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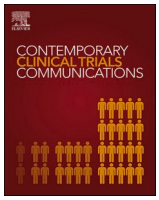

Protocol for a feasibility randomized controlled trial of gentle yoga in older patients discharged from phase II cardiac rehabilitation

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ABSTRACT

Background: Physical activity (PA) is essential following an acute cardiac event. Cardiac rehabilitation (CR) is commonly prescribed, and PA after CR is recommended. Because of age-related changes in functional ability and multi-comorbidity, many older cardiac patients struggle to continue performing PA at home after CR. Depressive symptoms and anxiety are prevalent in cardiac patients and associated with poor self-care, including lack of daily PA. Yoga has been demonstrated to improve psychological and physical health outcomes in cardiac patients, but it is unknown whether yoga, modified for older CR patients – Gentle Yoga – is beneficial in managing psychological distress and maintaining PA following phase II CR. Our specific aims are to:1) determine the feasibility and acceptability of a modified gentle yoga intervention delivered via video conferencing for older cardiac patients; 2) compare, at 3-month follow-up, the effects and determine effect sizes of a gentle yoga intervention versus control on psychological health and physical health.

Methods: We are conducting a 2-group (intervention versus control) randomized controlled pilot study. The intervention is a 12-week gentle yoga program delivered via video conference. Short-term effects will be evaluated at 3-month.

Conclusion: This study is designed to be suited for older cardiac patients who would not have access to supervised PA opportunities after facility-based CR to enhance PA. This study will provide data about the feasibility and acceptability of the protocol for older cardiac patients and will offer effect sizes to determine sample size for a fully powered randomized controlled trial.

1. Background

Cardiac rehabilitation consists of formal prescription-driven program (based on cardiac stress testing and monitoring)that includes physical activity (PA) in the form of exercise training, stress management, lifestyle change, and nutrition education [1]. Cardiac rehabilitation has three phases I) in-hospital evaluation, education or referral to phase II; phase II) exercise training and education supervised by nurses or physical therapists in an outpatient setting; and phase III) unsupervised, patient-directed maintenance of PA and lifestyle change [1]. Cardiac rehabilitation following acute cardiac events, such as acute coronary syndrome (ACS) and revascularization procedures, as well as chronic heart disease and heart failure (HF), is crucial for preventing recurrent cardiac events, improving functional status, and reducing coronary artery disease progression. [2–5],[1]

Continued engagement in PA is crucial to prevent recurrent events for patients after cardiovascular interventions (i.e., ST-segment elevation myocardial infarction [STEMI], non-STEMI, percutaneous or surgical revascularization, and unstable angina) when they have completed outpatient facility-based cardiac rehabilitation (CR) phase II [2,6]. It is also crucial to improve functional status in cardiac patients, including those with chronic heart disease, such as heart failure. Optimal secondary prevention uses comprehensive approaches that include PA [7]. However, more than half of patients who complete phase II CR reported

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not maintaining or engaging in PA in the home environment (phase III), even though they are given medical advice to engage in at least 30 min of PA at home most days of the week [8,9]. Furthermore, older patients (≥65 years) with acute cardiac events face more challenges in engaging in PA at home after completing CR due to a high probability of disease-related decline in physical mobility, loss of daily living activities, and depressive symptoms or anxiety [1,10].

Depressive symptoms and anxiety are prevalent in cardiac patients and are associated with poor self-care [11,12]. Despite successful treatment of cardiac events, the prevalence of depressive symptoms and anxiety among these patients ranges from 19 to 26 % for depressive symptoms and 26–27 % for anxiety [13–15]. Depressive symptoms and anxiety are associated with reduced functional capacity and increased severity of cardiac conditions [16,17]. However, most home-based or hybrid (home and facility) CR programs in clinical trials have not addressed depressive symptoms and anxiety [18–20]. Thus, there is limited knowledge about the impact that the management of depressive symptoms and anxiety has on PA, particularly when such management occurs in the home setting after phase II CR.

Gentle yoga, an increasingly popular exercise modality, consists of use of stretching and postures (i.e., guided, gentle movements) to enhance physical mobility, muscle strength, balance, and improve autonomic tone [21–23]. Breathing techniques and meditation are used to induce relaxation and manage psychological distress [24]. Yoga significantly reduces depressive symptoms, anxiety, and improves cardiac function in cardiac patients [22,25]. Gentle yoga may be particularly relevant for older adults who often cannot engage in or maintain the rigors of traditional PA. However, there are no such studies in older cardiac patients who have finished phase II CR.

