized clinical trial. *In preparation for submission to Gastroenterology.*

Chapter seven: D'Silva, A., Islam, Z. Marshall, D. A., Vallance, J. K., Nasser, Y., Rajagopalan, V., MacKean, G., & Raman, M. Experiences of Irritable Bowel Syndrome patients in a virtual yoga program: Qualitative findings from a clinical trial. *In preparation for submission to Clinical Gastroenterology and Hepatology.*

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I consider myself very fortunate to have the opportunity to pursue higher education when many very capable individuals cannot. I did so out of the need "to do more with my life" knowing that I could use what I know to make the world a better place, even if by a smidge. I now realize that this experience has not only shaped me as a professional but also who I am as a person – the way I think and how I view the world. I have many people to thank for this opportunity and the many accomplishments.

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not least, Dr. Yasmin Nasser, is also one of my committee members. Yasmin, you are too cool. It was a pleasure to work with you and learn from you. I hope we can continue to work together.

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Family and friends. Thank you to my husband and to the many friends and family members who supported me over the last few years. Everything from making meals to giving words of encouragement. I would especially like to thank my mom and dad-in-law. You have both been life savers since Olivia has been born and I cannot thank you enough for your support.

Dedication

This thesis is dedicated to my little girl Olivia.

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LIST OF SYMBOLS, ABBREVIATIONS, AND NOMENCLATURE

ANCOVA	Unadjusted analysis of variance
ANOVA	One-way analysis of variance
ANS	Autonomic nervous system
BGA	Brain-gut axis
CAM	Complementary and alternative medicine
CNS	Central nervous system
CBT	Cognitive behavioural therapy
ENS	Enteric nervous system
FODMAP	Fermentable oligosaccharides, disaccharides, monosaccharides, and polyols
GI	Gastrointestinal
GIs	Gastroenterologists
HPA	Hypothalamic-pituitary-adrenal
HRQOL	Health-related quality of life
IBS	Irritable bowel syndrome
IBS-C	Constipation predominant irritable bowel syndrome
IBS-D	Diarrhea predominant irritable bowel syndrome
IBS-M	IBS with a mixed stool pattern
IBS-QOL	Irritable bowel syndrome Quality of Life
IBS-SSS	Irritable bowel syndrome Symptom Severity Scale
IMAGINE	Inflammation, Microbiome and Alimentation Gastro-intestinal and Neuropsychiatric Effects
MBIs	Mind-body interventions
MVPA	Moderate-to-vigorous-intensity physical activity
QOL	Quality of life
RCT	Randomized controlled trial
REDCAP	Research Electronic Data Capture system
SSRIs	Selective serotonin reuptake inhibitors

TPB Theory of Planned Behaviour

CHAPTER ONE: INTRODUCTION

Overview

Irritable bowel syndrome (IBS) is a common chronic condition frequently associated with psychiatric and medical comorbidities, as well as incomplete symptom control leading to decreased quality of life and substantial direct and indirect medical costs (Gracie, Hamlin, & Ford, 2018). IBS patients experience poor health-related quality of life (Gracie et al., 2018), leading to decreased work productivity and frequent work absenteeism, highlighting the considerable socio-economic impact of IBS (Pare et al., 2006). The clinical management of IBS remains challenging, and many patients feel dissatisfied with their medical care (Halpert & Godena, 2011; Sabate et al., 2020). It is estimated that 50% of IBS patients seek complementary and alternative therapies (CAM) (Kong et al., 2005).

Altered stress response from psychological and physiological mechanisms may contribute to altered brain-gut signalling patterns and IBS symptoms. Psychological stressors, such as depression and anxiety, may influence gut function (e.g., reduced motility) and physiological stressors (e.g., infection) in the gut may affect the brain (Mayer, Labus, Tillisch, Cole, & Baldi, 2015). Therapies focusing on mind-body interactions and stress reduction may be adjunctive treatments for IBS. Mind-body interventions may facilitate interactions between the central nervous system, autonomic nervous system, endocrine, and the immune system, thereby offering mechanisms to modulate overall health.

Therapeutic yoga is a mind-body intervention consisting of physical postures, breathing exercises, and meditation. Yoga promotes the holistic integration of the physical body and psycho-emotional states to improve physiological, psychological, and emotional health (Rioux, 2015). Emerging research suggests yoga offers a safe and effective way to manage IBS with improvements in mental health, symptom severity, and quality of life in both adult and

adolescent populations (Schumann et al., 2016). Systematic reviews and randomized controlled trials (RCTs) suggest that yoga may be as effective as pharmacotherapy, cognitive-behavioural therapy, exercise, and the low fermentable oligosaccharides, disaccharides, monosaccharides and polyols (FODMAP) diet in reducing IBS symptoms and improving outcomes including stress, anxiety, and depression in IBS patients (Peterson, Bauer, Chopra, Mills, & Maturi, 2017; Ross & Thomas, 2010; Schumann et al., 2016).

Proposed mechanisms of action for yoga include developing body awareness (Kavuri, Raghuram, Malamud, & Selvan, 2015), structural and functional brain changes (e.g., decreased amygdala volume) (Holzel et al., 2010), altered gray matter density (Holzel et al., 2011) and neurotransmitter levels (e.g., increased gamma-aminobutyric acid and brain-derived neurotrophic factor levels (Holzel et al., 2010), and increasing parasympathetic activity and modulating hypothalamus-pituitary-adrenal axis function (Kavuri et al., 2015). These mechanisms will be discussed in more detail in the thesis.

The Research Gap

Despite evidence to support its use, gastroenterologists infrequently discuss alternative therapies such as yoga as part of IBS management (Hung, Kang, Bollom, Wolf, & Lembo, 2015). The reasons for failing to discuss these therapies when supported by evidence are unknown. Additional research is also needed to determine the level of acceptance of yoga as an IBS treatment among gastroenterologists since yoga is not currently included as part of clinical practice guidelines for IBS in Canada (Moayyedi et al., 2019) or the United States (B. E. Lacy et al., 2021). Further, determining if gastroenterologists recommend yoga to IBS patients, and if they are, at what frequency and at what stage of care recommendations occur are of interest and

may inform therapeutic sequencing. Research also has yet to explore social-cognitive correlates of yoga in the IBS population and determinants of intention to practice yoga to manage IBS.

When delivered in person, yoga is effective in managing IBS symptoms. Additional research is also needed to test the feasibility and efficacy of yoga as a therapeutic option when delivered virtually. The rationale for virtually-delivered interventions to manage IBS is increasing due to rising demand, limited healthcare resources, cost-effectiveness (Hanlon, Hewitt, Bell, Phillips, & Mikocka-Walus, 2018; Knowles & Mikocka-Walus, 2014), and because of their convenience and feasibility in a COVID-19 setting (Emard et al., 2021; Selman, McDermott, Donesky, Citron, & Howie-Esquivel, 2015; Winters, Post, & Flanagan, 2020). Virtual care tools may be effective in managing disease activity and improving outcomes in patients with digestive diseases (Helsel, Williams, Lawson, Liang, & Markowitz, 2018) and have demonstrated high acceptability and satisfaction among IBS patients (Dorn et al., 2015; Everitt, 2012; Hunt, Moshier, & Milonova, 2009; Ljotsson et al., 2011; Ljotsson et al., 2010).

Objectives and Hypotheses

Objective 1

Objective 1 aimed to identify patients' attitudes, subjective norms, perceived behavioural control for yoga, and underlying beliefs and intentions to practice yoga. We elicited behavioural, control, normative beliefs, perceived facilitators and barriers, and delivery mode preferences**.** We hypothesized that patients would report overall positive attitudes towards daily yoga practice and their intentions to do yoga would be influenced by their identified barriers and facilitators.

Objective 2

The second objective was to identify gastroenterologists' attitudes, perceived supports, barriers and facilitators and intention to recommend a yoga program as part of routine medical

care for patients with IBS. We hypothesized gastroenterologists will have a positive attitude towards yoga, may worry about colleagues' perceptions of them recommending yoga, and will report barriers to routinely recommending yoga to patients with IBS.

Objective 3

Yoga is effective in managing IBS symptoms when classes are delivered in person (A. D'Silva, MacQueen, G., Nasser, Y., Taylor, L. M., Vallance J. K., Raman, M., 2019; Schumann et al., 2016). The primary objective of the MY-IBS (Meditation and Yoga for Irritable Bowel Syndrome) randomized clinical trial was to explore the feasibility and efficacy of an eight-week virtual yoga program on IBS symptom severity compared to an advice-only control group. Secondary objectives were to determine a) whether a virtual yoga program improves the quality of life, mental health outcomes, stress, fatigue, COVID-19-related stress, and self-compassion; and b) determine potential predictors of intervention responders. We hypothesized that the yoga intervention would be feasible while also demonstrating efficacy and superiority compared to the control group in reducing IBS symptoms and secondary outcomes.

Objective 4

No study to date has evaluated participant experiences in a virtual yoga program for adult IBS patients. An embedded design experimental model qualitative sub-study using semi-structured interviews was included in the RCT. The goal of this sub-study was to explore and describe participants' experiences in a virtual yoga program, and its impact.

Thesis Overview

Chapter 2 provides a comprehensive literature review describing IBS, yoga, the evidence of yoga's efficacy in IBS, along with potential mechanisms of action. Lastly, the second chapter highlights what is known regarding IBS patients' and gastroenterologists' perspectives on yoga

as a therapy for IBS and provides a rationale for virtually delivered yoga interventions. The third chapter describes the mixed-methodology approach to RCT design with embedded post-intervention interviews along with theory. The next four chapters include the manuscripts, starting with the findings on the IBS patients' and gastroenterologists' perspectives on yoga in chapter four: *Gastroenterologist and patient attitudes towards yoga as a therapy for irritable bowel syndrome: An application of the theory of planned behaviour*. The next chapter includes the published RCT protocol design manuscript in its entirety: *Meditation and Yoga for Irritable Bowel Syndrome: Study Protocol for a Randomized Clinical Trial (MY-IBS Study).* The sixth chapter presents the findings from the MY-IBS Study: *Meditation and Yoga for Irritable Bowel Syndrome (MY-IBS Study): A Randomized Clinical Trial*. The last manuscript presented in chapter seven study aimed to explore patients' experiences of a virtually delivered yoga intervention for IBS: *Experiences of irritable bowel syndrome patients in a virtual yoga program: Qualitative findings from a clinical trial.* The final chapter summarizes the body of work presented in this thesis and reflects on the key findings and future research directions.

CHAPTER TWO: LITERATURE REVIEW

Introduction

This chapter provides a comprehensive literature review, including the description of IBS, its prevalence, diagnosis, risk factors, pathogenesis, and treatments. In this chapter, yoga is also introduced, its evidence from RCTs in IBS, along with potential mechanisms of action. Lastly, this chapter highlights what is known regarding IBS patients' and gastroenterologists' perspectives on yoga a therapy for IBS and provides a rationale for virtually delivered yoga interventions.

Irritable Bowel Syndrome

IBS is the most common functional gastrointestinal (GI) disorder worldwide that affects between 12% and 18% of the Canadian population ("IBS Global Impact Report," 2018). Sex (biological attributes, e.g., female or male) and gender (socially constructed roles, behaviours, expressions and identities of girls, women, boys, men, and gender diverse people) influence the risk of developing certain diseases, how well we respond to medical treatments, and how often we seek health care (CIHR, 2020). Females are twice as likely to be affected compared to males, and the incidence is higher among those under 50 years of age (Lovell & Ford, 2012). A diagnosis of IBS is based on established diagnostic criteria (e.g., Rome Criteria) as shown in Table 1. The Rome IV criteria were derived from a consensus process by a multinational group of experts in the field and continue to be the current standard for diagnosing IBS (Ford, Lacy, & Talley, 2017). According to these criteria, an IBS diagnosis is obtained through a detailed history of symptoms, and the absence of warning signs (e.g., unexpected weight loss, GI bleeding, family history of bowel cancer or inflammatory bowel disease) together with the serological exclusion of celiac disease (Moayyedi et al., 2019). Symptoms include abdominal pain related to defecation or in association with a change in stool frequency or form. Symptoms

must be chronic, occurring at least once per week, on average, in the previous three months, with a duration of at least six months (Ford et al., 2017). A complete IBS history includes identifying key stressors such as emotional, physical, or sexual abuse and psychological distress, including anxiety and depression (Kavuri et al., 2015).

The IBS-Symptom Severity Scale (IBS-SSS) is the most frequently used measure for evaluating IBS severity and is commonly used as an outcome measure in clinical trials because it is highly responsive to change with treatment (Francis, Morris, & Whorwell, 1997). Symptom reduction of at least 50 points on this scale is considered clinically meaningful. The IBS-SSS is a five-question survey that asks about the severity of abdominal pain, frequency of abdominal pain, the severity of abdominal distention, dissatisfaction with bowel habits, and interference with quality of life (QOL) over the past 10 days. Subjects respond to each question on a 100-point visual analogue scale. Scores on the IBS-SSS range from 0 to 500 with higher scores indicating more severe symptoms. Patients can be categorized as having mild (75-175), moderate (175-300), or severe (>300) IBS (Francis et al., 1997).

Based on the Rome IV criteria, IBS is classified into four subtypes based on the predominant stool pattern: diarrhea-predominant (IBS-D), constipation-predominant (IBS-C), IBS with a mixed stool pattern (IBS-M), or unclassified (IBS-U) (Table 1).

Table 1. Rome IV Criteria for IBS.*

Patient has recurrent abdominal pain (≥1 day per week, on average, in the previous 3 months), with an onset ≥6 months before diagnosis
Abdominal pain is associated with at least two of the following three symptoms:
Pain related to defecation Change in frequency of stool Change in form (appearance) of stool
Patient has none of the following warning signs:
Age ≥ 50 years, no previous colon cancer screening, and presence of symptoms Recent change in bowel habit Evidence of overt GI bleeding

Nocturnal pain or passage of stools Unintentional weight loss Family history of colorectal cancer or inflammatory bowel disease Palpable abdominal mass or lymphadenopathy Evidence of iron-deficiency anemia on blood testing Positive test for fecal occult blood
Subtyping IBS by predominant stool pattern
1. IBS with constipation: hard or lumpy stools ≥25% and loose or watery stools <25% of bowel movements 2. IBS with diarrhea: loose or watery stool ≥25% and hard or lumpy stools <25% of bowel movements 3. Mixed IBS: hard or lumpy stool ≥25%and loose or watery stools ≥25%of bowel movements
*This information is from Ford et al., 2011 and Lacy et al., 2017

The rationale for these subtypes is to guide effective diagnosis and therapy, improve the homogeneity of patients recruited for clinical trials, and increase knowledge of potential pathophysiological mechanisms (Ford et al., 2017). A summary of specific treatment approaches based on the IBS subtype is shown in Figure 1.

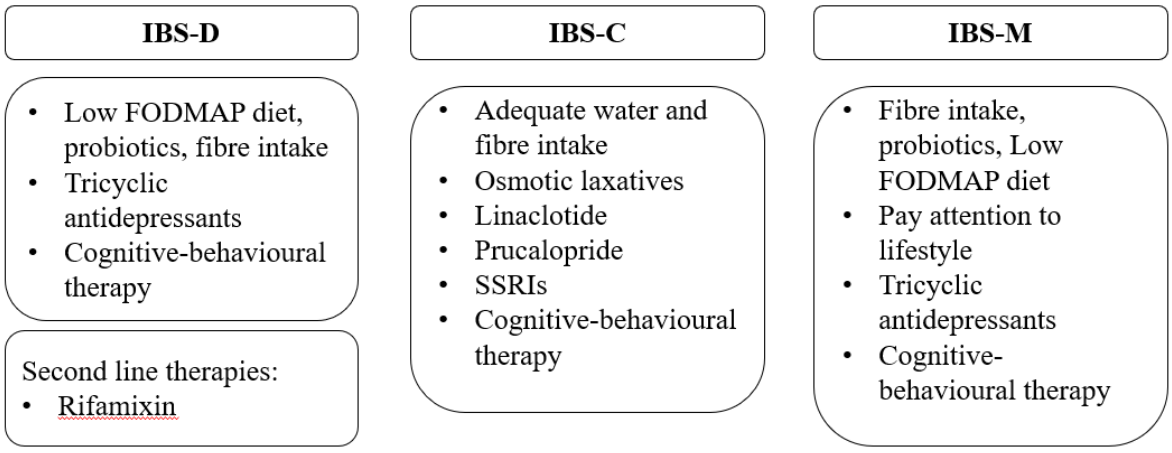

Figure 1. Treatment approaches based on the IBS subtype. Adapted from the Alberta Health Services' IBS Primary Care Pathway.

IBS Treatments

To date, no comprehensive disease model has emerged to guide the development of novel and effective IBS therapies (Mayer et al., 2015). Clinical treatments are focused on symptom

relief, and target the pathophysiology, such as accelerated transit, and dysbiosis of the gut microbiota, as effective disease-modifying treatments are still lacking. A summary of therapies for IBS and their efficacy is presented in Table 2. Quality of evidence is rated based on the number and quality of available clinical trials and the reproducibility of the results (Chey, Kurlander, & Eswaran, 2015; Moayyedi et al., 2019). Evidence-based therapies to treat IBS symptoms consist of physical activity, elimination diets, including but not limited to a low FODMAP diet (Staudacher, Whelan, Irving, & Lomer, 2011), increasing dietary fibre (Ford et al., 2008), prebiotics and probiotics (Ford, Harris, Lacy, Quigley, & Moayyedi, 2018), pharmacological therapies including antispasmodics (Ford et al., 2008), secretagogues (C. J. Black et al., 2018), antidepressants (Ford, Talley, & Moayyedi, 2011), antidiarrheals (Ford et al., 2009), S5-HT_4 agonists (Ford et al., 2009), and antibiotics (Ford et al., 2018), and cognitive-behavioural therapy (CBT) and hypnotherapy. Despite some of the therapies, such as the low-FODMAP diet and CBT, being categorized to have low evidence to support their use in IBS, these therapies are recommended in the treatment of IBS because they also consider the risk to benefit ratio, patients' values and preferences, cost and resource allocation, and quality of evidence.

Table 2. Summary of Therapies for IBS.

Treatment	Quality of evidence	Efficacy	Subtype benefits
Low FODMAP diet	Low	0.67-0.89	All
Dietary fibre	Moderate	0.83-0.90	IBS-C
Peppermint oil	Low	0.54	All
Prebiotics and probiotics	Low	0.71-0.92	All
Antispasmodics	Low	0.31-0.70	All
Secretagogues	Moderate to high	0.88	IBS-C
Antidepressants	High	0.73	All
Antidiarrheals	Very low	0.78	IBS-D
5-HT_3 antagonists	Moderate	0.78	IBS-D and IBS-M
S5-HT_4 agonists	Moderate	0.78	IBS-D
Antibiotics	Moderate	0.84	IBS-D and IBS-M

Cognitive behavioural therapy	Low	0.69	All
Hypnotherapy	Low	0.74	All

Note: Efficacy is reported as the relative risk (RR) of symptoms persisting; FODMAP: fermentable oligosaccharides, disaccharides, monosaccharides and polyols. Quality of evidence (low, medium, high) was determined by the GRADE (Grading of Recommendation Assessment, Development and Evaluation) approach: Low=the true effect might be markedly different from the estimated effect; Moderate=the true effect is probably close to the estimated effect; High=high confidence that the true effect is similar to the estimated effect.

Current therapies are effective for only a portion of patients with IBS. Many pharmacological treatments are solely based on symptom reduction without substantial benefits on the underlying disease course and may be associated with side effects, leaving some patients dissatisfied with their medical care (Katiraei & Bultron, 2011). The main barriers to treatment uptake are accessibility, cost, difficulty in adherence, and side effects. The influence of central processes and stress on IBS symptomology emphasizes the importance of appropriately selected therapies and provides a biological basis for the efficacy of psychological and stress-reduction treatments in at least a subset of patients with IBS. Potential centrally focused management options include drug therapy, psychotherapy, and mind-body interventions. Overall, a holistic approach to management that embraces lifestyle changes, dietary interventions, medications, or behavioural strategies is most likely to provide sustained treatment benefits.

The Biopsychosocial Model of IBS

IBS is a disease of unknown etiology. Throughout the literature, two views emerge on how IBS develops: one is the medical view of IBS as a strict disease of the GI tract, while the other is the psychosomatic/biopsychosocial view in which IBS is seen as a more complex multisymptomatic disorder. Patients with IBS also present with other somatic, visceral, and psychiatric comorbidities (Enck et al., 2016). Therefore, IBS is best described as a "biopsychosocial composite of patient-reported GI and extra-intestinal symptoms, degree of

disability, and illness-related perceptions and behaviours" (Corsetti & Whorwell, 2017). This model suggests that psychological (e.g., emotions, cognitions, and behaviour), social (e.g., support), and physiological (e.g., abdominal pain) factors may induce and exacerbate symptoms (Mayer et al., 2015) (Figure 2).

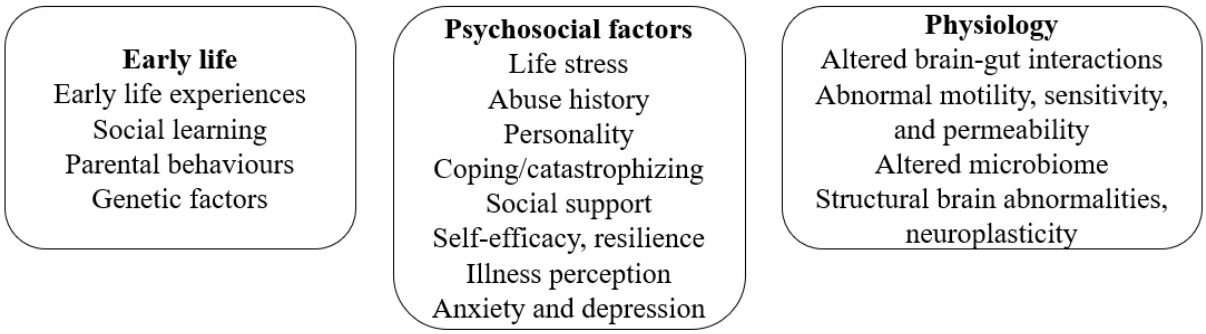

Figure 2. The biopsychosocial model of IBS.

Association between GI symptoms and psychological factors have been found in IBS, with as many as half of patients presenting with psychiatric illnesses, including anxiety, depression, panic disorder, and posttraumatic stress disorder (Van Oudenhove et al., 2016). Approximately 20% of patients with IBS have one or more psychiatric disorders, most commonly depression and generalized anxiety disorder (Whitehead, Palsson, & Jones, 2002). Among those who have experienced traumatic events (e.g., relationship difficulties, job loss), increased IBS symptoms are prevalent (Bradford et al., 2012)**.** Suicidal ideation is also common (38%) (Miller, Hopkins, & Whorwell, 2004).

Early adverse life events

The link between the history of early adverse life events and the risk of developing IBS is well documented. Early adverse life events are more common among IBS patients compared to those without IBS. IBS patients report a higher prevalence of physical abuse (61% vs 49%) emotional abuse (55% vs 27%), and sexual abuse (31% vs 18%). Evidence from brain imaging

studies identified structural and functional brain alterations with self-reports of early adverse life events. These include alterations in the activity of the brainstem, amygdala, and networks involved in determining the salience of somatic, visceral or environmental stimuli (Mayer et al., 2015). These results suggest the experience of early adverse life events can lead to altered resting-state activity in the salience and the central executive network in adults with IBS (Mayer et al., 2015).

Extraintestinal symptoms

The prevalence of other comorbidities in IBS is high. Comorbid or extraintestinal symptoms such as fatigue (51%) and fibromyalgia (33%) occur most frequently with IBS (Whitehead et al., 2002). In addition, at least 20% of IBS suffers are diagnosed with other functional GI disorders including functional dyspepsia, gastroesophageal reflux disease, and chronic nausea (Whitehead et al., 2002). IBS patients with at least one comorbid condition or somatic symptom report having more severe GI symptoms, more anxiety and depression, and lower QOL compared to those who do not (Sperber, Carmel, & Atzmon, 2009; Sperber et al., 2000).

The role of stress

IBS is a stress-sensitive disorder. Stress has been found to exacerbate IBS symptoms, creating a feedback loop between psychological processes and IBS symptoms (Van Oudenhove et al., 2016). IBS is often diagnosed following a major psychological stressor, and symptoms appear to worsen during periods of stressful events (Konturek, Brzozowski, & Konturek, 2011). The early literature suggested GI symptoms arise first and psychiatric manifestations such as mood and anxiety disorders develop later (Sykes, Blanchard, Lackner, Keefer, & Krasner, 2003). More recent evidence suggests psychological stressors and mood and anxiety disorders may

precede the development of IBS (Drossman, 2016; Jones et al., 2017). A study examining 3007 IBS patients found that 2355 (or 78%) were diagnosed with a mood or anxiety disorder before IBS (Jones et al., 2017). The time between mood or anxiety diagnosis and IBS was longer (4.0 years) than the time between an IBS diagnosis and a mood or anxiety disorder (median 1.5 years) (Jones et al., 2017).

In patients with IBS, the brain undergoes functional and structural remodelling in response to stress. When stress is excessive or chronic, stress-induced brain plasticity is seen in areas associated with fear-related memories and self-regulatory behaviours such as the prefrontal cortex, hippocampus, and amygdala (Van Oudenhove et al., 2016). Patients with IBS also have increased activation of the amygdala resulting in increased anxiety and fear in response to pain. Evidence also supports the link between psychological stress and its influence on various aspects of GI function through efferent pathways. The emotional-arousal brain circuits (e.g., hypothalamus, amygdala, and periaqueductal gray) control the output of the efferent autonomic nervous system (ANS) and the hypothalamic-pituitary-adrenal (HPA) axis (Van Oudenhove et al., 2016). These changes can alter the GI motor, immune or barrier function, colonic motility, intestinal permeability and secretion, plus changes in gut microbiota composition (Van Oudenhove et al., 2016). Managing stress in patients with IBS is an essential component in the treatment of this disorder.

Illness related perceptions and behaviours

Personality, coping strategies, perceived self-efficacy, and resilience may be indirectly involved in the modulation of the body's response to various stressors and act as predictors of IBS symptom severity (Muscatello, Bruno, Scimeca, Pandolfo, & Zoccali, 2014). IBS patients have been shown to have a high level of neuroticism (a negative personality trait associated with

poor self-regulation and inability to manage stress), lower coping skills, and lower self-efficacy and resilience (i.e., the ability to recover or adapt positively to stress compared to healthy controls) (Dabek-Drobny, Mach, & Zwolinska-Wcislo, 2020; Park et al., 2018). IBS patients who have higher neuroticism, lower self-efficacy, and lower resilience have worse IBS symptom severity, greater early adverse life events, stress hyperresponsiveness, and lower QOL (Dabek-Drobny et al., 2020; Park et al., 2018).

Health-Related Quality of Life

Disease burden in IBS can be measured by GI symptom intensity, healthcare resource utilization, productivity loss, and health-related quality of life (HRQOL) (Addante et al., 2019). From the patient perspective, HRQOL serves as a gauge of physical and emotional disease burden (Addante et al., 2019). Despite medical and dietary interventions, many IBS patients continue to have an impaired HRQOL in both the physical and mental domains (Gracie et al., 2018). Determinants of HRQOL in IBS include physical symptoms (i.e., pain, bloating, overall severity) and mental symptoms (i.e., mindfulness, catastrophizing, anxiety, depression, illness-specific fears) and somatic symptoms (i.e., presence of widespread symptoms) (De Gucht, 2015; Lackner et al., 2014; Tkalcic, Hauser, & Stimac, 2010). More specifically, severe IBS symptoms are associated with impaired physical HRQOL, but the other predictors of physical HRQOL and mental HRQOL are associated with extraintestinal symptoms (e.g., fatigue, feeling nervous, tense, or hopeless) (Addante et al., 2019; Lackner et al., 2014). Mental symptoms and somatic symptoms are more predictive of mental HRQOL (Addante et al., 2019; Lackner et al., 2014). Highly impaired daily functioning is most evident in those with psychological impairments (Ballou & Keefer, 2017a). These impairments contribute to ongoing decreased work productivity

and frequent work absenteeism which highlights the considerable socio-economic impact of IBS (Pare et al., 2006).

The IBS-Quality of Life (IBS-QOL) is the most validated and highly responsive self-reported QOL measure specific to IBS that can be used to assess the impact of IBS and its treatment (Patrick, Drossman, Frederick, Dicesare, & Puder, 1998). An increment of at least 14 points on the IBS-QOL scale from baseline demonstrates efficacy. The IBS-QOL is a 34-item questionnaire that assesses the degree to which IBS interfered with QOL over the past 30 days. Each item is rated on a 1 to 5 Likert scale, with higher values indicating a lower QOL. The individual responses to the 34 items are summed and averaged for a total score and then transformed to a 0-100 scale for ease of interpretation with higher scores indicating better IBS specific QOL (Patrick et al., 1998).

Pathophysiology of IBS

IBS is a multifaceted disease of unknown etiology. Despite intense research efforts in this area, no single biological abnormality has been identified to explain IBS symptoms (Mayer et al., 2015). Proposed aetiological factors include chronic low-grade mucosal inflammation, increased mucosal permeability, dysbiosis or an altered microbiome, food intolerance, epigenetics and genetics, and altered brain-gut interactions (Defrees & Bailey, 2017; Enck et al., 2016; Holtmann, Ford, & Talley, 2016). Increasing evidence supports the altered structural and functional brain changes, the role of altered neural and immunological networks within the gut (enteric nervous system) and altered bidirectional signalling between the autonomic and central nervous systems and the GI tract in disease pathogenesis, often referred to as the "brain-gut axis" (BGA). The BGA demonstrates a connection between GI function, stress, and psychological

processes (Fichna & Storr, 2012). This evidence will be explored in detail in the following sections.

IBS pathophysiology includes alterations in the central executive network, the emotional arousal networks, the sensorimotor network, and the salience network (Enck et al., 2016). These neurobiological alterations have been correlated with IBS symptom severity and duration, a history of early adverse life events, and gut microbial composition (Enck et al., 2016).

Functional brain changes

Abnormal brain activity has been demonstrated in IBS and thought to alter cognitive and afferent processes contributing to abdominal pain dysregulation and higher psychiatric morbidity levels (Mayer et al., 2015). Several brain networks have demonstrated functional changes in patients with IBS compared to healthy controls: central executive network, emotional arousal network, sensorimotor network, and salience network.

Central executive network

Patients with IBS may have functional impairments in cognitive processes associated with the central executive network (Mayer et al., 2015). These abnormalities are thought to have a role in visceral hypersensitivity and IBS symptom severity. For instance, there is a link between cortical thickness and grey matter density of the dorsolateral prefrontal cortex and pain catastrophizing in IBS (Mayer et al., 2015). Further, deficient activation of inhibitory cortical regions involved in the downregulation of pain, emotion, and attention during expectation or experience of aversive Gi stimuli is seen (Mayer et al., 2015).

The emotional arousal network

The emotional arousal network is a link between stimulus appraisal (salience network) and ANS output (generated in the central autonomic network) to peripheral targets (e.g., GI tract,

gut microbes, immune system) (Mayer et al., 2015). This network determines the magnitude and duration of autonomic modulation of various gut functions and has been shown to reduce the inhibitory feedback loop in IBS compared to healthy controls (Mayer et al., 2015).

The sensorimotor network

IBS may be associated with alterations in brain networks responsible for the central processing and modulation of viscerosensory and somatosensory information such that, compared to healthy individuals, patients with IBS show increased low-frequency power of spontaneous brain oscillations in regions of the sensorimotor network suggesting increased neural activity (Mayer et al., 2015).

The salience network

Rectal distention experiments have consistently reported increased engagement of the salience network, the anterior insula, and anterior midcingulate cortex in patients with IBS, while disease-related alterations in the salience network have been reported during painful states in IBS (Mayer et al., 2015).

Structural brain changes

In addition to functional brain changes, IBS is also characterized by structural changes in white and grey matter. White matter abnormalities have been seen in the brain's sensory processing and modulation regions, along with increased cortical thickness in sensorimotor areas correlated with symptom severity and catastrophizing in patients with IBS (Van Oudenhove et al., 2016). Interestingly, after controlling for anxiety and depression, most of these differences disappear (Van Oudenhove et al., 2016).

Grey matter increases have been seen in the posterior insula, the primary viscerosensory cortex, cortical-modulatory prefrontal and parietal regions, and emotional circuits (Van

Oudenhove et al., 2016). Grey matter changes in these pain modulatory areas were correlated with IBS symptom duration (Mayer et al., 2015). Once again, most of these differences disappear when controlling for anxiety and depression scores. These findings are consistent with IBS's close relationship to mood disorders (Van Oudenhove et al., 2016). However, it is unknown whether these changes are pre-existing risk factors for disease or whether they are secondary changes (Van Oudenhove et al., 2016).

