

Original Research

Evaluation of the Transitional Pain Service Specialized Iyengar-Informed Yoga Program for Chronic Post-Surgical Pain: A Pilot Randomized Controlled Trial

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Academic Editor: Peta Stapleton

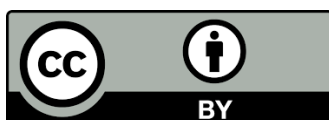
Collection: [Mind-Body Approaches that are Revolutionizing the Health Field](#)

OBM Integrative and Complementary Medicine
2025, volume 10, issue 3
doi:10.21926/obm.icm.2503041

Received: April 29, 2025

Accepted: September 22, 2025

Published: September 30, 2025



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Abstract

The objective of this randomized controlled trial (RCT) was to evaluate the feasibility and efficacy of a specialized Iyengar-informed yoga intervention for individuals who experience chronic post-surgical pain (CPSP). This prospective, multi-wave pilot RCT was pre-registered at clinicaltrials.gov (NCT03460028) and designed in accordance with the 2010 CONSORT statement. Participants (N = 21) with CPSP were out-patients or community members affiliated with a Toronto hospital. Participants were randomized to an 8-week yoga condition (treatment condition (TC); n = 10) or to a wait-list control condition ((CC); n = 11). The TC participated in an eight-week yoga program (program 1). The CC participated in the same yoga program after their waiting period (program 2). Pain, psychological, and mindfulness measures were collected at two time points for both conditions (before and after yoga program 1) and at a third time point for the CC (after yoga program 2). Of the 19 participants who attended a single yoga class, 100% completed their yoga intervention. There were no adverse events. Participants rated their program satisfaction as 9.73 ± 0.47 , on a scale of 0-10, in which higher numbers indicate greater satisfaction. Linear mixed effects growth models were conducted to evaluate main effects of condition at post-intervention, controlling for pre-intervention scores. Post-intervention scores on the primary outcome measure of pain catastrophizing did not differ significantly between the conditions. Pain interference scores were lower ($F_{1,13} = 5.14, p < 0.05$) in the TC compared to the CC. The yoga program for patients with CPSP (1) was feasible, safe, and satisfactory; (2) lacked efficacy in improving the primary study outcome of pain catastrophizing, and (3) demonstrated efficacy in improving pain-interference. This trial points to the merit of a specialized yoga program for CPSP, although further research is needed in this area.

Keywords

Chronic post-surgical pain; transitional pain; pain interference; Iyengar yoga

1. Introduction

The Transitional Pain Service (TPS) at Toronto General Hospital (TGH) was developed in 2014 as a world first service to address the need for comprehensive and expert treatment in the prevention and management of chronic post-surgical pain (CPSP) in the peri-operative period [1, 2]. CPSP is defined as pain that: 1) develops after a surgical procedure, 2) is at least two months in duration, 3) is a continuation of acute post-surgical pain or develops after an asymptomatic period, 4) interferes with health-related quality of life, 5) is localized to the surgical field and/or is projected to another area innervated by a nerve in the surgical field, and 6) is not caused by any other factors [3]. The prevalence rate of chronic pain in Canada is 18.9%, and it is estimated that approximately 10-70% of patients who undergo major surgery present with chronic post-surgical pain (CPSP) in the year or years following surgery [4, 5]. Incidence of CPSP with significant disability at one year is 5-10% and severe CPSP is associated with greater functional impairments at 6 and 12 months post-surgery [6, 7]. Psychological factors that reliably predict CPSP include depression, anxiety, posttraumatic stress symptoms, and pain catastrophizing, and some of these factors are also identified risk factors for

more intense peri-operative pain and opioid use, which in turn may influence hospital stay trajectory and health care utilization [1]. It follows that transitional pain treatment in the peri-operative period should be interprofessional in nature to address the multiple and intersecting components of pain. Goals of the TPS are to support safe and patient-centered opioid weaning, increase return to activities and functioning, reduce emotional distress, improve quality of life, and to reduce incidence and severity of CPSP pain and disability [1, 8]. The use of multimodal pre- and rehabilitative interventions, which include strengthening, stretching, balance, psychological components, exercise, and mind-body approaches (e.g., Tai Chi), has been recommended as a service option in transitional pain care to achieve comprehensive and preventative pain management [9, 10].

Yoga represents a unique opportunity to simultaneously address these various recommendations. It is a systematic set of mind-body practices that include physical postures involving strengthening and stretching, psychological components of concentration and meditative practices, and spiritual development that originates in Vedic/Indian traditions dating back to 3000 BC [11]. Randomized controlled trials have demonstrated that yoga results in improvements in pain and pain-related functional outcomes for a variety of musculoskeletal and neurologically-based pain conditions [12-16]. Yoga interventions for pain related to surgery are limited and there have been no published RCTs that evaluate a yoga program tailored to address CPSP specifically in a post-surgical population. One research group has proposed an evaluation of a post-lumbar spine surgery yoga program immediately post-surgery (phase 1) and for 8 weeks post-operatively (phase 2), and demonstrated feasibility for phase 1 [17, 18]. RCTs have been conducted to evaluate peri-operative yoga programs for individuals who have undergone surgery for breast cancer and coronary artery disease (e.g., mastectomy, coronary artery bypass surgery), with benefits to disease-related symptoms and/or psychosocial measures [19-22]. Additionally, a pilot single cohort feasibility study evaluated a short term, peri-operative, three session yoga skills training for women undergoing gynecological surgery and reported improvements in pain and distress in a pre- to post-session analysis [23]. Peri-operative yogic breathing techniques and yoga postures have been used in controlled research trials for patients undergoing total knee arthroplasty and thoracic surgery [24, 25]; both studies reported improvements in pain post-operatively but methodological issues make it impossible to draw firm conclusions from these trials.

Overall, the research literature points to the benefits of yogic practices and training in the peri-operative setting but no trials have evaluated specialized yoga interventions in the months or years following surgery as part of a transitional pain program or in addressing CPSP directly. Although none of the aforementioned studies evaluated Iyengar yoga, this form of yoga is selected for the current trial as it is a highly studied form of yoga for pain and disease types and is heralded for its application for medical populations [26]. Iyengar yoga promotes correct anatomical alignment in each posture, the integration of the breath with practice, a focus on sequencing of postures to culminate in a desired effect, and the use of props to foster both deepening and safety in practice. This manuscript presents the first randomized controlled trial to assess a specialized Iyengar informed yoga program compared to a wait-list control in individuals with CPSP. This novel yoga program represents a low-cost, non-invasive, and holistic health care option, and this trial provides a foundation for future specialized yoga programs in the field of peri-surgical transitional pain.