Traditionally, most yoga studies have taken place in person at a facility [26], as in the case of yoga-based cardiac rehabilitation studies [27]. However, these programs can be difficult to access or inconvenient for older cardiac patients [1]. Online-based yoga may decrease costs, increase convenience, and reach patients who cannot attend facility-based classes. Although several studies have reported that online yoga programs appear to be feasible and acceptable comparable to in-person programs [28], no online yoga study has specifically targeted older cardiac patients who need maintenance exercise after phase II CR.

In our study, we will address the knowledge gap about the potential for gentle yoga to improve physical and psychological health outcomes in older cardiac patients. The purpose of this randomized controlled pilot study is to examine effects of a structured gentle yoga program on physical and psychological health outcomes among cardiac patients over 65 years who have completed a facility-based outpatient phase II CR program. A structured gentle yoga intervention will be delivered for 12 weeks via video conferencing technology, a time and cost-effective delivery modality. Depressive symptoms and anxiety will be assessed to reflect psychological outcomes. The post-intervention effect will be assessed at 3-month follow-up. Physical outcomes (i.e., PA level, muscle strength, balance, and physical vulnerability) will be assessed using actigraphy, a handheld dynamometer, an inertial measurement unit, and a physical vulnerability instrument, respectively. Cardiac autonomic tone will be reflected by heart rate variability (HRV).

1.1. Study aims

The specific aims of this study are as follows:

Specific Aim 1: To determine the feasibility and acceptability (i.e., recruitment rates, retention rate, intervention adherence rates, acceptability, and satisfaction) of a modified gentle yoga intervention delivered via video conferencing for older cardiac patients.

Specific Aim 2: To compare, at 3-month follow-up, the effects and determine effect sizes of a gentle yoga intervention on psychological health, including depressive symptoms and anxiety and physical health, including balance, muscle strength, PA levels, cardiac autonomic function, and physical vulnerability.

2. Methods

2.1. Study design

This study is a 2-group randomized controlled trial (i.e., gentle yoga intervention versus control group) to determine the feasibility and preliminary efficacy and effect sizes of a structured gentle yoga intervention on psychological and physical health in 40 older adults who have completed phase II CR. Approval of the Institutional Review Board for the study was obtained from the University of Kentucky Office of Research Integrity. This trial was registered on ClinicalTrials.gov (NCT06235658).

2.2. Study patients

Eligible patients will be randomly assigned to the gentle yoga intervention (n = 20) or control groups (n = 20). Baseline data will be collected prior to randomization, and outcome data will be collected at 3-month follow-up. Eligible patients will (1) be ≥ 65 years of age; (2) have a history of acute myocardial infarction, stable angina, cardiac surgery (including heart transplantation, valve surgery, or coronary artery bypass), coronary artery angioplasty or stents within the preceding year; (3) have completed phase II CR; (4) be able to read and understand English; and (5) have no major comorbidities that limit ability to participate in a gentle yoga intervention.

Patients will be excluded if they (1) have incapacitating neurologic, orthopedic, or neoplastic conditions such as stroke with paralysis or cognitive impairment, terminal cancer, or a cognitive disorder (e.g., Alzheimer disease); (2) currently practice yoga or other types of mind-body exercises (e.g., meditation, tai-chi, qigong) within the past 3 months; and(3) have no home Wi-Fi access.

2.3. Recruitment

Eligible patients will be screened via electronic medical records and recruited from the UK Gill Heart and Vascular Institute's Cardiac Rehabilitation Program. We will contact eligible patients through text messages, emails, and phone calls, and distribute flyers at the University of Kentucky Hospital. We anticipate, there may be obstacles to recruitment. Some patients might be hesitant to participate in this yoga study due to their religious beliefs. In that case, we will clarify that this yoga study is not affiliated with any religion. If patients do not have an electronic device to join the study, we will lend them an iPad for the duration of the yoga classes.