The brain-gut axis

The BGA is a complex, bi-directional neurohumoral exchange of information between the cognitive and emotional centres in the central nervous system (CNS), the enteric nervous system (ENS) (the intrinsic neuronal network of the GI tract), and the gut microbiome. The BGA comprises the CNS, ENS, the gut wall in the periphery, and the endocrine system (e.g., the HPA axis) (Mayer et al., 2015). The HPA axis plays a major role in the biological response to stress, and dysregulation of the HPA axis is often observed in individuals with anxiety and depression (L. A. Uebelacker, Epstein-Lubow, G., Gaudiano, B. A., Tremont, G., Battle, C. L., Miller, I. W., 2010). An altered stress response, either psychological or environmental (e.g., life events) or physiological (e.g., infection, inflammation) may be involved in the impairment of this signalling (Coss-Adame & Rao, 2014), demonstrating a connection between GI function, stress, and psychological processes (Fichna & Storr, 2012).

The brain also interacts with the gut through immune components (e.g., cytokines) and GI components (e.g., microbiota, intestinal barrier, and intestinal immune response). The GI tract includes both the ENS and an extrinsic systemic neural network that includes sympathetic and parasympathetic connections to the CNS (Mayer et al., 2015). The extrinsic neural regulation of the GI tract is comprised of two pathways: afferent and efferent. Both pathways involve vagal

and spinal nerves, and they are mostly responsible for sensory transmission (Van Oudenhove et al., 2016). The vagus nerve conveys information from the gut to the brain, and the brain to the gut, particularly to the structures involved in homeostasis and regulation of attention, behaviour, and emotion, such as the hypothalamus, amygdala, anterior cingulate and prefrontal cortex (Van Oudenhove et al., 2016). The interactions between the ENS and the CNS are mediated by the sympathetic and parasympathetic branches of the ANS and multiple neural, endocrine and neuroimmune pathways (Mayer et al., 2015). The BGA is, therefore, an important communication system for healthy regulation of food intake, digestion, gut sensations, and control of bowel movements as it can exert changes in intestinal motility and secretion, intestinal epithelial permeability, immune function and even gut microbial composition (Mayer et al., 2015).

Altered brain-gut axis interactions and central connectivity

An altered BGA results in peripheral and central sensitization resulting in visceral hypersensitivity, increased pain perception, and altered GI motility. In IBS, the ENS and CNS are thought to be hypersensitive, showing increased responses to various visceral and external stimuli, which are not consciously perceived in healthy individuals under normal physiological conditions (Mayer et al., 2015). The cause of this hypersensitivity is thought to originate either in the brain through altered central pain networks or exposure to chronic and increased sensory input from the gut (Mayer et al., 2015). Chronically increased ANS output results in the remodelling of various peripheral cells in the ENS and immune system and even in the gut microbiota's composition and function (Mayer et al., 2015). The immune and microbiota-related signalling can be fed back to the brain, generating circular regulatory loops (Mayer et al., 2015).

Pain perception involves sensory, emotional, and cognitive processing and is processed by a network of cortical and subcortical regions referred to as the pain matrix (Van Oudenhove et al., 2016). Compared to healthy controls, the subjective experience of visceral pain in IBS results from the conscious perception of salient gut-brain signals induced by noxious stimuli, necessitating a behavioural response (Van Oudenhove et al., 2016). These signals are processed in the homeostatic-afferent network (brainstem sensory nuclei, thalamus, posterior insula) and integrated with and modulated by emotional-arousal (locus coeruleus, amygdala, subgenual anterior cingulate cortex) and cortical-modulatory neurocircuits (prefrontal cortex and anterior insula, perigenual anterior cingulate cortex) (Van Oudenhove et al., 2016). From here, the information is projected in a top-down fashion to brainstem areas, which, in turn, send descending projections to the dorsal horn of the spinal cord, where pain transmission is modulated (Van Oudenhove et al., 2016). Therefore, pain perception arises from a complex psychobiological process where input is processed and modulated by the brain (Van Oudenhove et al., 2016). In addition to increased cortical activation, corticotropin-releasing factor in the amygdala increases stress, GI symptoms, and anxiety symptoms. These mechanisms help us understand the influence of the cognitive and affective processes outlined on GI symptom perception in IBS patients and constitute the basis for a model of IBS as a disorder of gut-brain signalling (Van Oudenhove et al., 2016). More specifically, dysfunction of this process may result in allodynia, a non-noxious stimuli being perceived as painful or unpleasant which leads to chronic visceral pain - a hallmark feature of IBS (Van Oudenhove et al., 2016).

Altered brain-gut axis interactions and enteric and peripheral connectivity

Visceral sensitivity is defined as increased sensitivity to visceral stimuli described as an intensification of pain signalling to the brain induced by luminal, mechanical (e.g., distention), or

chemical stimuli in the GI tract, which leads to altered symptomology (Coss-Adame & Rao, 2014). It could be either the perception of normally non-noxious stimuli as painful (allodynia) or increased intensity of noxious stimuli (hyperalgesia) (Ballou & Keefer, 2017a). Therefore, visceral hypersensitivity is considered a key mechanism in abdominal pain (Coss-Adame & Rao, 2014). Visceral hypersensitivity has been shown to manifest in a dose-response fashion (i.e., the more severe the abdominal pain, the lower the threshold) in rectal balloon distention studies in response to both noxious and non-noxious stimuli among patients with IBS (Coss-Adame & Rao, 2014). Further, increased visceral hypersensitivity is associated with increased IBS symptom severity (Coss-Adame & Rao, 2014).

Although visceral hypersensitivity has been demonstrated in IBS, its pathophysiology is poorly understood. The two CNS regions that have been consistently found to have increased activation in IBS patients in response to visceral pain are the dorsal cingulate cortex and insula (Coss-Adame & Rao, 2014). Visceral hypersensitivity may be mediated by a variety of factors acting on the central (e.g., stress, hypervigilance, and symptom-induced anxiety) and peripheral pathways (e.g., alterations in serotonin signalling, gut barrier dysfunctions, gut microbiota, and mucosal immune response), but to which degree each of these mechanisms contribute to the overall perception of visceral pain remains unclear, as there are various mechanisms involved throughout the BGA (Coss-Adame & Rao, 2014).

Altered brain-gut axis interactions and somatic hypersensitivity

IBS is also characterized by somatic hypersensitivity or the increased multiple somatic symptoms or somatization. Somatization can be described as a medically unexplained syndrome without pathological findings (Van Oudenhove et al., 2016). Somatization is thought to explain IBS's frequent extra-intestinal symptoms (Van Oudenhove et al., 2016). Patients with IBS have

consistently reported higher somatization scores on self-reported, validated scales indicating central sensitization and somatization. Approximately two-thirds of IBS patients experience somatic illnesses such as fibromyalgia, headaches, and chronic pelvic pain (Coss-Adame & Rao, 2014). These findings support central sensitization in IBS in at least a subset of patients, as not all patients report high somatization scores or are hypersensitive to rectal distention (Coss-Adame & Rao, 2014). Thus, targeting the BGA could be a potential therapeutic intervention in managing the stress response and the somatic and visceral hypersensitivity in patients with IBS. Consequently, the role of mind-body interventions for IBS has been of growing interest, since such interventions are thought to be beneficial in reducing stress and improving outcomes among patients with IBS.

Mind-Body Therapies

While pharmacological and dietary treatments are beneficial for specific GI symptoms for some IBS patients, they have not shown efficacy in targeting the full range of GI symptoms, particularly in more severe patients (Radziwon & Lackner, 2017). Up to half of IBS patients seek non-pharmacological treatments to manage their symptoms (Kong et al., 2005). Mind-body interventions (MBIs) target the CNS and the psychological factors contributing to IBS symptoms and may be useful adjunctive treatments for IBS. Over the past two decades, several mind-body therapies have been developed to help IBS patients self-manage symptoms. MBIs most commonly include CBT, hypnotherapy, yoga, mindfulness, and breathing techniques.

Cognitive-behavioural therapy and hypnotherapy

CBT and hypnotherapy are the most widely accepted by IBS patients and physicians, with CBT tested more rigorously in multiple randomized controlled trials (C. J. Black, Thakur, E. R., Houghton, L. A., Quigley, E. M. M., Moayyedi, P., Ford, A. C., 2020). CBT helps patients

make the connection between thoughts, emotions, and physical symptoms and to modify cognitive biases to enhance psychological and physical health (Beck, Rush, Shaw, & Emery, 1979). CBT improves symptoms and psychological distress, leading to an improvement in QOL among patients with IBS (Henrich et al., 2015; Laird, Tanner-Smith, Russell, Hollon, & Walker, 2016). Similarly, gut-directed hypnotherapy research also has reported reductions in IBS symptoms and psychological distress, with improved QOL. Hypnotherapy directs patients to control physiological responses and symptoms not typically under conscious control (Gonsalkorale, Houghton, & Whorwell, 2002).

Psychological treatments are moderately effective in RCTs (e.g., demonstrate medium effect sizes) for relieving symptoms of IBS, and have small effects on psychological distress and QOL (Henrich et al., 2015; Laird et al., 2016). More specifically, a systematic review found self-administered or minimal contact CBT (RR 0.61; 95% CI 0.45 to 0.83), face-to-face CBT (RR 0.62; 95% CI 0.48 to 0.80,) and gut-directed hypnotherapy (RR 0.67; 95% CI 0.49 to 0.91) had the highest efficacy among psychological therapies used in the treatment of IBS (C. J. Black, Thakur, E. R., Houghton, L. A., Quigley, E. M. M., Moayyedi, P., Ford, A. C., 2020). Unfortunately, the risk of bias in trials was high suggesting the efficacy of psychological therapies is therefore likely to have been overestimated (C. J. Black, Thakur, E. R., Houghton, L. A., Quigley, E. M. M., Moayyedi, P., Ford, A. C., 2020).

Despite these encouraging results, these MBI therapies have been inadequately disseminated and few patients have access to these treatments (Kinsinger, 2017). Variable third-party reimbursement, a lack of qualified professionals, and poor patient and clinician acceptance have limited widespread adoption of these therapies in clinical practice (Chey et al., 2015). This gap warrants the investigation of alternative MBIs with increased accessibility. Interestingly,

CBT and hypnosis appear efficacious in minimal contact formats (e.g., phone, online delivery) (C. J. Black, Thakur, E. R., Houghton, L. A., Quigley, E. M. M., Moayyedi, P., Ford, A. C., 2020; Radziwon & Lackner, 2017). Access to MBIs may improve with the development of virtual- or application-based programs.

Yoga

Yoga is a traditional mind-body-breath discipline, that includes components of yogic postures or *Asanas*, structured breathing (*Pranayama*), and meditation (*Dyana*). Yoga philosophy was first described by Patanjali in *Yoga Sutras* as composed of eight practices or limbs: ethical life choices (*Yamas*), personal observances (*Niyamas*), posture practices (*Asanas*), breathing exercises (*Pranayama*), and four stages of meditation: sense withdrawal (*Pratyahara*), concentration (*Dharana*), meditation (*Dhyana*), and absorption (*Samadhi*) (Brems et al., 2016). Yoga therapy integrates the individual's physical body, psycho-emotional states, and spiritual conditions to improve physiological, psychological, and emotional health (Rioux, 2015). Pranayama or breath regulation includes modulation of breathing pace by slowing down or pacing the breath, manipulating nostrils, chanting, or breath-holding (Saoji, Raghavendra, & Manjunath, 2019). Meditation is a form of mental training that requires either stilling or emptying the mind to achieve a state of "detached observation" or "restful alertness" (Chen et al., 2012).

Although an ancient and established practice in Eastern cultures, yoga is now increasingly popular in Western cultures. The United States National Health Interview Survey from 2002 to 2017 reported practicing yoga or other MBIs such as tai chi or qigong increased from 5.8% in 2002 to 14.5% in 2017; most commonly among individuals with acute and chronic pain, arthritis, and depression (Wang, Li, Choudhury, & Gaylord, 2019). Reasons for the

increase were reported to be the holistic approach of these disciplines and perceived benefits (Wang et al., 2019). According to a 2008 survey and interviews (L. R. Harris, Roberts, L., 2008), yoga is a preferred therapy among 77% of IBS patients, surpassing hypnotherapy, acupuncture, homeopathy and the use of suppositories. This preference was largely due to using non-medical alternatives for initial management and avoiding side effects associated with conventional therapies. There is evidence that yoga has physical benefits (reduced pain, improved energy levels, muscular strength, and flexibility) and mental health benefits (reduced stress, anxiety and depression), while also developing body awareness for an overall improved sense of well-being (Chen et al., 2012; Pascoe & Bauer, 2015; Rocha et al., 2012).

Evidence for yoga as therapy for IBS

A small number of studies have examined the safety and efficacy of yoga as a therapy to manage IBS symptoms. A 2016 systematic review of six RCTs examining traditional yoga practice for adult (four RCTs) and adolescent patients (two RCTs) with IBS concluded yoga was a safe, feasible, and effective treatment option for IBS (Schumann et al., 2016). We published a narrative review summarizing yoga RCTs in adult IBS patients (A. D'Silva, MacQueen, G., Nasser, Y., Taylor, L. M., Vallance J. K., Raman, M., 2019). Detailed methods and findings from the four RCTs among adult IBS patients are presented in Appendix A and discussed here.

Taneja et al. (2004) compared the efficacy of an unsupervised yoga intervention including 12 postures and breathing twice a day for two months to loperamide 2-6 mg/day for two months in 22 males with diarrhea-predominant IBS. After two months, both groups showed improvements in the primary outcome of bowel symptoms scores with lower scores indicating less symptom frequency and severity (yoga: 1.55±1.81; loperamide: 2.75±1.48, $p<0.001$; Talley's Bowel Disease Questionnaire) and secondary outcomes (anxiety $p<0.05$, gastric motility

$p<0.01$, and physical flexibility $p<0.01$) with no significant between group differences (anxiety $p=0.65$, gastric motility $p=0.149$, and physical flexibility $p<0.372$). The autonomic symptom score (e.g., diarrhea, constipation, abdominal pain, urinary disturbances, headaches) showed a marginal decrease ($p=0.051$) and a significantly higher parasympathetic reactivity measured by the expiratory-to-inspiratory ratio in the yoga intervention compared to loperamide (yoga: 1.71±0.22; loperamide: 1.44±0.16; $p=0.05$).

Kavuri et al. (2015) investigated the benefits of a 12-week supervised yoga program (n=33) consisting of postures, relaxation, breathing and meditation (and participants were asked to reduce their prescription medications and supplements used for IBS, if any, to three days per week) compared to a combination group (n=33) (the same yoga program and conventional treatment including continued medication, if any) and an advice only wait-list control group (n=31)(continuation of medications, if any, and advice to walk 60 minutes three times per week for 12 weeks). The conventional treatments and medications were not described. Seventy-eight males and females of all IBS subtypes were assessed at six and 12 weeks, however, no differences between IBS subtypes were examined in this study. Significant improvements in the yoga and combination groups compared to the wait-list group were found at six and 12 weeks for multiple outcomes. There were significant differences in IBS symptom scores measured using the IBS-SSS (IBS Severity Scoring Scale) between both yoga and control groups (mean difference=226.3±16.0; $p<0.001$) and combination and control groups (mean difference=189.7±16.6; $p<0.001$). There was a significant difference between yoga and control groups (mean difference=56.5±5.7, $p<0.001$) and between combination and control groups (mean difference=45.0±5.7) in QOL (IBS-Quality of Life). Within group score changes were not provided for either outcome. In addition, anxiety, depression, GI-specific anxiety, autonomic

symptom score, hip and trunk flexibility, and handgrip strength all significantly improved in the yoga and combination groups. Prescription and non-prescription medication for IBS symptoms as well as herbal and dietary supplement use decreased significantly by week six and at week 12 for the yoga and combination group compared to the wait-list group. Most of the participants in these groups either stopped or reduced medication and supplement use. There were no significant differences between yoga and combination groups in any of the examined outcomes.

Schumann et al. (2016) examined the effects of a twice-weekly supervised hatha yoga, meditation, and yoga nidra program. Hatha yoga includes breath control, physical postures, and meditation, and yoga nidra is a whole-body deep relaxation technique (L. A. Uebelacker, Epstein-Lubow, G., Gaudiano, B. A., Tremont, G., Battle, C. L., Miller, I. W., 2010). This group was compared to a group that received three sessions of nutritional counselling on the low-FODMAP diet. After two months, both interventions were equally beneficial at 12 and 24 weeks in reducing IBS symptoms measured using the IBS-SSS. Compared to the low-FODMAP group, the yoga group also experienced a statistically significant improvement in anxiety at 12 weeks, and improved body awareness at week 24 compared to the low FODMAP group. Participants included both males and females of all IBS subtypes and explorative subgroup analysis revealed similar intervention benefits across all sub-types of IBS. Overall, yoga was found to be as effective in symptom reduction as the low FODMAP diet, and more effective at improving mental health scores and body awareness. In comparison to dietary interventions like the low FODMAP diet shown to reduce physical symptoms such as pain and gas, yoga also appears to reduce stress, leading to down regulation of sympathetic dominance, resulting in reduced symptoms of anxiety and depression.

In a study by Shahabi et al. (2016), 16 sessions of supervised Iyengar yoga delivered over 12 weeks were compared to a bi-weekly supervised outdoor moderate-intensity walking program. Iyengar yoga is a systematized form of Hatha yoga utilizing postures where the emphasis is placed on awareness and precision of body alignment, often with the aid of props (Shahabi et al., 2016). Twenty-seven males and females of all IBS subtypes (yoga: 17; walking: 10) completed the study. No differences between IBS subtypes were explored. Both interventions were found to be beneficial. Yoga demonstrated a significant decrease in IBS severity measures, visceral sensitivity index, and severity of somatic symptoms (Patient Health Questionnaire-15). Supervised walking showed significant decreases in overall GI symptoms, negative affect, and anxiety following the three-month intervention. However, after a six-month follow-up of 20 participants using a questionnaire, continued efficacy of walking was found compared to Iyengar yoga. Yoga participants expressed it was difficult to continue to practice yoga and use props without supervision, and walking was more easily integrated into daily life. Although the practice of yoga appears beneficial for patients with IBS, yoga not requiring props may be more feasible.

Studies comparing the effects of yoga and moderate-to-vigorous-intensity physical activity (MVPA) exercise in other populations report yoga may be as effective as, or more effective than MVPA at improving a variety of health-related outcome measures in both healthy and diseased populations (Ross & Thomas, 2010). Comparable benefits between yoga and MVPA were seen in the improvement in disease-specific symptoms (e.g., diabetes, multiple sclerosis, kidney disease), cholesterol and blood glucose levels, and indicators of oxidative stress, but yoga was more effective than MVPA in reducing symptoms of fatigue, anxiety and depression, and improving social functioning, QOL, and sleep (Ross & Thomas, 2010). A meta-

analysis of 22 RCTs comparing the effects of yoga on physically active and inactive controls among older adults reported significant effects favouring yoga for physical function outcomes (e.g., balance, lower body flexibility, lower limb strength) and HRQOL outcomes (e.g., depression, perceived mental health, sleep quality, and vitality) compared to inactive controls and lower limb strength, lower body flexibility, and depression compared to active controls (Sivaramakrishnan et al., 2019).

Yoga appears comparable to and in some studies more effective than CBT in reducing stress and improving QOL (Grensman et al., 2018). Investigations into mindfulness-based stress reduction therapies among healthy adults revealed yoga accounted for the largest effect on reduced psychological symptoms, stress, and improved well-being when compared to meditation alone (Carmody & Baer, 2008). Among individuals with IBS, therapies inclusive of postures, diaphragmatic breathing, and meditation were more effective in reducing IBS symptom severity and improving QOL compared to CBT (Zomorodi, Rasulzadeh Tabatabaee, Arbabi, Falah, & Daryani, 2014). These findings suggest yoga may have beneficial effects in IBS patients, where postures, breathing relaxation techniques, and meditation are integrated into a single therapy.

Strengths and limitations of yoga literature in IBS

There are several strengths and weaknesses in the studies conducted to date. The four studies examined included fewer than 180 patients with heterogeneity across studies in terms of design, intervention, and outcome measures. Strengths included the use of homogeneous criteria to confirm the diagnosis of IBS, diverse recruitment strategies resulting in the examination of varying degrees of symptom severity, use of active control groups, mostly supervised interventions, and an attempt to monitor compliance and report adverse event outcomes. Limitations of the published studies include variable sample sizes (n=21-78), intervention

heterogeneity (yoga style, intention length), the use of various comparison groups, as well as inconsistencies in (a) the range and type of outcomes, (b) follow-up periods (none to six months), and (c) reporting acceptability, compliance with therapies, and adverse outcomes. Despite methodological limitations, these studies provide preliminary support for yoga as a beneficial therapy for IBS. Given the high comorbidity of IBS and its impact on patients' daily life, there has been a growing interest in holistic interventions for IBS to manage and reduce symptoms and improve outcomes, but additional efforts are needed to integrate these therapies into routine clinical practice.

Yoga Mechanisms of Action in IBS

Several mechanisms for the efficacy of yoga have been found. These mechanisms are summarized here and presented in Appendix B.

The nervous system and the stress response

Yoga may be effective at reducing inappropriate activation of the ANS and increasing parasympathetic nervous system activity (Balasubramaniam, Telles, & Doraiswamy, 2012). A systematic review of 25 randomized control trials showed evidence that yoga practice leads to better regulation of the sympathetic nervous system and HPA axis and decreased stress (e.g., decreased cortisol levels), as well as a decrease in depression and anxiety symptoms in a range of populations (Pascoe & Bauer, 2015). Increasing evidence suggests yoga regulates the HPA axis and inflammatory processes by triggering a relaxation response (Jeter, Slutsky, Singh, & Khalsa, 2015). This relaxation response is based on the notion that patients with stress-related physical impairment develop inefficient respiratory patterns such as shallow breathing, which, if chronic, may intensify physiological arousal that aggravates somatic complaints (Van Oudenhove et al., 2016). However, the relative effects of these different yoga types on the HPA axis and the

sympathetic nervous response in response to acute and chronic stress have not been adequately examined (Ross & Thomas, 2010). For these reasons, yoga may be an effective therapy for IBS, providing IBS symptom relief and improving cognitive state, through improved regulation of the sympathetic nervous system and the HPA axis.

Increased body awareness

Several research studies have emphasized yoga makes us feel more connected to our bodies (Kavuri et al., 2015). Improved self-awareness and emotional response to stress have also been demonstrated (J. P. Jamieson, Nock, & Mendes, 2012). Increasing body awareness teaches us how to respond effectively and appropriately when emotional systems are aroused (Eriksson, Andren, Kurlberg, & Eriksson, 2015). The first step is to perceive the sensations in our body and then connect with them on an emotional level (Eriksson et al., 2015). For these reasons, yoga has the potential to be applied as holistic therapy in IBS. Yoga's emphasis on developing body awareness could influence IBS symptoms management as these patients are known to lack body awareness (Kavuri et al., 2015).

Breathing

Previous studies, including experimental designs, suggest that yogic breath-based techniques such as alternate nostril breathing are beneficial in various clinical populations (e.g., asthma, stroke, hypertension, cancer, type II diabetes) and may be as effective as conventional treatments in treating anxiety and depression (Saoji et al., 2019), which are commonly found in IBS. Studies using breathing interventions have also reported benefits in IBS symptom management, including reducing stress, cognitive performance, central neural processing, increased parasympathetic nervous system dominance and decreased sympathetic activity (Peterson et al., 2017).

The efficacy of various breathing techniques and their biological mechanisms are primarily unknown (Peterson et al., 2017). The breathing pace has been shown to modify psychophysiological responses, whereby slow breathing activates the brainstem cardiorespiratory center. In contrast, fast breathing increases parasympathetic activity and decreases sympathetic activity, with an overall reduction in perceived stress using both techniques compared to controls by promoting improved cognitive function in the domains of attention, visuomotor speed, and memory retention capacity (Peterson et al., 2017; Saoji et al., 2019). Studies also indicate breathing exercises increase thoracic volume and stimulate the vagus nerve resulting in increasing parasympathetic dominance (Saoji et al., 2019). Additional studies should investigate the beneficial effects of pranayama practices to better understand their potential clinical application as integrative IBS therapies.

Meditation

Meditation practice is associated with an array of cognitive and emotional benefits in a variety of populations. At a neurobiological level, meditation has been shown to reduce cortisol and catecholamine levels (such as epinephrine and norepinephrine) (Chen et al., 2012). Nonreactivity was associated with reduced pain catastrophizing and IBS severity (Aucoin, Lalonde-Parsi, & Cooley, 2014). It is proposed meditation may lead to a decrease in reactivity to thoughts, emotions and physical sensations, which leads to a reduction in visceral sensitivity – a hallmark of IBS (Chen et al., 2012). Meditation has also been found to reduce anxiety and depressive symptoms across various health conditions in a systematic review and meta-analysis of 40 randomized controlled trials (Chen et al., 2012). A decrease in anxiety and depressive symptoms was correlated to the ventromedial prefrontal cortex and anterior cingulate cortex activation in healthy controls (Tang, Holzel, & Posner, 2015).

Chen et al. (2012) proposed that meditation may help develop helpful coping mechanisms to facilitate a calming response to stress. Meditation techniques are highly effective in stress reduction, and such stress reduction may mediate changes in brain function (Tang et al., 2015). Meditation may reduce stress by improving self-regulation, which enhances neuroplasticity (Tang et al., 2015). Meditation may also directly modulate stress processing via a bottom-up pathway, through which it alters the sympathetic–adrenal–medullary and HPA axes by increasing activity in the parasympathetic nervous system (Tang et al., 2015). Some forms of meditation training have also been found to reduce stress-induced cortisol secretion, but future research is needed to further explore these relationships (Tang et al., 2015).

Using neuroimaging to elucidate neurological mechanisms' underlying effects of meditation on the brain has found significant structural and functional changes. These include increased cortical thickening in the brain regions related to sensory, cognitive, and emotional processing were associated with practice (Aucoin et al., 2014) and alterations in the posterior cingulate cortex, which is involved in self-referential processing (Hilton et al., 2017). It is possible that engaging the brain in meditation affects brain structure by inducing dendritic branching, synaptogenesis, myelinogenesis, or adult neurogenesis (Tang et al., 2015). Meditation training has also been shown to enhance grey-matter density in the hippocampus (Tang et al., 2015). These findings suggest meditation may have multidimensional effects on brain morphology, therefore warranting further inquiry into meditation as a potential intervention strategy for IBS.

IBS in the COVID-19 Era

Approximately two-thirds of IBS patients were stressed during the first few months of the COVID-19 pandemic (Alzahrani et al., 2020) with 12% reporting worsening GI symptoms

(Oshima et al., 2020). Besides increased GI symptoms, IBS patients also experienced significant increases in stress, psychological distress, social withdrawal, more frequent presentation to a physician, and decreased quality of life (Kamp, Levy, Munson, & Heitkemper, 2021; Quek et al., 2021; Sabate et al., 2021). The higher stress was seen in patients who have altered coping strategies (Sabate et al., 2021). Anxiety, sleep disturbance, a feeling of loss of control, and isolation contributed to greater IBS severity during the pandemic (Noble, Hasan, Whorwell, & Vasant, 2022). These findings emphasize the need for access to therapies within a biopsychosocial model for IBS targeting the brain-gut axis during the recovery phase during and post-pandemic.

The Rationale for Virtual Delivery of Yoga Interventions

The rationale for virtually delivered interventions to manage IBS is increasing due to rising demand, limited healthcare resources, accessibility, and cost-effectiveness (Hanlon et al., 2018; Knowles & Mikocka-Walus, 2014), and because of their convenience and feasibility in a COVID-19 setting (Emard et al., 2021; Selman et al., 2015; Winters et al., 2020). Virtual care is defined as "any interaction between patients and/or members of their circle of care, occurring remotely, using any forms of communication or information technologies, to facilitate or maximize the quality and efficacy of patient care" (T. Jamieson, Wallace, R., Armstrong, K., Agarwal, P., Griffin, B., Wong, I., Bhatia, S., 2015).

A recent systematic review found that online tools may be effective in managing disease activity and improving outcomes in patients with digestive diseases (Helsel et al., 2018). This review also highlighted the high acceptability and satisfaction with the use of online interventions among patients with digestive diseases, including patients with IBS (Tonkin-Crine, Bishop, Ellis, Moss-Morris, & Everitt, 2013). To date, virtually delivered yoga interventions have not been

tested in IBS. Such interventions have been explored recently in prospective studies among other clinical populations such as cancer (Emard et al., 2021; Winters et al., 2020), chronic obstructive pulmonary disease and heart failure (Selman et al., 2015) and mood disorders (L. Uebelacker et al., 2018). A systematic review of eight Hatha yoga studies reported participant satisfaction with an online yoga intervention while demonstrating feasibility (e.g., attendance) among various clinical and non-clinical populations (Brosnan, Nauphal, & Tompson, 2021).

These studies concluded online yoga was helpful with symptom management and has the potential to address the behavioural, psychological, and social challenges faced by patients during and beyond the COVID-19 pandemic. Further, the participants in these studies reported the online yoga programming to be safe, easy to use, and convenient to access. The utilization of virtually delivered yoga interventions represents an opportunity to provide a great support resource for patients with IBS to meaningfully improve their outcomes.

Patient Perspectives of Yoga

Half of IBS patients seek CAM therapies, ranging from 21 to 73% (Kong et al., 2005), but 72% do not inform their doctors of CAM use (Eisenberg, 2001). The United States 2012 National Health Interview Survey found mind-body exercises were used by 12% of IBS patients (Dossett, Davis, Lembo, & Yeh, 2014). A survey from 2008 determined yoga is a preferred therapy among 77% of IBS patients, surpassing hypnotherapy, acupuncture, homeopathy, and the use of suppositories (L. R. Harris, Roberts, L., 2008); however, these two are the only studies conducted to date that explored the perspectives of IBS patients on yoga. Although research suggests yoga is equally as effective in managing IBS symptoms as pharmacotherapy, CBT, exercise, and the low FODMAP diet to reduce IBS symptoms, stress, and treating symptoms of anxiety and depression in IBS patients (Peterson et al., 2017; Ross & Thomas, 2010; Schumann

et al., 2016), more research is needed to determine the perspectives of IBS patients towards yoga as a therapy. More importantly, research has yet to explore the social-cognitive correlates of yoga in the IBS population.

Gastroenterologist Perspectives of Yoga

The attitudes of gastroenterologists who provide care to IBS patients toward yoga have not yet been explored. A systematic review examining healthcare professionals' attitudes toward CAMs, including yoga, found that physicians (largely primary care physicians) had more negative perspectives toward CAM compared to nurses and other healthcare professionals (Sewitch, Cepoiu, Rigillo, & Sproule, 2008). Older, more experienced, male physicians were less likely to recommend CAM therapies to their patients compared to younger, less experienced, female physicians. Even when physicians had positive views toward CAM, it was not reflective in their prescription pattern, highlighting the discrepancy between their attitudes and behaviours (Sewitch et al., 2008). Barriers to recommending CAM therapies included lack of evidence for efficacy and potential side effects and interactions with medications; however, physicians are in favour of increased knowledge of CAM as many of them do not feel adequately prepared to counsel patients about the use of CAM (Sewitch et al., 2008).

Additional efforts are also needed to determine the level of acceptance of yoga among gastroenterologists since yoga is not currently part of routine clinical practice guidelines, while also determining if gastroenterologists currently recommending yoga to IBS patients (given evidence for its efficacy), and if they are, at what frequency and at what stage of care recommendations occurs.

Study Objectives

The objectives and hypotheses of this thesis are as follows: *Objective 1* aimed to identify patients' attitudes, subjective norms, perceived behavioural control for yoga, and underlying beliefs and intentions to practice yoga. We elicited behavioural, control, normative beliefs, perceived facilitators and barriers, and delivery mode preferences**.** We hypothesized that patients would report overall positive attitudes towards daily yoga practice and their intentions to do yoga would be influenced by their identified barriers and facilitators. *Objective 2* aimed to identify gastroenterologists' attitudes, perceived supports, barriers and facilitators and intention to recommend a yoga program as part of routine medical care for patients with IBS. We hypothesized gastroenterologists will have a positive attitude towards yoga, may worry about colleagues' perceptions of them recommending yoga, and report several barriers to routinely recommending yoga to patients with IBS. *Objective 3* was to determine the efficacy, feasibility, and safety of an eight-week virtual yoga program on IBS symptom severity compared to an advice-only control group. Secondary objectives were to determine a) whether a virtual yoga program improves the quality of life, mental health outcomes, stress, fatigue, COVID-19-related stress, and self-compassion; and b) determine potential predictors of intervention responders. We hypothesized that the yoga intervention would be feasible and safe while also demonstrating efficacy and superiority compared to the control group in reducing IBS symptoms and secondary outcomes. *Objective 4* was to explore and describe participants' experiences in a virtual yoga program, and its impact.