The objective of this RCT was to evaluate the feasibility and efficacy of a specialized Iyengar-informed yoga intervention for individuals with persistent post-surgical pain. Feasibility: We

hypothesized that the specialized Iyengar-informed yoga program would be feasible, as measured by reasonable rates of recruitment, retention, intervention adherence and completion, measure completion, and program satisfaction. Efficacy: (1) Participants in the yoga condition (treatment condition: TC) would demonstrate greater improvements in pain catastrophizing (primary outcome measure) from pre- to post-intervention compared to the wait-list control condition (CC). Specifically, it was predicted that after controlling for pre-intervention levels, the scores on a measure of pain catastrophizing would be significantly lower in the TC compared to the CC at post-intervention. (2) The TC was expected to show greater improvements in pain and psychological measures from pre- to post-intervention compared to the CC. Specifically, it was predicted that after controlling for pre-intervention levels, scores on measures evaluating pain, pain interference, psychological inflexibility, anxiety, depression, and sensitivity to pain traumatization would be significantly lower in the TC than the CC at post-intervention, and that scores on measures evaluating self-compassion and mindfulness would be significantly higher in the TC than the CC.

2. Materials and Methods

2.1 Ethics Statement

The study was approved by the Research Ethics Board (ID: 17-5942) at the University Health Network (UHN). This study was completed in compliance with the WMA Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects.

2.2 Trial Design Overview

This prospective, multi-wave pilot randomized controlled trial (RCT) was designed in accordance with the CONSORT statement and was registered at clinicaltrials.gov (NCT03460028). The completed CONSORT Checklist can be found in the supplementary materials.

This RCT used a parallel, crossover design and involved two conditions: the Iyengar-informed yoga condition (treatment condition: TC) and the wait-list control condition (CC). The study was non-blinded as participants and researchers were aware of the condition to which the participant was assigned. Participants were randomized to one of two conditions with a 1:1 ratio. Participants ($n = 10$) randomized to the TC received a once weekly, 8-week Iyengar-informed yoga intervention and participants ($n = 11$) randomized to the CC received the same 8-week intervention after the TC had completed their intervention. The incorporation of multiple waves ensured that the yoga intervention class sizes remained small and that each individual participant received adequate personalized attention and instruction. Recommendations for the design of yoga research trials have not specified class size limitations [26], but clinical experience suggests that populations experiencing medical complexity would benefit from smaller class sizes and a greater degree of individualized attention. The authors designed the program to consist of small class sizes that occur at a low weekly frequency, with a specialized video for home practice, in order to address participant medical vulnerability, potential barriers regarding travel to the hospital and attendance, and possible participant drop-out.

2.3 Participants

The RCT took place at Toronto General Hospital (TGH), University Health Network (UHN), in Toronto, Canada. The yoga interventions were conducted at ELLICSR: Health, Wellness, and Cancer Survivorship Centre at TGH. Recruitment was completed through posting and circulating posters with information about the trial at sites across TGH, and through referrals from staff (physicians, psychologists, and physiotherapists) at the TPS. Recruitment and follow up occurred from April, 2019-March, 2020. A member of the research team completed eligibility screening for interested participants. Participation in this trial was offered to individuals who were patients at the TPS and/or individuals who learned of the study through visiting TGH, who responded to the recruitment posters, and who met all study criteria. Specific inclusion criteria were that the participant: 1) had undergone surgery prior to commencing the yoga intervention, and was at least 3 months post-surgery, 2) had persistent pain, 3) was 18 years of age or older, 4) was able to speak and read English, 5) was able to commit to one weekly, one hour yoga class for 8 weeks with assigned home practice using a video, and 6) able to provide a note from their physician indicating it was safe for them to participate in gentle yoga. Specific exclusion criteria were that the participant: 1) was undergoing active treatment for cancer (chemotherapy, radiation), 2) had cognitive limitations or language comprehension issues that would impact participation (only as flagged by care team), 3) had a regular yoga practice in the last six months (1-3 classes per week for several consecutive months), 4) was pregnant, and 5) was enrolled in another research trial evaluating a mind-body intervention (e.g., Tai Chi, Qi Gong). The classification of post-surgical pain was broad. There was no maximum cut-off for months elapsed since surgery.

Persons who met eligibility requirements and who continued to express an interest in learning more about the study were invited to a group information session or to an individual meeting with several research team members (KC, DW, ST). Participants were provided with an overview of the trial and the yoga intervention and had questions answered. A member of the research team at the Department of Anesthesia at TGH and who was not involved in the research project conducted the informed consent process and obtained informed consent from participants (DW, ST). Participants (N = 23) provided written, informed consent to participate. The flow of participants through the study are reported in Figure 1 and participant demographics are reported in Table 1.