2.4. Study assessment

Patients who agree to join this study will be scheduled for a total of four assessment appointments: two for the baseline and two for the 3-month follow-up. Prior to their visits, the principal investigator (PI) will inform patients about specific activities to avoid, such as high-intensity exercise, heavy food, and caffeinated drinks, in order to ensure the accuracy of the measures of assessment [29,30]. The first appointment is for a brief presentation about the study and a baseline assessment. This presentation covers the content in the informed consent, such as who is involved, what the study involves, where it takes place, its duration and the other components that align with the informed consent form. Following this presentation, patients who agree to proceed and sign the consent form will undergo the following series of tests: 1) a short-term heart rate variability test, assessing autonomic heart function using a Polar 10, which will take 10 min; 2) a balance test, which will take 5 min; and 3) a muscle strength test, which will take 30 min. Following this specific order will give study patients rest between their trials. After completing baseline data collection, patients have the option to fill out questionnaires either immediately or at their home using either an electronic survey system (REDCap) or a paper copy at

their preference. The PI will ask patients to wear the ActiGraph watch for 9 days to measure their PA levels and return the watch to the research facility. We will repeat this procedure during the 3-month follow-up visit.

2.5. Intervention content

In the intervention group, patients will attend two virtual 60-min gentle yoga sessions per week for 12 weeks. The goal is that each patient attends 24 sessions in 12 weeks. The certified yoga instructor will deliver structured gentle yoga sessions to groups of at least 5 patients, but no more than 7 to ensure quality sessions. We will offer 36 sessions over the course of 12 weeks (that is three sessions per week) in order to increase patient ability to attend two sessions per week and to allow for make-up sessions if needed. Furthermore, we will also add one additional weekfor make-up sessions. Each session will be conducted using the Zoom platform, with patients joining from their homes. The PI, who is a certified MediYoga yoga instructor, has collaborated with other certified yoga instructors (trained in the Vinyasa and Hatha traditions), a physical trainer (with a master's degree in kinesiology and experience teaching older adults), and nursing faculty with expertise in CR to adapt the yoga programs and basic exercise postures to accommodate the needs of older cardiac patients [31–33].

At the first yoga session, we will present a video that provides information on how gentle yoga fits into self-care for cardiac patients. It will also cover the benefits of gentle yoga for cardiac patients, along with important tips. To ensure safety, the PI (a trained nurse with experience in cardiac patient care) will ask all patients if they have experienced any cardiac symptoms (i.e.., chest pain, shortness of breath, palpitations, fatigue, and vomiting) in the 24 h before the class begins. After the safety check, we will then teach basic gentle yoga components that include deep breathing with warm-up stretching, physical postures, meditation, and relaxation (Table 1).

All sessions begin with 5 min of long, deep breathing, which has the effect of increasing parasympathetic tone (i.e., improving autonomic nervous system tone) [34]. After breathing practice, participants perform a 10-min warm-up routine. The yoga instructor will introduce 4–5 different stretching exercises focusing on 1) neck and head, 2) shoulders, arms, and hands, 3) torso, and 4) lower body. Before the yoga instructor begins the physical postures, she will demonstrate the day's postures. Yoga instructors will modify physical postures on an individual basis as needed to fit individual patients' physical abilities. Yoga postures will include only low to moderate intensity poses where movements are smooth and predictable, which will allow basic muscle training to be combined in a way that maximizes joint operation while avoiding rapid or unexpected movements [35]. The total duration of this yoga posture practice will be 25 min. Following gentle yoga posture practice, the participant will wind down with stretches lasting 2 min. To conclude, the yoga instructor will lead patients in a 5-min meditation session and then allot 5 min for patients to share their thoughts about the class.

The PI attends 100 % of all classes to observe delivery, provide technical support, and ensure safety, thus maintaining intervention fidelity. The PI will use a checklist to monitor whether the poses instructed by the yoga teacher are performed according to the planned sequence. If there is a discrepancy between the planned sequence and the class, the PI will discuss it with the yoga instructor to ensure fidelity.

The control group will not receive yoga but will receive printed or electronic versions of the American Heart Association "Life's Essential 8″ at baseline, including information on how to increase and maintain cardiovascular health. Life's Essential 8 provides information on key health behaviors, including engaging in physical activity, smoking cessation, ensuring sleep health, maintaining a healthy weight, and maintaining healthy levels of blood lipids, blood glucose, and blood pressure. Since it is important to ensure an unbiased comparison and to maintain study integrity, the control group will receive no other

Table 1
Yoga module for the study participants.