CHAPTER THREE: METHODOLOGY AND THEORY

Introduction

This chapter aims to describe the research methods used in this thesis and the application of mixed-methods research in the context of this thesis (RCT and embedded qualitative study). This chapter also outlines the theoretical and methodological approaches to qualitative research and concludes with a discussion on the researcher's background and position in the study. The research questions outlined in this thesis were anticipated to be best answered using different methodologies, both quantitative and qualitative.

Cross-sectional Studies

Objectives 1 and 2 were answered using a cross-sectional survey design. Objective 1 sought to determine the attitudes of gastroenterologists towards yoga as a therapy for IBS and objective 2 sought to determine the levels of intention of IBS patients to practice yoga. Cross-sectional studies are observational studies in which all data is collected at a single point in time. The benefit of conducting a cross-sectional survey is that can be done with limited time and resources. The challenges with cross-sectional study designs are the lack of causal inferences and insensitivity to time-dependent frequency changes. In this study design, causality cannot be inferred between beliefs about yoga and outcomes of interest (i.e., one cannot conclude that yoga impacts health).

The Theory of Planned Behaviour

Standardized and validated surveys that collect attitudes towards yoga from either the patient or gastroenterologist perspective are currently unavailable. The survey instruments were therefore developed based on previous literature and the Theory of Planned Behaviour (TPB) standardized questions to elicit responses (Ajzen, 2019) and pilot-tested with a small sample of reviewers, including a patient representative.

The TPB is a widely used social-cognitive theory to understand health behaviours in various disease and non-disease populations, including cancer (Finne et al., 2018), older adults (Senkowski, 2019), healthy adults (Darker, French, Eves, & Sniehotta, 2010), cardiac rehabilitation (Bermudez et al., 2021), dementia (Nyman, Adamczewska, & Howlett, 2018), diabetes (Plotnikoff, Courneya, Trinh, Karunamuni, & Sigal, 2008), and rheumatoid arthritis (Larkin, Kennedy, & Gallagher, 2015). This model has been used to understand the influencing factors of adoption, motivation, and adherence to physical activity interventions (Buchan, Ollis, Thomas, & Baker, 2012).

In this theory, determining the decision-making process is an important piece of understanding why an individual engages in a behaviour. Intention is an indication of a person's readiness to perform a given behaviour and the most immediate or proximal determinant of behaviour is influenced by these factors (Buchan et al., 2012), therefore readiness to act can be operationalized by asking whether people intend to engage in the behaviour (Icek Ajzen, 1991).

The TPB proposes intention to engage in a behaviour is influenced by three constructs: *attitude* (the degree to which a person evaluates a behaviour as favourable), *subjective norm* (the perceived social pressures individuals feel from important others), and *perceived behavioural control* (an individual's perception of the ease or difficulty of performing a behaviour) (Ajzen, 2011) (Figure 3).

Attitude

Attitude toward a behaviour is the degree to which performance of the behaviour is positively or negatively valued. Attitude is composed of instrumental (beneficial or harmful) and affective (pleasant or unpleasant) components. Attitude is influenced by behavioural beliefs, which are beliefs about outcomes from performing a behaviour (Glanz, 2015).

Subjective norms

Subjective norm is the perceived social pressure from important others to engage or not to engage in a behaviour. It includes injunctive (social pressures from others) or descriptive (whether important others perform this behaviour). Subjective norms are influenced by normative beliefs, which are beliefs of important individuals about the behaviour (Glanz, 2015).,

Perceived behavioural control

Perceived behavioural control refers to an individual's perceptions of their ability to perform a given behaviour. It includes self-efficacy (ease or difficulty) and controllability (personal control over the behaviour). Perceived behavioural control by control beliefs, which are facilitators and barriers to performing the behaviour (Glanz, 2015).

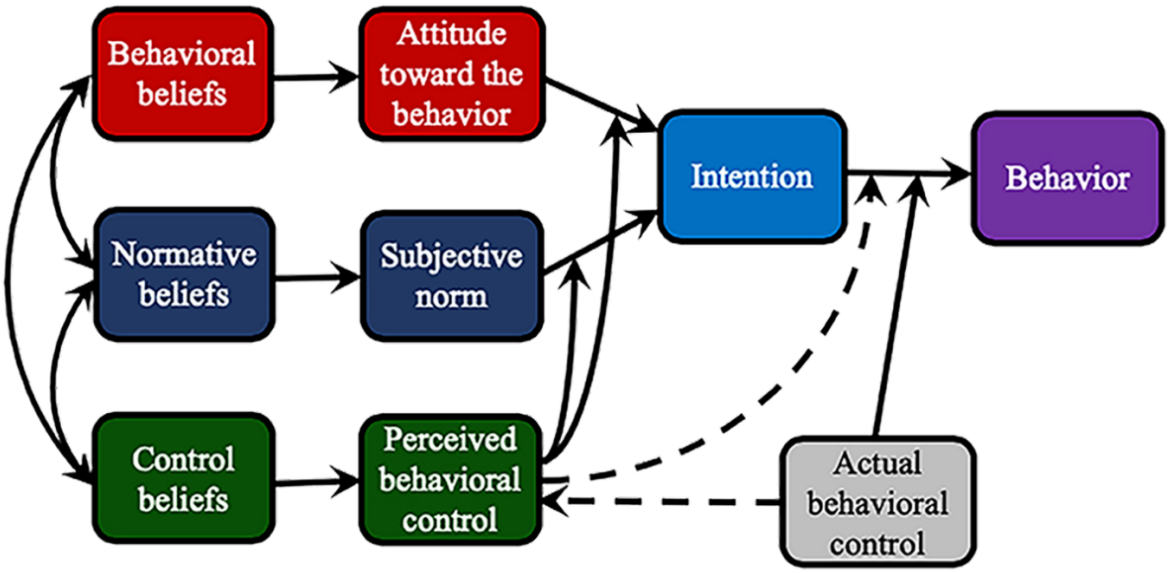

Figure 3. The Theory of Planned Behaviour from Ajzen, 2019.

Mixed-methods Research

Objectives 3 (RCT) and 4 (interviews) were answered using mixed-methods research. Objective 3 sought to determine the efficacy, feasibility, and safety of a virtual yoga intervention. Objective 4 sought to explore the experience of participants in the yoga program. To answer these questions, a qualitative study was embedded within the RCT (i.e., embedded qualitative data in a quantitative design).

Mixed-methods research is defined as the type of research focusing on research questions that call for real-life contextual understandings in which a researcher combines elements of qualitative and quantitative research approaches for the broad purposes of breadth and depth of understanding (Johnson, Onwuegbuzie, & Turner, 2007). In the context of the research question, different research approaches and strategies may need to be integrated, both qualitative and quantitative methods of data collection. In mixed-methods research, there are several challenges to be considered. Mixed-methods research requires time and resources to carry out multiple forms of data collection and analysis.

The embedded design

The embedded experimental model is a mixed-methods design in which one data set provides a supportive, secondary role in a study based primarily on the other data type (J. W. Creswell & Clark, 2011). Researchers use this design when they need to combine qualitative or quantitative data to answer different, but related, research questions within a largely qualitative or quantitative study. In the embedded design-experimental model, the researcher can include qualitative data to follow up on the results of an experiment. The model is illustrated in Figure 4. The qualitative study is sequential to the quantitative study, with higher weight given to

quantitative data. This method was selected based on its alignment with the proposed research and its ability to interpret the study findings based on both quantitative and qualitative findings.

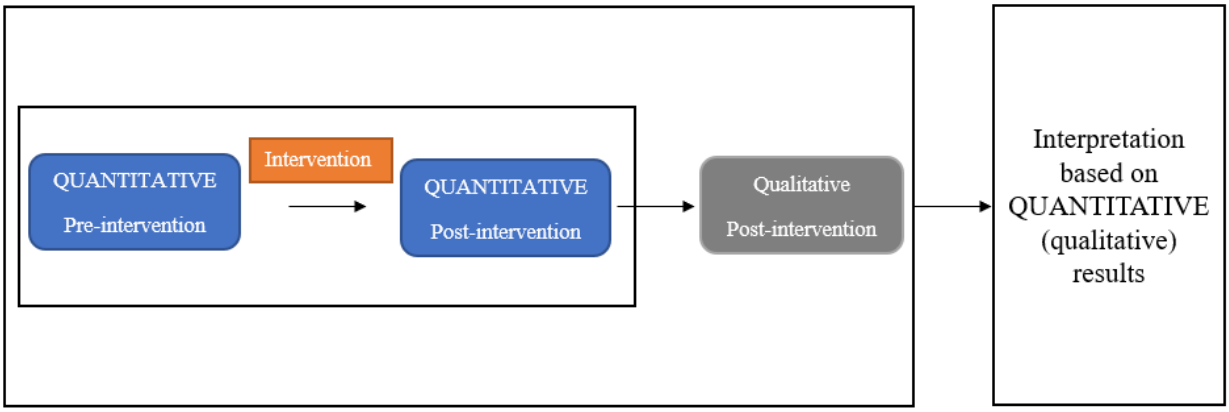

Figure 4. Embedded design-experimental model.

Randomized controlled trials

The randomized controlled trial (RCT) is a prospective study that measures the efficacy of a new intervention or treatment and is the gold standard for studying causal relationships (Hariton & Locascio, 2018). Participants are randomly assigned to one of two groups: (1) the experimental group receiving the intervention that is being tested, and (2) the other comparison or control group receiving the alternative (conventional) treatment (Kendal, 2003) (Figure 5). The two groups are then followed up to see if there are any differences between them in the outcome. These results are used to assess the efficacy of the intervention or the extent to which treatment does patients more good than harm (Kendal, 2003). RCTs provide the highest level of evidence among all study designs (Hariton & Locascio, 2018). Randomization is the cornerstone of a RCT and is not found in other study designs (Altman, 1991). In randomization, confounding variables are equally distributed between the two groups, therefore, reducing bias inherent with other study designs, although confounding variables may arise through chance (Altman, 1991).

RCTs also have drawbacks, including the high cost in terms of time and resources, issues with generalizability, and loss of follow-up (Hariton & Locascio, 2018).

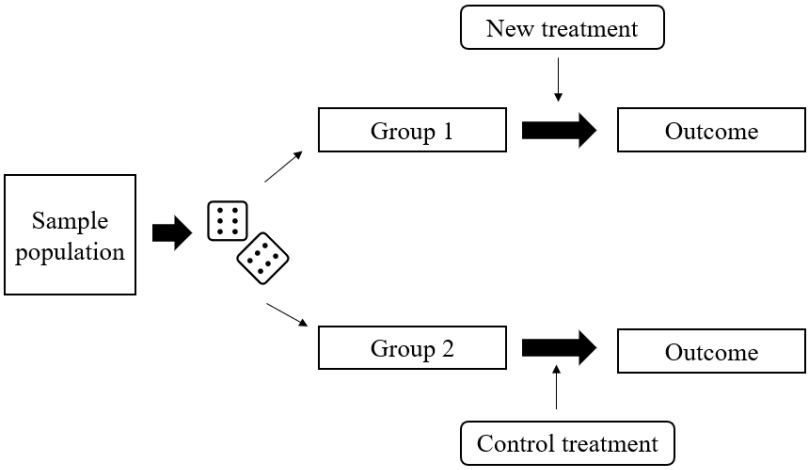

Figure 5. Randomized controlled trial adapted from Kendal, 2003.

Qualitative research

Qualitative research aims to understand people and the social and cultural contexts within which they live (Sparkes, 2013)**.** The research question for Objective 4 was: *'What is the experience of IBS patients in a virtual yoga program?'* was appropriate for qualitative inquiry because it values subjective lived experience. There can be multiple truths, or experiences, for individuals who have IBS that have participated in a virtual yoga program. For objective 4, and as with qualitative inquiry, a hypothesis is not required as it describes and interprets participants' experience in a yoga program. The priority of this qualitative study is to collect non-numerical data, acquired through interviews with the participants. Deductive data analysis will be used to generate an analytic template and inductive data analysis will be used to generate new nodes in the template and patterns and themes that will aim to provide an understanding of participant experiences.

Philosophical approach

This research question will be approached through an interpretative framework focused on pragmatism where the focus is on the outcomes of the research where what works and solutions to a problem are applied (J. W. Creswell, Poth, C.N., 2013). Pragmatism is not committed to any single philosophy, methodology, or reality, however, its ontology (or our assumptions about the nature of the world and the way of constructing reality) suggests that reality is presumed to be the practical effect of ideas (J. W. Creswell, Poth, C.N., 2013). There is no singular concept of reality, rather reality is ever-changing depending on what is useful or practical in solving a problem. The pragmatic philosophical perspective was chosen because the pragmatism paradigm allows researchers the "freedom of choice" (J. W. Creswell, Poth, C.N., 2013) to choose methods or a combination of methods and approaches that serve their purpose and advance the research. Pragmatism is application-focused and used mixed methods to answer questions centred on addressing a problem such as that of evaluating an intervention. Other approaches, such as interpretivist philosophy (people interpret meanings of their experience), constructivist (multiple perspectives make up reality), and constructivism (we construct our reality), do not have this flexibility.

The overall phenomena or problem in this study involves gathering perspectives from program participants on their experience in the program to improve the feasibility and efficacy of the intervention. There is no singular version of reality that would address this research question, rather, reality depends on what is practical in the real world as explored through the lived experiences of the participants in the study. This ontological belief (reality changes based on what works) fits the research question and its goal to evaluate whether this program is feasible and effective in a practical real-world setting.

The epistemology, or how knowledge of how reality is acquired and created, is not concretely defined in pragmatism. Rather, a pragmatic paradigm would allow for the use of different ways of thinking or processes of acquiring knowledge, that would lead to a solution for a research problem (J. W. Creswell, Poth, C.N., 2013). Through this lens, it can be argued that there is no right or wrong way to begin thinking about this problem, or how to approach understanding the experiences of the study participants, outside of what application will provide most useful to solving the research problem.

Researcher Role and Reflexivity Practices

In qualitative research, it is said the researcher is the research instrument. Therefore, it is important to understand who the researcher is, their beliefs, biases, and personal experiences. Transparency about the researcher's position and potential biases and assumptions is vital in judging accounts of qualitative research and the authenticity of the findings (Reid, Brown, Smith, Cope, & Jamieson, 2018). Discussing the researcher's role and their relationship with the participants not only increases the credibility of the findings but also deepens our understanding of them (Dodgson, 2019).

As a graduate student studying and living with IBS, and someone who believes yoga is beneficial for physical and mental health, I have a positive relationship with yoga. I see the yoga program being examined as a unique opportunity to improve IBS patients' well-being, as has been my personal experience. These beliefs and experiences may not be shared with my participants. Additionally, I may not understand the barriers, motivations, and preferences to participate in a virtual yoga program, and this understanding may influence what questions I ask, how they are asked, and how I interpret the data. In terms of considerations of reflexivity, I acknowledged that in my role as the researcher, my own experiences influence all phases of the

research process. Since my role in the research process is that of a passive outsider, I was introspective about personal biases and how they may affect my interpretation of the findings. Further, I used several critical reflection practices to address reflexivity.

Sharing my personal experience as an IBS patient and my existing relationship with the participants as the study coordinator helped develop rapport with my participants. Participants may be more comfortable and willing to share and discuss their experiences with someone who understands them or is sympathetic to their situation. Sharing this information with my participants before the interview allowed me to use my experiences with IBS in a helpful way to build rapport. Unfortunately, this pre-existing relationship may have affected what information the participants may be willing to share with me. For instance, they may be more likely to provide positive feedback, and less likely to share negative thoughts about the intervention.

To avoid projecting my own experiences and using them to understand participants' experiences, I kept a journal for self-monitoring and an audit trail of my thoughts, reasoning, judgement, and emotional reactions. Reflexive journaling is a strategy that facilitates reflexivity by acknowledging the values and experiences of the researcher and encourages them to talk about their presuppositions and experiences and rationales behind them during the research process (Ortlipp, 2015). This process makes the researcher an acknowledged part of the data analysis and interpretation process. Reflective journal data was used as secondary data while helping build the trustworthiness of the findings by supporting my subjectivity (Ortlipp, 2015). For instance, I noted I sometimes shared my personal IBS experiences in the interview to demonstrate compassion and a shared experience, but this approach may have influenced the participants' responses. Also, through the audit trail, I realized emerging patterns of sub-questions which later became integrated into the interview questions for the remaining

interviewees. These checks were ongoing with constant reflection on my position and how my position may influence the research process. To further practice reflexivity, I utilized peer review. A senior qualitative researcher, who has experience in qualitative research in the context of health services research, reviewed my findings and provided feedback.

CHAPTER FOUR

Gastroenterologist and patient attitudes towards yoga as a therapy for irritable bowel syndrome: An application of the theory of planned behaviour

Gastroenterologist and patient attitudes towards yoga as a therapy for irritable bowel syndrome: An application of the theory of planned behaviour

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Abstract

Objectives: To identify IBS patients' attitudes, subjective norms, perceived control and intention to practice yoga and gastroenterologists' attitudes and current yoga recommendations for their patients with IBS.

Methods: Gastroenterologists and IBS patients completed online surveys including Theory of Planned Behaviour (TPB) constructs. Among IBS patients, multiple linear regression determined the multivariate associations between TPB variables and intention to practice yoga while controlling for significant socio-demographic variables. Gastroenterologists were asked about their attitudes and current yoga recommendations for patients with IBS. Chi-square analyses examined associations between gastroenterologists' demographics and recommending yoga. Binomial logistic regression described associations between attitude variables and current yoga recommendations.

Results: For patients (n=109), controllability ($\beta=0.5$, $p<0.001$), affective attitude ($\beta=0.4$, $p<0.05$), and self-efficacy ($\beta=0.3$, $p<0.05$) were significantly associated with intention to do yoga in the regression model. TPB variables explained 34% of the variance in patients' intentions to practice yoga. The binomial regression analysis revealed that gastroenterologists (n=79) who have confidence in recommending yoga (39%) were seven times more likely to recommend it (odds ratio=7.3, $p=0.002$) and those who agreed yoga improves IBS symptom severity (54%) were ten times more likely to recommend yoga (odds ratio=10.1, $p<0.001$). Most (86%) wanted more evidence to support efficacy of yoga for IBS and 44% asked for more knowledge on how to refer a patient.

Conclusion: Controllability, affective attitude, and self-efficacy predicted IBS patients' intentions to practice yoga. Although gastroenterologists believed yoga is safe and beneficial for IBS patients, most do not recommend yoga due to a lack of confidence and scientific evidence.

Keywords: Irritable bowel syndrome, gastroenterologists, yoga, complementary and alternative medicine, theory of planned behaviour.

Introduction

Irritable bowel syndrome (IBS) is a prevalent (10-20%) gastrointestinal disorder involving alterations of the gut-brain axis. IBS symptoms include abdominal pain and disordered defecation associated with some relief of symptoms following the passage of bowel motion (Drossman, 2016). IBS symptoms impair quality of life and lead to a significant cost burden to health care systems(B. E. Lacy et al., 2021). The clinical management of IBS remains challenging and many patients feel dissatisfied with their medical care (Halpert & Godena, 2011; Sabate et al., 2020), leading to 50% of patients who seek complementary and alternative medicine (CAM), medical products and practices that are not part of standard medical care(Kong et al., 2005). Emerging research demonstrates yoga as a CAM is safe and effective in treating IBS (Schumann et al., 2016). Yoga is the preferred CAM among 77% of IBS patients (L. R. Harris, Roberts, L., 2008) surpassing hypnotherapy, acupuncture, homeopathy, and the use of suppositories (L. R. Harris, Roberts, L., 2008).

Yoga is a mind-body-breath discipline that is as effective as pharmacotherapy, cognitive-behavioural therapy, exercise, and the low FODMAP diet to reduce IBS symptoms and improve stress, anxiety, and depression in IBS patients (Peterson et al., 2017; Ross & Thomas, 2010; Schumann et al., 2016). Yoga may reduce inappropriate activation of the autonomic nervous system and regulate the hypothalamus-pituitary-adrenal axis and inflammatory processes by triggering a relaxation response (Jeter et al., 2015). Despite evidence to support its use, gastroenterologists (GIs) infrequently discuss CAM therapies as part of IBS management (Hung et al., 2015). The reasons for failing to discuss CAM therapies supported by evidence are unknown.

The Theory of Planned Behavior (TPB) is a widely used social-cognitive theory to understand health behaviours in various disease and non-disease populations, including cancer (Finne et al., 2018), older adults (Senkowski, 2019), healthy adults (Darker, French, Eves, & Sniehotta, 2010), cardiac rehabilitation(Bermudez et al., 2021), dementia (Nyman, Adamczewska, & Howlett, 2018), diabetes (Plotnikoff, Courneya, Trinh, Karunamuni, & Sigal, 2008), and rheumatoid arthritis (Larkin, Kennedy, & Gallagher, 2015) (see Figure 1). The TPB proposes intention to engage in a behaviour is influenced by three constructs (Ajzen, 2011): an individual's *attitude* (the degree to which a person evaluates a behaviour as favourable), *subjective norm* (the perceived social pressures individuals feel from important others), and *perceived behavioural control* (an individual's perception of the ease or difficulty of performing a behaviour)(Glanz, 2015).

The objectives of this study were to a) use the TPB model to identify IBS patients' attitudes, subjective norms, perceived behavioural control, and intention to practice yoga, and b) identify GIs' attitudes, barriers, facilitators, and current yoga recommendations as part of routine medical care for IBS patients.

Methods

Participants and procedures

Adults diagnosed with IBS by a healthcare professional (e.g., physician, nurse, dietitian) based on Rome IV criteria were recruited through a) gastroenterology clinics in Calgary, Alberta, b) social media, c) self-referrals, and d) IBS patients enrolled in the IMAGINE cohort study at the University of Calgary. GIs across Canada who provided care to adult patients with IBS through the Canadian Association of Gastroenterology membership were identified. GIs and

patients received an email invitation asking them to complete a cross-sectional online survey using the Research Electronic Data Capture (REDCAP) system (P. A. Harris et al., 2019; P. A. Harris et al., 2009). Two email reminders were sent two weeks apart to increase participation rates. The University of Calgary Conjoint Health Research Ethics Board approved this study (ID: REB19-1456, ID: REB19-1113).

Patient survey

The patient survey assessed socio-demographic, clinical, and TPB variables. *Socio-demographic information* was captured by self-report and included age, gender, ethnicity, marital status, education, and annual family income. Clinical information included self-reported comorbidities, years since IBS diagnosis, current IBS medications (e.g., over-counter medications and supplements), and the use of CAMs to manage IBS symptoms. Yoga questions included yoga delivery preferences, past yoga experience, and complementary and alternative medicine (CAM) use.

TPB survey questions were developed based on the previous literature and TPB standardized questions to elicit responses(Ajzen, 2019) and pilot-tested with a small sample of reviewers (Appendix C). Yoga was defined as doing a practice consisting of postures, meditation, and breath work. We defined intention as *doing yoga every day for 10-20 minutes for the next eight weeks*.

Attitude was measured by two items (instrumental and affective attitude) on a 7-point Likert scale. Instrumental attitudes were measured with one item; “Doing yoga every day for 10-20 minutes for the next eight weeks would be” from 1 (very bad) to 7 (very good). Affective attitudes were measured by one item; “Doing yoga every day for 10-20 minutes for the next eight weeks would be” from 1 (unpleasant) to 7 (pleasant).

Subjective norm (injunctive and descriptive norms) was measured by two items on a 7-point scale. Injunctive norms were measured with one item; "Most people who are important to me would support me to do yoga daily for 10-20 minutes for the next eight weeks," from 1 (strongly disagree) to 7 (strongly agree). Descriptive norms were measured with one item; "Most people like me will do yoga daily for 10-20 minutes for the next eight weeks," from 1 (very unlikely) to 7 (very likely).

Perceived behavioural control (self-efficacy and controllability) was measured by two items on a 7-point scale. Self-efficacy was measured with one item; "I am confident that I can commit to doing yoga every day for 10-20 minutes for the next eight weeks," from 1 (not at all confident) to 7 (very confident). Controllability was measured with one item; "Doing yoga daily for 10-20 minutes for the next eight weeks is up to me," from 1 (strongly disagree) to 7 (strongly agree).

For *behavioural beliefs* patients listed what they believed to be the top three advantages and disadvantages of participating in daily yoga. For *normative beliefs*, patients listed the top three individuals or groups they believe would approve or disapprove of them participating in daily yoga. For *control beliefs*, patients listed what they thought were the top three main factors or circumstances that make it easier (facilitators) or more difficult (barriers) to engage in daily yoga. *Intention* to practice yoga was assessed using one item measured on a 7-point scale from 1 (very unlikely) to 7 (very likely): "I intend to do yoga daily for 10-20 minutes for the next eight weeks".

Gastroenterologist survey

This survey assessed attitudes, perceived supports, barriers, facilitators, and if they currently recommend yoga to patients with IBS. We defined yoga as "*a practice that includes at*

least one of the following components: postures, breathing techniques, or meditation". Demographic information included age, gender, province of residence, and the number of years in practice. We asked GIs to report their yoga practice and personal use of CAM. The survey questions were developed based on previous literature and pilot-tested with a small sample of reviewers (Appendix D).

Attitudes were assessed by asking GIs to respond to a list of statements on their beliefs about yoga, how likely they were to make a recommendation for yoga, and their delivery modality preferences on a 7-point Likert scale from strongly disagree/very unlikely (1) to strongly agree/very likely (7). *Perceived support* was assessed by asking GIs to list anyone who supports or does not support them in recommending yoga. *Barriers and facilitators* to recommending yoga were assessed by asking respondents to select one or more circumstances from a list that would make it more difficult (barriers) or easier (facilitators) to recommend yoga to their IBS patients. *Behaviour* was assessed by asking if they currently recommend yoga (yes or no).

Data analysis

The descriptive analyses summarized socio-demographic and clinical information, and survey responses. For the patient survey, one-way analysis of variance (ANOVA) explored associations between intention and categorical demographic and clinical variables (age ≤43 vs. >43), gender, marital status, annual family income, ethnicity, and the number of comorbidities (≤2 vs. 3 or more). Multiple linear regression analysis determined the multivariate associations between TPB variables (attitudes, subjective norms, and perceived behavioural control) and intention to do yoga while controlling for socio-demographic and clinical variables found to be significantly correlated with intention.

For the gastroenterologist survey, attitude responses were averaged and then grouped into agreement (strongly agree/agree), neutral, and disagreement (disagree/strongly disagree). Chi-square analyses examined associations between GI demographics/personal practice of yoga and current yoga recommendation (yes or no). Binomial logistic regression described associations between attitude variables (independent variables: yoga improves IBS symptoms, I feel confident in recommending yoga, there is sufficient scientific evidence on yoga for IBS) and whether the gastroenterologist currently recommends yoga (dependent variable: yes or no). The exponential beta coefficient was interpreted as the odds ratio. We used SPSS 26 for all analyses and an α=0.05 was set as the threshold for determining statistical significance.

Results

Patient survey

A total of 109 individuals with IBS responded to the survey (Table 1). The mean age of the sample was 43 years (SD=14.6), 92% women, and 88% Caucasian. Half of the respondents were married (55%). Most participants (91%) practiced yoga in the past for an average of 6.1 (SD=5.5) years on average. More than half (54%) utilized CAM, and a third (33%) practiced yoga. Few patients recall a yoga recommendation by their physician (8%). Patients were most interested in doing yoga at home using online resources (76%) or attending an in-person yoga class (51%).

Patient's intention to practice yoga

All TPB variables were associated with intention (Table 2). The strongest correlation was observed between intention and affective attitude ($r=0.72$, $p<0.001$). Multiple linear regression analyses examining the correlations of intentions to engage in daily yoga revealed that TPB variables explained 33.7% of the variance in intention ($R^2=0.337$, $p<0.001$). The strongest

independent correlate of intention was controllability (β=0.5, 95% CI: 0.2-0.9, p<.001), followed by affective attitude (β=0.4, 95% CI: 0.01-0.7, p=0.043) and self-efficacy (β=0.3, 95% CI: 0.00-0.5, p=0.04).

Patients' behavioural, normative, and control beliefs

The most common advantages of practicing yoga were relaxation, flexibility, and strength (see Table 3). The most common disadvantages were lacking time, self-discipline, and cost. For *normative beliefs*, the most common individuals or groups who would approve of IBS patients engaging in daily yoga were partners, family, and friends. Some patients (17%) listed at least one individual or group who would disapprove of them doing daily yoga, and these were employer/coworkers, family, and religious groups. For *control beliefs*, patients perceived that they would engage in daily yoga if they were in a scheduled weekly group class led by an instructor, delivered online by a video or an application, was low-cost, and they had accountability. The most common *barriers* concerning daily yoga were the lack of time and inability to schedule it into daily life, lack of transportation, and lack of space and skills to do yoga.

Gastroenterologist survey

Seventy-nine out of 450 invited GIs completed the survey (18% response rate), and Table 4 contains a summary of their characteristics. Two-thirds of the respondents were male (66%) and practiced in Alberta (62%). Three-quarters (72%) of respondents were early or mid-career physicians with 15 years or less of experience, and the majority were providing adult IBS care (87%). Half of the physician respondents (48%) practiced yoga and a third practiced meditation (30%) and mindfulness (33%).

Gastroenterologists' attitudes and beliefs

GIs' attitudes and beliefs toward yoga as an effective treatment for patients with IBS are presented in Table 5. Most respondents agreed yoga is safe (94%), reduces stress (87%), improves anxiety (82%) and health-related quality of life (85%), and does not interfere with conventional IBS treatments (92%). Half (54%) believed yoga has the therapeutic ability to improve IBS symptoms. When asked to indicate how likely they are to recommend yoga as a treatment to their IBS patients, 54% of GIs agreed with this statement. Only 15% believed scientific evidence to support the use of yoga as an effective treatment for IBS is sufficient, with 38% indicating a neutral response. Thirty-nine percent agreed or strongly agreed they were confident in recommending yoga and 39% currently recommend yoga to their IBS patients. Most GIs stated they would recommend yoga to their IBS patients (84%). For those who were unwilling to recommend, five out of thirteen cited lack of evidence (38%) as the top reason. GIs who practice yoga were more likely to recommend it compared to those who do not (92.1% vs. 47.0%, p=0.048). When recommending yoga, 53% of GIs indicated they were likely to recommend a face-to-face yoga class and 43% would recommend a yoga class delivered virtually (Table 5). Eighty-five percent were willing to refer their patients to a study testing such a program.

Gastroenterologists' recommendations of yoga

The binomial logistic regression explained 51% of the variance in yoga recommendations (R^2=0.507). Agreeing that yoga improves IBS symptoms added significantly to the model (odds ratio=10.1, 95% CI: 2.5-40.8, p<0.001) as did confidence in recommending yoga (odds ratio=7.3, 95% CI: 2.1-25.4, p=0.002), but agreeing there is sufficient scientific evidence for yoga in IBS was not significant (odd ratio=2.5, 95% CI: 0.7-9.4, p=0.166).

Gastroenterologists' barriers and facilitators

The main barriers to recommending yoga were lack of knowledge about how or where to refer a patient (n=35, 44%), not enough knowledge to be able to discuss yoga with their patient (n=32, 41%), and concern regarding the cost of doing yoga for the patient (n=32, 41%) (Table 6). GIs were not concerned about the safety of yoga for IBS (n=4, 5%). Most respondents (n=68, 86%) wanted to see more evidence to support the efficacy of yoga for IBS and informational resources on yoga that can be given to patients during their clinic visits (n=54, 68%).

Discussion

Our study is the first to use a theoretical framework to examine the attitudes of GIs and patients towards yoga as a therapy to manage IBS. The patient survey found TPB variables explained 34% of the variance in intention to practice yoga among IBS patients. We also found a GIs had positive attitudes and beliefs toward yoga, but it was not reflected in their prescription pattern, highlighting a discrepancy between their attitudes and behaviours.

In breast, prostate, and colorectal cancer populations a similar TPB variable model (attitudes, perceived behavioural control, subjective norm, and planning) explained 11%, 24%, and 24% of the variance in physical activity, respectively (Forbes, Blanchard, Mummery, & Courneya, 2014). In a sample of 120 type II diabetes patients, TPB variables (attitudes, perceived behavioural control, subjective norm, and planning) explained 45% of the variance in intention to engage in physical activity (Ferreira & Pereira, 2017). Attitudes and perceived behavioural control were significantly associated with intention to engage in physical activity, whereas subjective norm was not associated with intention.

In our study, the intention to engage in yoga was driven primarily by perceived behavioural control and attitude. IBS patients' perceived controllability and self-efficacy were

among the strongest predictors of their intentions to practice yoga. These findings are consistent with the notion that perceived behavioural control predicts behaviour directly (R. E. Rhodes, Nigg, C. R., 2011), particularly self-efficacy (Sheeran, Klein, & Rothman, 2017). Self-efficacy is also the strongest predictor of intention to engage in physical activity among cancer survivors (Hirschey et al., 2020). The finding that affective attitude was also a significant predictor of intention is similar to other chronic diseases, including cancer, type II diabetes, and individuals with physical disabilities.

