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A Protocol for a Mixed Methods, Single-Arm, Hybrid Effectiveness-Implementation Trial Evaluating a 12-week Yoga Intervention Delivered by Videoconference for Young Adults Diagnosed With Cancer

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Abstract

Background: Cancer among young adults (18-39 years) is relatively rare, but remains a leading cause of disability, morbidity, and mortality. Identifying strategies to support young adults' health following a diagnosis of cancer is important. Yoga may enhance health and could be delivered by videoconference. However, little research exploring yoga, and no research exploring videoconference delivery of yoga has been conducted with this cohort. We worked with young adults affected by cancer and developed, piloted, and refined a yoga intervention delivered by videoconference.
Objective: To evaluate our yoga intervention in a full-scale, mixed methods, single-arm, hybrid effectiveness-implementation trial.
Methods: Young adults 18 years or older, diagnosed with cancer between the ages of 18-39 years of age, and at any stage along the cancer trajectory are eligible. Participants receive 2 yoga classes/week over 12-weeks by videoconference and complete assessments at baseline, post-intervention, and 6- and 12-month follow-ups. Assessments include self-reported questionnaires (ie, stress, yoga barriers, physical activity behaviour, fatigue, cognition, cancer-related symptoms, general health, health-related quality of life, self-compassion, mindfulness, group identification), physical assessments (ie, aerobic endurance, flexibility, range of motion, balance, functional mobility), and a semi-structured interview (post-intervention only; exploring perceptions of acceptability, feasibility, and experiences). Quality improvement cycles occur every 6 months. Repeated measures analysis of variance will be conducted to explore effectiveness, descriptive statistics and responder/non-responder analyses will be used to explore implementation, and qualitative interview data, analyzed using content analysis and reflexive thematic analysis, will bolster effectiveness and implementation findings.

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Discussion: As the first full-scale trial to evaluate yoga delivered by videoconference for this cohort, findings will make substantial contributions to young adults' supportive cancer care.
Conclusion: This protocol, reporting on yoga delivered by videoconference for young adults diagnosed with cancer, will enhance transparency and reproducibility and provide a reference for forthcoming trial results.
Trial registration: NCT05314803 at clinicaltrials.gov.

Keywords
cancer care, oncology, patient-oriented research, patient engagement, methodology, mixed methods, physical activity, movement, mindfulness

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Background

Cancer among young adults 18-39 years of age is a leading cause of disability, morbidity, and mortality.[1,2] Further, young adults diagnosed with cancer experience a range of negative effects in the short- and long-term,[3,4] which can adversely impact all dimensions of quality of life.[5,6] Identifying strategies to support young adults' health and quality of life following a diagnosis of cancer is important. Yoga, a practice that includes physical postures, mindfulness, breath work, and relaxation techniques may be one such strategy.

There is convincing evidence from systematic reviews and meta-analyses that yoga enhances physical, psychological, and cognitive outcomes, and, when practiced in a group-setting, feelings of social connection and support in adults diagnosed with cancer (>18 years of age).[7-10] There is also evidence suggesting yoga may improve body composition, decrease leptin, and attenuate systemic inflammation associated with increased risk of cancer onset, recurrence, and early mortality,[11-16] and that as little as a single yoga session can augment heart rate variability,[17] another factor associated with disability, morbidity, and early mortality.[18] Among young adults diagnosed with cancer, many of whom are overweight or obese,[19] insufficiently active,[20] and face numerous barriers to engaging in protective health behaviours,[21] yoga may be an ideal supportive care strategy.

Despite the potential yoga holds to support young adults diagnosed with cancer, it has rarely been studied in this cohort. Early evidence suggests a 7-week, DVD-based yoga intervention is feasible, enjoyable, and possibly beneficial among young adults with non-curative cancer,[22] and findings from a cross-sectional survey highlight young adults diagnosed with cancer who participate in yoga do so to enhance aspects of their physical (eg, flexibility, side-effects) and psychological health (eg, anxiety relief, promote relaxation).[23] However, there remains a lack of research evaluating the effects of yoga in this cohort, which may be due to the challenges associated with recruiting and engaging young adults diagnosed with cancer.[24] Young adults face barriers (eg, time, commute, appointments) to engaging in trials and are a small and spread-out population.[24-26]

Delivering yoga by videoconference synchronously (ie, in real time) has been shown to be acceptable among adults (>18 years of age) diagnosed with cancer,[27-29] and may be one way to address some of the barriers young adults diagnosed with cancer face. Further, videoconference-based delivery could get ahead of future public health (pandemic) restrictions,[30] and be a useful modality for technology-adept young people who: report heavy reliance on the internet for health information,[31,32] desire interactive online interventions,[33] and want access to physical activity (including yoga) led by trained professionals.[34] To address the lack of research exploring yoga interventions delivered by videoconference to this cohort, we integrated perspectives from 12 young adults diagnosed with cancer and developed an 8-week yoga intervention delivered by videoconference. We evaluated this intervention in a single-arm hybrid effectiveness-implementation pilot trial.[35] Findings suggest the yoga intervention and trial were safe (no adverse events reported), partially feasible, and potentially beneficial, with significant changes observed over time in functional mobility, flexibility, perceived stress, and selected quality of life and mindfulness domains.[35] Based on these positive initial findings and participant feedback, we worked with a patient advisory board and modified the yoga intervention and trial, and are currently testing a 12-week yoga intervention delivered by videoconference in a full-scale, mixed methods, single-arm, hybrid effectiveness-implementation trial. The co-primary aims of this trial are to: (1) determine the effectiveness of the yoga intervention on behavioural, psychological, cognitive, and physical outcomes, and (2) determine feasibility and utility of implementation.