Order	Practice				Duration (60 min)
1	Opening				5 min
2	Yogic Long Deep Breathing, 3-part breath - Pranayama				5 min
	Warm-up Stretching - Sukshma Vyaya • Neck circle • Head up and down • Turning left and right • Tensing and relaxing shoulder • Hand pull • Roll wrists and ankles • Point and flex				10 min
3	Yoga postures – Asana	Segment 1, Weeks 1–4, (Opening something better)	Segment 2, Weeks 4–8, (Boost your power)	Segment 3, Weeks 8–12, (Find your balance)	25 min
	Down dog	✓	✓	✓	
	Down dog to Plank movement		✓	✓	
	Cat-cow	✓	✓	✓	
	Seated Mountain	✓	✓	✓	
	Seated Half-Moon	✓	✓	✓	
	Seated Cobra	✓	✓	✓	
	Forward Fold	✓	✓	✓	
	Seated Figure four pose	✓	✓	✓	
	Seated Supine twist	✓	✓	✓	
	Half Lift	✓	✓	✓	
	Shoulder Lift	✓	✓	✓	
	Arm Crosses	✓	✓	✓	
	Double Arm Crosses	✓	✓	✓	
	Leg March	✓	✓		
	Leg March with a band		✓	✓	
	Foot Circles	✓	✓	✓	
	Arm Circles	✓	✓		
	Arm Circles with weights		✓	✓	
	Chair Butterfly	✓	✓	✓	
	Crescent Lunge	✓	✓	✓	
	Warrior I	✓	✓	✓	
	Warrior II	✓	✓	✓	
	Warrior III		✓	✓	
	Reverse Warrior			✓	
	Bird Dog			✓	
	Pyramid			✓	
	Tree	✓	✓	✓	
	Leg Extensions and Lift	✓	✓	✓	
	Shoulder Press	✓	✓		
	Shoulder Press with Weights		✓	✓	
	Shoulder Press with a band			✓	
	Lateral Arm Raise	✓	✓		
	Lateral Arm Raise with Weights		✓	✓	

(continued on next page)

Table 1 (*continued*)

Order	Practice				Duration (60 min)
	Forward Arm Raises	✓	✓		
	Forward Arm Raises with Weights		✓	✓	
	Shoulder Press	✓	✓		
	Shoulder Press with Weights		✓	✓	
	Shoulder Press with a band			✓	
	Shoulder roll	✓	✓	✓	
	Bicep Curls with Weights		✓	✓	
	Triceps Extension		✓	✓	
	Triceps Stretching		✓	✓	
4	Cool down stretching				2 min
5	Guided meditation - Dhyana • Basic breathing meditation				5 min
6	Relaxation - Savasana				3 min
7	Closing - Share the experience				5 min

intervention from us.

2.6. Adverse event reporting and safety monitoring

Although this is a low-risk yoga trial, the PI will take the following steps before the yoga classes during assessment to minimize or prevent potential injuries. The PI will determine and account for any physical limitations that participants have and give individual cautions. The PI will help participants select an appropriate chair that provides balance and support for performing yoga postures, explain how to select an armchair with a straight back that does not have stability issues and to place it on a flat surface. The PI will also suggest appropriate clothing and footwear that will be comfortable and safe during the yoga classes, provide a yoga mat to enhance stability, and request all participants to agree to keep their cameras on during the entire yoga classes to ensure their safety.

During and after the yoga classes, both the yoga instructor and the PI will monitor participants for symptoms and will stop the yoga session to question any participant who appears to be having symptoms or who reports having symptoms. If symptoms resolve quickly, the participant will be advised not to continue with the yoga and to consult their physician about whether they can continue in the yoga program. If medical intervention is needed, the PI will immediately call EMS to go to the participant's home.

2.7. Outcome measures

All outcome measures are presented in Table 2.

2.7.1. Recruitment and adherence rate

The recruitment rate (%) will be calculated by dividing the total number of patients enrolled by the number of eligible patients approached and then multiplying it by 100. Retention rate will be calculated by dividing the total number of enrolled patients by the number of patients who complete the study multiplied by 100. The intervention adherence rate will be calculated by dividing the total number of sessions attended by the total number of intervention sessions required (i.e., 24) and multiplying that number by 100. In addition, we will report the proportion of participants who attended more than 80 % of the classes.

Table 2
Study outcomes and measures.