We found GIs had positive attitudes and beliefs toward yoga. Yet, it was not reflective in their prescription pattern, highlighting a discrepancy between their attitudes and behaviours. GIs who had experience practicing yoga were more likely to recommend yoga compared to GIs who did not. Previous literature has not explored these relationships among GIs in the context of IBS. There are similar findings regarding this discrepancy between beliefs on CAMs, including yoga, and prescription patterns among GIs treating inflammatory bowel disease (Lindberg, 2013), infectious disease physicians (Shere-Wolfe, Tilburt, D'Adamo, Berman, & Chesney, 2013), and general practitioners (Sewitch et al., 2008). Although GIs had positive attitudes toward yoga to manage stress and mental health in IBS, these beliefs did not translate to beliefs yoga can improve IBS symptoms through the brain-gut axis connection. This belief may be influenced by the perception yoga is a physical activity rather than a practice that includes breathing and meditation. We did not find any of the demographic characteristics examined (e.g., age, gender, years of experience, province) associated with recommending yoga among GIs.

A major barrier to recommending CAM is the lack of scientific evidence for its use (Shere-Wolfe et al., 2013; Singhal & Roy, 2018), noting physicians primarily rely on scientific evidence and clinical research to guide their treatment plan (Shere-Wolfe et al., 2013). In our

study, only 15% of GIs agreed the scientific evidence for yoga is sufficient. However, our regression model indicated lack of scientific evidence was not predictive of GIs' recommendation of yoga. Those who agreed yoga is beneficial for IBS were ten times more likely to recommend yoga to their IBS patients. There is sufficient evidence to support the use of yoga as a therapy in managing IBS (Schumann et al., 2016), however, yoga is not included in clinical practice guidelines for IBS (Moayyedi et al., 2019). Building awareness and providing education about yoga as therapy among GIs is needed to shift their attitudes and beliefs towards yoga to meet patients' needs and offer adequate information (Lindberg, 2013; Sewitch et al., 2008).

It is encouraging many GIs are willing to recommend yoga. Yet GIs cited lack of knowledge as the main barrier. Half considered themselves unqualified or lacked sufficient knowledge of yoga to provide appropriate advice and recommendations around yoga. Further, our regression model revealed those who are confident in recommending yoga are seven more times likely to recommend it. Lack of knowledge among physicians has been a well-cited reason for the reluctance to recommend yoga and other CAM therapies to patients(Singhal & Roy, 2018). One in five patients listed their doctor as a normative referent that would approve of doing yoga. This finding highlights a gastroenterologist's recommendation is one factor to consider in promoting yoga as a therapy for patients with IBS. This also presents an opportunity for GIs to increase their knowledge and understanding of CAM to support patients holistically. Patients may be inclined to integrate holistic solutions when such recommendations come from a credible source such as their physician(Harvey et al., 2018).

Our findings provide a foundation for future research exploring the acceptance of such therapies. This study has limitations that warrant mention. First, we lacked information about

how GIs in our study were compensated (fee-for-service or flat fee). Method of compensation and time spent discussing IBS therapies may be correlated, but we did not find limited clinic time to be a major barrier. There may have been a selection bias where GIs that prescribed yoga, personally practiced yoga or had positive attitudes towards yoga were more likely to participate in the study. Further, our small sample size of gastroenterologists limited the number of dependent variables explored in the regression analysis. Our study results may not be generalizable, as two-thirds of the GIs practiced in Alberta and patients were primarily Caucasian, women, had a high household income and reported a history of previous yoga practice.

Since theory-informed design could play an important role in intervention efficacy, we propose additional research to build on these findings and further explore factors (e.g., emotions, personality traits, or past behaviour (Ajzen, 2011)) that may influence IBS patients' intention to use yoga as a therapy. Future research using theoretical frameworks should also measure behaviour to determine if intentions translated into yoga behaviour. Any intervention should consider patient barriers (e.g., cost) and facilitators (e.g., accountability) to doing yoga in various environments (e.g., virtual delivery) and support systems (e.g., group class). Lastly, considering the interests of GIs in virtually-delivered yoga interventions, we propose future research consider developing and testing the feasibility and efficacy of such programming.

Affective attitude, controllability, and self-efficacy are key theoretical correlates of intention to practice yoga in patients with IBS. Researchers can use these findings to develop theoretically salient supportive lifestyle interventions for this population. In addition, GIs may consider increasing their knowledge of yoga supported by evidence to provide therapeutic

options given that many IBS patients turn to these therapies. GI's attitudes toward such therapies play an important role in establishing a positive patient-physician relationship.

Authors' contributions:

AD was involved in all aspects of study design, recruitment, data collection and analysis, and is the lead author of the manuscript.

DM, JKV, YN, and LMT assisted with study design respective to their expertise.

YN provided their clinical expertise and patient recruitment through the clinic.

MR is the senior author and has guided the work of this research to support AD with their training.

All authors reviewed the manuscript for study design and provided critical insight into manuscript content and approved the final version for submission.

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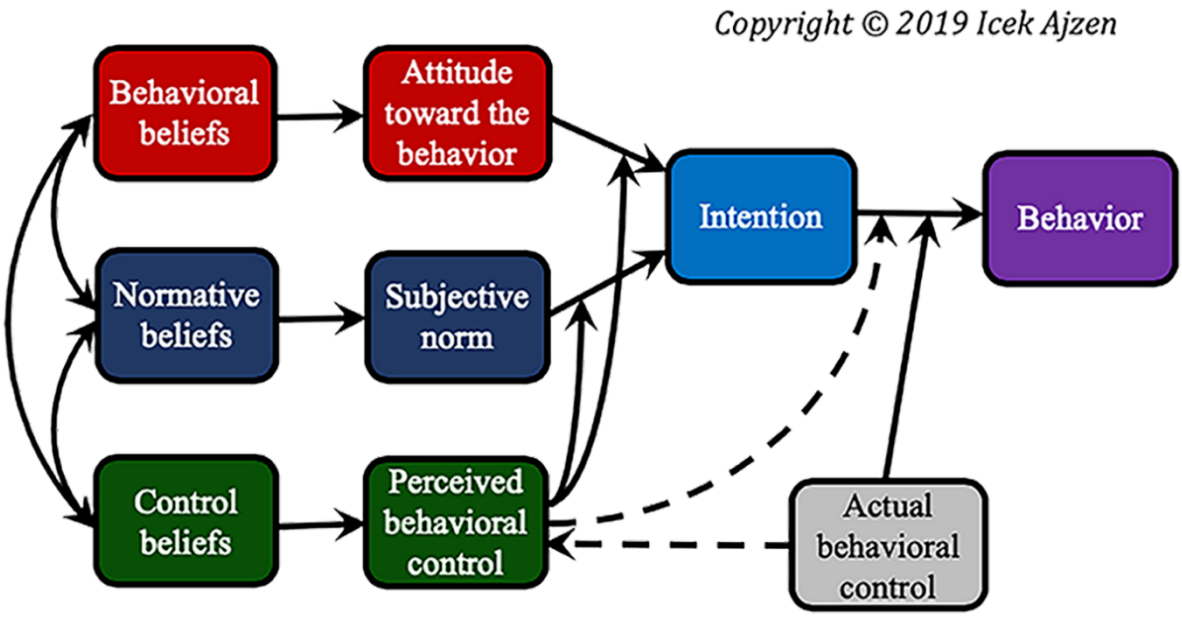

Figure 1. The Theory of Planned Behaviour.

Table 1. Patient characteristics (N=109)

	n (%)
Age (mean (SD))	43.0 (14.6)
Gender	
Women	100 (91.7)
Men	8 (7.3)
Transgender	1 (0.9)
Ethnicity	
Caucasian	96 (88.1)
Other	13 (11.9)
Marital Status	
Common law	14 (12.8)
Married	60 (55.0)
Never married	25 (22.9)
Separated or divorced	8 (7.3)
Education	
High school, trade, or apprenticeship	10 (9.2)
University or college	79 (72.5)
Graduate or professional school	20 (18.3)
Income	
≤$99,999	49 (45.0)
>$100,000	42 (38.5)
Prefer not to disclose	18 (16.5)
Currently on IBS medications	24 (22.0)
Currently taking over-counter supplements for IBS	56 (51.4)
Currently under the care of a gastroenterologist	23 (21.1)
Comorbidities*	
Anxiety	57 (52.3)
Depression	50 (45.9)
Chronic fatigue syndrome	3 (2.8)
Fibromyalgia	9 (8.3)
Chronic nausea	6 (5.5)
Acid reflux disease	27 (24.8)
Inflammatory bowel disease	14 (12.8)
Do you personally use/practice any CAM?*	59 (54.1)
Yoga	36 (33.0)
Mindfulness	31 (28.4)
Meditation	31 (28.4)
Cognitive behavioural therapy	12 (11.0)
Hypnotherapy	2 (1.8)
Acupuncture	16 (14.7)
Massage	31 (28.4)
Teas	27 (24.8)
Oils	21 (19.3)
Herbal medicines	22 (20.2)

Has your physician recommended you try any of the following?*	
Yoga	9 (8.3)
Mindfulness	9 (8.3)
Meditation	17 (15.6)
Breath watching	5 (4.6.)
Unsure	31 (28.4)
Has another health professional recommended you try yoga?	
Yes	25 (22.9)
No	70 (64.2)
Unsure	12 (11.0)
Have you ever practiced or tried yoga?	
Yes	99 (90.8)
Do you currently practice yoga?	
Yes	38 (34.9)
Do you plan on continuing to practice yoga?	
Yes	36 (97.4)
Would you be interested in trying yoga?	
Yes	63 (57.8)
No	2 (1.8)
Unsure	6 (5.5)
Which of the following would you prefer?*	
Attending an in-person yoga class	56 (51.4)
Doing yoga at home self-instructed	35 (32.1)
Doing yoga at home using online resources	83 (76.1)
No preference	8 (7.3)

Note: Other ethnicities include Chinese, Indigenous, Latin American, Middle Eastern, and South Asian; SD: standard deviation. Note. The responses may not add up to 100% due to missing values. *Respondents could select more than one option.

Table 2. Multiple regression analysis to predict intention among patients from the TPB variables (n=107).

Predictors	Untandardized β (95% CI)	R^2	*F*-ratio	df	*P*
Instrumental attitude	0.06 (-.35, .47)				.772
Affective attitude	0.35 (.01, .68)				.043*
Injunctive norm	-0.11 (-.39, .17)				.431
Descriptive norm	0.19 (-.02, .39)				.081
Self-efficacy	0.25 (.00, .50)				.044*
Controllability	0.51 (.17, .86)				.004**
Total model		.337	8.572	6	<0.001***

Note: β: unstandardized regression coefficient; CI: confidence interval; df: degrees of freedom. *p<.05; **p<.01, ***p<.001. Two patient records were missing data and were not included in this analysis.

Table 3. Most common self-reported behavioural, normative, and control beliefs of IBS patients regarding daily yoga practice (N=109).

	N
Behavioural beliefs	
Perceived advantages (*Response percentage 100%)	
Relaxation	62
Flexibility	51
Strength	22
Stress relief	19
Calming	17
Mindfulness	11
Pain management	10
IBS symptom management	8
Perceived disadvantages (*Response percentage 86%)	
Time	61
Lacking self-discipline	9
Cost	9
Don't know how	9
Lacking space	7
Previous health condition	7
Concerned how it will affect IBS	6
Fatigue	5
Normative beliefs	
People that would approve (*Response percentage 86%)	
Partner	66
Family	33
Friends	26
Doctor	23
People that would disapprove approve (*Response percentage 32%)	
Employer or coworkers	6
Me	3
Family	3
Religious group	3
Control beliefs	
Facilitators (*Response percentage 82%)	
Group class	21
Low cost	21
Instructor	21
Online classes	16
Accountability	15
Having the time	14
Scheduled	13
Weekly class	13
Videos or app	11
Barriers (*Response percentage 89%)	

Lack of time/scheduling	40
Cost	17
Feeling unwell	10
Transportation	12
Lacking space	8
Work commitments	8
Location	8
Lack of skill	8
IBS symptoms	7

Note: Respondents were asked to list (text free field) up to three answers for advantages, disadvantages, beliefs, supportive and unsupportive individuals, barriers, and facilitators.
*Response percentage indicates the number of respondents who provided at least one response for each question.

Table 4. Gastroenterologist characteristics and recommendation patterns of complementary and alternative medicine (N=79).

	n (%)
Age (years)	
30-39	18 (22.8)
40-49	28 (35.4)
50-59	22 (27.8)
60-69	9 (11.4)
70+	2 (2.5)
Gender	
Female	27 (34.2)
Male	52 (65.8)
Years of experience	
0-4	12 (15.2)
5-9	14 (17.7)
10-14	18 (22.8)
15-19	4 (5.1)
20-25	1 (1.3)
26 year or more	12 (15.2)
Clinical practice*	
Children (0-11 years)	6 (7.6)
Adolescents (12-17 years)	13 (16.5)
Adults (18+ years)	69 (87.3)
Province or territory	
Alberta	49 (62.0)
British Columbia	4 (5.1)
Manitoba	4 (5.1)
New Brunswick	2 (2.5)
Nova Scotia	4 (5.1)
Ontario	14 (17.7)
Quebec	2 (2.5)
Currently recommended CAMs*	
Yoga	31 (39.2)
Meditation	33 (41.8)
Mindfulness	39 (49.4)
CBT	43 (54.4)
Hypnotherapy	9 (11.4)
Acupuncture	11 (13.9)
Massage	11 (13.9)
Teas	7 (8.9)
Oils	7 (8.9)
Herbal medicines	16 (20.3)
Other**	4 (5.1)
Personally practice*	
Yoga	38 (48.1)

Meditation	24 (30.4)
Mindfulness	26 (32.9)
CBT	5 (6.3)
Hypnotherapy	0 (0.0)
Acupuncture	6 (7.6)
Massage	26 (32.9)
Teas	5 (6.3)
Oils	2 (2.5)
Herbal medicines	1 (1.3)
Other***	5 (6.3)
Willing to recommend yoga	
Yes	66 (83.5)
No	13 (16.5)
Reasons for not recommending yoga (n=13)*	5 (38.5)
Lack of evidence	3 (23.1)
Not beneficial	5 (38.5)
Reason not provided	
Yoga setting recommendation	
Home-based	12 (15.2)
Attend a class	35 (44.3)
Online or web-based	6 (7.6)

Note: CAMs: complementary and alternative medicines; CBT: cognitive behavioural therapy. The responses may not add up to 100% due to missing values. *Respondents could select more than one option; **Other includes cardiovascular exercise, CBD; ***Other includes exercise, acupressure, Pilates, chiropractic, prayer. Values may not add up to 100% due to missing data.

Table 5. GIs' attitudes, beliefs, and intentions to recommend yoga for patients with IBS (N=79).

	Agree n (%)	Neutral n (%)	Disagree n (%)
Attitudes and beliefs			
Yoga is safe for patients with IBS	73 (93.7)	3 (3.8)	2 (2.5)
Yoga reduces stress	69 (87.3)	7 (8.9)	3 (3.8)
Yoga improved health-related quality of life	67 (84.8)	9 (11.4)	3 (3.8)
Yoga reduces the symptoms of anxiety*	65 (82.3)	11 (13.9)	2 (2.5)
Yoga reduces the symptoms of depression	49 (62.0)	22 (27.8)	8 (10.1)
Yoga improves IBS symptom severity	43 (54.4)	29 (36.7)	7 (8.9)
GIs should recommend yoga to their patients with IBS	38 (48.1)	32 (40.5)	9 (11.4)
The scientific evidence to support the use of yoga as an effective treatment for IBS is lacking	35 (44.3)	30 (38.0)	12 (15.2)
I am confident in recommending yoga as an effective treatment for IBS	31 (39.2)	26 (32.9)	22 (27.8)
Yoga improves compliance with conventional IBS treatments	16 (20.3)	51 (64.6)	12 (15.2)
My colleagues approve of yoga as a treatment for IBS patients	15 (19.0)	48 (60.8)	15 (19.0)
Yoga interferes with conventional IBS treatments*	2 (2.5)	3 (3.8)	73 (92.4)
Web-based yoga program	Agree n (%)	Neutral n (%)	Disagree n (%)
I am willing to refer patients to a research study testing a web-based yoga program for IBS patients	68 (86.1)	6 (7.6)	5 (6.3)
A web-based yoga program has the potential to improve patients' engagement in their own care	62 (78.5)	13 (16.5)	4 (5.1)
I believe my patients would be interested in a web-based yoga program	60 (75.9)	14 (17.7)	5 (6.3)
I am willing to recommend a web-based yoga program to my patients with IBS	54 (68.4)	20 (25.3)	5 (6.3)
I am concerned about the safety of an online yoga program that is not supervised by a qualified instructor	8 (10.1)	16 (20.3)	54 (68.4)
	Likely n (%)	Neutral n (%)	Unlikely n (%)
Recommendation patterns			

How likely are you to recommend yoga as a treatment to your IBS patients?	43 (54.4)	21 (26.6)	15 (19.0)
How likely are you to recommend yoga to your IBS patients that is delivered face-to-face by a certified yoga instructor?	42 (53.2)	21 (26.6)	16 (20.3)
How likely are you to recommend yoga to your IBS patients that is delivered electronically (e.g., online videos, web-based) whose content is developed by a certified yoga instructor?	34 (43.0)	21 (26.6)	24 (30.4)

Note: SD: standard deviation. Responses were collected on a 7-point Likert scale from strongly disagree/very unlikely (1) to strongly agree/very likely (7) and means calculated based on these responses. Agreement (strongly agree/agree), neutral, and disagreement (disagree/strongly disagree) are grouped. *Values may not add up to 100 percent due to missing data.

Table 6. Barriers and facilitators for GIs to recommend yoga (N=79).

	n (%)
Barriers	
I do not have the *knowledge* on how or where to refer a patient	35 (44.3)
I do not have the *knowledge* on yoga to discuss it with the patient	32 (40.5)
I feel that patients will be concerned about the *cost* of doing yoga	32 (40.5)
I am not convinced of the literature on the *efficacy* with respect to yoga for IBS	30 (38.0)
There is limited *time* during a patient visit	28 (35.4)
This is not part of my regular clinic *routine*	27 (34.2)
My *training* does not qualify me to discuss it	15 (19.0)
I am not convinced of the literature on the *safety* with respect to yoga for IBS	4 (5.1)
Facilitators	
Having more *evidence* that supports the efficacy of yoga for IBS	68 (86.1)
Informational *resources* on yoga (e.g., pamphlets) that can be given to patients	54 (68.4)
Posters in the clinic so that patients can ask about yoga	31 (39.2)
Have in-clinic *support* to speak to patients about yoga	26 (32.9)
Having more *evidence* that support the safety of yoga for IBS	18 (22.8)

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CHAPTER FIVE

Meditation and Yoga for Irritable Bowel Syndrome: Study Protocol for a Randomized Clinical Trial (MY-IBS Study)

Meditation and Yoga for Irritable Bowel Syndrome:

Study Protocol for a Randomized Clinical Trial (MY-IBS Study)

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Abstract

Introduction: When delivered in person, yoga is effective in managing Irritable Bowel Syndrome (IBS) symptoms. Research is needed to test the feasibility and efficacy of yoga as a therapeutic option when delivered virtually. The primary aim of the Mind and Yoga for IBS (MY-IBS) randomized controlled trial is to determine the effects of an eight-week virtual meditation and yoga intervention on IBS symptom severity compared with an advice-only active control group.

Methods and analysis: Adults diagnosed with IBS will be randomized to receive either an Upa yoga intervention or an advice-only control group. The intervention will consist of weekly online classes for eight weeks delivered by a facilitator using Microsoft Office Teams and daily home practice. Feasibility will be evaluated by examining recruitment and attrition rates, adherence, participant satisfaction with the program, and safety. The primary outcome is IBS symptom severity, and key secondary outcomes include (but not limited to) quality of life, anxiety and depression symptoms, COVID-19 related stress and anxiety, and fatigue. Outcomes will be assessed at baseline, four weeks, and eight weeks. An embedded design experimental model sub-study will be conducted post-intervention using qualitative research methods to identify participants' experiences in the yoga program.

Ethics and dissemination: This study has been approved by the Conjoint Health Research Ethics Board (REB ID 20-0084). Findings will be disseminated through peer-reviewed publication, conference presentation, and social media.

Trial registration number: NCT04302623

Introduction

Stress is a physical, mental, or emotional response that causes tension in the mind or the body (Crosswell & Lockwood, 2020). Altered stress response from psychological and physiological mechanisms may contribute to altered brain-gut signalling patterns and IBS symptoms. Psychological stressors, such as depression and anxiety, may influence gut function (e.g., reduced motility). Physiological stressors (e.g., infection) in the gut may affect the brain (Mayer et al., 2015). Therapies focusing on mind-body interactions and stress reduction may be adjunctive treatments for IBS. Stress management techniques that include both mind and body interventions such as yoga (Schumann et al., 2016) have been effective in improving IBS symptom severity and mental health outcomes (Ballou & Keefer, 2017b; Schumann et al., 2016). Mind-body interventions may modulate the brain-gut axis directly by reducing sympathetic activity and increasing parasympathetic activity and the hypothalamus-pituitary-adrenal axis (Kavuri et al., 2015).

Yoga is a traditional *mind-body-breath* discipline that includes a triad of postures, structured breathing, and meditation (Brems et al., 2016). Our recent review (A. D'Silva, MacQueen, G., Nasser, Y., Taylor, L. M., Vallance J. K., Raman, M., 2019) identified four randomized controlled trials that examined traditional yoga practice as therapy for IBS patients (V. Kavuri et al., 2015; Schumann et al., 2018; Shahabi et al., 2016; Taneja et al., 2004). These trials demonstrated yoga was more effective compared to pharmacological treatment and equally effective as dietary interventions or moderate-intensity walking. Physical and mental health improvements included IBS symptom severity, gastric motility, and depression.

Research is needed to determine the feasibility and efficacy of virtual yoga programming as a therapeutic option for patients with IBS. The rationale for virtually delivered interventions to

manage IBS is increasing due to rising demand, limited healthcare resources, and cost-effectiveness (Hanlon et al., 2018; Knowles & Mikocka-Walus, 2014). A recent review found virtual care tools may be effective in managing disease activity and improving outcomes in patients with digestive diseases (Helsel et al., 2018). This review also highlighted the high acceptability and satisfaction with virtual care among patients with IBS (Dorn et al., 2015; Everitt, 2012; Hunt et al., 2009; Ljotsson et al., 2011; Ljotsson et al., 2010).

The primary objective of the MY-IBS (Meditation and Yoga for Irritable Bowel Syndrome) study is to explore the feasibility and efficacy of a virtual yoga program for patients with IBS. MY-IBS is a mixed-methods study including a randomized controlled trial and semi-structured interviews. The primary aim of this randomized controlled trial is to determine the effects of an eight-week virtual yoga intervention on IBS symptom severity, measured with the IBS Symptoms Severity Scale, compared to an advice-only control group. Secondary aims are to determine whether a) a yoga program delivered virtually is feasible for adults with IBS, b) improves health outcomes including quality of life, stress, and fatigue, and c) improves mental health outcomes including depression and anxiety symptoms. An embedded design experimental model qualitative sub-study using semi-structured interviews will explore and describe participants' experiences in the yoga program, and its impact. We hypothesize that the program will be feasible and effective in improving outcomes in the intervention group compared to the control group.

Methods

Study design overview

The quantitative study is a superiority randomized non-blinded two-group controlled trial. The qualitative study will use semi-structured interviews and thematic analysis to explore and describe intervention participant experiences and views of the yoga program.

Patient involvement

Patients with lived experience were involved in the conduct of this study. During the development stage, patient partners were invited to participate in a series of discussions with the research team to define the study research question, study design, choice of outcome measures, and methods of recruitment. Following the completion of the trial, the patient partners will be involved in the dissemination of this research.

Sample and selection

The MY-IBS stud will be conducted at the University of Calgary in Alberta, Canada starting March 2021 and ending early 2022. To be eligible in this study, participants must be diagnosed with IBS based on Rome IV criteria by a health care professional (e.g., physician, nurse, dietician), be 18-70 years old, have an adequate understanding of English, have an ability to provide written informed consent, score at least 75 out 500 points on the IBS Symptoms Severity Scale indicating mild IBS symptoms, and be on stable doses of medications for IBS (including anti-depressants) without major changes to diet or physical activity levels for at least eight weeks prior to starting the intervention. Individuals across Canada are eligible to participate. Exclusion criteria include a major physical impairment that would prevent the individual from doing yoga determined by either the patient or the study coordinator, and diagnosis of any major cognitive, psychological, or psychiatric disorder (e.g., major depression, schizophrenia) as identified by the treating physician or healthcare practitioner or screened by the study coordinator using the Patient Health Questionnaire-9.

Participants will be identified through (a) gastroenterology clinics across Calgary, Alberta; (b) gastroenterologists across Canada who indicated an interest in this study for their IBS patients in a previous survey conducted by our team (not published); (c) participants from the previous survey who indicated an interest in this study and have given consent to be contacted; (d) through social media; (e) self-referrals through the study website and the University of Calgary participate in research portal; (f) Canadian Association of Gastroenterologists monthly newsletter; and (g) participants with IBS who are enrolled in the IMAGINE (Inflammation, Microbiome and Alimentation Gastro-intestinal and Neuropsychiatric Effects) cohort study at the University of Calgary and have given their consent to be contacted for future studies.

Participant screening will use the Patient Health Questionnaire-9 (PHQ-9). Individuals who score 20 points or higher on the PHQ-9 indicating severe depression will not be eligible to participate. Reasons for exclusion are lack of compliance in interventional studies among these individuals, potential heterogeneity in the small sample size of participants, and skewed results if patients seek treatment for their depression during the trial.

Interventions

Yoga intervention group

Before their first class, the intervention group will receive an introductory video. The video will consist of information on IBS, information on the style of yoga they will be learning, and the rationale for yoga as a treatment for IBS. The intervention will be delivered online by a certified yoga facilitator in class sizes of less than ten participants using the Microsoft Office Teams platform. Classes will be held once per week for the eight-week duration. The first session will be approximately 90 minutes and subsequent sessions up to 60 minutes. The

introductory session will include the class setup, introductions, teaching poses, corrections, and a question and answers period. The yoga facilitator will provide participants with modifications for common challenges to support best practices and ensure safety. Subsequent classes will include a review from the previous week, a question and answer period, individual corrections and modifications, and introduce new practices. In addition to the online class component, study staff will ask participants to practice the yoga program at home every day. They will also have access to the yoga videos, written program instructions, and frequently answered questions accessible through the study website to help support their home practice (https://cumming.ucalgary.ca/research/ascend/resources/patient-resources/my-ibs).

Upa Yoga, developed by the Isha Foundation of Inner Sciences (https://isha.sadhguru.org/us/en), will be promoted. Upa Yoga maintains the ancient principles of Hatha Yoga and will be delivered by a certified yoga facilitator from the Isha Foundation. The Upa Yoga program will consist of (a) directional movements and neck rotations, (b) hatha yoga-based Yoga Namaskar, (c) breathing practices or alternate nostril breathing, (d) mantra meditation consisting of AUM chanting (OM), and e) breath watching. Table 1 shows a description of the program and rationale. Our published prospective study examining the efficacy of Upa Yoga in patients with Inflammatory Bowel Disease (Kaur et al., 2021) shows improvements in mental health scores after an eight-week yoga program.

Advice-only control group

Control participants will receive a video including general education on IBS, the mind-gut connection in IBS, and the role of mind-body therapies in the management of IBS. These participants will also receive a list of IBS-related resources from the Canadian Digestive Health Foundation, a link to an IBS patient support group (www.ibspatient.org), and information about

physical activity guidelines from the World Health Organization. Control participants will be eligible to attend a two-week yoga program and receive the yoga videos eight weeks from the time of enrolment. Data on these participants will not be collected as this participation option is for participants who desire to receive the yoga sessions outside of the study.

Outcome measures

Feasibility outcomes

Recruitment, attendance, and attrition rates. Recruitment will be calculated by the percentage of participants who complete the eligibility and enrollment phases of the study. Attrition will be calculated by the percentage of participants who complete all study measures at baseline and eight weeks. A feasible intervention will be defined as class attendance of at least 75 percent (i.e., attendance in six out of eight classes) (V. Kavuri et al., 2015) and an attrition rate of less than 30 percent.

Adherence. Adherence will be defined as practicing daily yoga for at least 80% of the days for eight weeks (or 45 out of 56 days minimum). Each week a practice log will be provided to monitor the frequency and length of yoga. The yoga facilitator will take attendance during each online class. To increase program adherence, the study coordinator will email intervention participants weekly. Six months following the completion of the intervention, participants will be asked to report the average frequency (i.e., days per month) and duration (i.e., minutes) of their yoga practices over the last seven days to evaluate long-term maintenance.

Program satisfaction. Intervention participants will complete a survey regarding overall satisfaction with their program, including satisfaction with videos and online class instruction. Videos and online classes will be deemed acceptable if at least 70% of participants are at least satisfied (i.e., rank classes as either good, great, or excellent). Participants will also indicate

whether they would recommend the program to others on a scale from 1 (strongly disagree) to 7 (strongly agree) and provide feedback on how the program could be improved.

Assessment of harms. The study coordinator will screen potential participants and exclude those with any physical problems that may limit participation with yoga postures. Participants will be asked to report any adverse events experienced during the study period. Participants with adverse events (e.g., injury resulting from the program) will be advised to consult their physician to provide care as appropriate.

Efficacy outcomes

The primary outcome, IBS symptoms, will be measured using the *IBS-Symptom Severity Scale (IBS-SSS).* The IBS-SSS is a five-question survey that asks about the severity of abdominal pain, frequency of abdominal pain, the severity of abdominal distention, dissatisfaction with bowel habits, and interference with QOL over the past 10 days. Scores on the IBS-SSS range from 0 to 500 with higher scores indicating more severe symptoms. Participants can be categorized as having mild (75-175), moderate (175-300), or severe (>300) IBS. Symptom reduction of at least 50 points is considered clinically meaningful.

Secondary outcomes (*and their measures*) include quality of life (*IBS-Quality of life*), anxiety (*Generalized Anxiety Disorder-7*), depression (*Patient Health Questionnaire-9*), stress (*Perceived Stress Scale*), COVID-19 stress (*COVID-19 Stress Scale*), fatigue (*Modified Fatigue Impact Scale-21*), somatic symptoms (*Patient Health Questionnaire-15*), and self-compassion (*Self Compassion Scale-Short Form*) (Table 2). Intention to practice yoga will also be assessed. The intervention and control groups will be assessed on efficacy outcomes at baseline, four, and eight weeks. The intervention group will complete measures of efficacy outcomes six months after the intervention.

Sample size

We will recruit twenty-five participants per group. However, assuming 30% attrition rate, we will aim to recruit 33 participants per group. Symptom reduction of at least 50 points is considered clinically meaningful, however, a group difference of 80 points has been shown to represent a considerable self-reported improvement (Francis et al., 1997). We calculated the sample size using a mean difference of at least 83 points on the IBS-SSS (α=0.05, β=0.80, standard deviation of 103.8) (V. Kavuri et al., 2015).

Randomization, treatment allocation, and blinding

The study flow is shown in Figure 1. The study coordinator will obtain consent from participants who will then be enrolled in the study. Participants will be randomized after baseline assessment to either the yoga intervention or the advice-only control group. A statistician blinded to the randomization key will create a computer-generated REDCap randomized sequence to allocate participants based on gender (1:1:1 man:woman:other) and depression (1:1 depression:no depression). Participants will be aware of the group to which they are allocated, however, the principal investigator and data analyst will remain blinded to the randomization process.

Data management

All quantitative data will be entered into a secure REDCap database at the University of Calgary. Efficacy outcome measures, program satisfaction, attendance, and adherence will be entered by the participants. Recruitment, attrition, and safety will be recorded by the study coordinator who is not blinded to the randomization. After the study, data will be downloaded, and patient identifiers will be removed from the data file. Data will be stored in a password-protected file on a University of Calgary password-protected computer. The interviews will be

transcribed, deidentified, and uploaded to the University of Calgary's secure SharePoint site. Only the research team will have access to the data.