Methods

Study Design

To generate evidence for the role of yoga and explore implementation strategies, a mixed methods, single-arm hybrid effectiveness-implementation trial is underway. The mixed methods approach centres yoga adults' perspectives and

will offer a deeper understanding of effectiveness and implementation at trial cessation.[36] The single-arm design ensures all participants have access to the yoga intervention, a recommended supportive care strategy in adult oncology,[37,38] enables the yoga intervention to be implemented in a 'real world' setting,[39] and is one way to conduct research with rare, hard-to-reach populations like young adults diagnosed with cancer, as they require smaller sample sizes than comparative trials. The Standard Protocol Items Recommendations for Intervention Trials checklist[40] was followed in the preparation of this protocol (see Supplemental File 1). The CheckList sTandardizing the Reporting of Interventions For Yoga guidelines[41] and relevant elements of the Consolidated Standards of Reporting Trials (CONSORT) for eHealth interventions[42] and the Standards for Reporting Implementation Studies statement[43] will be followed when reporting full trial results, to ensure clear reporting of the yoga intervention.

Ethics

This study was designed and is being carried out in accordance with the principles of the Declaration of Helsinki. Participants are provided with written information regarding the study prior to obtaining their informed consent online. Approvals from the research ethics boards at the University of Calgary (HREBA.CC-20-0098) and the University of the Fraser Valley (HREB-101288) were obtained and any/all protocol modifications will be communicated immediately to relevant parties (eg, ethics boards, trial participants, trial registry). Consent forms and other documents given to participants are available upon request from the corresponding author. The study was registered in a publicly accessible registry for clinical trials (https://clinicaltrials.gov/ct2/show/NCT05314803).

Recruitment and Participants

Young adults diagnosed with cancer are recruited through: (1) email via the study teams' contact lists (from prior programs and studies), (2) social media via unpaid posts made by the study team and cancer support organizations on Facebook, Twitter, and Instagram (which has been shown to be one of the most cost-effective methods, per participant, to recruit young adults diagnosed with cancer to behavioural trials),[44] and (3) snowball sampling (current and past participants are encouraged to share information about the trial with their contacts). Young adults are eligible to participate if they: (1) are currently aged 18 years or older, (2) were diagnosed with cancer between the ages of 18-39 years of age, (3) are at any stage along the cancer trajectory (ie, from diagnosis onward), (4) confirm they are able to safely engage in yoga, as assessed by completing the Get Active Questionnaire[45] and obtaining medical clearance (if indicated), and (5) can participate in English. There is no criterion related to prior yoga experience in general, but participants may not enrol in the trial more than once.

Sample Size

The sample size was set based on the co-primary effectiveness aim, for the outcome of stress. In our pilot work, a large effect size was observed.[35] Estimating a large effect size, and 80% power at the 5% level of significance, 70 participants were indicated. Accounting for an expected loss to follow-up rate of 20%, and requisite power for exploring additional effectiveness outcomes of behavioural, psychological, and physical outcomes, the sample size was set to 88 participants over 5 years. No sample size estimation was performed for the co-primary implementation aim.

Procedures

Figure 1 depicts the flow of participants through the trial. Following self-referral and self-confirmation of eligibility, participants are asked to provide informed consent via a web-based form housed on Research Electronic Capture (REDCap; currently version 10.0.32).[46,47] Once informed consent is provided, study staff ask participants to complete assessments at baseline (week 0), which consist of completing self-reported questionnaires via REDCap and physical assessments by videoconference. Once baseline assessments are completed, participants begin the 12-week yoga intervention. All participants complete a post-intervention (week 12) assessment, which consists of the self-reported questionnaires via REDCap, physical assessments by videoconference, and an interview by videoconference. At 6- (week 24) and 12-month (week 52) follow-up times, all participants are again asked to complete self-reported questionnaires via REDCap and physical assessments by videoconference. To enhance the likelihood of completing assessments and to maximize data collection, automated follow-up reminders from REDCap are sent every 3 days, and emails are sent every 5 days to those who have not yet completed (or scheduled) physical assessments.

Additional data (eg, recruitment, attendance, adherence) is collected throughout the intervention and trial by study staff. The assessment schedule and details are provided in Table 1 and further details covering assessments of reach, effectiveness, adoption, implementation, and maintenance are provided below.

Yoga Intervention

The yoga intervention was developed over 4 months in response to findings from our pilot trial,[35] a patient advisory board, and expertise of the study team. Specific modifications to the 8-week pilot intervention included: lengthening the intervention (from 8- to 12-weeks), increasing the frequency of classes (from one class each week to two classes each week), and including both 'slow flow'- and 'relaxation'-style classes. The result was a 12-week yoga intervention for young adults diagnosed with cancer delivered in a group format. Two 60-min classes are offered each week, and no specific instructions are given for home practice beyond these