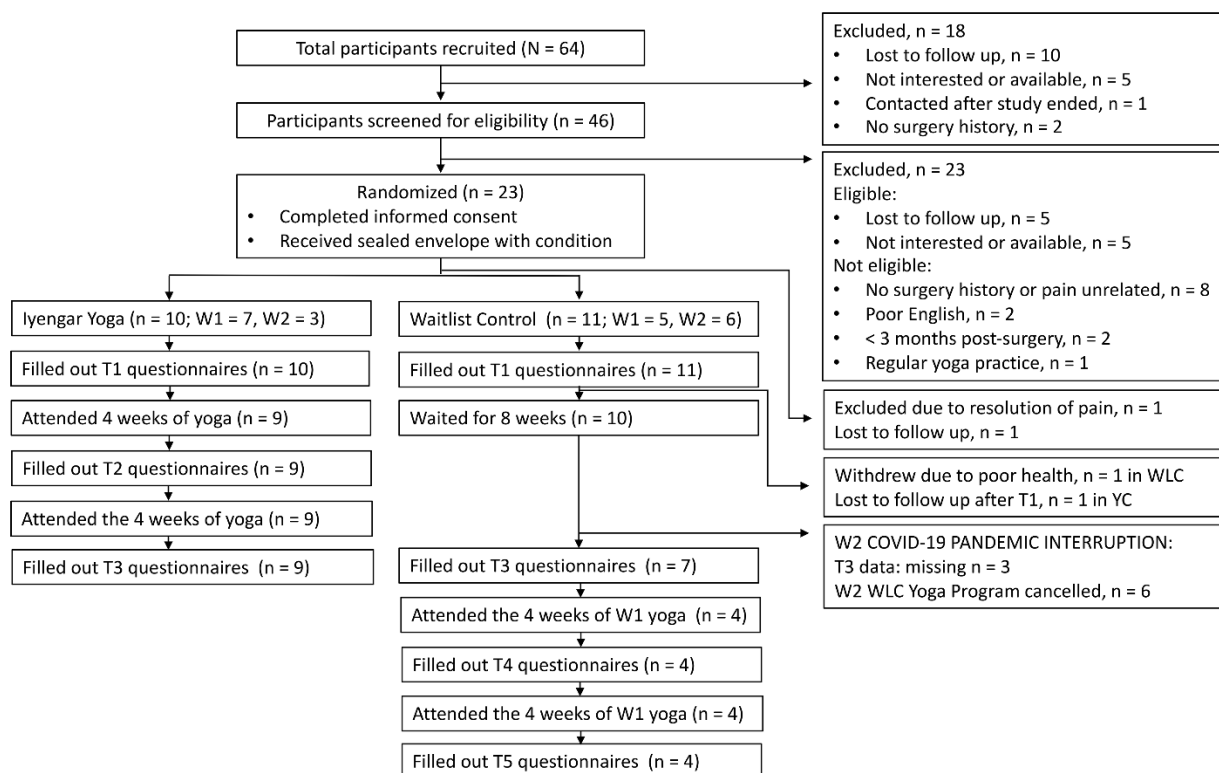


Figure 1 Flow of Participants Through the RCT. Caption: W1 = Wave 1, W2 = Wave 2, WLC = Wait-list Control, T1, T2, T3, T4, T5 = Time-point 1, 2, 3, 4, 5, respectively.

Table 1 Demographics of the Sample (N = 21) by Condition (Yoga Condition, n = 10, Control Condition, n = 11).

Demographic	Level	TC	CC
n		10	11
Gender (frequency, %)	Female	6 (60.0)	7 (63.6)
	Male	4 (40.0)	4 (36.4)
Age (years, mean (SD))		60.56 (13.41)	57.73 (10.90)
BMI (mean, (SD))		31.23 (5.93)	33.25 (16.79)
Annual income (frequency, %)	<\$20,000	0 (0.0)	1 (9.1)
	\$21,000-40,000	4 (40.0)	1 (9.1)
	\$41,000-60,000	0 (0.0)	2 (18.2)
	\$61,000-80,000	1 (10.0)	1 (9.1)
	\$81,000-100,000	2 (20.0)	3 (27.3)
	>\$100,000	1 (10.0)	3 (27.3)
	NA	2 (20.0)	0 (0.0)
Level of education (frequency, %)	High-school	2 (20.0)	0 (0.0)
	University/college	5 (50.0)	7 (63.6)
	Post-graduate	2 (20.0)	4 (36.4)
	NA	1 (10.0)	0 (0.0)

Employment (frequency, %)	Employed, FT	0 (0.0)	3 (27.3)
	Employed, PT	1 (10.0)	0 (0.0)
	Employed, modify	0 (0.0)	1 (9.1)
	Retired due to age	3 (30.0)	2 (18.2)
	Retired due to disability	3 (30.0)	4 (36.4)
	Other	1 (10.0)	1 (9.1)
	NA	2 (20.0)	0 (0.0)

2.4 Procedure and Interventions

The time sequence of data collection relative to the interventions and waiting periods is shown in Figure 1. Data was collected at three time points for the TC and the relevant time points for this article are the pre- (T1) and post- (T3) yoga intervention data collection time points. Data was collected at these same time points for the CC, and T3 also served as their pre-yoga intervention data collection time point for the crossover component of the trial design. Additionally, data was collected for the CC post- (T5) yoga intervention. Additional mid-intervention data collection points (T2, T4) are to be presented in an additional manuscript but are included in Figure 1 to visually depict the comprehensive study protocol. At T1, participants in both groups filled out the questionnaire package and forms regarding demographic information, pain-related health information, and treatments/medication. Participants completed the questionnaire packages either on site prior to or after a yoga class, as appropriate, or at home and returned the package to a member of the research team. All data was stored on the Department of Anesthesia research server and hard copy materials were kept in a locked cabinet at the Pain Research Lab at TGH.

2.4.1 Sample Size Estimation

Sample size estimation using a generic moderate effect size of 0.55, an alpha level of 0.05, and a power level of 0.95, indicated that a sample size of 46 would be sufficient to detect a between condition differences in the outcome variable. Sample size calculation was based on a between conditions design in which there were two groups and 1 covariate (pre-intervention scores). Calculations were done with G*Power 3 (Dusseldorf, Germany). The effect size for this trial was determined with considerations of what is acceptable and meaningful within the yoga research and rehabilitative literature [27, 28].

2.4.2 Minimizing Bias

Steps to minimize or avoid bias were taken through an interdisciplinary team approach to trial design and through having multiple team members involved in the collection and analysis of data, as well as in the writing and publishing of the results. Data was entered by a research assistant not associated with the project. Chronological bias is minimized through the use of the prospective RCT design.

2.4.3 Randomization Schedule

Randomization schedules were generated by an employee at the department of Anesthesia not otherwise involved in the trial using Research Randomizer, a free internet service affiliated with the

Social Psychology Network. For both Waves 1 and 2, randomization to TC or CC was done in block sizes of 6 and stratified by sex. An opaque envelope containing the participant number and group assignment was prepared, sealed, and numbered for each participant. The envelope was opened by a study researcher after informed consent was obtained and participants were informed of the condition to which they were assigned.

2.4.4 Iyengar-Informed Yoga Condition

After informed, written consent to participate was obtained, participants randomized to the TC took part in an eight-week Iyengar-informed yoga program at a frequency of one, 60-minute class per week. There was accompanying home practice using a video at a frequency of 1-3 sessions per week, and the link to the video was provided to the participants after the first yoga class. The yoga video was housed on a private YouTube channel only accessible to the participants. The dosage of one class per week was decided in alignment with the yoga literature [26]. The classes were offered at no cost to the participants. The program was designed and taught by a Yoga Alliance certified yoga teacher (KC) with 1) a 500-hour yoga teacher training (YTT) certification, 2) training in yoga philosophy and mindfulness-based practices and 3) experience teaching yoga to limited mobility populations. The yoga teacher had an assistant (VG), who had also completed 500 hours YTT certification and who had observed a similar yoga research trial intervention for a medical population [29]. Both teachers trained (500-hour YTT) under Gitte Bechsgaard (GB), the director of Vidya Institute, who has expertise in yogic philosophy and Vedic traditions, and who offers international yoga workshops in collaboration with senior level Iyengar Yoga Teachers. GB holds a Level 3 Iyengar Yoga Certification, which involves multiple trips to the Ramamani Iyengar Memorial Yoga Institute in Pune, India and has over 30 years of experience teaching yoga. Additionally, GB teaches a certificate program through Vidya Institute, titled: Patañjali Yoga Sūtra's 4 Module Certificate Course and both the yoga teacher and assistant had completed this certification. The class structure and content were based on a protocol developed by GB and the study researchers that has been used before in research trials evaluating yoga for individuals with complex medical conditions in a hospital setting [29, 30].