Data analysis

Descriptive analysis will summarize participant characteristics and feasibility outcomes. Univariate analysis of variance (ANOVA) will examine baseline differences between groups for variables with continuous data. Chi-square tests will examine baseline differences between groups for categorical variables. Unadjusted ANOVA and adjusted analysis of covariance (ANCOVA) models will compare differences in scores from baseline and post-intervention data within and between groups using the intent-to-treat analysis for primary and secondary outcome measures. A multivariate logistic regression model examining determinants of responders (a minimum improvement of at least 50 points on the IBS-SSS scale) versus non-responders will be developed to predict a response to the intervention. This model will consider practice in minutes, baseline depression, anxiety, and IBS symptom severity scores. An α of 0.05 will be the threshold for determining statistical significance. If the frequency of missing data is >5%, we will perform additional analyses using imputation methods. The analysis will be conducted using SPSS version 26.

Post-intervention interviews

Participants who were randomized to the intervention and did not withdraw from the study will be invited by email to participate in an interview. We aim to recruit women and men and have equal representation of those who benefited from the program (i.e., experienced improvements in their IBS symptom severity) as well as individuals who did not. We anticipate needing to interview between 10 and 15 participants to reach both code and meaning saturation (Hennink, Kaiser, & Marconi, 2017) aiming for a maximum variation sample.

Semi-structured interviews will capture participants' experiences, program satisfaction, facilitators and barriers to participation, perceptions of social support and supervised learning, perceived impact on IBS symptoms and overall physical and mental health, and input on improving future programming (Table 3). Interviews will happen virtually using Microsoft Office Teams and be approximately 30 to 45 minutes in length. The study coordinator will interview the participants, take notes during the interview, and reflect following each interview. Interview recordings will be transcribed verbatim without identifying information. Data will be coded and analyzed in duplicate using NVivo 12. Thematic analysis inductively reveals patterns and themes providing an understanding of participant experiences, with the program and their perspectives on its impact. Thematic analysis is a method for systematically identifying, organizing, and offering insight into patterns of meaning (themes) across a data set (Braun, 2006). This method makes sense of shared meanings and experiences that allows the researcher to identify what data is important to the research question (Braun, 2021).

Discussion

The MY-IBS study aims to determine the feasibility and efficacy of an eight-week virtual yoga and meditation program combined with the home-based practice for patients with IBS. Determining feasibility will be based on study recruitment, adherence, safety, and program satisfaction. Improved IBS symptom management (the primary outcome) will determine intervention efficacy. Secondary outcomes include quality of life, stress, fatigue, depression, anxiety, COVID-19-related stress and anxiety, and self-compassion. These findings will inform potential predictors of responders versus non-responders. Predictors may be considered in clinical practice to target the IBS patients most likely to benefit from the yoga intervention.

Interview themes and patterns will refine and inform the development of future virtual yoga programming designed for IBS patients.

To our knowledge, there are no studies of virtual yoga and meditation in the IBS population. The findings from this study may have implications for the management of IBS. The virtual delivery of yoga represents an opportunity to increase access to effective management therapies for patients with IBS. The COVID-19 pandemic has called for the reorganization of health care including the utilization of virtual care. Nearly 90% of care in the United States has been delivered virtually since the pandemic (Kendzerska et al., 2021). Due to the COVID-19 pandemic, there is increased psychological distress and gastrointestinal symptoms among individuals with IBS (Kamp et al., 2021; Oshima et al., 2020) compared to individuals without IBS (Sabate et al., 2021). The present study offers a unique opportunity to examine prospectively the feasibility and efficacy of a yoga and meditation program delivered virtually to individuals living with IBS with the COVID-19 pandemic restrictions taken into consideration. Study findings may aid in developing interventions and services tailored to patients with IBS. New insight into outcomes will be beneficial for healthcare leaders in planning how to allocate existing resources to support these services and potentially lessen the burden of IBS on both the individual and the healthcare system.

Ethics and dissemination

Ethics

The study protocol, informed consent form, and other study documents were reviewed and approved by the University of Calgary's ethics board. All protocol modifications will be submitted for review and approval by the ethics board. The trial participants will be informed of

any modifications, and re-consented by the study coordinator, if required. Further, the trial registry for this study will be updated.

Participation is voluntary and will not influence standard clinical care. All participants will provide informed written consent and have the right to withdraw from the study at any time. Pending consent from the participant, all data collected up to the time of withdrawal will be used in the final data analyses as advised by the CONSORT guidelines (Moher et al., 2010).

Dissemination

Our targeted knowledge users and audiences will include researchers, healthcare professionals and service providers, persons with lived experiences, community groups, and professional organizations (e.g., Canadian Association of Gastroenterology). Our goal will be to increase topic area knowledge among these groups and inform future research. Our strategies will include conference presentations, publication in a peer-reviewed journal, social media campaigns, development of virtually delivered tools such as mobile applications to increase accessibility and affordability and educational material distributed through the Digestive Health Foundation, IMAGINE SPOR Chronic Disease Network, and Primary Care Networks across Alberta.

Table 1. Overview of the Upa Yoga program.

Program Component	Description	Rationale
Directional Movement of the Arms	This practice involves extending the arms in four directions (sideways, front, up and down) by rotating the wrists, while consciously focusing on the inhalation and exhalation of breath with each movement.	Studies show that fibromyalgia is common among patients living with IBS (Erdrich, Hawrelak, Myers, & Harnett, 2020). This could lead to pain in the muscles and joints, fatigue, and sleep concerns. The principle behind this practice is to lubricate the fluids in the joints, increase circulation and activate the energy nodes in these joints. Doing these practices every day can relieve muscle and joint stiffness and reduce pain over time. This practice is recommended by the Isha Foundation to increase strengths and flexibility in preparation for Yoga Namaskar.
Neck Practices	There are five sets of neck practices, each stretching the neck and the final one working on the shoulder area.	The main cause of neck pain is usually muscle tension. Perceived stress can increase muscle tension. These neck exercises help relieve stress that can aggravate IBS symptoms. This practice is recommended by the Isha Foundation to increase strength and flexibility in preparation for Yoga Namaskar.
Yoga Namaskar	This practice involves a series of seven consecutive steps of upper body stretching and squatting, aligned with breath.	This practice activates the lumbar region of the spine and strengthens the spinal muscles (Vasudev, 2021). While Yoga Namaskar has not been specifically studied in patients with IBS, yoga squatting postures have been associated with a significant decrease in depression among nine individuals with IBD (Kaur et al., 2021) and anxiety in a randomized self as control study in 30 healthy subjects (Chandrasekeran, 2014).
Alternate Nostril	The participant sits cross-legged with the spine comfortably erect and eyes closed.	Alternate nostril breathing is traditionally considered to

Breathing (Nadi Shuddhi)	Closing the right nostril with the thumb, inhaling and exhaling through the left nostril. This is repeated on the right nostril by closing the left nostril with the ring finger.	alleviate mental unrest and promote physical and mental balance (Cramer, Lauche, Klose, Langhorst, & Dobos, 2013; Saraswati S. M, 1985). It has been demonstrated to decrease perceived stress and improve autonomic function in a randomized control trial compared to control subjects in healthy male volunteers and decreased state anxiety in a prospective study (Naik, Gaur, & Pal, 2018; Telles, Vishwakarma, Gupta, & Balkrishna, 2019).
Mantra Meditation (AUM chanting)	The participants sit cross-legged, and with eyes closed, uttering each of these 3 sounds 7 times. The important aspect of this utterance is the awareness of the reverberations each of the sounds produces in the corresponding parts of the body: a - below the navel, o - mid-point of the chest, m - pit of the throat.	This mantra is thought to facilitate the energy flow, and through vibratory mechanisms, creates peace and harmony leading to increased mental alertness and may improve symptoms of depression (Rao et al., 2018; Telles, Nagarathna, & Nagendra, 1995).
Breath watching	The participants sit cross-legged with eyes closed and hold a hand gesture called the Yoga Mudra (the tips of the thumb and index finger come together forming a circle). They are instructed to maintain a gentle focus on the mid-point between both eyebrows (at the level of the pineal gland) while being conscious of the gentle movement of breath happening in their body.	Breathing in a focused manner can be used as a tool to promote positive changes to the mind, body and emotions (Arch & Craske, 2006). A significant reduction in the level of state anxiety was found in a group of healthy male volunteers when they practiced breath awareness.

Table 2. Efficacy outcomes measures.

Measure	Description	Scoring	Time	
Primary outcome			**Baseline**	**8 weeks**
IBS-Symptom Severity Scale (IBS-SSS)	The IBS-SSS is a five-question survey that asks the severity of abdominal pain, frequency of abdominal pain, severity of abdominal distention, dissatisfaction with bowel habits, and interference with QOL over the past 10 days. Subjects respond to each question on a 100-point visual analogue scale[22]. The IBS-SSS scale is the most frequently used severity measure for evaluating IBS severity and is commonly used as an outcome measure in clinical trials because it is highly responsive to change with treatment[22].	Scores on the IBS-SSS range from 0 to 500 with higher scores indicating more severe symptoms. Participants can be categorized as having mild (75-175), moderate (175-300), or severe (>300) IBS. Symptom reduction of at least 50 points is considered clinically meaningful; however, the primary endpoint will be the proportion of participants in each group who demonstrate a symptom reduction of 83 points or more, based on the variables used in the sample size calculation[22].	✓	✓
Secondary outcomes				
IBS-Quality of life (IBS-QOL)	The IBS-QOL is a 34-item questionnaire that assesses the degree to which IBS interfered with QOL over the past 30 days. Each item is rated on a 1 to 5 Likert scale, with higher values indicating a lower QOL[25]. The IBS-QOL is currently the most validated and highly responsive self-reported QOL measure specific to IBS that can be used to assess the impact of IBS and its treatment[25].	The individual responses to the 34 items are summed and averaged for a total score and then transformed to a 0-100 scale for ease of interpretation with higher scores indicating better IBS specific QOL[25]. An increment of at least 14 points on the IBS-QOL scale from baseline will demonstrate efficacy.	✓	✓
Generalized Anxiety Disorder (GAD-7)	GAD-7 is seven items, score from 0 (not all at) to 3 (nearly every day), providing a severity score between 0-21. Scores of 5, 10, and 15 represent cut points for mild, moderate, and severe anxiety. The GAD-7 also is effective at identifying the presence of other anxiety disorders including panic disorder, social anxiety disorder, and post-traumatic stress disorder[26].	A 5-point change on the GAD-7 is considered clinically significant.	✓	✓

Physical Health Questionnaire (PHQ-9)	The PHQ-9 is a 9-item survey with each item scored from 0 (not at all) to 3 (nearly every day) totalling from 0 to 27 points. Scores of 5, 10, 15, and 20 represent cut points for mild, moderate, moderately severe and severe depression. The PHQ assesses major depressive disorder, panic disorder, and anxiety disorder[27].	A 5-point change is considered clinically significant.	✓	✓
Perceived Stress Scale (PSS)	The PSS is a 14-item survey that measures perceived stress, or the degree to which situations in one's life are appraised as stressful, on a four-point scale (0=never, 4=very often) over the last 30 days. The PSS is the most widely used psychological instrument for measuring the perception of stress[29].	An 11-point change is considered clinically significant [28].	✓	✓
COVID-19 Stress Scales (CSS)	COVID-19 related stress and anxiety will be measured using the 36-item CSS survey on five scales: (1) COVID danger and contamination fears, (2) COVID fears about economic consequences, (3) COVID xenophobia, (4) COVID compulsive checking and reassurance-seeking, and (5) COVID traumatic stress symptoms[33].	Not reported.	✓	✓
Modified Fatigue Impact Scale-21.	This is a self-reported questionnaire consisting of 21 statements that reflect the perceived impact of fatigue on cognitive, physical, and psychosocial functioning. Participants are asked to rate the extent to which fatigue has caused problems for them during the last four weeks. Each item is rated on a 5-point scale reflecting how often the person is limited in activities by fatigue, ranging from 0 (never) to 4 (almost always)[31].	A 16-point change is considered clinically significant[30].	✓	✓
Patient Health Questionnaire-15 (PHQ-15)	The PHQ-15 measures the severity of 15 somatic symptoms (e.g., fatigue, energy, sleeping trouble, and pain) during the past 4 weeks for a score of 0 to 30. Items can be scored as 0 (not at all), 1 (bothered a little), or 2 (bothered a lot). PHQ-15 scores of 5, 10, and 15 represent cut	A 5-point change on the PHQ-15 is considered clinically significant.	✓	✓

	points for low, medium, and high somatic symptom severity, respectively[32].			
Self-Compassion Scale – Short Form (SCS-SF)	Participants will be asked to complete a 12-item self-reported scale measuring their self-compassion, including self-kindness, self-judgement, humanity, isolation, and mindfulness subscales. To encourage their practice and feelings of self-compassion, participants will receive self-compassion messages weekly by email.	Subscale scores are computed by calculating the mean of subscale items responses. Participants will indicate how often they behave in the stated manner, using a scale from 1 (almost never) to 5 (almost always) for a total of 60 points with lower scores indicating more self-compassion[34].	✓	✓

Table 3. Semi-structured interview questions and probes.

1. **What have you done in the past to manage your IBS?**
    a. Have you tried yoga or mediation?
    b. Have you tried exercise?

2. **I would like to start by asking you what you were hoping for or expecting from the program?**
    a. Why did you join this study?
    b. Did anyone influence your decision to join?
    c. Did that meet your expectations?

3. **Next, I would like to discuss your overall experience in the MY-IBS yoga program in which you participated. Could you describe for me what participating in this program was like for you?**
    a. What did you like most about it?
    b. What didn't you like?
    c. Did this change over the course of the program?

    Sub-questions: *yoga facilitator/supervision, the timing of sessions/scheduling, length of sessions, attending with other members, online experience versus in-person, social support/other participants.*

    d. What was that like?
    e. What stood out for you?
    f. What emotions were you aware of at the time?
    g. What else do you remember about that experience?

4. **How has participating in this program affected how you manage or live with your IBS?**

    Sub-questions: *change in IBS symptoms; physical health, fatigue; mental health - stress, anxiety, depression; feeling better about myself; ability to live with my IBS.*

    a. Tell me more about that.
    b. Can you give me an example of what you mean?
    c. How has that affected you?

5. **What, if anything, has helped you to do your practices at home?**

    Sub-questions*: social support, family support, convenience*

    a. Tell me more about that.
    b. Can you give me an example of what you mean?
    c. How has that affected you?

6. **What challenges did you have, if any, doing your practices at home?**

    Sub-questions*: family, supervision/safety, schedule/time*

    a. Are you satisfied with how you did?
    b. Tell me more about that.

   c. Can you give me an example of what you mean?
   d. How has that affected you?

7. **What, if anything, has helped you to attend the weekly online class?**
   Sub-questions*: social support, family support, HCP support, yoga facilitator, supervision/safety, online classes, schedule/length*
   a. Tell me more about that.
   b. Can you give me an example of what you mean?
   c. How has that affected you?

8. **What challenges did you have, if any, to attend the weekly online class?**
   Sub-questions*: social support, family, yoga facilitator, supervision/safety, online classes, schedule, technical difficulties*
   a. Are you satisfied with how you did?
   b. Tell me more about that.
   c. Can you give me an example of what you mean?
   d. How has that affected you?

9. **We are interested in any ideas you have about how we might make this program better. What could we do differently?**
   Sub-questions: *content, timing, facilitator, videos, website, delivery, other supports*
   a. Would you explain that further?
   b. Can you give me an example of what you mean?

10. **Based on your experience with yoga, would you incorporate yoga to help manage your IBS? If so, how?**

11. **Before we conclude, is this anything else you would like to say about your experience with this program, that we haven't had a chance to talk about yet?**

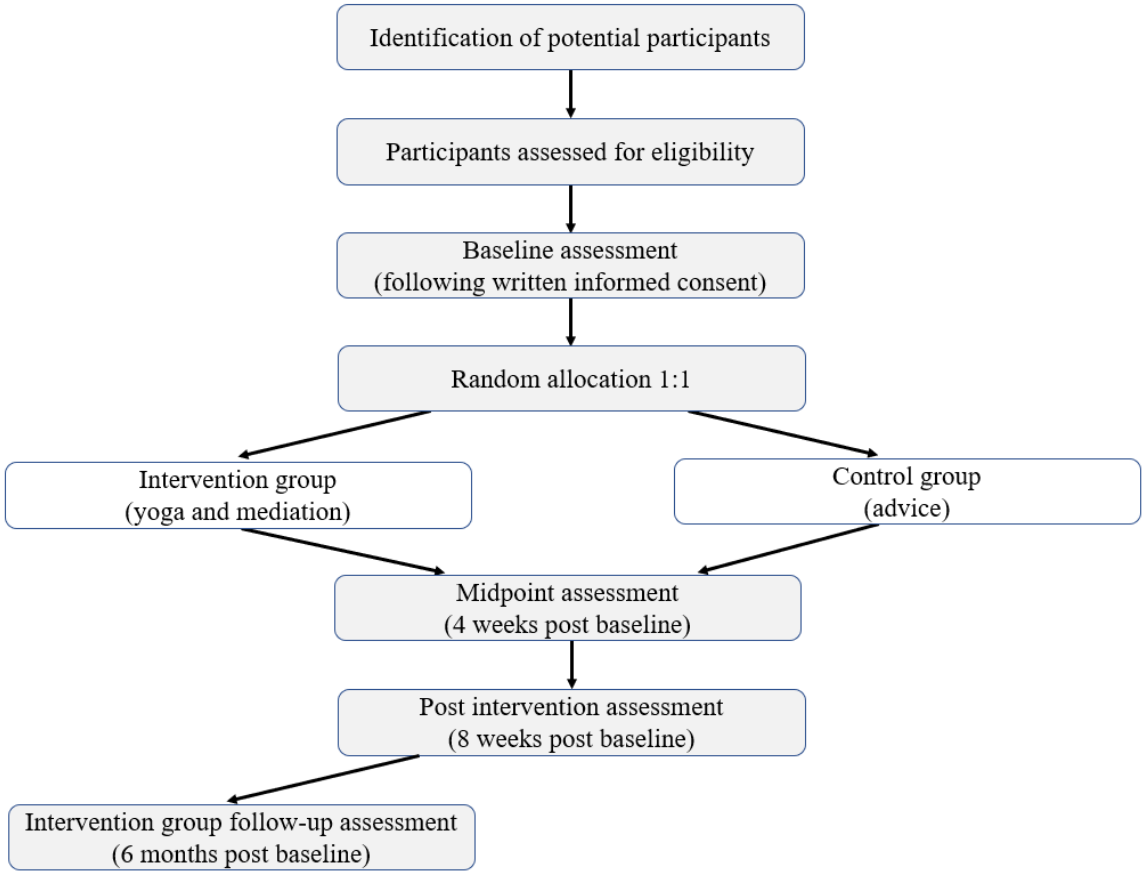

Figure 1. Participant flowchart based on the CONSORT guidelines.

Strengths and limitations of this study:

- Mixed methods study composed of a trial and interviews
- First virtual yoga intervention in Irritable Bowel Syndrome
- Canada-wide recruitment
- Self-reported outcome measures
- Lack of data capture on frequency of yoga practice in the control group

Authors' contributions: State how each author was involved in writing the protocol.

AD is involved in all aspects of protocol design and lead author of the manuscript. DM, JKV, YN, VR, and GM assisted with design of the protocol respective to their expertise. DM and GM assisted with the qualitative aspects of the protocol. JKV lead the statistical aspects of the protocol. YN provided their clinical expertise and patient recruitment through the clinic. VR provided their expertise in yoga therapy. MR is the senior author on the protocol and has guided the work of this research to support AD with their training. All authors reviewed the manuscript for study design and provided critical insight into manuscript content and approved the final version for submission.

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Data availability: Deidentified participant data will be made available upon reasonable request from the study principal investigator.

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CHAPTER SIX

Meditation and Yoga for Irritable Bowel Syndrome (MY-IBS Study): A Randomized Clinical Trial

Meditation and Yoga for Irritable Bowel Syndrome (MY-IBS Study):

A Randomized Clinical Trial

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Abstract

Background: Delivered in person, yoga is effective in managing Irritable Bowel Syndrome (IBS) symptoms. In other chronic conditions, yoga delivered virtually is feasible in the COVID-19 context. The evidence for efficacy, feasibility, and safety of virtually delivered yoga for IBS patients is unknown.

Methods: Adults diagnosed with IBS were randomized to either Hatha yoga intervention of eight weekly online classes delivered virtually and daily home practice or an advice-only control group and assessed at baseline and post-intervention. We used an unadjusted analysis of variance (ANCOVA) to determine differences between and within groups on the primary outcome (decrease of ≥50 points in IBS symptom severity (IBS-SSS)), and secondary outcomes (quality of life, anxiety and depression, fatigue, somatic symptoms, perceived stress, COVID-19 stress, and self-compassion). We assessed feasibility through recruitment and attrition rates, adherence, participant satisfaction, and safety (i.e., adverse events). Applying the Theory of Planned Behavior (TPB), we assessed the association between baseline intention to practice yoga and total yoga practice minutes and between total practice minutes and change in IBS-SSS using multivariate logistic regression analysis.

Results: Seventy-nine people participated (mean age 45.4 years (SD=14.0), 92% women). IBS-SSS decreased significantly in the treatment group (Δ_{change}=54.7, p=0.028), but not in the control group (Δ_{change}=22.6, p=0.277). Fourteen patients (37%) in the yoga group reached a clinically relevant decrease of ≥50 points on the IBS-SSS post-intervention compared to eight patients (20%) in the control group (p=0.242). No significant difference was found between groups in IBS-SSS score post-intervention (p=0.149) but significant differences in favour of the treatment group for quality of life (p=0.030), fatigue (p=0.035) and perceived stress (p=0.040) were identified. In the treatment group, 97% had high intentions at baseline and 34% post-intervention. Intention was not significantly associated with yoga practice in minutes (p=0.288) or change in IBS-SSS scores from baseline to post-intervention (p=0.52). The yoga program demonstrated feasibility.

Conclusion: Virtually delivered yoga is safe and feasible, and effective in reducing IBS symptoms. Based on the primary endpoint, the intervention was not superior to an advice-only control group.

Ethics: This study has been approved by the Conjoint Health Research Ethics Board (REB ID 20-0084).

Trial registration number: NCT04302623.

Introduction

Irritable bowel syndrome (IBS) is a common chronic condition frequently involving alterations of the gut-brain axis. IBS is associated with psychiatric comorbidities, incomplete symptom control, and impaired quality of life (QOL) (Drossman, 2016). Altered stress response from psychological and physiological mechanisms may contribute to altered brain-gut signalling patterns and IBS symptoms (Mayer et al., 2015). Therapies focusing on mind-body interactions and stress reduction may be adjunctive treatments for IBS.

Yoga is a mind-body therapy that includes physical postures (asanas), breathing exercises (pranayama), and meditation (Schumann et al., 2016) to improve physiological, psychological, and emotional health (Rioux, 2015). Yoga interventions have been evaluated for IBS in adult and adolescent populations (Evans, Seidman, Lung, Sternlieb, & Zeltzer, 2018; V. Kavuri et al., 2015; Kuttner L, 2006; Ljotsson et al., 2011; Schumann et al., 2018; Shahabi et al., 2016; Taneja et al., 2004; Zernicke et al., 2013). Proposed mechanisms of action for yoga target the brain-gut axis directly by reducing sympathetic activity, increasing parasympathetic activity and modulating hypothalamus-pituitary-adrenal axis function (Kavuri et al., 2015). Yoga may be as effective as pharmacotherapy, cognitive-behavioural therapy, exercise, and the low FODMAP diet to reduce IBS symptoms, symptoms of anxiety and depression, and stress in IBS patients (Peterson et al., 2017; Ross & Thomas, 2010; Schumann et al., 2016). The rationale for virtually-delivered interventions to manage IBS is increasing due to limited healthcare resources and higher cost-effectiveness (Hanlon et al., 2018; Knowles & Mikocka-Walus, 2014). A yoga program delivered virtually is convenient and feasible in a COVID-19 setting (Emard et al., 2021; Selman et al., 2015; Winters et al., 2020) and post-pandemic where virtual care is accepted and

expected. There is no evidence to demonstrate the feasibility and efficacy of virtually delivered yoga for IBS patients.

The primary objective of the Meditation and Yoga for Irritable Bowel Syndrome (MY-IBS) study was to examine the efficacy and feasibility of a virtual eight-week yoga program on IBS symptom severity compared to an advice-only control group. Secondary objectives were to determine a) whether a virtual yoga program improves the QOL, mental health outcomes, perceived stress, fatigue, COVID-19-related stress, and self-compassion, and b) the level of intention to practice yoga at baseline and whether intention correlated with practice minutes.

Methods

Study design overview

MY-IBS was a randomized two-group controlled trial conducted at the University of Calgary in Alberta, Canada from March 2021 to December 2022. Participants were not blinded to trial arms. Eligible participants were diagnosed with IBS based on Rome IV (B. Lacy & Patel, 2017) criteria by a health care professional (e.g., physician, nurse, dietician), were 18-70 years old, had an adequate understanding of English, scored at least 75 out of 500 points on the IBS Symptoms Severity Scale indicating at least mild IBS symptoms (Francis et al., 1997), and were on stable doses of medications for IBS (including anti-depressants) without major changes to diet or physical activity patterns for at least eight weeks before starting the intervention. Exclusion criteria included a major physical impairment that would prevent the individual from doing yoga determined by either the patient or the study coordinator and diagnosis of any major cognitive, psychological, or psychiatric disorder (e.g., major depression, schizophrenia) as identified by the treating physician or healthcare practitioner or screened by the study coordinator using the

Patient Health Questionnaire-9. Individuals who scored 20 points or higher on the PHQ-9 indicating severe depression were not eligible to participate.

Individuals across Canada were eligible to participate. Participants were recruited between March and October 2021 and identified through a) gastroenterology clinics across Calgary, Alberta, b) participants from a previous survey who indicated an interest in this study and provided consent to be contacted, c) social media, d) self-referrals, e) Canadian Association of Gastroenterologists monthly newsletter, and f) participants with IBS who are enrolled in the IMAGINE (Inflammation, Microbiome and Alimentation Gastro-intestinal and Neuropsychiatric Effects) cohort study at the University of Calgary.

Interventions

Yoga intervention group

The details of the yoga program have been published elsewhere (D'Silva, 2022) and are briefly summarized here. Upa Yoga was developed by the Isha Foundation of Inner Sciences and maintains the ancient principles of Hatha Yoga. The yoga program was delivered by a certified yoga facilitator from the Isha Foundation. The Upa Yoga program consisted of a) directional movements and neck rotations, b) Hatha yoga-based Yoga Namaskar, c) breathing practices or alternate nostril breathing, d) mantra meditation consisting of AUM chanting (OM), and e) breath watching. The intervention was delivered online weekly for eight weeks. Classes were delivered in sizes of three-to-seven participants using the Microsoft Office Team® platform for approximately 60 minutes. The participants were also asked to practice at home every day with the support of yoga videos.

Advice-only control group

Control participants received a brief video including general education on IBS, the mind-gut connection in IBS, and the role of mind-body therapies in the management of IBS. These participants also received a list of IBS-related resources from the Canadian Digestive Health Foundation, a link to an IBS patient support group (www.ibspatient.org), and information about physical activity guidelines from the World Health Organization. The intervention group did not receive these resources.

Outcome measures

Efficacy outcomes

The intervention and control groups were assessed on efficacy outcomes at baseline and eight weeks. The primary endpoint measure was at least a 50-point difference on the *IBS-Symptom Severity Scale (IBS-SSS)* between the groups post-intervention (Francis et al., 1997; B. E. Lacy et al., 2021).. Scores on the IBS-SSS range from 0 to 500 with higher scores indicating more severe symptoms. Participants can be categorized as having mild (75-175), moderate (176-300), or severe (>300) IBS.

Secondary outcomes (*and their measures*) include quality of life (*IBS-QOL*) (Patrick et al., 1998), anxiety (*Generalized Anxiety Disorder-7*) (Spitzer, Kroenke, & Williams, 2006), depression (*Patient Health Questionnaire-9*) (Kroenke, Spitzer, & Williams, 2001), perceived stress (*Perceived Stress Scale*) (Cohen, Kamarck, & Mermelstein, 1983), COVID-19-related stress (*COVID-19 Stress Scale*), fatigue (*Modified Fatigue Impact Scale-21*) (Chwastiak et al., 2005), somatic symptoms (*Patient Health Questionnaire-15*) (Kroenke, Spitzer, & Williams, 2002), and self-compassion (*Self Compassion Scale-Short Form*) (Neff, 2003).

The Theory of Planned Behavior (TPB) was applied to determine whether the intention to practice yoga at baseline correlated with practice minutes. Intention to practice yoga was

measured from 1 (very unlikely) to 7 (very likely) with “I intend to do yoga daily for 30-40 minutes for the next eight weeks”.

Feasibility outcomes

Attrition was calculated by the percentage of participants who completed all study measures at baseline and eight weeks. *Adherence* was defined as class attendance of at least 75 percent (i.e., attendance in six out of eight classes) (V. Kavuri et al., 2015) and an attrition rate of less than 30 percent. *Assessment of harms* was based on any adverse events experienced during the yoga intervention (e.g., physical injury). *Program satisfaction* was evaluated with a survey, including overall rating of the program (poor, ok, good, great, and excellent), and satisfaction with videos and online class instruction on a scale from 1 (strongly disagree) to 7 (strongly agree). Program satisfaction was achieved if at least 70% of participants were satisfied (i.e., rank the program as either good, great, or excellent). Participants also indicated whether they would recommend the program to others.

Sample size

Symptom reduction of at least 50 points on the IBS-SSS is considered clinically meaningful (Francis et al., 1997). A considerable patient-reported improvement has been determined to be 80 points (Francis et al., 1997). The sample size (25 per group) was calculated using a mean difference of at least 80 points on the IBS-SSS (α=0.05, β=0.80, standard deviation of 103.8) (V. Kavuri et al., 2015). Assuming a 30% attrition rate, we aimed to recruit 33 participants per group.

Randomization, treatment allocation, and blinding

Participants were randomized after baseline assessment to either the yoga intervention or the advice-only control group. A statistician blinded to the randomization key created a

computer-generated REDCap randomized sequence to allocate participants. Participants were aware of the group to which they were allocated. The principal investigator and data analyst remained blinded to the randomization process.

Data analysis

Participant characteristics and feasibility metrics for both treatment and control groups as well as program adherence for the treatment group only were summarized using descriptive statistics. Fisher Exact tests examined baseline differences between groups for categorical variables. Percentages were calculated to determine the proportion of participants in each group who reached clinical significance.

Adjusted analysis of variance (ANOVA) was used to determine the differences between and within groups in the primary and secondary outcomes after the intervention. Multiple comparisons (i.e., post hoc) were adjusted using Bonferonni corrections. Multiple multivariate logistic regression to examine determinants of response to intervention. Responders were defined as individuals with a reduction of 80 points or more on the IBS-SSS scale (Schumann et al., 2018). Baseline scores for efficacy outcomes, attendance, and practice minutes were considered for inclusion based on correlation with response. Potential variables with a correlation p-value greater than 0.20 were included in the regression models to analyze potential determinants of response.

Fisher Exact tests were used to determine whether the proportion of individuals falling in each intention category differed between treatment and control groups at baseline and post-intervention separately and if any changes in proportions of intentions between baseline and post-intervention. In the treatment group only, regression analysis was used to determine if intention predicts total yoga practice in minutes and whether there was a relationship between

total practice minutes and change (baseline to week 8) in IBS-SSS. All analysis was conducted using RStudio version 1.4.1717 using R version 4.1.1.

Results

Participant characteristics

A total of 142 patients expressed interest in participating and 63 were excluded (see Figure 1 for exclusion reasons). The remaining 79 participants were randomized to the yoga group (n=38) or the control group (n=41). Patient characteristics are summarized in Table 1. The mean age was 45.4 years (SD=14.0). The majority of patients were women (92.4%) and Caucasian (81%). The mean IBS diagnosis duration was 11.5 (SD=10.7) years. There were no baseline differences between groups in socio-demographic variables.

Primary outcome

The sample mean IBS-SSS was moderate at 245.3 (SD=86.6) points at baseline and 207.9 (SD=100.21) at week 8. The percentage of patients meeting the ≥50-point decrease in IBS-SSS post-intervention was 37% (n=14) in the yoga group compared to 20% (n=8) in the control group (p=0.242). In the yoga group, the IBS-SSS score decreased from 255.2 (SD=90.7) at baseline to 200.5 (SD=103.9) post-intervention (Δ_{change}=54.7, p=0.028) and from 236.1 (SD=82.6) at baseline to 213.5 (SD=98.5) post-intervention in the control group (Δ_{change}=22.6, p=0.277). The difference between groups in IBS-SSS was 32.1 points and this difference was not significant (p=0.149) (Table 2).