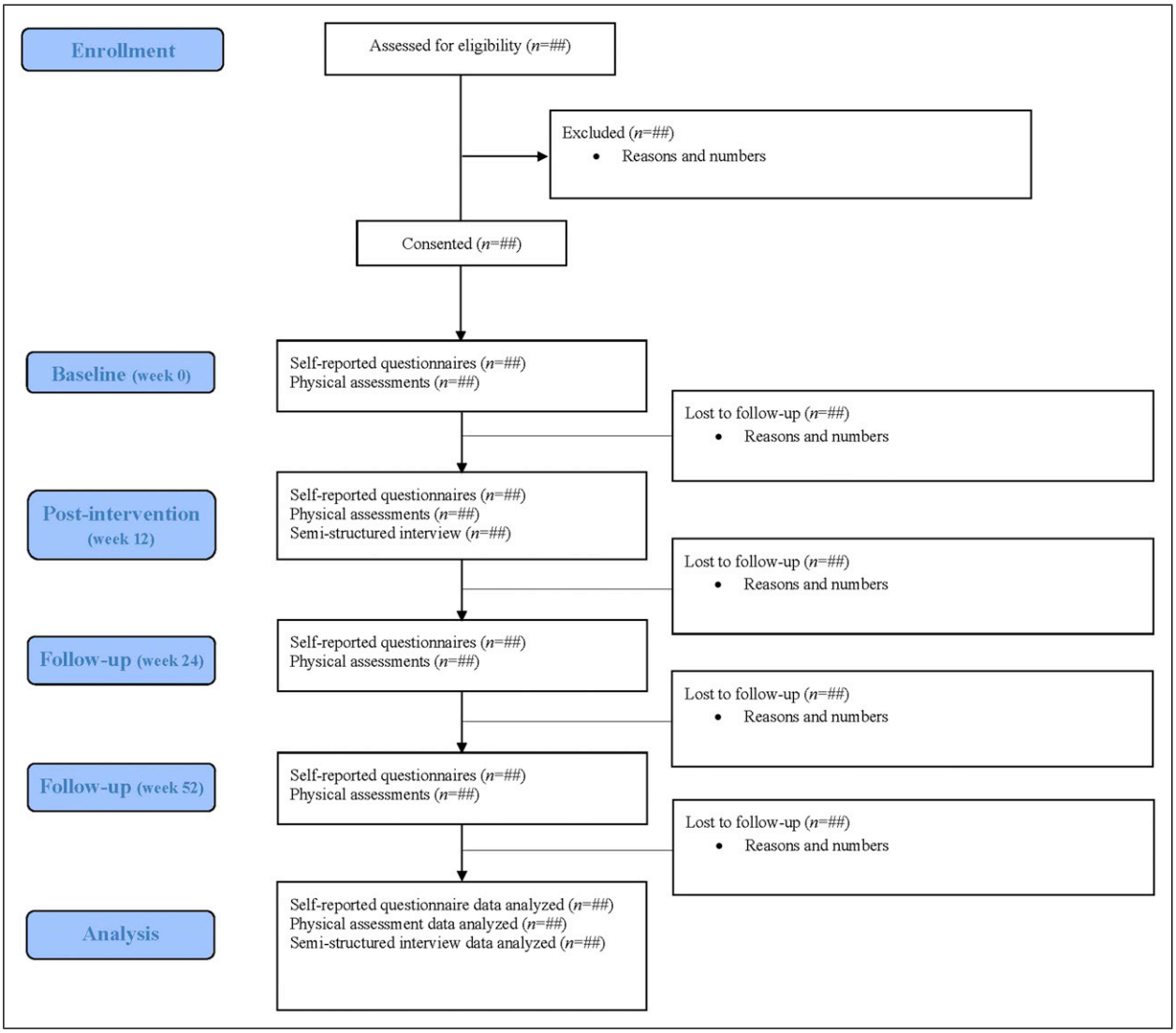

Figure 1. CONSORT flow diagram.

two classes (ie, participants are neither asked to refrain from nor engage in additional practice). The first class is a 'slow flow class' that combines vinyasa and hatha traditions and focuses on building strength, flexibility, and range of motion. The second class is a 'relaxation class' that integrates yin and restorative traditions and focuses on relaxation and meditation. Both classes include physical postures, breathwork, meditation, and relaxation. Each week of the intervention has a specific theme comprising a physical focus and energetic intention (eg, chest opening and practicing gratitude). At the beginning of each class, participants are prompted to check-in with how they are feeling (and can choose to share via the chat feature in Zoom or by unmuting if they feel comfortable). Throughout class, participants are offered modifications (including seated postures), reminded of common contraindications and provided alternative poses, and are continuously supported in choosing postures that feel appropriate and comfortable. Classes are recorded and a password protected time sensitive link (ie, expires 7 days after the class was recorded) is distributed to absent participants (number of views are tracked). Class sizes are capped at 20 participants. See Table 2 for a general sequence of each style of class (ie, slow flow, restorative) within the intervention. The entire 12-week protocol is available from the corresponding author.

Classes are delivered, following protocol, by a yoga instructor who has at least 200-hour yoga teacher training, Thrive Health Exercise Oncology training, Yoga Thrive Teacher Training Certification (or similar), who has previously delivered yoga to individuals (of varying ages) diagnosed with cancer, and who has completed trial training (including attending a workshop covering roles and responsibilities and reviewing all manuals and protocols). Each class is supported by two student moderators who have completed the Thrive Health Exercise Oncology training and

Table 1. Outcome Measures and Time Points.