2.4.5 Wait-List Control Condition (CC)

Participants who were randomized to the CC proceeded to a waiting interval of 8 weeks in which no yoga intervention was provided. Study personnel provided information to these participants that they would participate in the Iyengar-informed yoga intervention after their waiting interval was complete. During the waiting period, these participants were instructed not to engage in a yoga practice.

2.4.6 Iyengar-Informed Yoga Program

Yoga has multiple definitions and meanings across various scriptures and ancient texts, including the Vedas, Upaniṣads, Brahmanical texts (Bhagavad Gita, as part of the Mahābhārata) and Sāṃkhya philosophy. According to Patañjali's Yoga Sūtras and associated commentary (Vyāsa's Bhāṣyam), which falls under Sāṃkhya and dualistic doctrine, yoga is defined as concentration, meditative contemplation, and the art of separating the inner abiding consciousness (puruṣa) from that of the

material plane of the mind and body (prakṛti). This yoga intervention drew from the philosophy of Patañjali's Yoga Sūtras and the definition of yoga therein.

The yoga classes incorporated a variety of traditional aspects of yoga, such as yoga philosophy (jñāna), breathing practices (prāṇāyāma), physical postures (āsana), mindfulness (smṛti sādhanā), and meditation/relaxation (pratyahara-based dhāraṇā, dhāraṇā, dhyāna) techniques. This integrated approach to yoga has been previously outlined by the authors in trials evaluating yoga for populations that experience pain and limited mobility [31]. At the beginning of every class, a philosophy teaching from Patañjali Yoga Sūtras (~5 minutes, see Figure 2) was provided, along with instructions for the application of the concept in class. Subsequently, a breathing or concentration practice (prāṇāyāma or dhāraṇā) (~5-10 minutes) was taught and instructions for the observance and control of the breath were given. The āsana practice occurred for 35-40 minutes. The āsana protocol included: preparatory arm work (shoulder and arm rolls), ūrdhva hastāsana, baddhanguliyāsana, brief standing sequence with chair (ūrdhva hastāsana, hastāsana (arms to the side), ūrdhva hastāsana, modified uttanāsana sequence), adho mukha śvānāsana (modifications: hands to the wall, hands on a chair, over a table), utthita trikonāsana with chair, prasārita pādottānāsana with hands on chair or blocks, vṛksāsana, supta pādānguṣṭhāsana, supta baddhakoṇāsana, and śavāsana. The class ended with a relaxation practice that incorporated mindfulness (smṛti sādhanā) with a focus on subtle principles of energy and the breath, and the cultivation of well-being.

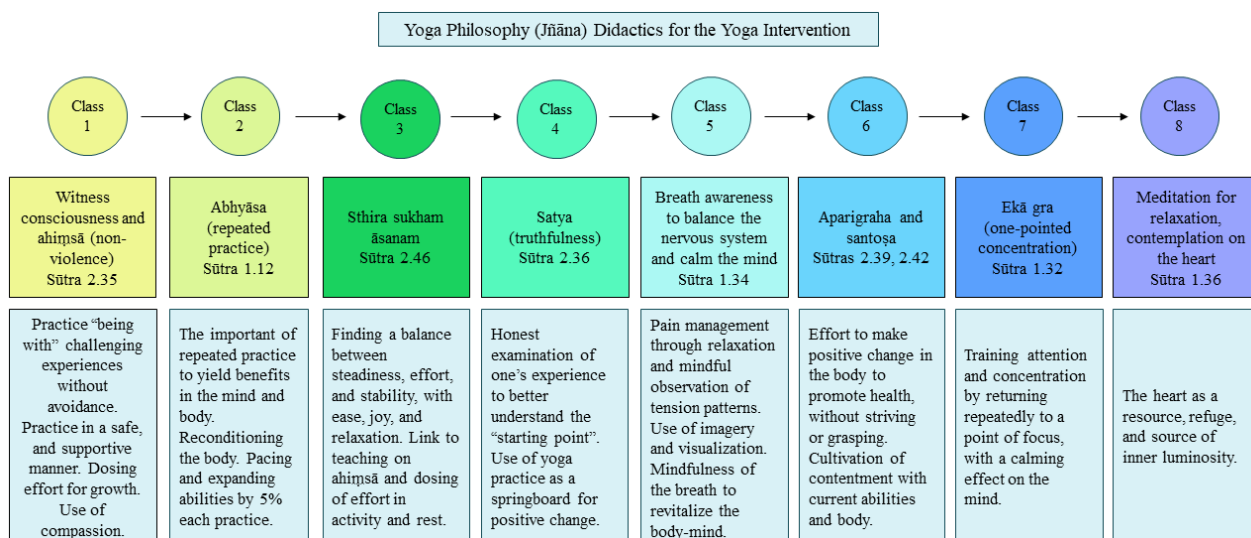


Figure 2 Yoga Philosophy (jñāna) Didactics for the Yoga Intervention.

The sequence of the āsanās was designed in accordance with Iyengar methodology and the yoga intervention is classified as Iyengar-informed yoga. The postures in this intervention were sequenced to promote the progressive development of skill and awareness of muscular engagement through the successive postures in a class. Repetition of poses from class to class engendered learning and the integration of the actions of each of the postures. As the participant ability level increased, a greater number of variations in the sequence were provided toward the end of the intervention. Individual instructions were provided to participants who required assistance or tailoring to ensure safety and accessibility of the postures with respect to chronic pain or post-surgical considerations. Participants were encouraged to balance principles of pacing and

modification with principles of increasing tolerance, endurance, flexibility, and strength. For all standing and balance postures, modifications were offered for a seated variation using a chair and additional props, such as a bolster, strap, chair(s), block, table, or the wall.

2.4.7 Data Entry

All data was entered into a Microsoft Excel document by a research assistant not otherwise associated with the project (NY). If participants erroneously endorsed two responses (instead of one) to a questionnaire item, a virtual coin-flip (justflipacoin.com) was undertaken to randomly determine which of the two responses to use. A 'heads' outcome was assigned to the higher number endorsed by the participant and a 'tails' was assigned to the lower number. A member of the research team (KC) ran the virtual coin flip using this website (justflipacoin.com) and was observed by DW.

2.4.8 Covid-19 Pandemic

This trial was interrupted by the Covid-19 pandemic. During March, 2020, the CC of Wave 2 was scheduled to receive their yoga intervention. Due to the pandemic, the management at ELLICSR at TGH discontinued all group programming and research interventions due to social distancing requirements and a local municipal shut down of services ("lock down"). The participants in this arm of Wave 2 received 1 class of their intervention, but it was discontinued after the first class and they did not receive the intervention as planned. Several participants who were scheduled to start on the second class of the intervention did not complete the third set of questionnaires, which they would have brought to their first class. In addition, the design of the study permitted additional waves (e.g., wave 3) to be conducted until the estimated sample size was fulfilled. However, the Covid-19 pandemic interrupted the trial and the second half of Wave 2 and potential future waves were not completed, thus resulting in a lower number of participants than originally anticipated.