Sub-group exploratory analysis of responders

Twenty-two patients were included in the responder analysis [14 (51.8%) and 8 (22.2%)] (i.e., responders in the treatment and control groups). The difference between the groups was

non-significant (p=0.143). Responders (n=22) reported improved IBS symptoms, QOL, perceived stress, and COVID-19 stress. In the treatment group, there were significant improvements in IBS symptoms (Δ=124.6), QOL (Δ=19.7), fatigue (Δ=12.7), somatic symptoms (Δ=3.4), self-compassion (Δ=4.4), and COVID-19-related stress (Δ=14.1). In the control group, responders improved significantly in IBS symptoms (Δ=132.1) and COVID-19-related stress (Δ=9.1). The proportion of change (i.e., from baseline to post-intervention) in outcome measures for treatment and control groups is shown in Table 3.

Determinants of response (variables with <0.2 p-value on their correlations) were perceived stress (p=0.125), self-compassion (p=0.009), COVID-19 stress (p=0.097), and total practice minutes (p=0.005). Perceived stress [odds ratio (OR)=-0.49, 95% CI: 0.25, 0.95, p=0.035], self-compassion (OR=0.68, 95% CI: 0.50, 0.93, p=0.016), COVID-19 stress (OR=1.09, 95% CI: 1.01, 1.78, p=0.025), and total practice minutes (OR=1.003, 95% CI: 1.001, 1.004, p=0.007) were predictors of response. The multivariable model, including determinants of response above, suggested that every additional minute a patient practices, they are 1.003 times more likely to be a responder. The mean overall practice minutes in the responder group (for those who received treatment) is 1213.6. The mean overall practice minutes in the non-responder group (for those who received treatment) is 594.8, for a difference of 618.8 minutes. Practicing 618.8 minutes more over eight weeks (or 77.4 minutes per week) resulted in being almost five times more likely to be a responder.

Secondary outcomes

We observed between group differences post-intervention favouring the treatment group for QOL, fatigue, and perceived stress (Table 2). There was a significant improvement in the treatment group in QOL (Δ-11.6), fatigue (Δ=-7.3), somatic symptoms (Δ=-1.9), perceived stress

(Δ=-2.3), and COVID-19-related stress (Δ=-8.4). In the control group, improvements were seen only in COVID-19-related stress (Δ=-6.2). There were no significant improvements in anxiety, depression, or self-compassion within groups. Although the changes in depression scores are not significant, between group differences were in favour of yoga (Δ=-0.5) compared to the control group (Δ=0.2). Anxiety scores were unchanged in both groups.

Previous yoga experience and intention to do yoga

Most participants had tried yoga in the past. Intention to do yoga was 6.5 (SD=0.7) at baseline and 4.0 (SD=1.8) at eight weeks for the treatment group and 6.5 (SD=0.6) at baseline and 5.2 (SD=1.7) at eight weeks for the control group. There was a significant change in proportions of intention to do yoga from baseline to post-intervention for both groups (treatment $p<0.001$; control $p<0.001$). In the treatment group, 97% had high intentions at baseline and 34% post-intervention. Low intentions increased from zero percent at baseline to 26% post-intervention. In the control group, 100% had high intentions at baseline, and 63% at 8-weeks. Low intentions increased from zero percent at baseline to 17% post-intervention. These differences were not significant between groups post-treatment ($p=0.058$). Participants were more likely to indicate neutral and low levels post-intervention, and this occurred more frequently for the treatment group. Intention was not significantly associated with yoga practice in minutes ($\beta=140$, $t=1.09$, $p=0.288$) or change in IBS-SSS scores from baseline to post-intervention ($\beta=0.025$, $t=0.66$, $p=0.52$).

Feasibility outcomes

The attrition rate was 20% (29% and 12% in the treatment and control groups, respectively). In the treatment group, seven out of eleven participants were randomized to the intervention but did not start the program, two participants withdrew due to changing work

schedules, one participant was hospitalized for a non-IBS-related concern, and one participant did not provide a reason. Average class attendance was 79% (SD=20%). Treatment participants accumulated an average of 1220.9 (SD=513.7) minutes doing yoga. No adverse or safety events were reported. Forty-one percent of participants rated the program as excellent, 30% as great, and 29% as good. All participants strongly agreed the practice videos and feedback on their practices were helpful and the yoga facilitator was knowledgeable and approachable. Fifty-two percent strongly agreed they would recommend the program to other IBS patients

Discussion

The MY-IBS study is the first to demonstrate the feasibility and safety of an eight-week virtual yoga program combined with the home-based practice for patients with IBS compared to an advice-only control group. The sample had moderate IBS symptom severity at baseline. Significant within-group improvements in IBS symptoms were observed in the treatment group only. We did not find significant differences in IBS symptoms between groups post-intervention as measured by the IBS-SSS. Based on an improvement of 50 points or more on the IBS-SSS, 37% of the treatment participants and 20% of the control participants were classified as responders, and this difference was not significant. One other study(V. Kavuri et al., 2015) comparing a 12-week supervised yoga program to a combination group (yoga program and conventional treatment) and advice only wait-list control group identified responders using an improvement of 50 points or more on the IBS-SSS as the threshold of clinically significant symptom improvement. This study found 100% of the treatment participants and 22% of controls were responders at week 12. The response in the control group may be explained by the high placebo effect in IBS. Based on a meta-analysis of 19 studies examining the placebo response in complementary and alternative medicine trials of IBS, the rate was 42.6% (Dorn et al., 2007).

Taken together, virtually delivered yoga is safe and feasible, and effective in reducing IBS symptoms. However, based on the primary endpoint, the intervention was not superior to an advice-only control group.

To our knowledge, there are no studies evaluating yoga delivered virtually in the IBS population. In-person yoga interventions have been evaluated among adult IBS patients in four other randomized controlled trials (RCTs) with various comparison groups described below (V. Kavuri et al., 2015; Schumann et al., 2018; Shahabi et al., 2016; Taneja et al., 2004). Our findings on the primary outcome of interest (IBS symptom severity) are comparable to those observed in an RCT comparing 16 sessions of supervised Iyengar yoga delivered over 12 weeks (n=17) to a bi-weekly supervised outdoor moderate-intensity walking program control group (n=10) (Shahabi et al., 2016). The yoga group demonstrated a significant decrease in IBS severity measures (a mean decrease of 3.4 points on a 21-point scale). Similarly, in an RCT that compared the efficacy of an unsupervised yoga intervention including 12 postures and breathing twice a day for two months to loperamide 2-6 mg/day for two months in 22 males with diarrhea-predominant IBS, both groups showed improvements in the primary outcome of bowel symptoms scores (yoga: 1.55±1.81; loperamide: 2.75±1.48, $p<0.001$; Talley's Bowel Disease Questionnaire with scores ranging from 0 to 7) with no significant between group differences (Taneja et al., 2004). However, an RCT comparing a 12-week supervised yoga program consisting of posture, relaxation, breathing and meditation (and participants were asked to reduce their prescription medications and supplements used for IBS, if any, to three days a week) to a combination group (the same yoga program and conventional treatment including continued medication, if any) and an advice only wait-list control group (continuation of medications, if any, and advice to walk 60 minutes three times per week for 12 weeks) in 78 IBS patients found a significant difference

between both yoga and control groups (Δ=226.31±16.; p<0.001) and combination and control groups (Δ=189.72±16.63; p<0.001) in IBS symptom scores (V. Kavuri et al., 2015).

We also determined predictors of yoga response using a reduction of 80 points on the IBS-SSS. Fifty-two percent of the treatment participants and 22% of the control participants were classified as responders. One other study (V. Kavuri et al., 2015) identified responders using an improvement of 50 points or more on the IBS-SSS as the threshold of clinically significant symptom improvement. This study found 100% of the treatment participants and 22% of controls were responders at week 12. Responders in our study reported improved IBS symptoms, QOL perceived stress, fatigue, somatic symptoms, and COVID-19-related stress. The response in the control group may be explained by the high placebo effect in IBS. Based on a meta-analysis of 19 studies examining the placebo response in complementary and alternative medicine trials of IBS, the rate was 42.6% (Dorn et al., 2007). Our prediction model suggests increased perceived stress is less likely to result in a response, while high self-compassion and greater practice time are more likely to result in a response. Although these finding are statistically significant, they are not clinically meaningful and would not change clinical practice. Therefore, future research should continue to explore predictors or response to determine predictive criteria that helps identify those patients with IBS who are most likely to respond. These predictors may be considered in clinical practice to select the IBS patients most likely to benefit from the yoga intervention.

Our study suggests beneficial effects of yoga for QOL, fatigue, somatic symptoms, perceived stress, and COVID-19-related stress among IBS patients. These outcomes were not frequently assessed in the other RCTs. Stress and somatic symptom improvements have been found only in the yoga group in three separate RCTs (V. Kavuri et al., 2015; Schumann et al.,

2018; Shahabi et al., 2016). Fatigue was not assessed in the aforementioned RCTs and based on a meta-analysis examining fatigue prevalence in IBS, the search did not yield any interventional studies for comparison (Han & Yang, 2016). However, the literature on other chronic diseases such as cancer (Song et al., 2021) and multiple sclerosis (Cramer, Lauche, Azizi, Dobos, & Langhorst, 2014) suggests yoga interventions are effective at managing fatigue.

We did not observe any within-group or between-group differences for anxiety and depression, especially considering the evidence base for yoga for each condition (Cramer et al., 2018; Cramer, Lauche, Langhorst, & Dobos, 2013). The lack of significance may be driven both by the low baseline levels of anxiety and depression and a sample size powered to detect changes in IBS symptoms. Similar to this study, other RCTs reported mixed findings, with two studies finding improvements in anxiety (Shahabi et al., 2016) and depression (Schumann et al., 2018; Shahabi et al., 2016) in the yoga group and another study not finding any significant between group differences in anxiety. However, within group differences were observed for both groups (Taneja et al., 2004). In contrast, another RCT found both within and between group differences (V. Kavuri et al., 2015). The differences in yoga interventions and comparator groups make it challenging to compare our findings to other studies as some of these studies did not report baseline anxiety and depression.

The yoga intervention in this study was feasible in terms of adherence (79%), attrition rate (20%), and high program satisfaction. Adherence was reported in three of the previously described RCTs, varying from 62-90% (V. Kavuri et al., 2015; Schumann et al., 2018; Shahabi et al., 2016). The attrition rate is also comparable to the other RCTs varying from 5-24%. Safety was also demonstrated without any adverse events. We also explored participants' intention to practice yoga over the next eight weeks. Intention to practice yoga was higher at baseline in the

treatment group, but there was a significant decrease in proportion in intentions for both groups. A decrease of 63% in intention from baseline to post-intervention among the treatment group is unexpected, especially considering the demonstrated feasibility and high satisfaction with the program. This finding may be due to the lack of improvement in IBS symptoms among some participants.

Strengths and limitations

This study is the first to evaluate the efficacy and feasibility of a virtual yoga intervention. The yoga intervention was developed by an international yoga foundation and delivered by an experienced yoga instructor and at-home practice was supported by videos. We recruited patients from across Canada, using heterogeneous recruitment methods including gastroenterologist offices, primary care physician clinics, and social media. These results may not be generalizable as our sample is largely composed of educated Caucasian women with a high family income. Our data is also limited by the lack of data capture on the frequency of yoga practice, if any, in the control group. Lastly, our sample did not include patients with severe depression. Lastly, seven out of eleven treatment participants did not start the intervention.

Future studies should consider including objective measures of autonomic function testing (e.g., electrocardiogram), sympathetic reactivity tests (e.g., mental arithmetic test), and parasympathetic reactivity tests (e.g., heart rate variability in deep breathing) to determine physiological mechanisms of yoga efficacy. Future studies with a larger sample size should also investigate the effects of yoga on IBS subgroups (IBS-D, C, or M) individually and the long-term effects of yoga.

Conclusion

Our study results suggest that virtually delivered yoga is safe and feasible. Yoga improved IBS symptoms and a breadth of other psychological and physiological outcomes that are understudied but frequently affect patients with IBS. The intervention was also found to be safe without any adverse events. The virtual delivery of yoga represents an opportunity to increase access to effective management therapies for patients with IBS. Combining the convenience and flexibility of virtual programs and the social benefits of in-person interactions into hybrid programming may improve program efficacy, intervention adherence, and patient outcomes.

Authors' contributions:

AD was involved in all aspects of study design, recruitment, data collection, and is the lead author of the manuscript.

DM, JKV, YN, and VR assisted with study design respective to their expertise.

JH led the statistical analysis.

YN provided their clinical expertise and patient recruitment through the clinic.

VR provided their expertise in yoga therapy and facilitated classes.

MR is the senior author and has guided the work of this research to support AD with their training.

All authors reviewed the manuscript for study design and provided critical insight into manuscript content and approved the final version for submission.

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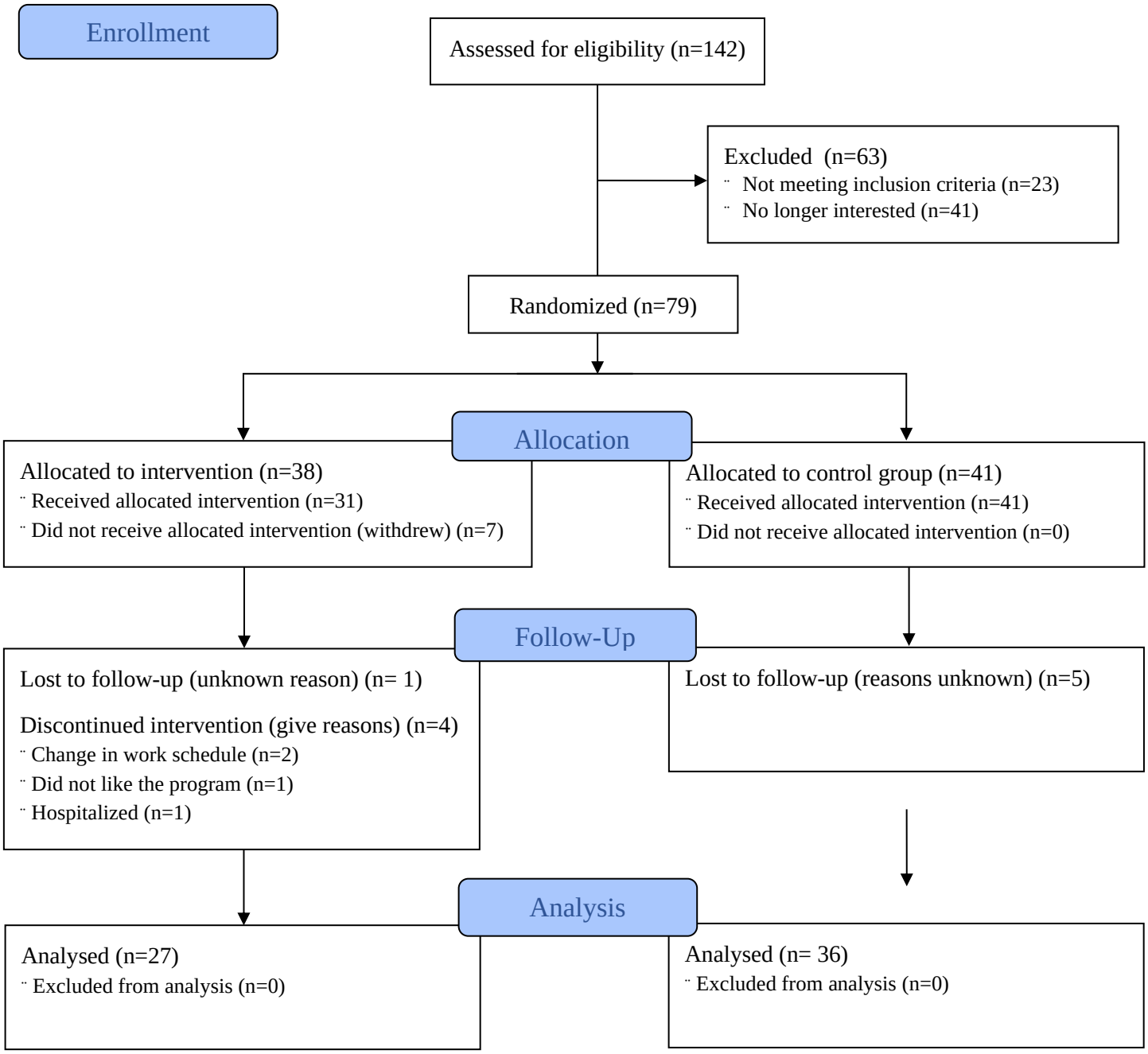

Figure 1. Participant flowchart based on the CONSORT guidelines.

Table 1. Participant baseline socio-demographic characteristics by group (N=79).

	n (%)		
	Overall (N=79)	**Control (n=41)**	**Treatment (n=38)**
Gender (women)	73 (92.4)	37 (90.2)	36 (94.7)
Age (mean (SD))	45.37 (14.0)	47.10 (14.8)	43.50 (12.9)
Ethnicity			
Caucasian	64 (81.0)	36 (87.8)	28 (73.7)
Other*	15 (19.0)	5 (12.2)	10 (26.3)
Marital status**			
Married	40 (65.6)	20 (60.6)	20 (71.4)
Never Married/Widowed	21 (26.6)	13 (31.7)	8 (21.1)
Diagnosis duration in years (mean (SD))	11.51 (10.7)	11.56 (11.8)	11.45 (9.5)
IBS type			
Constipation-predominant	16 (20.3)	7 (17.1)	9 (23.7)
Diarrhea-predominant	29 (36.7)	19 (46.3)	10 (26.3)
Mixed (diarrhea and constipation)	30 (38.0)	13 (31.7)	17 (44.7)
Unsure	4 (5.1)	2 (4.9)	2 (5.3)
Current therapies			
Prescription IBS medications	15 (19.0)	6 (14.6)	9 (23.7)
Over counter supplements for IBS	44 (55.7)	23 (56.1)	21 (55.3)
Restricted diet	43 (54.4)	22 (53.7)	21 (55.3)
Cognitive behavioural therapy	12 (15.2)	5 (12.2)	7 (18.4)
Hypnotherapy	1 (1.3)	1 (2.4)	0 (0.0)
Relaxation therapy	5 (6.3)	3 (7.3)	2 (5.3)
Stress management therapy	6 (7.6)	4 (9.8)	2 (5.3)
Comorbidities			
Celiac disease	1 (1.3)	1 (2.4)	0 (0.0)
Inflammatory bowel disease.	72 (91.1)	38 (92.7)	34 (89.5)
Gastroesophageal reflux disease	25 (31.6)	14 (34.1)	11 (28.9)
Functional dyspepsia	3 (3.8)	1 (2.4)	2 (5.3)
Peptic ulcer disease	1 (1.3)	0 (0.0)	1 (2.6)
Dysphagia	2 (2.5)	1 (2.4)	1 (2.6)
Chronic fatigue syndrome	2 (2.5)	2 (4.9)	0 (0.0)
Fibromyalgia	5 (6.3)	3 (7.3)	2 (5.3)
Chronic pelvic pain	3 (3.8)	2 (4.9)	1 (2.6)
Migraine or tension headaches	25 (31.6)	13 (31.7)	12 (31.6)
Temporomandibular joint disorder	9 (11.4)	5 (12.2)	4 (10.5)
Experience with yoga			
I currently practice yoga	3 (3.8)	3 (7.3)	0 (0.0)
I have practiced yoga regularly in the past, but do not currently practice	23 (29.1)	9 (22.0)	14 (36.8)
I have tried yoga a few times in the past, but do not currently practice.	45 (57.0)	23 (56.1)	22 (57.9)
I have never tried yoga	8 (10.1)	6 (14.6)	2 (5.3)

*Other ethinicities include Black, Indigenous, South American, Middle Easterns, and South Asian.
**Missing data: 22.8%

Table 2. Within and between group differences in primary and secondary efficacy outcomes (N=79).

	Treatment (n=38)				Control (n=41)				Difference in difference between groups[a]	Difference in difference between groups
	Baseline	Week 8	Δ_{change}	p-value[b]	Baseline	Week 8	Δ_{change}	p-value[c]		p-value[d]
Primary endpoint[e]										
IBS Symptoms	255.2 (90.7)	200.5 (103.9)	-54.7	0.028*	236.1 (82.6)	213.5 (98.5)	-22.6	0.277	-32.1	0.149
Secondary endpointse										
Quality of Life	87.6 (21.9)	75.9 (22.1)	-11.6	0.047*	83.6 (26.9)	78.3 (28.0)	-5.3	0.399	-6.3	0.030*
Depression	7.5 (3.6)	7.0 (4.0)	-0.5	0.069	6.9 (3.8)	7.1 (4.6)	0.2	0.828	-0.7	0.056
Anxiety	5.9 (3.5)	5.9 (3.7)	0.06	0.199	5.6 (4.6)	6.1 (5.6)	0.5	0.703	-0.4	0.112
Fatigue	38.1 (11.4)	30.7 (18.0)	-7.3	0.045*	36.2 (17.4)	32.9 (19.6)	-3.3	0.433	-4.0	0.035*
Somatic symptoms	12.8 (3.1)	10.9 (3.6)	-1.9	0.116	12.8 (3.7)	11.9 (4.1)	-0.9	0.292	-1.0	0.077
Perceived stress	6.6 (2.3)	4.3 (3.6)	-2.3	0.074	6.7 (2.6)	6.2 (3.4)	-0.5	0.472	-1.8	0.040*
COVID-19 stress	20.2 (17.1)	11.7 (10.9)	-8.4	0.005**	22.2 (12.9)	16.1 (12.6)	-6.2	0.037*	0.3	0.142
Self-compassion	17.18 (5.66)	18.89 (4.89)	1.7	0.297	17.68 (5.4)	19.14 (6.06)	1.5	0.270	-2.3	0.219

Note: All baseline and week 8 are presented as means (standard deviation). *p<0.05; **p<0.01. [a]Testing the difference between the change in the treatment group (baseline and week 8) and the change in the control group (baseline and week 8). [b]This p-value tests the change from baseline to week 8 in the treatment group. [b] This p-value tests the change from baseline to week 8 in the control group. [c] This p-value tests the difference between groups. [a]Analyzed using ANCOVA.

Table 3. Changes in outcome measures for treatment and control groups among responders (n=22).

	Treatment (n=14)			Control (n=8)		
	Baseline	Week 8	p-value	Baseline	Week 8	p-value
IBS Symptoms	278.6 (82.7)	150.1 (81.2)	<0.001***	262.9 (75.5)	130.8 (91.4)	0.007**
Quality of Life	92.6 (21.4)	72.9 (22.0)	0.024*	78.1 (24.9)	72.0 (24.9)	0.630
Depression	8.0 (3.4)	6.5 (2.7)	0.202	6.3 (3.9)	5.8 (5.7)	0.840
Anxiety	5.9 (3.4)	4.5 (2.4)	0.235	4.4 (5.0)	5.4 (8.0)	0.769
Fatigue	37.5 (11.6)	24.8 (17.9)	0.034*	26.6 (15.9)	22.5 (17.8)	0.633
Somatic symptoms	12.9 (3.5)	9.6 (3.7)	0.020*	11.6 (2.8)	9.5 (3.7)	0.221
Perceived stress	5.9 (1.4)	5.21 (2.83)	0.454	5.3 (2.4)	7.3 (3.0)	0.162
COVID-19 stress	26.2 (15.0)	12.1 (10.4)	0.007**	18.9 (5.3)	20.8 (7.4)	0.569
Self-compassion	14.1 (5.0)	18.6 (5.1)	0.028*	16.1 (9.0)	7.0 (5.2)	0.026*
Note: All values are presented as means (standard deviation). *p<0.05; **p<0.01; ***p<0.001.						

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CHAPTER SEVEN

Experiences of irritable bowel syndrome patients in a virtual yoga program: Qualitative findings from a clinical trial

Experiences of Irritable Bowel Syndrome Patients in a Virtual Yoga Program: Qualitative Findings from a Clinical Trial

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Abstract

Background and aims: In-person yoga interventions have shown feasibility and efficacy in improving the outcomes of irritable bowel syndrome (IBS) patients, but experiences in virtual yoga interventions have not been examined. This study aimed to explore patients' experiences of a virtually delivered yoga intervention for IBS.

Methods: An embedded qualitative sub-study was included in a randomized controlled trial examining the feasibility and efficacy of a virtual yoga program among adult IBS patients. Semi-structured interviews captured participants' past and current experiences, program satisfaction, perceived impact on IBS symptoms and overall physical and mental health, facilitators and barriers to participation, perceptions of social support and supervised learning, and input on improving future programming. Data were coded and analyzed in duplicate using NVivo 12. An analytic template based on the interview guide was developed and thematic analysis identified themes, as well as the relationship between themes and sub-themes.

Results: Among the 14 participants (all women, mean age 47.7 years), three major themes were identified: (1) positive experience in the yoga program including reasons for joining the program, program efficacy, change in experience over time, controllability and self-efficacy, things liked and disliked about the program, barriers and facilitators, (2) incorporating yoga into IBS management, and (3) recommendations for program improvement.

Conclusion: IBS patients' experience in a virtual yoga program was positive with improvements in physical and mental health outcomes. Considering the barriers and facilitators to participating in an online yoga program along with participant recommendations may improve future intervention design and delivery to increase self-efficacy and confidence among IBS patients.

Keywords: irritable bowel syndrome, yoga, meditation, qualitative, virtual health.

Ethics and dissemination: This study has been approved by the Conjoint Health Research Ethics Board (REB ID 20-0084).

Introduction

Yoga offers a complementary approach to the management of irritable bowel syndrome (IBS) with improvements in mental health, symptom severity, and quality of life in both adult and adolescent populations (Evans et al., 2018; V. Kavuri et al., 2015; Kuttner L, 2006; Ljotsson et al., 2011; Schumann et al., 2018; Shahabi et al., 2016; Taneja et al., 2004; Zernicke et al., 2013). In-person yoga interventions have demonstrated safety, feasibility, and efficacy (A. D'Silva, MacQueen, G., Nasser, Y., Taylor, L. M., Vallance J. K., Raman, M., 2019; Schumann et al., 2016), but only one study explored participants' experiences in a yoga program among 18 adolescents (Evans et al., 2018). The adolescents noted the importance of home practice and parental support to achieve maximal, sustained benefits and inclusion of accessible skills by adding guided mediation and breathing exercises for yoga interventions (Evans et al., 2018). No study to date has evaluated adult participant experiences in a virtual yoga program for adult IBS patients. Virtually delivered cognitive behavioural therapy has shown efficacy while offering accessibility and cost savings for IBS patients compared to face-to-face delivery (Sugaya, Shirotsuki, & Nakao, 2021). Virtual care tools may be effective in managing disease activity and improving outcomes in patients with digestive diseases (Helsel et al., 2018) and have been found to have high acceptability and satisfaction among IBS patients (Dorn et al., 2015; Everitt, 2012; Hunt et al., 2009; Ljotsson et al., 2011; Ljotsson et al., 2010).

The MY-IBS (Meditation and Yoga for Irritable Bowel Syndrome) randomized controlled trial (RCT) was conducted to explore the feasibility and efficacy of a virtual eight-week yoga program for patients with IBS. The trial aimed to determine the feasibility and the effects of the yoga program on IBS symptom severity, mental health, quality of life, stress, fatigue, COVID-19-related stress, and self-compassion, compared to an advice-only control group. The results of

the RCT study have been published elsewhere (A. D'Silva, Marshall, D. A., Nasser, Y., Taylor, L. M., Vallance, J. K., Raman, M., 2022). An embedded design experimental model qualitative sub-study using semi-structured interviews was included in the RCT. The aim of this sub-study was to explore and describe participants' experiences in a virtual yoga program, and its impact.

Methods

Sample and selection

Participants were eligible to participate in the RCT if they were diagnosed with IBS based on Rome IV criteria by a health care professional (e.g., physician, nurse, dietician), 18-70 years old, had an adequate understanding of English, scored at least 75 out 500 points on the IBS Symptoms Severity Scale indicating mild IBS symptoms, and were on stable doses of medications for IBS (including anti-depressants) without major changes to diet or physical activity levels for at least eight weeks before starting the intervention. Individuals across Canada were eligible to participate. Exclusion criteria included a major physical impairment that would prevent the individual from doing yoga determined by either the patient or the study coordinator or diagnosis of any major cognitive, psychological, or psychiatric disorder (e.g., major depression, schizophrenia) as identified by the treating physician or healthcare practitioner or screened by the study coordinator using the Patient Health Questionnaire-9. Participants who were randomized to the yoga program and did not withdraw from the study (n=27) were invited by email to participate in an interview. We anticipated needing to interview between 10 and 15 participants to reach both code (heard it all) and meaning saturation (understand it all) (Hennink et al., 2017). The study protocol was approved by the University of Calgary Conjoint Health Ethics Board (REB20-0084) and the trial was registered (NCT04302623).

Yoga program

The details of the yoga program have been published elsewhere (A. D'Silva, Marshall, D. A., Nasser, Y., Taylor, L. M., Vallance, J. K., Raman, M., 2022) and are briefly summarized here. Upa Yoga, developed by the Isha Foundation, maintains the ancient principles of Hatha Yoga and was delivered by a certified yoga facilitator from the Isha Foundation. The Upa Yoga program consisted of a) directional movements of the arms and neck rotations, b) Hatha yoga-based Yoga Namaskar, c) breathing practices or alternate nostril breathing, d) mantra meditation consisting of AUM chanting (OM), and e) breath watching. The intervention was delivered online weekly for eight weeks in class sizes of less than ten participants using the Microsoft Office Teams platform for approximately 60 minutes. The participants were also asked to practice at home every day.

Study design

The embedded experimental model is a mixed-methods design in which one data set provides a supportive, secondary role in a study based primarily on the other data type (J. W. Creswell & Clark, 2011). Researchers use this design when they need to combine qualitative or quantitative data to answer different, but related, research questions within a largely qualitative or quantitative study. In the embedded design-experimental model, the researcher can include qualitative data to follow up on the results of an experiment. A qualitative approach is appropriate for exploring meaning related to participants' subjective experiences during interventions (Cramer, Lauche, Haller, et al., 2013). This method was selected based on its alignment with the proposed research and its ability to interpret the study findings based on both quantitative and qualitative findings.

Data collection

The semi-structured interview guide and questions are provided in Table 1. The interview guide was organized into the following domains: 1) previous yoga experience and reasons for joining, 2) current experience in the program, and 3) recommendations for future programming. The interviews were conducted virtually using Microsoft Office Teams and ranged between 20 to 60 minutes in length. The study coordinator (AD) interviewed the participants, asking probing questions to further explore relevant themes and topics as they emerged, took notes during the interview, and reflected following each interview. Interview recordings were transcribed verbatim by one of the study investigators (VR). Interviews were conducted with all participants who wished to interview, but coding saturation was reached by interview eight and meaning saturation was reached by interview eleven.

Data analysis

Data were coded and analyzed in duplicate by AD and ZI using NVivo 12, and descriptive statistics were utilized to analyze the demographic variables using SPSS 28. The coders developed an analytic template consisting of parent and child codes based on the interview guide. This template was reviewed by a senior qualitative researcher (GM) and updated as the interviews were coded to accommodate emerging nodes. Subsequently, this template was refined to develop an initial list of broader themes that represented the current patterns in the data and applied across all transcripts.

Each transcript was read and re-read, and memoing was done to record our thinking along the way about patterns and meanings of the data. The first step in the analytic process was to have two researchers independently code the first five transcripts, compare their coding, debate any inconsistencies, and make needed changes to the analytic template. The coders

continued to meet weekly to discuss their coding of the remaining interviews and communicated any changes in the analytic template. Once the initial coding was completed, a thematic analysis process was used to identify patterns and themes and inductively reveal an understanding of participant experiences in the program (Braun, 2021). This stage of the analysis involved re-organizing codes into three main themes and continuing to memo about each theme and sub-theme, as well as relationships between these themes. This involved one researcher, who immersed themselves in re-reading interviews, quotes under codes and using a mind-mapping tool to explore relationships. A visual representation (concept map) was developed in NVivo to capture the key findings of the study. A final list of themes and subthemes was discussed with the senior qualitative researcher (GM).

Results

Participant characteristics

Fourteen of the 27 treatment participants agreed to participate in an interview, and their characteristics are summarized in Table 2. The participants were all women (47.7±12.5 years old), largely Caucasian (71.4%), and most had at least an undergraduate education (92.6%). The average number of years diagnosed with IBS was 13.5 (SD±10.4). Most of the participants had tried yoga in the past (86%). In comparing the interviewed with the non-interviewed participants in age, years since diagnosis, baseline IBS severity, post-intervention IBS severity, total practice minutes, and class attendance, the only difference was in class attendance, with interviewees attending more classes (6.93 versus 5.77 out of 8 classes, p=0.16). Only one participant reported not having any prior exposure to yoga. For those who tried yoga in the past, some did not do so to manage their IBS symptoms, but for stress relief and relaxation (n=5). Most participants

(n=11) reported a positive experience with yoga, whereas those that reported negative experiences attributed these to injuries or pain felt during practice.

Three main themes were identified using the analysis process described earlier: (1) current experience in the yoga program, (2) incorporating yoga into IBS management, and (3) recommendations for improvement. The main themes, sub-themes, and key findings are summarized in Figure 1 and described below.