Domain	Outcomes	Measurement	Timepoint	
			Time 1, (Baseline)	Time 2, (3 months)
Process evaluation	Program feasibility	Recruitment Rate Retention Rate Intervention Adherence Rate Treatment Acceptability Adherence scale (10-item) Client Satisfaction Questionnaire (8-item)		X
Psychological Distress	Depressive symptoms	Patient Health Questionnaire-9 (9-item)	X	X
	Anxiety	Brief Symptom Inventory, anxiety scale (6-item)	X	X
Physical function	Physical activity	ActiGraph GT9X Link (worn on the wrist)	X	X
	Muscle strength	Handheld dynamometry on hip, quadriceps, biceps	X	X
	Balance	Inertial Measure Unit	X	X
	Physical vulnerability	Vulnerable Elders Survey-13 (13-item)	X	X
Cardiac function	Short-term heart rate variability	Abdomen-positioned ActiGraph GT9X Link with Polar H9 heart rate monitor on the chest	X	X
Others	Sociodemographic and Clinical information	Structured questionnaires (e.g., age, sex, race, marital status, education, employment, social support, and living status)	X	

2.7.2. Acceptability and satisfaction

We will use modified versions of the Treatment Acceptability Adherence Scale (TAAS) and The Client Satisfaction Questionnaire (CSQ) to assess acceptability of the yoga intervention at 3-months follow-up [36,37]. The TAAS is a 10-item self-report questionnaire designed to evaluate treatment acceptability and adherence. Items are rated on a 7-point Likert-type scale (1 = disagree strongly; 7 = agree strongly). The total score is a sum of seven items, ranging from 10 to 49. This instrument is valid and reliable [36]. The CSQ is an 8-item self-report questionnaire to evaluate participant satisfaction with a specific intervention. Items are rated on a 4-point Likert-type scale (1 =

very satisfied; 4 = quite dissatisfied). This instrument was validated for patients and has internal consistency reliability [37]. For both instruments, higher scores indicate higher levels of acceptability of treatment and greater satisfaction.

2.7.3. Depressive symptoms

Depressive symptoms will be measured using the Patient Health Questionnaire-9 (PHQ-9) developed to correspond to symptoms used in the DSMV-IV to diagnose clinical depression [38]. Nine symptoms are rated on a 4-point Likert scale (0 = 'Not at all; 3 = 'Nearly every day'), with possible total scores ranging from 0 to 27 and higher scores indicating higher levels of depressive symptoms [38]. Validity and reliability of this scale for cardiac patients have been reported [39].

2.7.4. Anxiety

Anxiety will be measured using the Brief Symptom Inventory (BSI), anxiety subscale, which consists of 6 items rated on a 5-point Likert scale (0 = not at all; 4 = extremely) [40]. The total score ranges from 0 to 24, with a higher score reflecting greater anxiousness. The BSI-anxiety has been found to be valid and reliable in cardiac patients [40].

2.7.5. Physical activity

Physical activity will be measured using actigraphy, the gold-standard for measuring PA objectively. We will use the ActiGraph (GT3X Link model), a triaxial instrument, which is the most widely used wearable accelerometer in clinical research [41,42]. The ActiGraph has been validated to measure activity levels of cardiovascular patients [43]. Patients will wear the device on their non-dominant wrist for nine consecutive days. Data are considered valid for analysis if patients wear the ActiGraph for 600 min or more each day [44]. Data will be downloaded from the ActiGraph and analyzed using ActiLife 6.2 software platform. In addition, we will manually examine the data to confirm validity of ActiLife data. We will use the Troiano algorithm to validate wearable time with the typical sampling period ranging from 3 to 7 days [45]. A low-frequency filter will be used to convert raw data (the filter allows better detection of low-intensity activity) [46]. Physical activity level is automatically calculated for time spent in each of four different intensity levels of activities (i.e., sedentary, light, moderate, and vigorous) for each day [47]. Sedentary time, light-intensity, moderate-intensity, and vigorous-intensity activities were defined as the total number of minutes with $\leq$99, 100–1951, 1952–5724, and $\geq$5725 counts/min, respectively. We will compare intervention effects on times spent in the various activity intensities, and sedentary bout.

If a participant does not complete 9 days of data collection with the ActiGraph, they will be asked to wear the watch for another 9 days. They will be instructed again on the importance of adhering to this request. The yoga intervention will not begin until they have collected activity data for 9 days. If, after a second attempt, the participant fails to comply, they will be replaced by another patient. In preliminary studies done by the authors, all patients have worn the ActiGraph as indicated.