2.5 Measures

The measures completed at the data collection intervals were: the Brief Pain Inventory – Short Form (BPI-SF), the Visual Analogue Pain Scale (VAPS) – Pain Unpleasantness, the Pain Catastrophizing Scale (PCS), ID Pain, Sensitivity to Pain Traumatization Scale – 12 Item (SPTS), The Psychological Inflexibility in Pain Scale (PIPS), the Patient Health Questionnaire – 9 (PHQ-9), the General Anxiety Disorder – 7 (GAD-7), the Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF), and the Self-Compassion Scale – Short Form (SCS-SF). Additionally, the Yoga Program Satisfaction assessment tool was completed by participants upon completion of their yoga program. Descriptions of each measure follow below.

2.5.1 Brief Pain Inventory – Short Form (BPI-SF)

The BPI-SF is a 9-item self-report questionnaire that measures aspects of pain and pain interference for activities of daily living [32]. In the BPI-SF, individuals are asked to report on the best, worst, average and current pain levels according to 11-point scales (0-10). These items make up the Pain-Severity subscale of the BPI-SF. Individuals respond to items regarding how pain interferes with functioning in seven important areas of life, using 11-point scales. These items

comprise the Pain-Interference subscale of the BPI-SF. The BPI has strong internal consistency (Cronbach's $\alpha = 0.85$ and 0.88 for the Intensity and Interference scales, respectively) and adequate construct validity (scores on the Interference scale correlate with other pain disability measures) and it is sensitive to treatment [33].

2.5.2 Visual Analogue Pain Scale (VAPS) – Pain Unpleasantness

The VAPS for pain unpleasantness is a single item questionnaire that queries individuals on the affective component of pain [34]. Individuals are asked to rate the unpleasant quality of their pain by placing a single 'x' on a 15 cm. line, which has the anchor words 'not unpleasant' at the left end of line and the anchor words 'the most unpleasant sensation imaginable' at the right end of the line. VAPS have been shown to be reliable, generalizable, internally consistent measures of pain intensity and unpleasantness for clinical and experimental pain [34]. A VAPS has superior psychometric properties to a simple numeric rating scale of pain in that it demonstrates ratio validity and therefore provides accurate estimates of ratio in pain intensity and percent changes in pain [34].

2.5.3 Pain Catastrophizing Scale (PCS)

The PCS is a 13-item self-report questionnaire that measures negative pain appraisal in relation to experienced or expected pain [35]. Participants report on the extent to which they experience relevant cognitions and emotions related to pain experience by identifying a number from 0 ('not at all') to 4 ('all the time') for each questionnaire item. Scores range from 0-52, with higher scores indicating higher levels of pain catastrophizing. Elevated scores are considered to be above a cut-off score of 25-30. The PCS yields a total score and three subscale scores assessing rumination (repeated focus on pain sensations), magnification (amplifying the threat value of pain sensations) and helplessness (perceived inability to manage pain). The PCS has high internal consistency (coefficient α : total PCS = 0.87 , rumination = 0.87 , magnification = 0.66 , and helplessness = 0.78) [35].

2.5.4 ID Pain

The ID Pain is a 6-item measure of symptoms suggestive of pain with a neuropathic component (e.g., 'Does the pain feel like pins and needles?', 'Is it hot/burning?') [36]. Participants answer according to yes/no answers. One point is awarded for 'yes' answers for items 1-5 and -1 point is awarded for a 'yes' answer for item 6. The ID Pain has been shown to predict the diagnosis of neuropathic pain by pain specialists [36]. The ID Pain is one of the measures of neuropathic pain recommended by the Neuropathic Pain Special Interest Group of the International Association for the Study of Pain (IASP) [37]. The ID Pain has 78-83% sensitivity and 65-80% specificity and moderate levels of construct validity/hypothesis testing [38].

2.5.5 Sensitivity to Pain Traumatization Scale – 12 Item (SPTS)

The SPTS-12 is a 12-item self-report measure designed to evaluate the propensity to develop anxiety-related cognitive, emotional, and behavioral reactions to pain that resemble symptoms of a traumatic stress reaction [39]. Each item is rated on a 5-point rating scale using response options from 0 ('Not at all true') to 4 ('Entirely true'). Total scores (sum of all items) range from 0-48 with

higher scores indicating higher levels of sensitivity to pain traumatization. The SPTS-12 has a one-factor structure, good convergent and divergent validity, and excellent internal consistency (0.84-0.92) in community and clinical samples [39].

2.5.6 The Psychological Inflexibility in Pain Scale (PIPS)

The PIPS is a 16-item scale used to assess pain coping based on the acceptance and commitment therapy approach to pain management [40]. Participants answer according to how true each item is using a 7-point scale ranging from 1 ('never true') to 7 ('always true'). There are two subscales: one is focused on behavioral avoidance of pain and valued activities (*avoidance*: 10 items), and the other is focused on problematic thinking patterns associated with pain (*cognitive fusion*: 6 items). The PIPS has demonstrated good reliability and validity [40]. It has been significantly correlated with both subscales (activity engagement and pain willingness) of the gold standard questionnaire for chronic pain acceptance, the CPAQ [41].

2.5.7 Patient Health Questionnaire – 9 (PHQ-9)

The PHQ-9 is a 9-item questionnaire that queries depressive symptoms [42]. Participants respond according to the degree to which they have been bothered by symptoms over the past two weeks according to a 4-item scale ranging from 0 ('not at all') to 3 ('nearly every day'). There is an additional question regarding the impact of symptoms on functional ability. The total possible score is 27, with higher scores indicating higher levels of depressive symptoms. It has strong internal reliability (Cronbach's $\alpha = 0.86-0.89$) and test-retest reliability is excellent [42]. Additionally, higher depressive severity scores are associated with declining functional status, indicating good construct validity [42].

2.5.8 General Anxiety Disorder – 7 (GAD-7)

The GAD-7 is a 7-item questionnaire that queries symptoms of general anxiety [43]. Participants answer according to the degree of bother they have experienced over the past two weeks using a scale of 0 ('not at all') to 3 ('nearly every day'). There is a total possible score of 21 with higher scores representing higher levels of anxiety. This scale has strong internal consistency (Cronbach's $\alpha = 0.92$) and good test-retest reliability (intraclass correlation = 0.83) [43]. At a cut-off score of 10, both sensitivity and specificity exceed .8, with sensitivity maximized at this point [43]. Higher scores on the GAD-7 are associated with lower scores on functional abilities (e.g., pain, physical, social roles) [43].