Theme 1: Current experience in the yoga program

Five subthemes were determined: reasons for joining the program, changes or evolution over time, barriers, and facilitators at home and in class, program likes, dislikes, and efficacy.

Reasons for joining the program

Most participants joined intending to improve their IBS symptoms, improve their mental health, and contribute to the growing knowledge of IBS management. Participant ID 8 suggested "*I guess definitely something that I could use as an alternative for treating the IBS because I don't have many tools in my toolbox. So yeah, just something that would help."* However, most participants joined the program with low expectations, largely due to the failure they have experienced with previous treatments. For example, participant ID 51 said "*I still continue to try things, but I'm so far into my acceptance of what, you know, that I don't really expect anything anymore."*

Changes or evolution over time

Several participants stated they expected the program to be physically challenging, however, their perception of yoga changed as they learned of the meditative and breathing exercises. Throughout the program, participants found their consistency was an important

determinant of program efficacy. Participants also expressed increased body awareness and control allowing them to better manage their IBS.

"It's giving me firmer conviction that I do have some control over providing my body support, as opposed to it's completely out of my hands and I need to rely on ingestion of something or someone else trying to I guess, remediate it." – Participant ID 89

Controllability and self-efficacy

Those that had maintained a routine throughout the program had higher levels of self-efficacy and controllability and were more likely to incorporate it into IBS management. Participant ID 51 stated *"So having that accountability and having that group that you meet with every week and see how your progress goes and having someone who can give you, you know, targeted feedback, what you should be improving on and things like that."* Social support and accountability were factors that allowed participants to continue the program, despite poor motivation.

Things liked or disliked about the program

Online delivery of this program was preferred by most of the participants because of convenience. Of the yoga components, participants enjoyed alternate nostril breathing the most, with mixed views about Yoga Namaskar. Supplementary resources such as videos helped adhere to practice at home. Among disliked components were the warm-up exercises including hand movements, and neck stretches by some.

Barriers and facilitators

Barriers include external influences such as unexpected events, lack of time and confidence, and maintaining consistency as well as motivation. Participant ID 82 stated *"I think the biggest challenge was just not wanting to do some of them and forgetting and not having*

time. Yeah. But I think that they are biggest part was trying to do the ones that I didn't like to do." Facilitators included online delivery and videos, accountability in the form of homework and attendance, and social support from other classmates.

Program efficacy

Program efficacy includes five subthemes: Benefits for physical health, IBS symptoms, mental health, other benefits, and no benefits. Most of the participants found the program effective for IBS management and a few referred to yoga as 'a tool in my toolbox'. Particularly, alternate nostril breathing was found to be effective in reducing symptom severity thus improving pain coping, anxiety, and stress resulting in better overall health. Others reported sleeping better on days when they practiced yoga, felt physically active, and experienced increased self-compassion. For example, participant ID 51 stated *"I did benefit in a measurable way, but it wasn't physically…It was more the self-compassion side of things. And like I wasn't beating myself up about it, it wasn't like it just changed my mindset in a way that benefited me and my IBS. But physically, it didn't actually change me symptomatically."*

Those who noticed reduced pain severity were likely to be more consistent with their practices and incorporated yoga as a part of IBS management. Those that did not see a symptomatic benefit, however, still found the program helpful. As participant ID 34 described *"Like I felt enough better than I'm motivated to continue doing it. Because I see the difference."*

Theme 2: Incorporating yoga into IBS management

When asked "Would you incorporate yoga to help manage your IBS?", the participants responded in one of three ways: yes and why, no and why, and maybe. The incorporation of yoga as an IBS management option was influenced by consistency throughout the program, benefits attained (e.g., experiencing fewer IBS flare-ups), and available time. Participant ID

14 described, *"I think I definitely saw like in terms of having like pain crisis and severe symptoms, some of those practices definitely helped with that. So I'm more likely to actively do something about it rather than just try to suffer through it. I know that there are tools out there that I can use to help with that. So I'm more likely now to turn to using some of those practices when I am suffering more".* Although most participants did incorporate yoga into their IBS management, they differed in the amount and interval of practice, and components of the program that were used in these practices. Participant ID 6 describes, *"Yeah, I definitely take the key parts that I like and I do incorporate that. So whether I'm doing daily stretching or whatnot or after I've worked out in our incorporate some of the Namaskar and the alternate nostril breathing."* Thus, participants chose to tailor these practices to their needs, schedule, and comfort. Those participants who chose not to incorporate yoga were influenced by events in their personal life or believed their IBS was influenced by triggers such as food requiring alternative management strategies. As participant ID 81 explained, *"To be honest, I haven't been consistent with everything that happened in last couple of months with a lot of like life changes. But I have realized that incorporating yoga might be helpful for my symptoms. So yeah, once I am a bit more used to my schedule, I want to incorporate more yoga for sure because it also helps me sleep better."*

Theme 3: Recommendations for improvement

The participants provided several suggestions on how to improve this program, largely around changes in program components. They suggested excluding the warm-up practices and including more meditative components and pelvic floor and abdominal exercises. They also suggested the creation of a hybrid yoga program that allows the participants to connect with the instructor and one another in person. Participant ID 6 commented *"I'm not sure how it would*

work, but it would be nice to have like an option, like if you want to attend the live class, you could or you could sign in online, right? And so those people who want to do it in the comfort of their home could, but those who want to get out and be with people could, that might be a really neat option?" Other suggestions included the availability of more class timings and offering classes with varying levels of difficulty to accommodate varying physical fitness levels (e.g., a class for beginners and advanced practices).

Discussion

The aim of this study was to explore and describe participants' experiences in a virtual yoga program, and its impact on their ability to manage their IBS.

Theme 1: Current experience in the yoga program

Participants shared differing views on the benefits they experienced, including physical (e.g., weight loss, stronger abdomen, and exercising regularly), mental (e.g., reduced catastrophizing, stress reduction), spiritual (e.g., self-awareness), and sleep improvements. Participants found alternate nostril breathing helped to cope with IBS pain most effectively. Many noted it was a great addition to their toolbox for managing IBS. Similarly, one study evaluating yoga for rheumatoid arthritis found focused breathing an effective, and convenient tool for coping with pain (Cartwright, Cahill, & Sadana, 2020). Consistent with our study, another study reported breath watching was very convenient to incorporate daily since it could be done anywhere (Kahya & Raspin, 2017). Multiple studies found yoga as beneficial for pain reduction, leading to improved sleep (Anderzen-Carlsson, Persson Lundholm, Kohn, & Westerdahl, 2014; Cartwright et al., 2020; Lazaridou et al., 2019; Loudon, Barnett, & Williams, 2017; Seeney & Griffin, 2020; Selman et al., 2015; Winters et al., 2020). Although all

participants noted improvements in mental health, some did not experience an improvement in their IBS symptoms; however, these individuals still reported feeling more relaxed, and less stressed, and developed greater body awareness, better pain coping skills, self-awareness, and self-acceptance.

Consistency and expectations of the program impacted how participants felt about their symptomatic improvement. Expectations have effects similar to a placebo whereby perception before the program influences the outcomes; masking the true benefits experienced by participants (Schoultz, Macaden, & Hubbard, 2016). Participants who reported experiencing little or no symptomatic benefit may have been negatively influenced by their perception or expectations from the program because the program did not meet their expectations, making it challenging to interpret their experiences. Future programming would benefit from formally addressing program expectations at the start of the study.

Participants evolved in multiple ways throughout the program. Some experienced a change in the perception of how yoga could be beneficial in managing their IBS. Although their initial motivation was to manage their IBS symptoms, experiencing additional benefits changed their perception of the power of practicing yoga for overall physical and mental well-being. Additionally, those with an initial negative perception of yoga found their perspective shift as they were exposed to meditative and breathing components of the program. Participant motivations also evolved as they shifted their focus away from previous experience and comparison to other participants to focus on their pace and their own experience. Some participants also developed spiritually as their self-awareness and self-compassion grew.

Self -awareness, a common benefit of yoga (Anderzen-Carlsson et al., 2014; Cartwright et al., 2020; Cramer, Lauche, Haller, et al., 2013; Goncalves AV, 2016; Kahya & Raspin, 2017;

Loudon et al., 2017; McCall, Thorne, Ward, & Heneghan, 2015; A. M. Rhodes, 2015; Seeney & Griffin, 2020), allows participants to focus on their bodily sensations, and helps them effectively cope with their pain because of the increased sense of physical control (Anderzen-Carlsson et al., 2014). This increased autonomy elevates self-esteem and confidence (Anderzen-Carlsson et al., 2014), and thus overall well-being. For our participants, increased self-compassion allowed for the non-judgmental perception of pain, acceptance of one's condition, and healthier pain coping mechanisms. They expressed satisfaction rather than frustration with their current progress, by being more accepting of their condition. Acceptance empowers patients to self-manage their health conditions, resulting in greater self-efficacy (Lazaridou et al., 2019; Loudon et al., 2017) and confidence (Cartwright et al., 2020; Lazaridou et al., 2019; Loudon et al., 2017). In turn, greater self-efficacy promotes the incorporation of yoga into one's life (Loudon et al., 2017).

Participants identified several common barriers and facilitators to participating in the program. Time was a major barrier as has been cited in other literature (Glynn et al., 2020; Huberty et al., 2018; Schoultz et al., 2016). However, commitment and accountability played an integral role in finding time to practice (Schoultz et al., 2016). Once again, those who were more committed to the program were more likely to find time to practice.

Major facilitators were access to practice videos, accountability, and social support. Videos have been found to increase adherence to practices (Huberty et al., 2018; Kuttner L, 2006), accountability helps foster commitment and self-discipline (Huberty et al., 2018; Selman et al., 2015), and social support motivates participants and helps them feel more comfortable (Goncalves AV, 2016; Huberty et al., 2018; Selman et al., 2015). Additional benefits of the virtual nature of the program were mentioned. These were convenience (i.e., no travel), less time

required to prepare for a class, and flexibility to accommodate the class within their work schedule and around other commitments.

Theme 2: Incorporating yoga into IBS management

The perceived efficacy of the program influenced the incorporation of yoga into IBS management. Similar to another study (McCall et al., 2015), we found participants who demonstrated higher commitment and accountability were more likely to adhere to the program, in class and at home. These participants also reported more benefits from the program and a higher likelihood of incorporating yoga into IBS management. Consistent with another study (Evans et al., 2018), the home practice was associated with maximal benefits. In contrast, non-adherence to class attendance and home practice resulted in fewer benefits and a reduced likelihood of continuing with yoga past the intervention period. This finding is consistent with another study where improved functionality helped with self-discipline, or self-regulation of effort (Loudon et al., 2017). Future intervention design should include ways to foster self-discipline as an enabler to increase class attendance and compliance. Taken together, the evolution of individuals through commitment-driven participation helped them excel in obtaining symptomatic benefits.

Ongoing commitment to the program and incorporation of yoga into IBS management was also aided by the ability of the participants to individualize their practices by performing the most helpful components (e.g., breath watching). Future programming should seek to understand the needs of their patient population and tailor the intervention to these needs to increase adherence and maintenance.

Theme 3: Recommendations for program improvement

Several recommendations to optimize the program's feasibility and efficacy were discovered. Other studies suggest tailoring yoga to fit the needs of the condition being addressed (Cartwright et al., 2020; Loudon et al., 2017; Moscoso et al., 2019; Seeney & Griffin, 2020; Winters et al., 2020) and our participants expressed the same sentiment. Most participants wished to see the warm-up exercises removed and more breathing and meditation exercises added. Breathing exercises are the preferred yoga program component in other populations (Cartwright et al., 2020; Goncalves AV, 2016; Kahya & Raspin, 2017; Lazaridou et al., 2019; Selman et al., 2015). Another suggestion was to replace uncomfortable or challenging poses (i.e., Yoga Namaskar) with easier ones for those with more severe IBS symptoms and other comorbidities such as back and neck pain. Participants also recommended having varying levels of difficulty (e.g., gentle yoga versus moderate-intensity yoga) to accommodate different fitness levels. A hybrid program consisting of both in-person interaction and virtual elements was also proposed. The social benefits of being with people with a similar condition are numerous (Anderzen-Carlsson et al., 2014; Emard et al., 2021; Kahya & Raspin, 2017; Loudon et al., 2017; McCall et al., 2015; Selman et al., 2015). The convenience and flexibility of virtual programs and the social benefits of in-person interactions in future programming may improve program efficacy intervention adherence and patient outcomes.

This study adds important insights into the experience of IBS patients in a virtual yoga program and their recommendations for future improvement. This qualitative sub-study had a 52% response rate and similar demography to non-interviewees. Several measures were taken to ensure the rigour of the analysis, including triangulation [two coders; peer debriefing; multiple data collection e.g., (interviews, memoing, observation of yoga classes)]. The interviewer, who

also has IBS, met the class participants. This relationship, we believe, helped the participants feel more comfortable speaking about their experiences and struggles with managing IBS and their experience with the yoga program.

There are several limitations to consider when interpreting the study findings. Most importantly, selection bias is present since only participants who completed the yoga program were invited to participate in an interview. Further, these participants had higher class attendance rates compared to participants who were not interviewed. The generalizability of these results may be limited as the participants were women who had prior yoga experiences. The inclusion of a more diverse sample consisting of both women and males with varying levels of prior yoga experience would be beneficial for future research aiming to explore the experiences of IBS patients in yoga interventions.

Conclusion

This study described the experiences of IBS patients in a virtual yoga program. Program satisfaction was high with most participants experiencing positive physical and mental health benefits. Considering the barriers and facilitators to participating in an online yoga program along with participant recommendations may improve future intervention design and delivery to increase self-efficacy, confidence, and self-discipline among IBS patients. Participants who demonstrated higher commitment and accountability were more compliant and were more likely to incorporate yoga into their IBS management routine. For patients, the availability of virtually delivered interventions that are feasible, effective, and acceptable has the potential to overcome many of the known barriers such as time constraints, costs, and access to evidence-based resources. For clinicians, a virtual yoga program may be a useful resource to support their patients in the management of their IBS, given this is a convenient, effective, and acceptable

format for many patients. For future research, these findings imply the need to create more resources around yoga for IBS patients, particularly, through online delivery. The availability of low-cost hybrid yoga programs for IBS patients, tailored to their needs, can help patients manage their disease and improve their outcomes.

Table 1. Semi-structured interview questions and probes.

12. **What have you done in the past to manage your IBS?**
    a. Have you tried yoga or mediation?
    b. Have you tried exercise?

13. **I would like to start by asking you what you were hoping for or expecting from the program?**
    a. Why did you join this study?
    b. Did anyone influence your decision to join?
    c. Did that meet your expectations?

14. **Next, I would like to discuss your overall experience in the MY-IBS yoga program in which you participated. Could you describe for me what participating in this program was like for you?**
    a. What did you like most about it?
    b. What didn't you like?
    c. Did this change over the course of the program?

    Sub-questions: *yoga facilitator/supervision, the timing of sessions/scheduling, length of sessions, attending with other members, online experience versus in-person, social support/other participants.*
    d. What was that like?
    e. What stood out for you?
    f. What emotions were you aware of at the time?
    g. What else do you remember about that experience?

15. **How has participating in this program affected how you manage or live with your IBS?**

    Sub-questions: *change in IBS symptoms; physical health, fatigue; mental health - stress, anxiety, depression; feeling better about myself; ability to live with my IBS.*
    a. Tell me more about that.
    b. Can you give me an example of what you mean?
    c. How has that affected you?

16. **What, if anything, has helped you to do your practices at home?**

    Sub-questions*: social support, family support, convenience*
    d. Tell me more about that.
    e. Can you give me an example of what you mean?
    f. How has that affected you?

17. **What challenges did you have, if any, doing your practices at home?**

    Sub-questions*: family, supervision/safety, schedule/time*
    e. Are you satisfied with how you did?
    f. Tell me more about that.

g. Can you give me an example of what you mean?
h. How has that affected you?

18. **What, if anything, has helped you to attend the weekly online class?**
    Sub-questions*: social support, family support, HCP support, yoga facilitator, supervision/safety, online classes, schedule/length*
    d. Tell me more about that.
    e. Can you give me an example of what you mean?
    f. How has that affected you?

19. **What challenges did you have, if any, to attend the weekly online class?**
    Sub-questions*: social support, family, yoga facilitator, supervision/safety, online classes, schedule, technical difficulties*
    e. Are you satisfied with how you did?
    f. Tell me more about that.
    g. Can you give me an example of what you mean?
    h. How has that affected you?

20. **We are interested in any ideas you have about how we might make this program better. What could we do differently?**
    Sub-questions: *content, timing, facilitator, videos, website, delivery, other supports*
    c. Would you explain that further?
    d. Can you give me an example of what you mean?

21. **Based on your experience with yoga, would you incorporate yoga to help manage your IBS? If so, how?**

Before we conclude, is this anything else you would like to say about your experience with this program, that we haven't had a chance to talk about yet?

Table 2. Participant characteristics (N=14).

	n (%)
Age (mean years, SD)	47.7 (12.5)
Gender (women)	14 (100)
Ethnicity	
Caucasian	10 (71.4)
Other*	4 (28.6)
Marital Status	
Married, common law	11 (78.6)
Never married, separated, or divorced	3 (21.4)
Education	
University or college	10 (71.4)
Graduate or professional school	3 (21.4)
High school diploma	1 (7.1)
Annual family income	
<59,000	2 (14.3)
≥60,000	10 (71.4)
Prefer not to disclose	2 (14.3)
Years living with IBS (years mean, SD)	13.5 (10.4)
Type of IBS	
Mixed	6 (42.9)
Constipation-predominant	4 (28.6)
Diarrhea-predominant	3 (21.4)
Unsure	1 (7.1)
Currently on prescribed IBS medications	4 (28.6)
Currently taking over-counter supplements	9 (64.3)
Currently on a restricted diet for IBS	8 (57.1)
Currently using	
Cognitive-behavioural therapy	3 (21.4)
Relaxation therapy	1 (7.1)
Hypnotherapy	0 (0.0)
Stress-management therapy	0 (0.0)
Comorbidities	
Gastroesophageal reflux disease	4 (28.6)
Migraine or tension headaches	3 (21.4)
Functional dyspepsia	2 (14.3)
Temporomandibular joint disorder	2 (14.3)

Inflammatory bowel disease	1 (7.1)
Chronic pelvic pain	1 (7.1)
Celiac disease	0 (0.0)
Peptic ulcer disease	0 (0.0)
Chronic fatigue syndrome	0 (0.0)
Fibromyalgia	0 (0.0)
Experience with yoga	
I have tried yoga a few times in the past, but do not currently practice	8 (57.1)
I have practiced yoga regularly in the past, but do not currently practice	5 (35.7)
I have never tried yoga	1 (7.1)

Note. The responses may not add up to 100% due to missing values. *Other ethnicity includes South Asian and Middle Eastern.

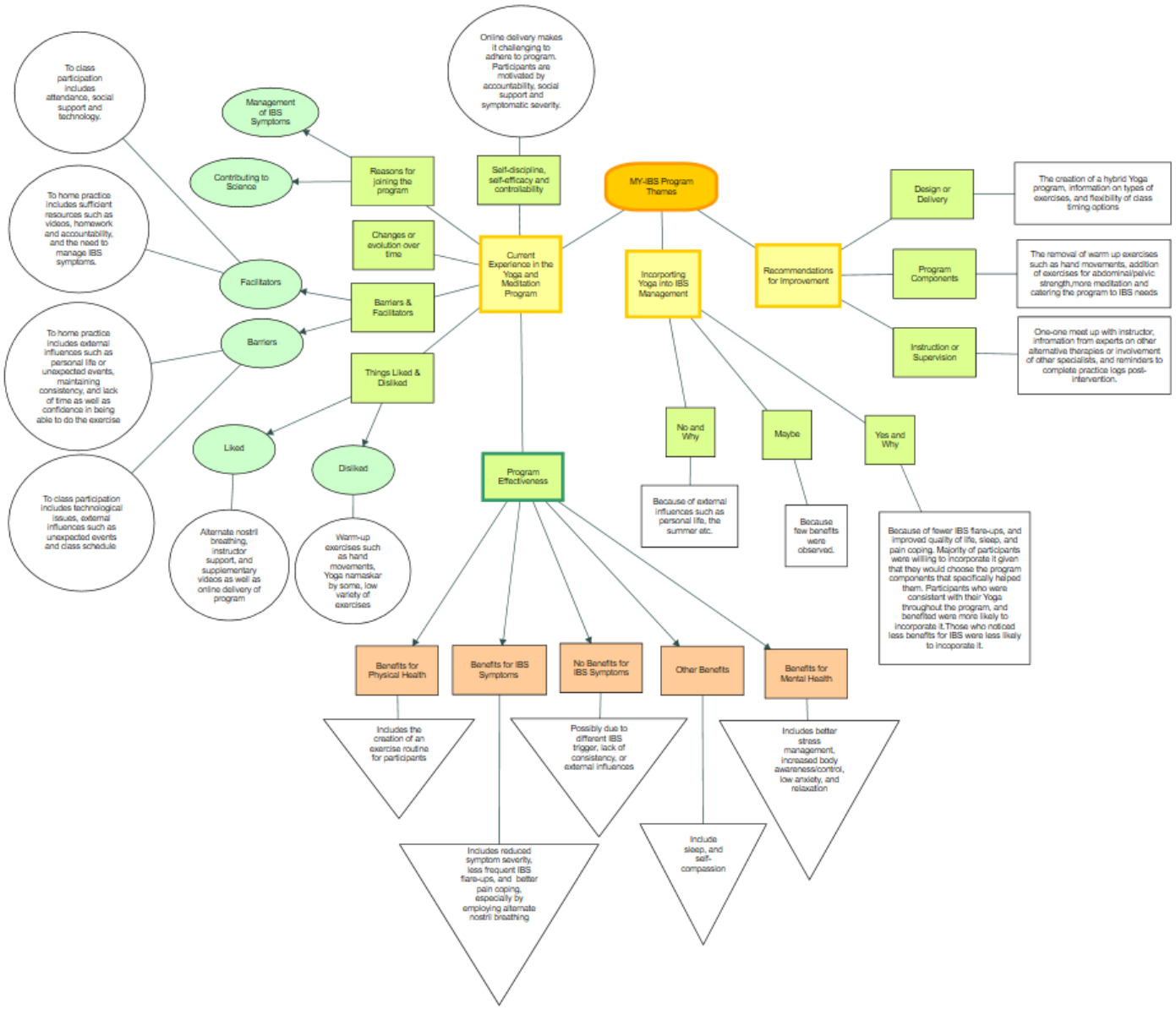

Figure 1. Visual representation of themes, sub-themes, and key findings.

Authors' contributions:

AD was involved in all aspects of study design, interviewing, coding, analysis, and is lead author of the manuscript.

ZI assisted with coding, analysis, and writing the manuscript.

DM, JKV, YN, VR, and GM assisted with design of the study respective to their expertise.

GM assisted with analysis.

VR provided their expertise in yoga therapy, facilitated the yoga classes, and transcribed the interviews.

MR is the senior author on the manuscript and has guided the work of this research to support AD with their training.

All authors reviewed the manuscript for study design and provided critical insight into manuscript content and approved the final version for submission.

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CHAPTER EIGHT: DISCUSSION

Summary of Chapters

This thesis set out to explore several research gaps surrounding the use of yoga as a therapy for the management of IBS. We first examined the acceptability of yoga as therapy among IBS patients and gastroenterologists and then determined the efficacy, feasibility, and safety of a virtually delivered yoga program. To date, no studies have explored these topics.

In the first chapter, an overview of the studies was presented, including the study objectives and hypotheses. In the second chapter, a comprehensive literature review was presented, including the description of IBS, its prevalence, diagnosis, risk factors, pathogenesis, and treatments. In this chapter, yoga was also introduced, its evidence from RCTs in IBS, along with potential mechanisms of action. Lastly, the second chapter highlighted what was known regarding IBS patients' and gastroenterologists' perspectives on yoga as a therapy for IBS. The third chapter described the research methods of the thesis studies, including a mixed-methodology approach to RCT design with embedded post-intervention interviews.

The next four chapters included the manuscripts, starting with the findings on the IBS patients' and gastroenterologists' perspectives on yoga in chapter four: *Gastroenterologist and patient attitudes towards yoga as a therapy for irritable bowel syndrome: An application of the theory of planned behaviour.* This cross-sectional survey study aimed to identify gastroenterologists' attitudes and intention to recommend yoga for their patients with IBS and identify IBS patients' attitudes, subjective norms, perceived behavioural control, and intentions to practice yoga. This study highlighted half of the gastroenterologists surveyed believed yoga improves IBS symptom severity and these respondents were ten times more likely to recommend yoga. Most gastroenterologists wanted to see more evidence to support the efficacy of yoga for IBS and their main barrier to recommending yoga was a lack of knowledge on how to refer a

patient. Gastroenterologists may wish to increase their knowledge of yoga to effectively and confidently provide this therapeutic option given many IBS patients turn to CAM therapies to manage their symptoms. Further, materials could be developed to demonstrate the current evidence base for yoga in IBS and shared among gastroenterologists to help increase their knowledge. Among IBS patients, the intention to engage in yoga was driven primarily by perceived behavioural control (controllability and self-efficacy) and attitude (affective attitude). Understanding the social-cognitive correlates of yoga based on a theoretical model can help us determine which factors are predictors of yoga practice and how these factors can be targets of future intervention design. Another key study finding was that patients preferred home-based yoga practice using online resources. These findings demonstrate the need for accessible and virtually delivered yoga programs. A summary of the findings from patients should be communicated to gastroenterologists so they may be more aware of what their IBS patients' beliefs about yoga, which factors may influence uptake, and how they can best support their patients.

The next chapter included the published RCT protocol design manuscript in its entirety; *Meditation and Yoga for Irritable Bowel Syndrome: Study Protocol for a Randomized Clinical Trial (MY-IBS Study).* The primary objective of the MY-IBS Study was to determine the effects of an eight-week virtual yoga intervention on IBS symptom severity, measured with the IBS Symptoms Severity Scale, compared to an advice-only control group. Secondary objectives were to determine whether a yoga program delivered virtually was a) feasible for adults with IBS, b) improved health outcomes including quality of life, stress, and fatigue, and c) improved mental health outcomes including depression and anxiety symptoms. An embedded design experimental

model qualitative sub-study using semi-structured interviews explored and described participants' experiences in the yoga program.

The sixth chapter presented the findings from the MY-IBS Study: *Meditation and Yoga for Irritable Bowel Syndrome (MY-IBS Study): A Randomized Clinical Trial.* The findings from the trial concluded virtually delivered yoga was a safe, feasible, and effective therapy for IBS. The yoga program demonstrated feasibility based on the attrition rate, adherence, and satisfaction. Safety was demonstrated based on no adverse events. Although no significant difference was found between the groups in the primary outcome (IBS-SSS score), between group differences were observed in favour of the treatment group for fatigue and stress. Within treatment group benefits also showed positive changes for IBS-SSS, fatigue, somatic symptoms, stress, and COVID-19 stress. These findings indicate yoga may have a valuable place in the management of IBS for some patients and the delivery of yoga virtually represents an exciting opportunity to develop and test these interventions further.

We also conducted an exploratory sub-analysis in the RCT. The goal of this sub-analysis was to determine which trial participants were responders, or those who reported a minimum reduction of 80 points or more in IBS-SSS score, and the dose of yoga resulting in a response. Responders showed improved IBS symptoms, quality of life, stress, and COVID-19 stress. The prediction model suggested higher self-compassion and greater practice time are more likely to result in a response; however, the odds ratios were small and not clinically meaningful. Future research should continue to explore predictors or response to determine predictive criteria that helps identify those patients with IBS who are most likely to respond in a clinical setting. With regards to yoga dosing, we determined that for each additional minute of practice, a patient is

1.003 times more likely to be a responder**.** Practicing an additional 77 minutes per week resulted in being almost five times more likely to be a responder.

The last manuscript presented in chapter seven explored patients' experiences in a virtually delivered yoga intervention for IBS; *Experiences of irritable bowel syndrome patients in a virtual yoga program: Qualitative findings from a clinical trial.* Four main themes were identified using thematic analysis: (1) current experience in the yoga program, (2) incorporating yoga into IBS management, and (3) recommendations for program improvement. Participants reported high program satisfaction with most experiencing positive physical and mental health changes from practicing yoga. The findings for this sub-study further supported the trial findings that the tested virtual yoga program was feasible, effective, and acceptable. For patients, the availability of virtually delivered interventions such as the one tested here has the potential to overcome many of the known barriers such as geography, time constraints, costs, and access to evidence-based resources. For clinicians, a virtual yoga program may be a useful resource to support their patients in the management of their IBS, given this is a convenient, effective, and acceptable format for many patients. For future research, these findings imply the need to create more yoga resources for IBS patients, particularly, through online delivery. The availability of low-cost hybrid yoga programs for IBS patients, tailored to their needs, can help patients manage their disease and improve their outcomes.

Strengths of the Current Research

The studies in this thesis are the first to a) use a theoretical framework (TPB) to examine the attitudes of gastroenterologists' and patients' beliefs towards yoga as a therapy to manage IBS and b) use mixed methods research to evaluate the efficacy and feasibility of a virtual yoga intervention in IBS, and c) explore the experiences of adult IBS patients in a yoga program. The

application of the theoretical framework increases our understanding of the influencing factors of adoption, motivation, and adherence to physical activity interventions and intention to perform a behaviour (i.e., practicing yoga).

The first study surveyed a geographically diverse sample of IBS patients and gastroenterologists across Canada. Further, IBS patients across Canada were eligible to participate in the yoga program, increasing access to patients who may otherwise be unable to attend the program in person. To evaluate the efficacy and feasibility of the virtual yoga program, mixed methods research was applied. Participants were randomized to a virtually delivered yoga intervention or an advice-only control group and the data were analyzed using an intent-to-treat procedure. This procedure attempts to preserve the baseline equivalence of groups established through randomization and reduces bias by avoiding analysis of only a subset of participants (e.g., excluding participants who do not adhere to or comply with the study protocol or drop out of the study) (Peduzzi, 2002). Further, the study groups did not differ at baseline concerning demographic variables (e.g., age, gender) and clinical variables (e.g., mean diagnosis duration). The RCT drop-out rate was 20%. The drop-out rate in online and mobile interventions has been reported to be 40% in RCTs (Meyerowitz-Katz et al., 2020). Although robust yoga protocols are lacking, our intervention protocol was developed per the criteria proposed by Sherman et al. (2012) to include a) style of yoga, b) specific class sequences, c) components of the yoga intervention, d) dose of yoga, e) facilitation of home practice, f) dealing with modifications, and g) selection of instructors (i.e., delivered by a certified Upa Yoga facilitator). Taken together, randomization, the intent-to-treat analysis, low dropout rate, trained instructor, and yoga videos to support home practice were strengths of the RCT.

For the qualitative study, the strengths include a 52% response rate and similar demography to non-interviewees. Several measures were taken to ensure the rigour of the analysis, including triangulation (two coders; peer debriefing; multiple data collection including interviews, memoing, and observation of yoga classes). The interviewer, who also has IBS, met the class participants. This relationship helped the participants feel more comfortable speaking about their experiences and struggles with managing IBS and their experience with the yoga program.

Taken together, these studies provide a comprehensive story of the role of yoga in IBS management from the perspective of the patient and the gastroenterologist. This research contributes to a better understanding of patients' wants and needs surrounding yoga as well as the factors influencing a gastroenterologist's decision to recommend yoga as a treatment to an IBS patient. Since yoga is not currently part of clinical management guidelines, these findings provide additional evidence to support the integration of yoga into such guidelines and the utilization of this therapy in the clinical setting. Further, with the increasing interest in virtual care delivery, demonstrating the efficacy, feasibility, and safety of other virtually delivered yoga interventions is the next step in providing accessible treatment options to IBS patients.

Limitations of the Current Research

The first study has several limitations. There may have been a selection bias whereby gastroenterologists and patients with positive attitudes towards yoga and prior yoga experience were more likely to participate in the study. The study also lacked information about how gastroenterologists were compensated (fee-for-service or flat fee). Method of compensation and time spent discussing IBS therapies may be correlated, but limited clinic time was not a major barrier to recommending yoga. The study results may also not be generalizable to all IBS

patients. Although patients from across Canada participated, using heterogeneous recruitment methods, the sample was largely composed of educated Caucasian women with a high family income who reported a history of previous yoga practice. In the patient survey, the TPB constructs did not fully explain patients' intentions. The TBP is limited in that it does not explore other potential contributing factors such as past behaviour, personality traits, and emotional state.