Outcome	Measure	Baseline (week 0)	Post-intervention (week 12)	Follow-up (week 24)	Follow-up (week 52)
Patient-reported outcomes					
Personal and medical information		X		X	X
Stress	Perceived Stress Scale	X	X	X	X
Barriers and facilitators to yoga participation	Exercise barrier self-efficacy scale (from Exercise Barriers and Facilitators questionnaire)	X	X	X	X
Physical activity	Modified Godin Leisure Time Exercise Questionnaire	X	X	X	X
Fatigue	Functional Assessment of Chronic Illness Therapy-Fatigue	X	X	X	X
Cognition	Functional Assessment of Cancer Therapy – Cognitive Function Version 3	X	X	X	X
Cancer-related symptoms	Edmonton Symptom Assessment Scale revised	X	X	X	X
General health	EuroQual – 5Dimensions Scale	X	X	X	X
Health-related quality of life	Functional Assessment of Cancer Therapy General Version 4	X	X	X	X
Self-compassion	Self-Compassion Scale	X	X	X	X
Mindfulness	Mindful Attention Awareness Scale	X	X	X	X
Group identification	Group Identification Scale		X	X	X
Physical assessments					
Aerobic endurance	2 Minute Step Test	X	X	X	X
Lower body flexibility	Seated sit and reach rest	X	X	X	X
Shoulder flexion range of motion	Shoulder flexion	X	X	X	X
Balance	Single-leg balance test	X	X	X	X
Functional mobility	30 Second Sit to Stand Test	X	X	X	X

comprehensive trial specific training. Moderators assist the yoga instructor by taking attendance, letting participants into the class (and removing last names), monitoring the chat for questions or comments from participants, monitoring videos for safety concerns, and demonstrating chair-options for all poses. To assist with demonstrating poses, in their trial training materials, moderators are provided with a detailed manual that includes descriptions and images detailing seated posture modifications for all poses included within the 12-week protocol.

To ensure participant safety, several precautions are being taken. Specifically, participants are required to self-screen to ensure they are medically able to safely participate in yoga, and are required to complete a detailed health intake (as part of their ***Personal and Medical Information*** questionnaire, described below). Study staff, including yoga instructors, review these intakes prior to each session and meet with participants or seek clarification regarding cancer or other medical concerns, when necessary. If additional support is required, Clinical Exercise Physiologists are consulted to provide safe alternatives and modifications. Classes are led by certified yoga instructors, with population-specific experience and training. Instructors follow a protocol that was developed for safe delivery of yoga to young adults diagnosed with cancer (avoiding or limiting poses that are commonly contraindicated). The protocol also includes pertinent verbal and visual safety cues and modifications throughout. Instructors are supported in intervention delivery by two student moderators. One moderator is responsible for monitoring the chat for questions or comments from participants and monitoring videos for safety concerns (which if noted are immediately communicated to the yoga instructor). The second moderator demonstrates modifications during class and provides chair-based options for all poses. During classes, moderators have immediate access to participants' full address, phone number, emergency contact information, and emergency protocols should a medical emergency occur.

Assessments

At baseline (week 0), post-intervention (week 12), and 6- (week 24) and 12-month (week 52) follow-up times, participants complete assessments. The assessments at each timepoint include self-reported questionnaires completed via REDCap and physical assessments conducted by videoconference. Post-intervention (week 12),

Table 2. Typical Sequence of Classes Within the 12-Week Yoga Intervention.

Class component	Slow flow example prompts, practices, and postures	Restorative example prompts, practices, and postures
Greeting	Open-ended questions to group: *How are you? What is your energy like today? How are you feeling?*	Open-ended questions to group: *How are you? What is your energy like today? How are you feeling?*
Supine (or seated)	Breathwork • Natural breath • Even counted breath • Box breath Postures • Modified wind relieving pose • Supported spinal twist • Lateral flexion • Core activation	Breathwork • Natural breath • Even counted breath • Box breath Postures • Modified wind relieving pose • Supported spinal twist • Lateral flexion • Legs up the wall
Seated or kneeling	Breathwork • Natural breath • Linking breath to movement Postures • Seated forward fold • Supported spinal twist • Lateral flexion • Cat and cow • Child's pose • Arm/leg extension • Seated tree pose	Breathwork • Natural breath • Linking breath to movement Postures • Lateral flexion • Cat and cow • Child's pose • Arm/leg extension • Seated tree pose
Standing	Breathwork • Natural breath • Joining breath to movement Postures • Tree pose • High lunge • Warrior II • Half Mar • Mountain • Chair	--
Seated or kneeling	Breathwork • Natural breath • Linking breath to movement Postures • Seated forward fold • Supported spinal twist • Lateral flexion • Dear pose • Seated Figure 4 • Neck release	Breathwork • Natural breath • Linking breath to movement Postures • Bridge • Supported reclined bound angle • Dear pose • Seated Figure 4 • Neck release
Closing - supine (or seated)	Breathwork • Natural breath • Even counted breath • Box breath Postures • Savasana (corpse pose) • Comfortable seat Mindfulness • Body scan • Visualization • Reading	Breathwork • Natural breath • Even counted breath • Box breath Postures • Savasana (corpse pose) • Comfortable seat Mindfulness • Body scan • Visualization • Reading

Notes. Every class in the 12-week session differed, including length of time spent in each component. Prompts, practices and postures aligned with the physical focus and energetic intention.

a semi-structured interview is also completed by videoconference.

Effectiveness

Self-Reported Questionnaires

Personal and Medical Information. A researcher-generated questionnaire is administered at baseline (week 0) collecting participants' age, location (ie, province), setting (ie, rural, urban), biological sex, current gender, marital status, education, annual income, employment status, ethnicity, cancer diagnosis, treatment status, and symptoms. This data is being collected to ensure safe delivery of yoga, describe the sample, and better understand reach. At 6- (week 24) and 12-month (week 52) follow-up times, additional medical questions are asked to gather data related to recent medical updates or changes since the last assessments in areas covering diagnosis, treatment, medications, and symptoms.