2.7.6. Muscle strength

Muscle strengths will be measured using the handheld dynamometry (HHD, Lafayette dynamometer, model01165APP; Lafayette Instrument Company, Lafayette, Ind., USA). This device measures the peak force exerted in kilograms for 5 s during muscle contraction on hips, quadriceps, and biceps (see Fig. 1). Each site will have three trials conducted, with a 2-min rest period between them. The first trial is a practice trial that will be discarded, while the following two trials will be averaged and used for analysis.

2.7.7. Balance

Balance will be measured using an Inertial Measurement Unit (IMU) device (DOT; Xsens Technologies, Enschede., the Netherlands). We attach the IMU sensor (a small device the size of a large watch face) to the participant's lower back at the level of L3 vertebra.

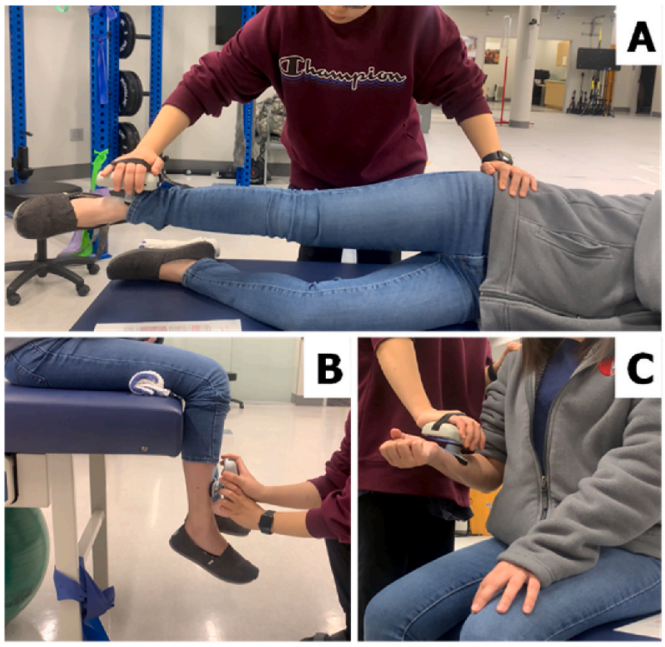

Fig. 1. Participants performing maximum isometric muscle strength test.

Patients stand without shoes on a mat with hands on hips for 30 s to measure balance. They will then rest for 30 s. This process is repeated two more times. The total estimated time for the balance test is 3–5 min. Signal processing, subsequent feature extraction, and analysis will be performed using MATLAB version R2018B (The Mathworks Inc., Natick, MA, USA). The root-mean-square (RMS) value of the acceleration signal will be used to quantify the magnitude and trajectory of postural sway in each direction. The RMS of the magnitude vector of the 3-axis acceleration signal will be used as the summary score.

2.7.8. Physical vulnerability

Physical vulnerability will be assessed using the Vulnerable Elders Survey 13 (VES-13) [48]. The VES-13 includes four dimensions: age, self-assessment of health, physical function, and living function. Each domain is scored differently. Age is scored as follows: 75–84 years = 1 point, $\geq$85 years = 3 points. Self-rated health is categorized into "fair and poor" or "good", "very good", or "excellent", with only the "fair and poor" category scoring 1 point. The physical function section assesses difficulty in performing physical activities (e.g., stooping, carrying 10 pounds, reaching, grasping small items, walking a quarter of a mile, heavy housework). Scores are assigned as 0 for "no difficulty, a little difficulty, or some difficulty" and 1 for "a lot of difficulty or unable to do", with a maximum score of 2. Living function covers tasks like shopping, managing money, walking, light housework, and bathing, with no difficulty scoring 0 points and further impairment scoring 4 points. The total score ranges from 0 to 15, with higher scores indicating greater vulnerability and a higher risk of injury. The VES-13, a commonly validated tool for screening older adults or patients to evaluate functional decline [48], has been validated and found reliable for individuals aged 65 years and older with various diseases, including cardiovascular disease [35,49].