2.5.9 Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF)

The FFMQ-SF is a 24-item self-report questionnaire developed from the pre-existing 39-item FFMQ and has been validated in individuals with depression, anxiety, and fibromyalgia [44]. It measures levels of mindfulness according to five facets: Observing, Describing, Acting with Awareness, Non-judging of Inner Experience, and Non-reactivity to Inner Experience. Participants answer each item by choosing the number that is representative of their experience, using a scale of 1 ('never or rarely true') to 5 ('very often or always true'). Total scores range from 0 to 120 and higher scores reflect greater levels of mindfulness. The FFMQ is based on a factor analytic study of five mindfulness questionnaires, with good internal consistency and construct validity [45, 46]. Total

facet scores of the FFMQ-SF are highly correlated with the original version, $r = 0.89, 0.98, 0.92, 0.96, 0.95$, for Observing, Describing, Acting with Awareness, Non-judging, and Non-reactivity, respectively [44].

2.5.10 Self-Compassion Scale – Short Form (SCS-SF)

The SCS-SF is a 12-item self-report questionnaire that measures levels of self-compassion, or the ability to hold one's feelings of suffering with a sense of warmth, security or concern [47]. The SCS-SF has been demonstrated to comprise a unidimensional construct of self-compassion and 6 subscales including: self-kindness, self-judgement, common humanity, isolation, mindfulness, and over-identified. Items are answered according to the statement: "How I typically act towards myself in difficult times", and are responded to on a Likert scale of 1 ('almost never') and 5 ('almost always'). This SCS-SF has adequate internal consistency (Cronbach's $\alpha \geq 0.86$ for three different samples), and an excellent correlation with the full version ($r \geq 0.97$ for three samples) [47].

2.5.11 Yoga Program Satisfaction

The Yoga Program Satisfaction assessment tool is a measure developed by the authors to assess the participant's satisfaction with the yoga program. This measure was developed as a modified version of the Yoga Satisfaction Scale, which has been previously used by the authors [48]. Participants were queried on their overall perceived level of satisfaction with the yoga program according to a 11-point numeric rating scale, from 0 ('not at all satisfied') to 10 ('completely satisfied').

2.6 Statistical Analysis

The questionnaire data was analyzed using the statistical software R version 4.0.3. Participant characteristics were summarized using descriptive statistics (mean $\pm$ SD; or frequency and percentages). The Shapiro Wilk was used to evaluate assumptions of normality. The authors had an a priori statistical analysis plan for the instance in which there was a high proportion of drop-outs or missing data. Due to the Covid-19 pandemic and the resultant discontinuation of wave 2 of the study, this a priori statistical analysis plan was used to analyze the study data. Between groups linear mixed effects growth models was conducted to evaluate group differences at post-intervention when controlling for pre-intervention scores. This is a method of analysis that is well suited for small samples sizes or large amounts of missing data.

3. Results

3.1 Participants

Participants had experienced pain for an average duration of 11.18 ± 11.35 years. When participants specified the number of years of post-surgical pain, that value was used. When unspecified, the duration of years with chronic pain was used. Participants had undergone the following surgeries: Aneurysm repair/Bentall procedure for a stroke during surgery ($n = 1$), orthopedic surgery ($n = 1$), heart transplant ($n = 1$), sternotomy ($n = 1$), kidney transplant ($n = 1$), CABG ($n = 1$), left shoulder surgery ($n = 1$), spinal surgery ($n = 2$: bilateral discectomy,

microdiscectomy, decompression and fusion), cardiac ablation and subcutaneous implantable defibrillator ($n = 1$), cancer surgery ($n = 6$: left hand, forearm, lumpectomy, mastectomy, thyroidectomy, thymoma), hysterectomy ($n = 2$), removal of kidney, intestine, gallbladder, pancreas ($n = 1$), removal of fibroid ($n = 1$), above knee amputation ($n = 1$), wrist surgery ($n = 1$), and surgical type unspecified ($n = 2$).

3.2 Feasibility

A total of 64 interested individuals were recruited for this study (see Figure 1), indicating a reasonable recruitment rate. Of the 23 participants who were randomized to a condition, 2 participants did not continue due to either resolution of their pain or they were lost to follow up. Of the 21 participants who completed T1 questionnaires, only 2 participants did not continue on to participate in a yoga intervention due to ill health or due to having been lost to follow up prior to the intervention commencing. Of the 19 participants who attended a single yoga class, 100% of the participants completed the yoga intervention, indicating good retention and intervention completion. This statistic does not include the CC of Wave 2, which was interrupted by the Covid-19 pandemic. Of the 13 participants who were in either condition in Wave 1 or in the TC of Wave 2, all participants completed all questionnaire packages, indicating good measure completion. The mean number of yoga classes that participants attended was 6.54 ± 0.97 out of 8 classes. Participants reported that they completed a mean of 1.39 ± 0.83 home practice sessions per week during the intervention, using the homework video they were provided. Intervention completion was good and homework adherence was adequate. Regarding program satisfaction, participants rated their overall satisfaction with the program as 9.73 ± 0.47 . There were no adverse events in either group in Wave 1 or in the TC of Wave 2.

3.3 Preliminary Analysis

The Shapiro-Wilk test revealed that the assumption of normality was violated for ID pain. Due to the robust nature of the F-test, with an alpha of 0.05, and the small sample size, transformations were not considered appropriate. Data collected at mid-intervention time points and for the crossover component of the trial will be presented in another manuscript.

3.4 Treatment Results

3.4.1 Between Group Linear Mixed Effects Growth Models

Linear mixed effects growth models were conducted to evaluate main effects of condition at post-intervention (T3) after controlling for pre-intervention scores (T1). Two models were evaluated for each variable. The first model included fixed factors (intercept, time, condition) and the second model included these same fixed factors and also random intercepts. Therefore, each initial model had four parameters and each final model had five parameters, when including the residuals. The method for estimating parameters was Maximum Likelihood. The TC had significantly lower T3 scores on the Pain Interference subscale of the BPI-SF, $F_{1,13} = 5.14$, $p < 0.05$. The mean estimates are presented in Table 2 and the effect sizes calculated from observed means are presented in Table 3. Effect sizes for the T3 observed means for each condition were calculated using an online

calculator (Effect Size Calculators (uccs.edu)). The random factor models were unstable and consequently were not used.

Table 2 Estimated Marginal Means of Measures for Between Conditions Analysis: Treatment Condition (TC; n = 9) and the Wait-list Control Condition (CC; n = 7).