Stress. The Perceived Stress Scale (PSS)[48] is a 10-item questionnaire designed to measure perceptions of stress over the past month. Items are scores on a 5-point scale ranging from 0 (*never*) to 4 (*very often*). After reverse scoring selected items, scores are summed with higher scores reflecting greater perceived stress. See Supplemental File 2 for further details on this and the remaining questionnaires described below.

Barriers to Yoga Participation. The 9-item barrier self-efficacy scale from the Exercise Barriers and Facilitators questionnaire[49] is being used to measure participants' confidence to overcome challenges (eg, when they are tired, when there is a lack of time) and exercise. Items are scored on a 11-point Likert-type scale from 0 (*not at all confident*) to 100 (*extremely confident*). Scores are interpreted as percentages, with higher scores indicating greater confidence. Total scores are calculated by summing the confidence ratings and dividing by the total number of items in the scale. Scores range from 0 to 100, and a higher score indicates higher self-efficacy to overcome barriers and engage in exercise.

Physical Activity. A modified version of the Godin Leisure Time Exercise Questionnaire (m-GLTEQ)[50] is being used to collect self-reported physical activity. The original questionnaire asks participants to consider the number of times per week they engage in mild, moderate, and strenuous leisure time exercise for 15 minutes or more. The modified version used herein asks participants to consider the number of times per week they engaged in mild, moderate, and strenuous activity and resistance training and flexibility exercise in their leisure time for 10 minutes or longer, and the average number of minutes per bout. Participants are instructed to answer, recalling their activity before their cancer diagnosis and over the past month. The m-GLTEQ is scored by calculating the total amount (time x frequency) of each intensity and type of physical activity (eg, resistance training) and summing totals. Participants can also be categorized as meeting or not meeting current physical activity recommendations.

Fatigue. The Functional Assessment of Chronic Illness Therapy-Fatigue (FACT-F) scale is a 13-item questionnaire to measure fatigue over a typical week (7 days).[51] Items are scored on a 5-point scale ranging from 0 (*not at all*) to 4 (*very much*). After reverse scoring (as appropriate), items are averaged (higher scores indicate less fatigue).

Cognition. The Functional Assessment of Cancer Therapy – Cognitive Function Version 3 (FACT-Cog v3) is a 37-item questionnaire designed to measure impairment of cognitive abilities (memory, attention, concentration, language, and thinking) over the past week (7 days).[52,53] Items are scored on a 5-point scale ranging from 0 (*never or not at all*) to 4 (*several times a day or very much*). After reverse scoring selected items, scores are summed to produce 4 subscale scores (perceived cognitive impairments, comments from others, perceived cognitive abilities, and impact on quality of life), with higher scores reflecting fewer cognitive problems and better quality of life.

Cancer-Related Symptoms. The Edmonton Symptom Assessment Scale Revised (ESAS-r)[54] is a 9-item questionnaire (and body diagram, though the diagram is not being used herein) designed to assess 9 common symptoms (eg, tiredness, drowsiness, anxiety) participants may be currently experiencing.[55] Items are scored on a 10-point scale ranging from 0 (*no*) to 10 (*worse possible*). After reverse scoring, greater scores indicate worse symptoms.

General Health. The EuroQual – 5 Dimensions Scale (EQ-5D 5 L)[56] includes 5-items designed to assess 5 domains of health (mobility, self-care, usual activities, pain and discomfort, anxiety and depression) and a single visual analogue scale. The 5-items are scored on a 5-point scale ranging from 1 (*no problem at all*) to 5 (*unable to/extreme problems*). Scores are computed by retaining the original rating on each scale. The visual analogue scale ranges from 0 (*the worst health you can imagine)* to 100 (*the best health you can imagine*). The higher the score, the better the overall health.

Health-Related Quality of Life. The Functional Assessment of Cancer Therapy General Version 4 (FACT-G v4)[57] is a 27-item questionnaire designed to measure health-related quality of life over the past 7 days across 4 subscales: physical, social, emotional, and functional well-being. Each item is scored on a 5-point scale ranging from 0 (*not at all*) to 4 (*very much*). After reverse scoring (as appropriate), scores on each subscale are summed, multiplied by the number of items in the scale and then divided by the number of items answered. A total score is computed by summing subscale scores. Higher scores indicate better health-related quality of life.

Self-Compassion. The Self-Compassion Scale[58] is a 26-item scale designed to measure how one typically acts towards themselves in difficult times across 6 subscales (self-kindness, self-judgement, common humanity, isolation, mindfulness, and overidentification). Each item is scored on a 5-point scale ranging from 1 (*almost never*) to 5 (*almost always*). After reverse scoring selected items, the means of each subscale are computed, and a total mean (the average of the 6 subscale means) is computed with higher scores indicating greater self-compassion.

Mindfulness. The Mindful Attention Awareness Scale (MAAS)[59] is a 15-item scale designed to measure core characteristics of dispositional mindfulness. Each item is scored on a 6-point scale ranging from 1 (*almost always*) to 6 (*almost never*). Scores are summed by computing a mean of the 15 items with higher scores indicating greater levels of dispositional mindfulness.

Group Identification. The Group Identification Scale (GIS) is a 4-item questionnaire measuring one's sense of belonging to a group.[60] Items are reported on a 7-point scale ranging from 1 (*I strongly disagree*) to 7 (*I strongly agree*) and are summed with higher scores capturing greater group identification.