2.7.9. Short-term heart rate variability

Short-term heart rate variability will be collected using the Polar H10 heart rate monitor (Polar Electro OY, Kempele, Finland). The PI will send a reminder about the precautions to be taken (e.g., avoiding caffeine, alcohol, smoking, intense physical activity, as these factors could affect the HRV measurement [see Table 3]) for successful HRV measurement the day before the scheduled test [29]. Study patients will lay supine for 10 min without speaking and remain as still as possible

Table 3
The list of questions before HRV data collection.

Did you drink any caffeine-containing drinks today?
If yes, when did you last drink a caffeine-containing drink and how much did you consume?
Have you consumed any alcohol in the past 24 h?
If yes, when was your last drink and how much alcohol did you consume?
Did you smoke within the last 24 h?
If yes, when was your last time smoking?
Did you exercise within the last 24 h?
If yes, when did you last exercise, for how long, and what type of exercise was it?
Were you prescribed any medication?
If yes, please list all the medications you are taking.
Did you take any prescribed medication before the visit?
If yes, please specify the medications.

[50,51]. We will place the Polar H10 heart rate monitor on the center of the sternum to measure HRV for 10 min. Data will be processed the using Kubios smartphone application (Kubios, LTd., Kuopid, Finland), then synchronized to Kubios HRV 3.5.0 software.

Kubios is a software program used to analyze HRV data, assessing typical time-domain, frequency-domain, and nonlinear measures of HRV [52]. We will collect mean heart rate and mean RR interval. We are assessing the time domain measures of root mean square of successive RR interval differences (RMSSD) and SDNN (Standard Deviation of NN [normal to normal RR] intervals) [52]. RMSSD and SDNN are measures in the time domain recommended for assessing HRV [53]. RMSSD reflects the activity of the parasympathetic nervous system, representing short-term variability in heart rate [53]. SDNN estimates overall HRV [53]. It captures all cyclic components responsible for variability in the entire duration of the HRV recording, not only the short-term variation [53]. In the frequency-domain analysis, we will express power in Hz, ms [2], logarithmic units, and normalized units (n.u) [52]. Very low frequency (0.0033–0.04 Hz) reflects the impact on HRV of mechanisms like the renin-angiotensin system and other long-term regulatory mechanisms [54]. Lower frequency (0.04–0.15 Hz) reflects both sympathetic and parasympathetic activities [54]. High frequency (0.15–0.40 Hz) reflects beat-to-beat heart rate changes and parasympathetic modulation of heart rate. HRV in these bands is quantified in ms [2], and lower frequency and higher frequency can be compared using normalized units (n.u.) [54]. In the nonlinear results, we will see the successive RR intervals plotted on a graph (Poincare plot), which can help identify patterns and anomalies in HRV, not easily detectable in numerical data alone [52].

2.7.10. Measures of other variables of interest

We will collect sociodemographic information and social support using a standardized questionnaire during the baseline assessment. This will include self-reported details on age, sex, race, ethnicity, marital status, education level (years and degrees), employment, living status, and smoking status (pack year of history). Social Support will be measured by the Multidimensional Scale of Perceived Social Support [55,56].

We will also collect clinical data that includes (1) type of cardiac event, (2) previous procedures, (3) the Charlson Comorbidity Index (CCI), a measure of medical comorbidities that are weighted by level of seriousness [57], (4) all medications (both prescribed and over-the-counter) and (5) body mass index (from height and weight).

2.8. Statistical consideration

2.8.1. Sample size

Random assignment will be determined from a computer-generated randomization plan overseen by a researcher not involved with the day-to-day operation of the study who is blinded to individual group assignments. Sample size calculations are derived from the effect sizes found in a meta-analysis of yoga's effects on physical and psychological health among older adults [58]. Since this meta-analysis reported that yoga produced more than medium effects on physical and psychological health [58], we aim to detect a medium to large standardized effect size ($f = 0.25–0.40$) using Cohen's F standardized effect size. This calculation is conducted using the repeated-measures design in G*power 3.1 [59,60], aimed at detecting a mean difference between two groups at two different time points and assessing the interaction between time and group. Recruiting 40 older cardiac patients, accounting for 25 % potential attrition rate [61], is considered an adequate number to detect the target effect size ($1 - \beta \geq 0.8–0.9$) with a type I error ($\alpha = 0.05$) to assess feasibility parameters to plan for a fully powered intervention in the future.