Measure	TC Estimated Mean (SE)	TC 95% CI	CC Estimated Mean (SE)	CC 95% CI
BPI-PS	5.62 (0.52)	4.52, 6.72	6.21 (0.55)	5.03, 7.39
BPI-PI	4.82 (0.44)	3.87, 5.76	6.18 (0.40)	5.31, 7.05
VAPS-PU	5.38 (0.53)	4.25, 6.51	6.64 (0.57)	5.43, 7.85
ID Pain	2.79 (0.33)	2.09, 3.50	2.69 (0.38)	1.90, 3.50
PCS	23.16 (2.38)	18.12, 28.20	22.01 (2.70)	16.29, 27.72
PIPS	67.72 (3.69)	59.90, 75.55	71.64 (4.18)	62.77, 80.51
PHQ-9	8.46 (1.01)	6.31, 10.60	10.84 (1.15)	8.40, 13.29
GAD-7	6.65 (1.02)	4.50, 8.82	7.87 (1.16)	5.42, 10.33
FFMQ-SF	79.87 (2.62)	74.33, 85.42	77.60 (2.99)	71.27, 83.92
SCS-SF	3.19 (0.17)	2.83, 3.55	3.18 (0.19)	2.77, 3.59
SPTS	21.00 (2.47)	15.77, 26.24	20.29 (2.80)	14.35, 26.22

BPI-PS: Brief Pain Inventory-Pain Severity; BPI-PI: Brief Pain Inventory-Pain Interference; VAPS-PU: Visual Analogue Pain Scale-Pain Unpleasantness; ID Pain: ID Pain of Neuropathic Symptoms; PCS: Pain Catastrophizing Scale; PIPS: Psychological Inflexibility in Pain Scale; PHQ-9: Patient Health Questionnaire-9; GAD-7: Generalized Anxiety Disorder-7; FFMQ-SF: Five Facet Mindfulness Questionnaire-Short Form; SCS-SF: Self-Compassion Scale-Short Form; SPTS: Sensitivity to Pain Traumatization Scale.

Table 3 Effect Sizes from T3 Observed Means for the Treatment Condition (TC) and the Wait-list Control Condition (CC).

Measure	T1 TC Mean (SD)	T3 TC Mean (SD)	T1 CC Mean (SD)	T3 CC Mean (SD)	Effect Size (Cohen's <i>d</i>)
BPI-PS	5.19 (2.03)	5.52 (2.14)	5.79 (1.04)	6.32 (0.81)	0.49
BPI-PI	4.88 (2.54)	4.48 (2.44)	5.80 (1.95)	6.47 (1.33)	1.01
VAPS-PU	6.00 (1.60)	5.13 (2.30)	6.79 (1.41)	6.93 (1.30)	0.96
ID Pain	3.33 (1.58)	3.00 (1.32)	2.57 (1.72)	2.43 (1.62)	-0.39
PCS	22.56 (10.63)	23.89 (11.10)	20.43 (16.18)	21.07 (14.95)	-0.21
PIPS - Total	70.56 (15.58)	67.22 (14.53)	72.14 (27.50)	72.29 (24.62)	0.25
PHQ-9	9.78 (5.02)	7.78 (5.43)	11.86 (6.01)	11.71 (4.86)	0.76
GAD-7	7.67 (5.12)	6.00 (4.82)	9.71 (5.94)	8.71 (5.56)	0.52
FFMQ-SF	73.44 (9.80)	77.33 (12.18)	80.43 (12.57)	80.86 (12.50)	-0.28
SCS-SF	3.06 (0.61)	3.22 (0.79)	2.95 (0.92)	3.13 (0.75)	0.12
SPTS	20.00 (11.99)	21.00 (10.78)	20.00 (12.97)	20.29 (12.67)	-0.06

BPI-PS: Brief Pain Inventory-Pain Severity; BPI-PI: Brief Pain Inventory-Pain Interference; VAPS-PU: Visual Analogue Pain Scale-Pain Unpleasantness; ID Pain: ID Pain of Neuropathic Symptoms; PCS: Pain Catastrophizing Scale; PIPS: Psychological Inflexibility in Pain Scale; PHQ-9: Patient

Health Questionnaire-9; GAD-7: Generalized Anxiety Disorder-7; FFMQ-SF: Five Facet Mindfulness Questionnaire-Short Form; SCS-SF: Self-Compassion Scale-Short Form; SPTS: Sensitivity to Pain Traumatization Scale.

4. Discussion

The results of this study indicate that a specialized Iyengar-informed yoga program for patients with chronic post-surgical pain was feasible and safe, and resulted in between groups improvements in pain interference. Regarding feasibility, the results showed adequate rates of recruitment, retention, intervention adherence and completion, measure completion, and program satisfaction. In particular, the low rate of attrition was notable considering the complex and impactful medical status of the participants and common issues regarding drop-out and withdrawal for these types of behavioural programs. In contrast, the results do not support the first efficacy hypothesis that a specialized Iyengar-informed yoga program for patients with chronic post-surgical pain is better than a wait-list control condition in improving pain catastrophizing. The results partially support the second efficacy hypothesis that a specialized Iyengar-informed yoga program is better than a wait-list control condition in improving pain-related and psychological outcomes. The results revealed a significant between-groups effect for pain interference, but not for pain severity/unpleasantness scores or psychological variables. Possible reasons for the lack of effect observed for pain intensity could be attributable to: 1) the small sample size and insufficient power to detect the hypothesized effects, 2) that pain intensity is a notoriously difficult treatment target for behavioural interventions for chronic pain, and 3) the heterogeneous pain presentations due to surgical variability and time elapsed since surgery. Participants who are further out from surgery could require increased doses of the intervention, a greater degree of specialization, or perhaps concurrent multi-disciplinary care.

4.1 Yoga and Pain Interference

The finding that pain interference was significantly lower in the TC condition compared with the CC at post-intervention is consistent with previous trials evaluating pain-interference in the context of a yoga intervention for chronic pain. In a randomized controlled trial evaluating yoga compared to usual care in individuals with a variety of types of chronic pain, within group improvements in pain interference for the yoga condition were reported [49]. Meta-analyses and systematic reviews of RCTs evaluating yoga interventions for individuals with chronic low back and neck pain and rheumatic disease have concluded that yoga results in short term improvements in pain-related disability compared to controls [12, 50, 51]. To date, this is the first study providing evidence that a specialized yoga program reduces pain interference in a chronic post-surgical pain population. Pain interference has been identified as a primary goal in chronic pain treatment and optimizing function is considered to be a more feasible and meaningful outcome than reducing pain intensity, which is often refractory to change.