Physical Assessments. Physical assessments are performed by two trained physical accessors at participants' convenience over videoconference following guidance for conducting assessments by videoconference for adults diagnosed with cancer.[61] This approach is being used in a larger trial assessing the effectiveness and implementation of exercise among adults diagnosed with cancer.[62] All assessments follow the Canadian Society of Exercise Physiology's Physical Activity Training for Health Protocol[63] and have been used previously (with no adverse events) in trials testing the effects of exercise among adults diagnosed with cancer[62,64] and yoga among young adults diagnosed with cancer.[35] Similar safety protocols are in place for the physical assessments as in the yoga intervention. Specifically, two assessors (who are qualified exercise professionals with relevant exercise and physical assessment, trial, and safety and emergency training) are present and conduct assessments. Assessors have immediate access to participants' full address, phone number, emergency contact information, and emergency protocols (including an adverse event form, which all study staff receive specialized training in) should a medical emergency occur.

Aerobic Endurance. To assess aerobic endurance, the 2 Minute Step Test[65] is performed. Participants begin by standing perpendicular to the camera (ie, right leg facing the camera) while marching in place for 2 minutes. The target knee height is determined by having the participant measure the distance between the patella and iliac crest to find the midpoint of the thigh. Participants are then instructed to measure the distance from the thigh midpoint to the floor, and this distance is recorded by the assessor. If the participant is unable to determine the thigh midpoint, target knee height is set so that the thigh is parallel to the floor when marching. On a 'ready-set-go' cue, participants begin marching in place and the number of steps completed within the 2-minute time frame on the leg facing the camera are recorded. Rate of perceived exertion is recorded after the assessment has been completed on a scale ranging from 0 (*nothing at all*) to 10 (*very*, *very hard*, *maximal*, *extremely strenuous exercise*).[66]

Lower Body Flexibility. To assess flexibility in the lower body, participants complete a seated sit and reach test.[67,68] This test is performed after the 2 Minute Step Test and after participants have the opportunity to stretch each leg twice for 20 s each. Once their warm-up stretch is completed, participants are instructed to place their chair perpendicular to the camera and sit on the edge of the chair, extending one leg out at a time with the ankle bent at 90°. Participants are then instructed to hold a ruler/measuring tape with both hands and lean forward to touch the toes of their extended leg. The knee of extended leg remains straight. Participants are asked to hold the maximum flexion position for 3 s and then measure the distance from the ruler/measuring tape device to the tip of their toes (reported to the nearest 0.5 cm). This is repeated for each leg twice and the better score is used, with greater scores indicating greater flexibility.

Shoulder Flexion Range of Motion. To assess shoulder flexion range of motion, participants are instructed to place a chair perpendicular to their camera. The participant is then instructed to sit tall, facing forward in the chair (ie, their shoulder perpendicular to the camera), with their feet flat on floor and their arms by their side (palms facing inward). Participants are then instructed to rotate their hand into a neutral position (ie, thumb facing up) and to keep their elbow extended. When the participant is ready, they perform their maximum shoulder flexion (ie, raise their arm in forward flexion, while remaining in the sagittal plane) without compensation (eg, arched back, bringing arm away from ear). Once the participant reaches their full range of motion position, the assessor takes a screenshot (ie, picture). This is repeated for each arm twice and the average of both trials is used. Range of motion is determined in degrees by measuring the final angle (pictured in the screenshot) with a goniometer, using the head of the humerus, midline of the humerus, and mid-axillary line as anatomical landmarks for consistent measurements. Higher scores on this assessment indicate greater shoulder range of motion.

Balance. To assess balance, the single leg balance test[69] is being used and participants are instructed to stand barefoot with hands on opposite shoulders, crossed in front of their chest, facing their camera. Once the participant is stable, the assessor asks the participant to stand on a leg of their choice,

lifting the opposite foot (so it is near, but not touching the standing leg). Time is started once the participant lifts their foot off the ground, to a maximum of 45 s. If/when participants lose their balance, within the initial 3 s of the trial, a second trial is allowed. In this case, the better trial for each leg is recorded, with higher scores indicating greater balance. This is then repeated for the opposite leg.

Functional Mobility. To assess functional mobility, the 30 Second Sit to Stand[67,68] is performed. Participants are instructed to sit on a chair with their hands on opposite shoulders in front of their chest. Participants are instructed to come to a full standing position and return to a seated position (ie, sit-to-stand) without assistance. On a 'ready-set-go' cue, the participant is instructed to complete as many sit-to-stands as possible in 30 s and the number of fully completed sit-to-stands within the 30 s time frame is recorded, with higher scores indicating greater functional mobility. This test is completed once.

Interviews. Post-intervention (week 12), participants complete interviews following a semi-structured guide, with a trained study staff member. Interviews start with rapport building between the interviewer and participant and answering questions the participant may have about the interview purpose and process. Then, participants are asked a series of open-ended questions (with probes) to ascertain the 'active ingredients' of the yoga intervention, to identify potential additional relevant outcomes and factors impacting implementation success, and to explore perceptions of acceptability and satisfaction. Qualitative interviews also seek to examine participants' barriers and facilitators to participating in the yoga intervention so as to inform our understandings of feasibility and utility of implementation (see ***Implementation*** below). The semi-structured interview guide being used can be found in Supplemental File 3. All interviews are conducted via Zoom, are audio-recorded using a Sony ICD-PX240 or Sony ICD-PX470 recorder and are transcribed verbatim.