The original design of the RCT was to compare an online yoga group to a face-to-face group; however, the COVID-19 pandemic impacted the study design. Since there have not been any previous studies examining online yoga interventions, it was deemed premature to compare the intervention to an active treatment condition. Self-selection of participants limited generalizability to motivated individuals, and this limitation is supported by the high level of intention to do yoga reported at baseline. Further, the generalizability of these results may be limited as the participants were mostly Caucasian women who had prior yoga experiences. Due to the nature of the intervention, the participants were not blinded to treatment condition and were aware of which group they were randomized to following completion of baseline assessment. The study is also limited by self-reported data and lack of data capture on the frequency of yoga practice, if any, in the control group. A potential threat to the validity of the results is the possibility the control group may have engaged in practicing yoga or gathering yoga-related resources. Although control participants were asked not to start practicing yoga or meditation during the eight-week study period, their use or practice was not tracked or discouraged. Also, the sample did not include patients with severe depression or suicidal ideation. For the qualitative sub-study, selection bias is present since only participants who completed the yoga program were invited to participate in an interview. Further, these participants had higher class attendance rates

compared to participants who were not interviewed. These factors may have selected patients who had positive views towards the study and benefited from the intervention.

Directions for Future Research

Given the evidence suggesting yoga is safe, feasible and effective for IBS patients, efforts are needed to educate gastroenterologists to increase their confidence in discussing yoga as a therapy for IBS. Educational interventions and knowledge dissemination strategies aimed at gastroenterologists may help increase their knowledge of yoga and provide them with the latest scientific evidence. Research suggests educational interventions can increase provider knowledge about the benefits of these therapeutic modalities, with a majority (90%) indicating they are more likely to recommend these therapies in the future (Koula & Knight, 2018). Physician educational interventions should be evaluated for their ability to increase knowledge and change behaviours (i.e., change their recommendation patterns). Further, the development of educational resources for gastroenterologists to provide to patients is needed. An example of an education intervention could be a brief video developed by trusted names, associations, and governing bodies in gastroenterology highlighting the evidence base for yoga in IBS. The level of knowledge would be measured before and after viewing the video, with changes in recommendation patterns assessed by the level of recommendations before viewing the video and once more at follow-up (e.g., three months).

Since theory-informed design could play an important role in intervention efficacy, we propose additional research to build on these findings and further explore factors (e.g., emotions, personality traits, or past behaviour) that may influence IBS patients' intention to use yoga as a therapy. Future research using theoretical frameworks should also measure behaviour to determine if intentions translated into yoga behaviour. Any intervention should consider patient

barriers (e.g., cost) and facilitators (e.g., accountability) to doing yoga in various environments (e.g., virtual delivery) and support systems (e.g., group class).

With a larger number of women experiencing IBS, future research should also consider the role of sex and gender in this disease. Whether these differences are a result of sex or gender is unknown. Although sex and gender are interrelated, gender-related characteristic of men and women can impact health outcomes in different ways sex. Strategies would include using varied recruitment and retaining strategies for both males and females (sex) and gender (men, women, transgender and others) for a more diverse samples of IBS patients, stratifying analysis by both sex and gender, and reporting results accordingly.

Future trials should conduct multi-centred RCTs with an active control group and follow-up assessments to explore if the benefits reported post-intervention remain unchanged. Sample size permitting, future studies should also investigate the effects of yoga on each subgroup of IBS (IBS-D, C, or M) individually and the long-term effects of yoga. With adequate funding, future studies should consider including objective measures of autonomic function testing (e.g., electrocardiogram), sympathetic reactivity tests (e.g., mental arithmetic test), parasympathetic reactivity tests (e.g., heart rate variability in deep breathing), and microbiome analysis to determine physiological mechanisms of yoga efficacy.

The research to date has indicated various types and doses of yoga interventions to be safe and effective. Nevertheless, due to the heterogeneity in intervention characteristics, assessed outcomes and measures used, it is difficult to determine the optimal style and dosing of yoga. The RCT responder sub-analysis revealed practicing 77 minutes more per week resulted in being five times more likely to be a responder. Additional research is needed to determine the optimal dosing of yoga required to achieve clinically meaningful symptom improvement in IBS. Future

interventions should aim to find ways to increase participation in yoga programs with the goal to produce more responders. In addition to exploring the dose-response relationship, future research should also consider exploring the long-term benefits of yoga and strategies to support the continued practice of yoga among IBS patients (e.g., behaviour change interventions).

Using a mixed-methods approach, this research offered insights into the experiences of IBS patients in a virtual yoga program and gathered their feedback on future program development and improvement suggestions. The study findings imply the need to create more resources around yoga for IBS patients, particularly, through online delivery. The availability of low-cost hybrid yoga (online and in-person) programs for IBS patients, tailored to their needs, can help patients manage their disease and improve their outcomes. Future studies are also needed to build the evidence base for virtual and hybrid yoga programming and evaluate the long-term effects and cost-effectiveness of such interventions in IBS. Combining the convenience and flexibility of virtual programs and the social benefits of in-person interactions into hybrid programming may improve program efficacy, intervention adherence, and patient outcomes. Researchers can use these findings to develop supportive lifestyle interventions for this population. Continuing to learn from those with lived experience may provide invaluable information on how to support the delivery of effective, feasible, and safe yoga programming. Lastly, the next step should be to translate research evidence into practice. Although much remains to be learned about the effects of yoga in IBS and how to best deliver these interventions, pathways for implementation would naturally be the next steps. Engaging patients as partners, and relevant key stakeholders (e.g., gastroenterologists) to develop safe and effective standardized yoga protocols and materials (e.g., videos, mobile application) to support the patient are needed.

Conclusion

Our findings provide a foundation for future research exploring the acceptance of yoga a therapy for IBS. Gastroenterologists may wish to increase their knowledge of yoga supported by evidence to provide therapeutic options given that many IBS patients turn to these therapies. Further, a gastroenterologist's attitude toward such therapies may play an important role in establishing a positive patient-physician relationship. Based on the TPB results, affective attitude, controllability, and self-efficacy are key theoretical correlates of intention to practice yoga in patients with IBS. Our study results suggest virtually delivered yoga is an effective, feasible, and safe therapeutic option for IBS. Yoga improved IBS symptoms and a breadth of other psychological and physiological outcomes that are understudied but frequently affect patients with IBS. The intervention was also found to be safe without any adverse events. The qualitative study adds important insights into the experience of IBS patients in a virtual yoga program and their recommendations for future improvement. Such interventions represent an opportunity to increase access to effective management therapies for patients with IBS.

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Appendix A: Characteristics and findings from yoga RCTs

Study	Intervention	Comparison	Inclusion criteria	Assessments	Results (primary outcomes(s))	Results (secondary outcomes)	Attrition	Compliance	Adverse event outcomes
Schumann et al, 2017 (Germany)	Average age = Not reported Hatha yoga supervised group session 75 minutes twice weekly for 12 weeks. One weekly class consisted of yoga postures and yogic breathing, the second explored yoga philosophy and meditation, including mantra meditation and yoga nidra (deep sleep relaxation techniques). Also given 3.5-hour video for home practice. (n=24)	Average age = Not reported Low-FODMAP diet (n=24)	Male and female, 18-75, ROME III criteria, all IBS-types	Baseline, 12 and 24 weeks	No statistically significant group differences at week 12 or at week 24 for IBS-SSS, but a statistical significance was found in the decrease of symptoms for both groups. Significant within-group improvements were observed in 3 of the 5 IBS-SSS categories in Yoga including duration of pain, bowel satisfaction and interference with life.	- No statistically significant between-group differences on the SF-36, except that the Yoga group showed a statistically significant improvement in the physical component subscale. - The CPSS and PSQ did not reveal between-group difference, but within-group comparison showed statistically significant improvement for both groups. - Statistically significant between-group difference on only one IBS-QOL subscale (decreased at week 12 for the FODMAP group due to avoidance of some foods). - Significantly lower scores on the HADS for the Yoga group for the anxiety subscale after 12 weeks, but no between-group differences for the depression subscale. - No statistically significant between-group differences at week 12, but a significant difference at week 24 of the Yoga group for BAQ scores.	Yoga: 5.81% FODMAP: 13.8%	Yoga group classes: 14.9±7.99/24 classes Yoga home practice: 96.3±38.2 minutes FODMAP: 2.62±0.68/3 sessions Diet compliance: 70.7±32.0 on the self-reported 100 visual analog scale 67.7±2.3 on the nutritionists-reported 100 visual analog scale	Yoga: The two reported adverse events in the yoga group were not related to the intervention. FODMAP: Three patients reported adverse events. One serious event related to a major depressive episode, with two nonserious events (a mild self-reported depressive episode and unwanted loss of weight).
Shahabi et al, 2016 (USA)	Average age = 34.7±11.6 Iyengar yoga supervised group 60 minutes of 16 biweekly sessions, plus home practice (n=17)	Average age = 39±15.0 Walking (moderate intensity, supervised, 60 minutes of 16 biweekly sessions) (n=10)	Male and female, 18-65, ROME III criteria, all IBS-types	Baseline, 16 session (8 weeks), 6 months	Yoga showed a significant decrease in IBS severity measures, visceral sensitivity, and severity of somatic symptoms. Walking showed significant decreases in overall GI symptoms, negative affect, and state anxiety.	- Yoga showed significant decreases in IBS severity measures, visceral sensitivity (VSI), and severity of somatic symptoms (PHQ-15) - Walking showed significant decreases in overall GI symptoms, negative affects, and state anxiety (STAI).	Yoga: 14.3% Walking: 8.6%	Yoga: 14.2±2.0/16 classes Walking: 13.8±3.1/16 classes	Not reported

Kavuri et al, 2015 (USA)	Average age = 45.8±12.7 Remedial Yoga Module (body-breath-mind) supervised session 60 minutes three times per week for 12 weeks (n=25)	Average age = 41.2±12.8 Combination group (Yoga intervention and conventional treatment) (n=26) Average age = 45.8±12.9 Wait-list control group (current care and lifestyle plus advised to walk 60 minutes three times per week) (n=27)	Male and female, 18 and above, ROME III criteria, all IBS-types	Baseline, 6 and 12 weeks	Significant IBS-SSS and IBS-QOL improvement in Yoga and Combination groups when compared to the Control group at week 6 and week 12. No significant difference between Yoga and Combination groups. Within group changes of Yoga and Combination showed significant improvements at week 6 and week 12.	- Significant improvements in Yoga and Combination groups in HADS and IBS-GAI compared to Control group at weeks 6 and 12. - Significant difference in the Autonomic Symptom Score between Yoga and Control groups, and Combination and Control groups at week 12. - Medicine and supplement use decreased significantly during week 6 for Yoga and Combination groups compared to the Control. - In the sympathetic reactivity tasks, there were no changes within the group or between the groups in the diastolic blood pressure, heart rate and blood pressure.	Yoga: 24% Combination group: 21%	Yoga: 90% Combination group: 90%	Three participants (yoga=2; combination=1) complained of lower back pain that was aggravated. Pain alleviated within a week and the participants completed the program. No adverse events related to the intervention. Other reported adverse events prompted patients to discontinue the study (flu, cataract surgery, and other diagnoses). Death of a Wait-list control group patient due to a cardiac arrest at home was also reported.
Taneja et al, 2004 (India)	Average age of both groups = 30.9±6.79 Yoga (12 asanas) plus pranayama (right-nostril breathing) twice a day for two months (n=9)	Conventional group (loperamide 2-6 mg/day for 2 months) (n=12)	Males only, 20-50, ROME II, IBS-D only	Baseline, 1 and 2 months	The overall autonomic symptom score showed a marginally significant decrease in yogic intervention groups as compared to the conventional group at 2 months. Subsequent comparison between groups showed a significantly higher expiratory-to-inspiratory (parasympathetic reactivity) in the yoga group at 2 months.	- No significant difference between the groups with respect to bowel symptom score (TBDQ), state anxiety (STAI), gastric motility, and physical flexibility. - Both groups showed improvements in all these outcomes over time. - No differences emerged for the measures of autonomic reactivity.	Yoga: 5% Conventional treatment: 0%	Not reported	Not reported

Notes: IBS-D: IBS-Diarrhea; GI: Gastrointestinal; IBS-SSS: IBS severity scoring system; IBS-QOL: IBS quality of life; SF-36: 35-item Short Form Survey; CPSS: Cohen perceived stress scale; PSQ: Perceived stress questionnaire; HADS: anxiety and depression scale; BAQ: body awareness questionnaire; BRS: Body responsiveness scale; VSI: Visceral sensitivity index; PHQ-15: Patient Health Questionnaire-15; STAI: State-trait anxiety inventory; IBS-GAI: IBS Global assessment of improvement score; TBDQ: Talley's bowel disease questionnaire.

Appendix B: Mechanisms of yoga for IBS

Therapeutic Targets for IBS	Description of Potential Mechanism(s)
Psychological Health, Self-Regulation, and the Stress Response	▪ Increased parasympathetic nervous system activity, counteracting the stress-induced activity of the sympathetic nervous system and improved regulation of the HPA system (Balasubramaniam et al., 2012) ▪ Reduction in cortisol levels (Innes, Bourguignon, & Taylor, 2005; Vera et al., 2009) ▪ Increased positive reappraisal reduces the negative impact of prolonged and repeated high stress-related neuroendocrine activity (Geisler, Kubiak, Siewert, & Weber, 2013; Sauer-Zavala, Walsh, Eisenlohr-Moul, & Lykins, 2012; Shapiro, Jazaieri, & Goldin, 2012) ▪ Increased gamma amino-butyric acid (GABA) levels in the thalamus correlated with improved mood (Streeter, Gerbarg, Saper, Ciraulo, & Brown, 2012; Streeter et al., 2010) ▪ Reduction in depressive and anxiety symptoms (S. D'Silva, Poscablo, Habousha, Kogan, & Kligler, 2012; A. W. Li & Goldsmith, 2012; L. A. Uebelacker, Epstein-Lubow, G., Gaudiano, B. A., Tremont, G., Battle, C. L., Miller, I. W., 2010) ▪ Increased self-awareness and improved behavioural correction processes when regulating emotional responses to stress (J. P. Jamieson et al., 2012) ▪ Structural brain changes in areas enhancing sensory awareness (sensory cortex and insula), attention (anterior and posterior cingulate), memory (hippocampus), and emotion regulation (orbitofrontal cortex) (Fox et al., 2014; Holzel et al., 2011; Tang et al., 2015)
Immune Function and Inflammatory Processes	▪ Regulates autonomic function through increased stimulation of the vagus nerve to reduce pro-inflammatory cytokines (IL-6, IL-2, c-reactive protein); reduction in tumor necrosis factor-alpha (TNF-α) and Interferon gamma (IFN-g) (Kaliman et al., 2014) ▪ Silencing of pro-inflammatory genes (RIOK2 and COX2), reversal of pro-inflammatory gene expression patterns that are related to cell cycle regulation and DNA damage changed expression, and an increase in antiviral gene expression (IRF-1) (D. S. Black et al., 2013; J. D. Creswell et al., 2012; Kuo et al., 2015) ▪ Increased activity of anti-inflammatory glucocorticoid receptor (GR), which indicates a change in HPA axis in terms of responding better to cortisol and inducing a faster stress response (Bower et al., 2014) ▪ Adverse early life events alter the gene expression of specific cell signalling proteins to cause colonic motor dysfunction in adulthood (Q. Li & Sarna, 2011). Changes in the global modification of histones (H4ac and H3K4me3) and silencing of several histone deacetylase genes (HDAC 2, 3, and 9) is seen in yoga compared to controls (Kaliman et al., 2014)

Appendix C: Patient Survey

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Patient Yoga Survey

Thank-you for joining this study!

In this survey, you will be asked questions about your experience with yoga as someone who has Irritable Bowel Syndrome. There are no right or wrong answers and all we ask is that you provide responses that are as honest and accurate as possible.

The survey should take about 10-15 minutes to complete.

Please complete the survey below.

Part 1: Questions about you

How old are you?

_____

What is your self-identified gender?

- ◯ Female
- ◯ Male
- ◯ Transgender
- ◯ Other
- ◯ Prefer not to disclose

Please specify your gender:

_____

Please select the ethnicity that best represents you:

- ◯ Indigenous (e.g. First Nations, Metis, Inuit)
- ◯ Caucasian (European descent)
- ◯ Black (e.g. African or Caribbean descent)
- ◯ Middle Eastern (e.g. Afghanistan, Iraq, Israel, Saudi Arabia)
- ◯ Latin American (e.g. Argentina, Brazil, Colombia, Mexico)
- ◯ Chinese (China, Hong Kong, Taiwan, Macao, Tibet)
- ◯ Japanese (Japan)
- ◯ Korean (North Korea, South Korea)
- ◯ Vietnamese (Vietnam)
- ◯ Filipino (Philippines)
- ◯ Other East Asian (e.g. Brunei, Cambodia, Laos, Malaysia, Myanmar, Singapore, Thailand)
- ◯ South Asian (e.g. Bangladesh, India, Pakistan, Sri Lanka)
- ◯ Other
- ◯ Unknown
- ◯ Prefer not to answer

Please tell us more about your ethnicity:

_____

Marital status

- ◯ Never married
- ◯ Married
- ◯ Common law
- ◯ Separated or divorced
- ◯ Widowed

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Education (please check highest level attained)
- ◯ Grade school
- ◯ High school diploma
- ◯ University or college
- ◯ Graduate or professional school (medical, law, etc.)
- ◯ Trade or apprenticeship
- ◯ Prefer not to disclose

Annual family income
- ◯ $100,000
- ◯ Prefer not to disclose

What year were you diagnosed with IBS? _____

Are you currently on any medications for your IBS prescribed by a physician?
- ◯ Yes
- ◯ No

Are you currently taking any over-counter supplements for your IBS?
- ◯ Yes
- ◯ No

Please specify the medication(s) in this box:

_____

Do you personally use/practice any complementary or alternative medicine?
- ◯ Yes
- ◯ No

((examples: acupuncture, tea, meditation))

Please select all that apply.
- ☐ Yoga
- ☐ Mindfulness
- ☐ Meditation
- ☐ Cognitive behavioral therapy
- ☐ Hypnotherapy
- ☐ Acupuncture
- ☐ Massage
- ☐ Teas
- ☐ Oils
- ☐ Herbal medicines
- ☐ Other

Please specify other: _____

Has a doctor or nurse ever said you had any of the following? Please select all that apply.
- ☐ Anxiety
- ☐ Depression
- ☐ Chronic fatigue syndrome
- ☐ Fibromyalgia
- ☐ Chronic nausea
- ☐ Functional dyspepsia (indigestion)
- ☐ Acid reflux disease
- ☐ Inflammatory bowel disease

Are you currently under the care of a gastroenterologist for your IBS?
- ◯ Yes
- ◯ No

Has your physician recommended you try any of the following? Please select all that apply.
- ◯ Yoga
- ◯ Meditation
- ◯ Mindfulness
- ◯ Breath watching
- ◯ Unsure

Has another health professional recommended you try yoga?
- ◯ Yes
- ◯ No
- ◯ Unsure

((example: family doctor, dietician))

Part 2: Your experience with yoga

Have you ever practiced or tried yoga before?
- ◯ Yes
- ◯ No

Do you currently practice yoga?
- ◯ Yes
- ◯ No

For how many months have you practiced yoga?
_____
((months))

On average, how many days per month do you practice yoga?
_____
((days))

On average, how long is each session in minutes?
_____
((minutes))

Do you plan on continuing to practice yoga?
- ◯ Yes
- ◯ No
- ◯ Unsure

Would you be interested in trying yoga?
- ◯ Yes
- ◯ No
- ◯ Unsure

Please tell us why you are not interested or unsure.
_____

Part 3: Your thoughts on yoga

What do you think about doing yoga for 10-20 MINUTES PER DAY FOR THE NEXT 8 WEEKS. There are no right or wrong responses; we are merely interested in your personal opinions.

DAILY yoga can be defined as practicing for at least 10 minutes per day.

For you, what are the main advantages of doing yoga DAILY? (e.g., feel more relaxed).

Please list up to 3 advantages that come to mind first. It's OK if can't think of any to list.

Advantage 1 _____

Advantage 2 _____

Advantage 3 _____

What do you think about doing yoga for 10-20 MINUTES PER DAY FOR THE NEXT 8 WEEKS. There are no right or wrong responses; we are merely interested in your personal opinions.

DAILY yoga can be defined as practicing for at least 10 minutes per day.

For you, what are the main disadvantages to doing yoga DAILY? (e.g., I don't like yoga)

Please list up to 3 disadvantages that come to mind first. It's OK if can't think of any to list.

Disadvantage 1 _____

Disadvantage 2 _____

Disadvantage 3 _____

For you, what factors or circumstances would make it easier (facilitators) for you to do a DAILY yoga practice? (e.g., having weekly classes with a group)
Please list up to 3.

Factor 1 _____

Factor 2 _____

Factor 3 _____

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For you, what factors or circumstances would make it more difficult (barriers) for you to do a DAILY yoga practice? (e.g., not being able to make it to weekly classes)
Please list up to 3.

Factor 1 _____

Factor 2 _____

Factor 3 _____

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Who are individuals or groups that would SUPPORT you to do a DAILY yoga practice? (e.g., doctor, partner).
Please list up to 3.

Person or Group 1 _____

Person or Group 2 _____

Person or Group 3 _____

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Who are individuals or groups that would NOT SUPPORT you to do a DAILY yoga practice? (e.g., doctor, partner).
Please list up to 3.

Person or Group 1 _____

Person or Group 1 _____

Person or Group 3 _____

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Please select the number below that best describes your personal thoughts about doing a DAILY yoga practice.

Doing yoga every day for 10-20 minutes for the next 8 weeks would be:	◯ 1 very bad ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 very good
Doing yoga every day for 10-20 minutes for the next 8 weeks would be:	◯ 1 unpleasant ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 pleasant
Most people who are important to me would support me to do yoga daily for 10-20 minutes for the next 8 weeks:	◯ 1 strongly disagree ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 strongly agree
Most people like me will do yoga daily for 10-20 minutes for the next 8 weeks:	◯ 1 very unlikely ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 very likely
I am confident that I can commit to doing yoga every day for 10-20 minutes for the next 8 weeks:	◯ 1 not at all confident ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 very confident
Doing yoga daily for 10-20 minutes for the next 8 weeks is up to me:	◯ 1 strongly disagree ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 strongly agree
I intend to do yoga daily for 10-20 minutes for the next 8 weeks:	◯ 1 very unlikely ◯ 2 ◯ 3 ◯ 4 neutral ◯ 5 ◯ 6 ◯ 7 very likely

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I would commit to a daily, 8-week long yoga program.

- ○ 1 very unlikely
- ○ 2
- ○ 3
- ○ 4 neutral
- ○ 5
- ○ 6
- ○ 7 very likely

I would be interested in a free 8-week yoga program designed for individuals with IBS.

- ○ 1 not at all interested
- ○ 2
- ○ 3
- ○ 4 neutral
- ○ 5
- ○ 6
- ○ 7 very interested

Which of the following do you prefer?
Please check all that apply.

- ☐ Attending a yoga class
- ☐ Doing yoga at home self-instructed
- ☐ Doing yoga at home using online resources (e.g., videos, mobile application)
- ☐ No preference

If there are any other comments you would like to make about this survey or if you would like to tell us more about your thoughts on yoga for IBS, please do so in the space provided here.

_____

May we contact you in the future regarding participation in a free yoga program?

- ○ Yes
- ○ No

My email address is:

_____

[Your email address will be used to contact you for participation in a free 8-week yoga program]

My phone number is:

_____
((000) 000-0000)

[Your phone number will be used to contact you for participation in a free 8-week yoga program]

We would like you to recall your average weekly physical activity in the PAST MONTH.

When answering these questions please:
- **Only count physical activity sessions that lasted 10 MINUTES OR LONGER in duration.**
- **Include only the physical activities that you did during your leisure time (e.g., going to the gym, the fitness centre at the leisure centre, walking the dog, going for a walk, swimming, bicycling). DO NOT include activities you do at work or around the house (e.g. mowing the lawn).**

--> Note that the difference between the three categories is the intensity of the activity:

STRENUOUS physical activity (heart beats rapidly, sweating)
(e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)

MODERATE physical activity (not exhausting, light sweating)
(e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)

MILD physical activity (minimal effort, no sweating)
(e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)

Considering a typical week (7 days) this PAST MONTH how many times per week on average, and for how long (duration), did you perform the following kinds of physical activity?

Strenuous physical activity times per week: _____
((times per week) ; If you have NOT performed this physical activity, please write '0'.)

Strenuous physical activity average duration: _____
((minutes); If you have NOT performed this physical activity, please write '0'.)

Moderate physical activity times per week: _____
((times per week); If you have NOT performed this physical activity, please write '0'.)

Moderate physical activity average duration: _____
((minutes); If you have NOT performed this physical activity, please write '0'.)

Mild physical activity times per week: _____
((times per week); If you have NOT performed this physical activity, please write '0'.)

Mild physical activity average duration: _____
((minutes); If you have NOT performed this physical activity, please write '0'.)

Appendix D: Gastroenterologist Survey

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Physician Yoga Survey

Please complete the survey below.

You will be able to see your colleagues' aggregate responses at the end of the survey.

Thank you!

Gastroenterologist Recommendations for Complementary or Alternative Therapies in Irritable Bowel Syndrome Survey

Part 1: Information about you

Age
- ◯ 30-39
- ◯ 40-49
- ◯ 50-59
- ◯ 60-69
- ◯ 70+

What is your self-identified gender?
- ◯ Female
- ◯ Male
- ◯ Prefer not to disclose

How many years have you worked as a gastroenterologist?
- ◯ 0-4 years
- ◯ 5-9 years
- ◯ 10-14 years
- ◯ 15-19 years
- ◯ 20-25
- ◯ 26 years or more

What age group(s) do you provide Irritable Bowel Syndrome (IBS)-related medical care to most often? (Check all that apply)
- ☐ Children (0-11)
- ☐ Youth (12-17 years)
- ☐ Adults (18+ years)

In which province or territory do you currently practice?
- ◯ AB
- ◯ BC
- ◯ SK
- ◯ MB
- ◯ ON
- ◯ QC
- ◯ NS
- ◯ PEI
- ◯ NFLD
- ◯ NB

As part of your general practice, do you currently RECOMMEND any complementary or alternative medicine to your IBS patients?
- ◯ Yes
- ◯ No

Please select all that apply:

- ☐ Yoga
- ☐ Mindfulness
- ☐ Meditation
- ☐ Cognitive behavioral therapy
- ☐ Hypnotherapy
- ☐ Acupuncture
- ☐ Massage
- ☐ Teas
- ☐ Oils
- ☐ Herbal medicines
- ☐ Other

Please describe other: _____

Have you ever PERSONALLY practice any of the following?

Please check all that apply:

- ☐ Yoga
- ☐ Mindfulness
- ☐ Meditation
- ☐ Cognitive behavioral therapy
- ☐ Hypnotherapy
- ☐ Acupuncture
- ☐ Massage
- ☐ Teas
- ☐ Oils
- ☐ Herbal medicines
- ☐ Other

Please describe other: _____

Part 2: Your attitudes and beliefs towards yoga

Please select the number below that best describes your personal thoughts about yoga as an effective treatment for patients with IBS.

For the purposes of this survey, we define yoga as practice that includes at least one of the following components: postures, breathing techniques, or meditation.

Strongly disagree:__1__:__2__:__3__:__4 (neutral)__:__5__:__6__:__7__: Strongly agree

	1	2	3	4	5	6	7
Yoga can be used as therapy for IBS	○	○	○	○	○	○	○
Yoga improves IBS symptom severity	○	○	○	○	○	○	○
Yoga reduces stress	○	○	○	○	○	○	○
Yoga reduces the symptoms of anxiety	○	○	○	○	○	○	○
Yoga reduces the symptoms of depression	○	○	○	○	○	○	○
Yoga improves health-related quality of life	○	○	○	○	○	○	○
Yoga is safe for patients with IBS	○	○	○	○	○	○	○
Yoga interferes with conventional IBS treatments	○	○	○	○	○	○	○
Yoga improves compliance with conventional IBS treatments	○	○	○	○	○	○	○

Please tell us why you think yoga is an unsafe treatment for patients with IBS.

Please tell us why you think yoga interferes with conventional IBS treatment.

If there are any other comments you would like to make in regards to your personal thoughts about yoga as an effective treatment for patients with IBS, please do so in the space provided here.

_____

Part 3: Your current practices

For the purposes of this survey, we define yoga as practice that includes at least one of the following components: postures, breathing techniques, or meditation.

IN THE NEXT 30 DAYS:

Very unlikely :_1_:_2_:_3_:_4 (neutral)_:_5_:_6_:_7__: Very likely

	1	2	3	4	5	6	7
How likely are you to recommend yoga as a treatment to your IBS patients?	○	○	○	○	○	○	○
How likely are you to recommend yoga to your IBS patients that is delivered face-to-face by a certified yoga instructor?	○	○	○	○	○	○	○
How likely are you to recommend yoga to your IBS patients that is delivered electronically (e.g., online videos, web-based) whose content is developed by a certified yoga instructor?	○	○	○	○	○	○	○

Do you currently RECOMMEND yoga to your patients with IBS?
- ○ Yes
- ○ No

What is the most common recommendation you would provide?
- ○ For my patient to try a home-based practice
- ○ To attend a class
- ○ Online resources, web-based
- ○ Other

Please describe other: _____

Would you be willing to recommend yoga to IBS patients?
- ○ Yes
- ○ No
- ○ Unsure

Please tell us why you would not be willing/unsure about recommending yoga as a therapy for IBS patients?

Please select the number below that best describes your current practices with your IBS patients.

Strongly disagree:__1__:__2__:__3__:__4 (neutral)__:__5__:__6__:__7__: Strongly agree

	1	2	3	4	5	6	7
I am confident in recommending yoga as an effective treatment for IBS	○	○	○	○	○	○	○
The scientific evidence to support the use of yoga as an effective treatment for IBS is lacking	○	○	○	○	○	○	○
My colleagues approve of yoga as a treatment for IBS patients	○	○	○	○	○	○	○

Please list anyone who SUPPORTS you in recommending yoga:

_____
((e.g., colleague, friend, spouse, manager, department/division head, other))

Please list the relationship (e.g., colleague) and do not list any names.

Please list anyone who DOES NOT SUPPORT you in recommending yoga:

_____
((e.g., colleague, friend, spouse, manager, department/division head, other))

Please list the relationship (e.g., colleague) and do not list any names.

If there are any other comments you would like to make about your current use of yoga as a treatment for patient with IBS, please do so in the space provided here.

_____

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Part 4: Your facilitators and barriers to recommending yoga

Which of the following factors or circumstance would make it more DIFFICULT (BARRIERS) for you to recommend yoga to your patients with IBS?

Please check all that apply.

- ☐ There is limited time during a patient visit
- ☐ This is not part of my regular clinic routine
- ☐ My training does not qualify me to discuss it
- ☐ I do not have the knowledge on yoga to discuss it with the patient
- ☐ I do not have the knowledge on how or where to refer a patient
- ☐ I feel that patients will be concerned about the cost of doing yoga
- ☐ I am not convinced of the literature on the efficacy with respect to yoga for IBS
- ☐ I am not convinced of the literature on the safety with respect to yoga for IBS
- ☐ Other

Please describe other:

_____

Which of the following factors or circumstance would make it EASIER (FACILITATORS) for you to recommend yoga to your patients with IBS?

Please check all that apply.

- ☐ Have posters in the clinic so that patients can ask about yoga
- ☐ Informational resources on yoga (e.g., pamphlets) that can be given to patients
- ☐ Have in-clinic support to speak to patients about yoga
- ☐ Having more evidence that supports the efficacy of yoga for IBS
- ☐ Having more evidence that support the safety of yoga for IBS
- ☐ Other

Please describe other:

_____

Are there any other alternative therapies you routinely discuss with your IBS patients?

_____

Part 5: Web-based yoga program

We are interested in testing the feasibility of a yoga program for IBS patients that is evidence-based and delivered on a web-based platform.

Please select the number below that best describes how you perceive the implementation of this web-based application into routine medical care for IBS patients.

Strongly disagree:__1__:__2__:__3__:__4 (neutral)__:__5__:__6__:__7__: Strongly agree

	1	2	3	4	5	6	7
GIs should recommend yoga to their patients with IBS	○	○	○	○	○	○	○
I am willing to recommend a web-based yoga program to my patients with IBS	○	○	○	○	○	○	○
I am willing to refer patients to a research study testing a web-based yoga program for IBS patients	○	○	○	○	○	○	○
I believe my patients would be interested in a web-based yoga program	○	○	○	○	○	○	○
A web-based yoga program has the potential to improve patients' engagement in their own care	○	○	○	○	○	○	○
I am concerned about the safety of a web-based yoga program, that is not supervised by a qualified instructor	○	○	○	○	○	○	○

If there are any additional comments you would like to make, please do so in the space here:

_____

Would you like to be notified when we begin to offer an online yoga program for patients with IBS?

○ Yes
○ No

Please enter your email address here to be notified. _____