2.8.2. Data analysis

Data will be analyzed using SPSS v. 29. Chi-square and t-tests, depending on the level of measurement, will be conducted to compare group characteristics (intervention vs. control) at baseline. If there are significant differences in characteristics, those characteristics will be added as covariates in subsequent analyses. To analyze specific aim 1, descriptive statistics will be conducted to determine recruitment, retention, and intervention adherence rates and to examine the level of acceptability and satisfaction of the intervention. For specific aim 2, since this is a pilot study, we will calculate the effect size using Cohen's d effect size for differences in all outcomes. To test the effect of the intervention on outcomes, we will conduct a repeated measures general linear mixed model with group (intervention and control) and time (two time points). We will control for characteristics (medications, underlying cardiac event, demographics) upon which the groups differ. These models will allow us to compare the effects of intervention or control on physical and psychological outcomes across time. The fixed effect factors will be group assignment, assessment time point (i.e., baseline, 3-month), and the interaction between group and time point, while random effects, will be subjects.

3. Discussion

We describe the protocol for a pilot trial aimed at determining the feasibility and preliminary efficacy of a gentle yoga intervention delivered online. This intervention will focus on reducing psychological distress (i.e., depressive symptoms and anxiety) and improving physical function (i.e., physical activity levels, upper and lower body muscle strength, balance, and physical vulnerability) in older adults who have been discharged from a phase II CR program. We will determine if this intervention will result in benefits similar to those seen in other yoga studies conducted with older adults affected by Parkinson's disease, stroke, or cancer [62–64].

Despite the well-known benefits of adherence to a healthy lifestyle from CR, the rate of adherence to CR or a continuation of healthy lifestyle is low [65,66]. Up to 40–70 % of patients discontinue exercise 6–12 month after completion of a CR program [66]. We hypothesize older adults experience a higher rate of discontinuing exercise because of the aging process, wherein PA decreases by 40–80 % each year [67]. Furthermore, distance, transportation, and cost are significant barriers

to continuation of CR [1,68]. The first step to continuing PA and stress management might be to provide an exercise intervention tailored to this population, considering barriers reported by previous studies. Therefore, we believe the use of mobile technology will allow study patients to attend the intervention without concerns about transportation, distance, and high cost.

3.1. Limitations

Potential difficulties in recruiting and retaining patients will be minimized because the PI, as a research assistant in the Research and Intervention for Cardiovascular Health (RICH) Heart program, has extensive training and experience in recruitment and data collection in older cardiac patients from previous studies. In order to increase recruitment, before starting this study, the PI presented information about the study to the CR staff. This included eligibility criteria, the purpose of the study, its design, and potential benefits. When visiting the CR center, the PI will inform the staff about which patients the PI intend to approach. Before the PI approaches potential study patients, the CR staff will introduce the PI and provide brief information about the study to enhance recruitment prospects. Once patients agree to join the study, the PI will send reminders before each assessment. Furthermore, to prevent confusion regarding the video conference program (Zoom), the PI will use the same meeting address for all yoga classes. Another strategy to promote participant retention is to send reminders before each session, which could help patients adhere to the study [69].

4. Conclusion

As this is the first trial to focus on older cardiac patients and determine if a virtual yoga intervention can improve their psychological and physical well-being, its effectiveness is currently uncertain. Despite this uncertainty, online-based yoga intervention has recently emerged as a promising way to deliver care to patients by combining the principles of continuous care and telehealth. Testing this innovative approach will allow future researchers to explore the effectiveness of online-based yoga as a low-cost, non-invasive intervention for other clinical populations. If the intervention proves effective, these findings may contribute to evidence on the effects of virtual yoga programs on psychological and physical well-being in older cardiac patients following phase II facility-based cardiac rehabilitation.

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CRediT authorship contribution statement

Geunyeong Cha: Writing – original draft, Software, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Misook L. Chung:** Writing – review & editing, Methodology, Data curation. **Nicholas R. Heebner:** Writing – review & editing, Supervision, Software, Methodology. **Ulf G. Bronas:** Writing – review & editing, Supervision, Methodology. **Martha J. Biddle:** Writing – review & editing, Supervision, Methodology. **Chin-Yen Lin:** Writing – review & editing, Methodology. **JungHee Kang:** Writing – review & editing, Methodology. **Jia-Rong Wu:** Writing – review & editing, Methodology. **Jessica H. Thompson:** Writing – review & editing, Supervision. **Ashmita Thapa:** Writing – review & editing, Methodology. **Debra K. Moser:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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