Implementation. To assess implementation we are recording and assessing reach, feasibility, fidelity, and adverse events throughout the trial. *Reach* is defined as the number of young adults who self-refer, are eligible, and participate (and reasons for non-participation after showing initial interest). *Feasibility* is defined as retention to the trial (ie, completion of assessments), adherence to the yoga intervention (ie, attendance), percentage of missing data, and participants' barriers and facilitators to the yoga intervention (collected via qualitative interviews). We also track all aspects related to delivery, including time and expertise to deliver and assess and cost of the yoga intervention implementation (eg, training, site delivery costs, administrative support). *Fidelity* includes the assessments of the delivery of content as intended. This is tracked using a standardized reporting form that is completed by moderators and yoga instructors within each class. *Adverse events* are tracked via a standardized reporting form (eg, date, severity, timing, site/location, duration, clinical action taken, outcome; Common Terminology for Adverse Events V5.0).[70] Participants, moderators, and instructors can report adverse events.

Quality Improvement Cycles

Throughout the trial, quality improvement cycles are scheduled to occur every 6 months. These cycles include reviewing participants' personal and medical information, fidelity data, and responses within interviews to items exploring acceptability. We host bi-annual meetings with the study team (including researchers, yoga instructors, and study staff [eg, assessors, moderators, research assistants]) and quarterly meetings with our patient advisory board to discuss trial delivery, explore additional supports/tools (eg, training, documents, workflows) that are required to facilitate implementation, and review informal feedback and emails from participants and the study team. The Consolidated Framework for Implementation Research,[71] which has been fully operationalized, guides data collection and is used to categorize data gathered. Quality improvement cycles are critical within pragmatic implementation research to enable timely reaction to knowledge gained and will ensure an optimized implementation approach at trial cessation. Any adaptations will be made carefully to avoid inflation of statistical error rates and operational bias[72] and modified or additional implementation strategies will be tracked to ensure transparency in reporting.

Data Management

All electronic questionnaires are housed on the REDCap server at the University of Calgary, which will be de-identified, downloaded, and stored in a secure (password protected) file for analysis. Physical assessment data are uploaded and inputted into REDCap within 5 days of each physical assessment. Audio-recorded interviews are stored in a secure (password protected) file and are permanently deleted within 5 days of the interview (prior to which they are transcribed verbatim and any identifying information is removed). All de-identified transcripts are stored in a secure (password protected) file. A master participant list is being stored separate to any survey results and password protected. Only members of the study team have access to this data.

Data Analysis

Preliminary Analyses. Descriptive statistics will be computed using means and standard deviations for continuous variables (or medians and interquartile ranges when the observed variables do not follow a normal distribution) and frequencies and percentages for categorical variables for personal and medical information and study outcomes (self-reported

questionnaires, physical assessments). The flow chart depicted in Figure 1 will be completed to summarize the process of recruitment and retention to the trial.

Main Analyses. Quantitative data will be managed in R. Descriptive analyses will be used to summarize participants' personal and medical information, behavioural, psychological, cognitive, and physical outcomes, and implementation outcomes. Following this, if data is normally distributed, repeated measures analysis of variance will be conducted to examine changes across time in stress and other outcomes (behavioural, psychological, cognitive, and physical). If data is non-normal, the Friedman test or generalized linear models will be used to examine changes across time. Responder/non-responder analyses will be performed via chi-square tests. Qualitative interview data will be transcribed verbatim and managed and analyzed in NVivo using content analysis[73] and reflexive thematic analysis,[74] as appropriate.

Additional Analyses. Given the amount of data collected within this trial, it is likely that additional exploratory analyses will be conducted. These analyses will seek to answer additional research questions and will only occur after the main analyses.

Patient Involvement

Patients' perspectives guided the development of the intervention and this trial and are critical to ongoing trial conduct. Specifically, 12 young adults diagnosed with varied cancers provided feedback to inform the 8-week yoga intervention and trial that was piloted previously. Pilot data were augmented with perspectives from pilot trial participants and the five young adults, who comprise the patient advisory board, to develop the 12-week yoga intervention being evaluated herein. The patient advisory board meets quarterly (as described above) to discuss timely topics (eg, reviewing data and participating in quality improvement cycles), explore additional supports/tools that are required to facilitate implementation, and review informal feedback and emails that have come in from participants and study staff, and communicates between meetings via Slack (an online communication platform) and email. Further, the patient advisory board contributes to the interpretation of results, such as the case within a manuscript reporting on participants' experiences within the 8-week pilot trial,[75] and the board actively contributed to this manuscript. See Supplemental File 4 for a brief description of patient advisory board members.

Dissemination Plans

Findings will be shared broadly with academic and non-academic audiences through national and international scientific presentations, peer-reviewed publications, national and local community meetings, infographics, educational videos, and trial updates on relevant websites. Study staff and patient advisory board members will be given credit as authors and additional contributors (eg, yoga instructors, assessors) in accordance with current recommendations. Results will be submitted to clinicaltrials.gov with a year year following trial completion.

Trial Status

Ethics approval was granted 12/08/2021 and recruitment started 30/08/2021. As of 06/11/2024, 115 young adults have self-referred and met the eligibility criteria, 83 consented and enrolled, 50 completed the intervention, and 44 completed the post-intervention assessment. The anticipated date of recruitment completion is 20/09/2026. The protocol reported herein is version 4 and it was last updated 12/05/2023.