A theoretical model outlining the influence of yoga on pain interference through resilience and vulnerability factors has been proposed for chronic pain [52]. This model hypothesizes that yogic practice fosters resilience by way of teaching new possibilities for cognitive pain appraisal, reducing psychological distress, and selecting adaptive behavioural responses to chronic pain, which are classified broadly as coping strategies. Chronic pain resilience is defined in this model as the absence of chronic pain-related functional impairment in the presence of persistent pain and is attributed to

cognitive-behavioural shifts occurring in yoga that buffer the chronic pain experience and alter activity engagement, thereby reducing pain interference [52]. Other contemporary frameworks for the mechanisms of yoga may provide insight into the changes in pain interference observed in the present study. It has been proposed that yoga provides self-regulatory skills that function in a bidirectional, synergistic system in which lower- and higher-level neural networks integrate and modify interoceptive input in the context of stress, and inhibits emotional reactivity, negative appraisal, and rumination, as well as vagal function, muscle tension, pain, and inflammation [53], which are all relevant for pain interference. Yogic principles teach equanimity of mind, witness consciousness, and mindful observation, which involve a neutral attitude towards experience, regardless of pain, emotional valence, or desirability, and as a result, when these principles are applied in practice, the cultivation of emotional resilience ensues. Yogic practice promotes the development of skillful mental and behavioural responses to perceived threats and prolonged stress states, which are important aspects of self-regulation and healthy adaptation [52, 53] and are useful in times of pain, stress or transition, such as in a post-surgical period of healing and recovery.

4.2 Limitations

There were a number of limitations to this trial. Firstly, the small sample size limits generalizability to a larger transitional, post-surgical population, and also introduces the possibility of a type 2 error. Secondly, the sample was quite heterogenous with respect to the time elapsed since surgery and types of surgery, which may have influenced individual experiences with pain and psychological functioning, and therefore responses to the treatment and outcomes. Thirdly, this trial was limited by the exclusive use of self-report measures. Fourth, trials using a waitlist-control design are limited by the possibility that participants in the waitlist-control condition may change their behaviour during the waiting period and may artificially inflate treatment effects [54]. In order to minimize this possible limitation, these participants were instructed not to engage in yoga or mind-body practices while they waited for their intervention. Fifth, the yoga teacher was also a study investigator which introduces possible bias. Sixth, a major limitation of this study was the lack of blinding, which again introduces possible influence on performance (e.g., participant or study staff behaviour) and measurement bias. These last two limitations were addressed by providing the option for participants to complete all study questionnaires in a private environment or at home. Lastly, this trial was discontinued prematurely due to the Covid-19 pandemic, such that approximately a quarter of the participants were not able to complete a specialized yoga intervention, and this resulted in a subsequent loss of data collection, a smaller sample size than anticipated, and a preclusion of a third wave of the study. This loss of participant data could have influenced the study results and further limits generalizability due to the smaller sample size. Although the trial was discontinued earlier than anticipated, the basic structure of the RCT design remained intact and the a priori between group statistical analysis could be completed and interpreted.

4.3 Future Directions

The evaluation of yoga in peri-operative transitional pain programs is an emerging area, and yoga as pre-habilitation may be useful as an auxiliary support in prevention endeavors. It is recommended to design and evaluate three phase, peri-operative yogic programs, including the

components: 1) a short-term, skills-based, pre-habilitative yoga prior to surgery, 2) a yogic program for the immediate-post surgical period while in hospital, with a focus on pain management, coping, and restoration, and 3) a longer-term yoga program focused on healing and rehabilitation strategies. A similar two phase post-surgical yoga intervention has been proposed for addressing post-lumbar surgery pain using an in-person hospital yoga program and a virtual/pre-recorded at home yoga program [17, 18] and this trial represents a new horizon of possibilities for the application of peri-operative yoga interventions in hospital-based surgical centres. The use of a pre-habilitation, transitional, and recovery-based yoga model should be tailored for surgical type for maximum benefit. In addition, theoretical frameworks for yoga's multi-process change mechanisms are now established and utilizing psycho-neuro-immune measurements would provide greater insight into how yoga may be useful in the prevention of CPSP. Lastly, addressing methodological issues that were limitations of the current study and that are common within the yoga research literature is recommended. For example, small sample sizes could be remedied through longer recruitment intervals and multi-wave trials and the lack of blinding could be improved through intentional trial design.

5. Conclusions

The results of this trial show that a specialized Iyengar-informed yoga program for patients with chronic post-surgical pain was feasible, safe, and satisfactory to participants, and showed a post-intervention between groups improvement in pain interference. Reducing pain interference is a well-established treatment goal for chronic pain populations and improving both function and quality of life are primary targets for the post-surgical period. Specialized yoga programs are low-cost and holistic, and once learned, yogic skills function as self-management and health cultivation techniques which can be practiced independently of a health care provider. Adequately powered RCTs are needed to determine if integrated yoga programs should be incorporated into the roster of patient programming in transitional pain services to augment mental wellness and provide holistic rehabilitation in the post-surgical period.

Abbreviation and Acronym List

BPI-SF-PI	Brief Pain Inventory-Short Form-Pain Intensity
BPI-SF-PS	Brief Pain Inventory-Short Form-Pain Severity
CPSP	Chronic post-surgical pain
FFMQ-SF	Five Facet Mindfulness Questionnaire-Short Form
GAD-7	Generalized Anxiety Disorder-7
PCS	Pain Catastrophizing Scale
PHQ-9	Patient Health Questionnaire-9
PIPS	Psychological Inflexibility in Pain Scale
RCT	Randomized controlled trial
SCS-SF	Self-Compassion Scale-Short Form
SPTS	Sensitivity to Pain Traumatization Scale-12 Item
TGH	Toronto General Hospital
TPS	Transitional Pain Service
TC	Treatment condition

UHN	University Health Network
VAPS-Unpleasantness	Visual Analogue Pain Scale-Pain Unpleasantness
CC	Wait-list control condition

Acknowledgments

The authors thank administrative teams at the Transitional Pain Service and ELLICSR: Health, Wellness, and Cancer Survivorship Centre at Toronto General Hospital, University Health Network.

Author Contributions

Curtis, Kathryn: Conceptualization, provided the intervention, writing (original draft, review, editing). Clarke, Hance: Conceptualization, writing (original draft, review, editing). Santa Mina, Daniel: Conceptualization, writing (review). Bechsgaard, Gitte: Conceptualization, writing (review). Weinrib, Aliza; Conceptualization, writing (review). Jones, Jennifer: Writing (review). Au, Darren: Statistical analysis, consultation. Katz, Joel: Conceptualization, writing (original draft, review, editing). All authors have read and approved the published version of the manuscript.

Funding

This work was supported by funds made available by Dr. Joel Katz's Canadian Institutes of Health Research Canada Research Chair (CRC) held at York University. Costs associated with the project that were covered by Dr. Katz's CRC included the purchase of yoga props and payment of the assistant yoga teacher.

Competing Interests

The authors declare no financial interest or benefits from the direct applications of the research.

Data Availability Statement

Hard copy and electronic data associated with the study are confidentially housed at the Pain Research Lab at Toronto General Hospital, University Health Network, Toronto, Canada. Data requests can be made to Kathryn Curtis (kathryn.curtis@uhn.ca).

Additional Materials

The following additional materials are uploaded at the page of this paper.

1. CONSORT Checklist.

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