Discussion

Yoga is one supportive care strategy that confers health benefits for adults diagnosed with cancer.[7-10] Yet, yoga has rarely been explored among young adults diagnosed with cancer. One reason for this may be due to the barriers young adults' face when presented with opportunities to participate in trials.[25] Delivering yoga by videoconference may overcome participation barriers and engage this a rare, hard-to-reach population. In our pilot trial, we found yoga delivered by videoconference was safe (no adverse events reported), partially feasible, and potentially beneficial, with significant changes observed over time in functional mobility, flexibility, perceived stress, and selected quality of life and mindfulness domains.[35] We also found that participants enjoyed the yoga intervention (ie, postures, format) and appreciated the expertise of the trained yoga instructors and moderators, but desired a longer intervention with more classes offered. This manuscript describes the relevant elements of the modified, 12-week yoga intervention and trial. Findings from this trial will generate evidence on the effectiveness of yoga delivered by videoconference and factors impacting implementation to inform ongoing efforts to ensure more young adults diagnosed with cancer have access to yoga. Ancillary findings could address additional gaps in knowledge by exploring possible pathways underlying the benefits of yoga, examining implementation utility, and determining for whom yoga has the greatest impacts.

Key strengths of our yoga intervention and trial include its effectiveness-implementation design, which enables us to generate evidence covering both yoga's effects in a 'real world' setting and implementation utility. The pragmatic design of this trial is a notable strength. Broad enrollment criteria and use of multiple and efficient recruitment strategies will increase the number of people who may benefit. Further, the videoconference-based nature of the trial may encourage participation of young adults who reside within and beyond urban centres and address participation barriers (eg, lack of time, unwillingness to travel). In addition, through utilizing

mixed methods and obtaining quantitative and qualitative data, it will be possible to evaluate each aspect of the intervention and trial in greater depth than if only looking at one type of data alone. These strengths will ensure that, should findings be positive, we are uniquely positioned to engage in scaling efforts to support broader uptake within young adult cancer care.

Nevertheless, there are limitations that should be considered. First, we are conducting physical assessments by videoconference. Though this has been done previously,[35,62,64] there is little evidence for the validity and reliability, and practical challenges (given the variable space and equipment participants have access to). We are seeking to enhance validity and reliability of results through two assessors (primary and secondary) and detailed tracking documents making note of participants' space and equipment for each assessment. Second, though we set our eligibility criteria to be as broad as possible, it could result in older adults who were diagnosed with cancer as a young adult participating, which may hinder our ability to generate evidence for individuals who currently are (or recently were) between 18-39 years of age. Further, the broad and inclusive eligibility criteria could result in a sample comprised of individuals with previous history of yoga practice. This could lead to ceiling effects, masking the potential this intervention may hold for those without a history of yoga. We will be able to capture participants' experience with yoga prior to this trial through our qualitative interviews and may be positioned to explore unique impacts of the intervention based on prior yoga history (as ***Additional Analyses***). Third, multiple instructors are involved in intervention delivery, which could introduce human error and variations class-to-class. We are seeking to address this through detailed class plans (protocols) that include written instructions, visuals, and video recordings, and requiring all instructors and moderators to complete comprehensive intervention and trial specific training. We are also tracking fidelity so we can report any deviations from the protocol. Relatedly, each class has two moderators, one of whom demonstrates chair-based options for participants who may require alternative postures. To enhance consistency between moderators and the chair-based pose modifications offered, moderators receive trial and intervention-specific training and a detailed manual that includes descriptions and images detailing modifications. Fourth, several questionnaires and assessments are being conducted herein, which may be viewed as burdensome. While efforts were made to reduce participant burden (eg, questionnaire versions with the fewest number of items were selected), the assessments may still be too long. Finally, the main drawback of using a single-arm experimental design is that it does not control for trends in improvement.

Conclusion

Given the ubiquity of the internet, delivering yoga by videoconference holds immense potential to support positive outcomes among young adults diagnosed with cancer. Building upon our past pilot work,[35] we anticipate that findings will contribute further evidence regarding the range of benefits yoga may confer for this cohort and vital data to inform ongoing implementation. All results will be reported transparently in forthcoming publications.

Appendix

List of Abbreviations

EQ-5D 5L:	EuroQual - 5Dimensions
ESAS-r:	Edmonton symptom assessment scale revised
FACT-Cog v3	Functional assessment of cancer therapy – cognitive function version 3
FACT-G v4	Functional assessment of cancer therapy general version 4
FACT-F:	Functional assessment of chronic illness therapy-fatigue
GIS	Group identification scale
MAAS	Mindful attention awareness scale
mGLTEQ	Modified godin leisure time exercise questionnaire
PSS	Perceived stress scale
REDCAp	Research electronic capture

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Authors' Contributions

Conceptualization: AW, SNCR; Investigation: AW, EM, SNCR; Methodology: AW, EM, SCNR; Resources: AW, SNCR; Supervision: AW, SNCR; Visualization: AW; Role/Writing – original draft: AW; Writing – review & editing: AW, EM, AJ, HC, LH, HM, LC, JD, SNCR, patient advisory board members.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: AW, EM, AJ, HC, LH, HM, LC, JD, and patient advisory board members declare that they have no competing interests. SNCR is co-founder of Thrive Health Services Inc, who provide preliminary training (Cancer and Exercise) for the yoga instructors and moderators involved.

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Ethical statement

Ethics Approval

Approvals from the research ethics boards at the University of Calgary (HREBA.CC-20-0098) and the University of the Fraser Valley (HREB-101288) were obtained and informed consent was obtained from all participants involved in the study.

Informed Consent

All participants provided consent for publication (as part of completing the informed consent form that was required for participation).

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Supplemental Material

Supplemental material for this article is available online.

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