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Prehabilitation program for elective coronary artery bypass graft surgery patients: a pilot randomized controlled study

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Abstract

Objective: To determine the feasibility of a cardiac prehabilitation (Prehab) program for patients waiting for elective coronary artery bypass graft (CABG).

Design: A two-group parallel randomized controlled trial.

Setting: Medical fitness facility.

Subjects: Seventeen preoperative elective CABG surgery patients were randomized to standard care (n = 9) or Prehab (n = 8).

Intervention: Standard care: three-hour preassessment appointment. Prehab: exercise and education classes for 60 minutes/day, twice weekly for at least four weeks.

Main measures: Data were collected at baseline, one week preoperatively, and three months postoperatively. The primary outcome measure was walking distance using a 6-minute walk test. Secondary outcome variables included 5-meter gait speed, and cardiac rehabilitation attendance three months postoperatively.

Results: Fifteen patients (standard care, n = 7; Prehab, n = 8) completed the study. No Prehab patients developed cardiac symptoms during study participation. Walking distance remained unchanged in the standard care group; whereas, the Prehab group increased their walking distance to mean ± SD 474 ±101 and 487 ±106 m at the preoperative and three month postoperative assessments ($p < 0.05$). Gait speed was unchanged in the standard care group, but improved in the Prehab group by 27% and 33% preoperatively and three months postoperatively, respectively ($p < 0.05$). Enrollment in cardiac rehabilitation three months postoperatively was higher for Prehab participants (100%) than standard care participants (43%; $p < 0.05$).

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Conclusion: These data provide evidence for the feasibility of a Prehab intervention to improve the health status of patients waiting for elective CABG surgery. A larger trial of 92 patients will be utilized to demonstrate the safety and efficacy of Prehab.

Keywords
Coronary artery bypass, exercise therapy, pre-habilitation

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Introduction

Patients who are waiting for coronary artery bypass graft (CABG) surgery are often fearful of being physically active.[1] However, this wait period offers an opportunity for preoperative rehabilitation, which might improve the safety and outcome of their prospective surgical intervention and encourage ongoing engagement in rehabilitation postoperatively. Our pilot, randomized controlled trial sought to demonstrate the feasibility of cardiac "prehabilitation" (Prehab) for patients waiting for first time elective CABG surgery.

Long wait times (> one month) for elective CABG surgery are associated with increased mortality rates compared with short wait times (< one month).[2] During this wait time, patients report being fearful of participating in physical activity and thus experience further cardiovascular de-conditioning.[1] Furthermore, poor physical fitness preoperatively is associated with a longer hospital stay.[3] Therefore, the safety, as well as the feasibility of enhancing preoperative physical fitness in the cardiac surgery population must be explored.

Cardiac Rehabilitation Programs (CRPs) enhance physical fitness among cardiac patients and significantly their reduce mortality rates;[4] however, elective CABG patients are generally not referred to CRPs until after their surgical intervention. Preoperative physical therapy has been utilized prior to cardiac surgery[5] and in other disease conditions, including lung cancer,[6] joint replacement, and abdominal surgery,[5] and is shown to reduce postoperative complications, such as postoperative atelectasis and pneumonia, and length of hospital stay – at least in cardiac and abdominal surgery.[5,7] However, these studies have primarily focused on inspiratory muscle training as a form of preoperative physical therapy; thus, less is known about the application of exercise therapy before CABG surgery to enhance physical fitness preoperatively.

Currently, there is little evidence demonstrating the feasibility of a Prehab program for elective CABG patients, with the strongest data showing that exercise therapy and education classes reduce the length of hospital stay by one day and intensive care unit length of stay by 2 hours.[8] It is also unknown if Prehab programs improve physical fitness prior to elective CABG surgery. Therefore, the purpose of this pilot, randomized controlled trial, was to determine the feasibility of a cardiac Prehab program for patients waiting for elective CABG surgery. We hypothesized that a Prehab intervention would improve physical fitness to a greater extent than current standard care before surgery (preoperatively).

Methods

This pilot study used a randomized controlled trial, parallel two-group (n = 17), repeated measures design. We recruited and enrolled patients scheduled to undergo first-time elective CABG surgery from February 2011 to May 2012 (Figure 1) at baseline, preoperatively and three months postoperatively. We included patients with a minimum estimated four week wait-time, with no history of unstable angina, myocardial infarction in the last week, or dementia, ejection fraction >30%, and who were sedentary prior to enrollment. We excluded patients with physical limitations or exercise-induced arrhythmias. Study procedures were initiated following ethical approval from the

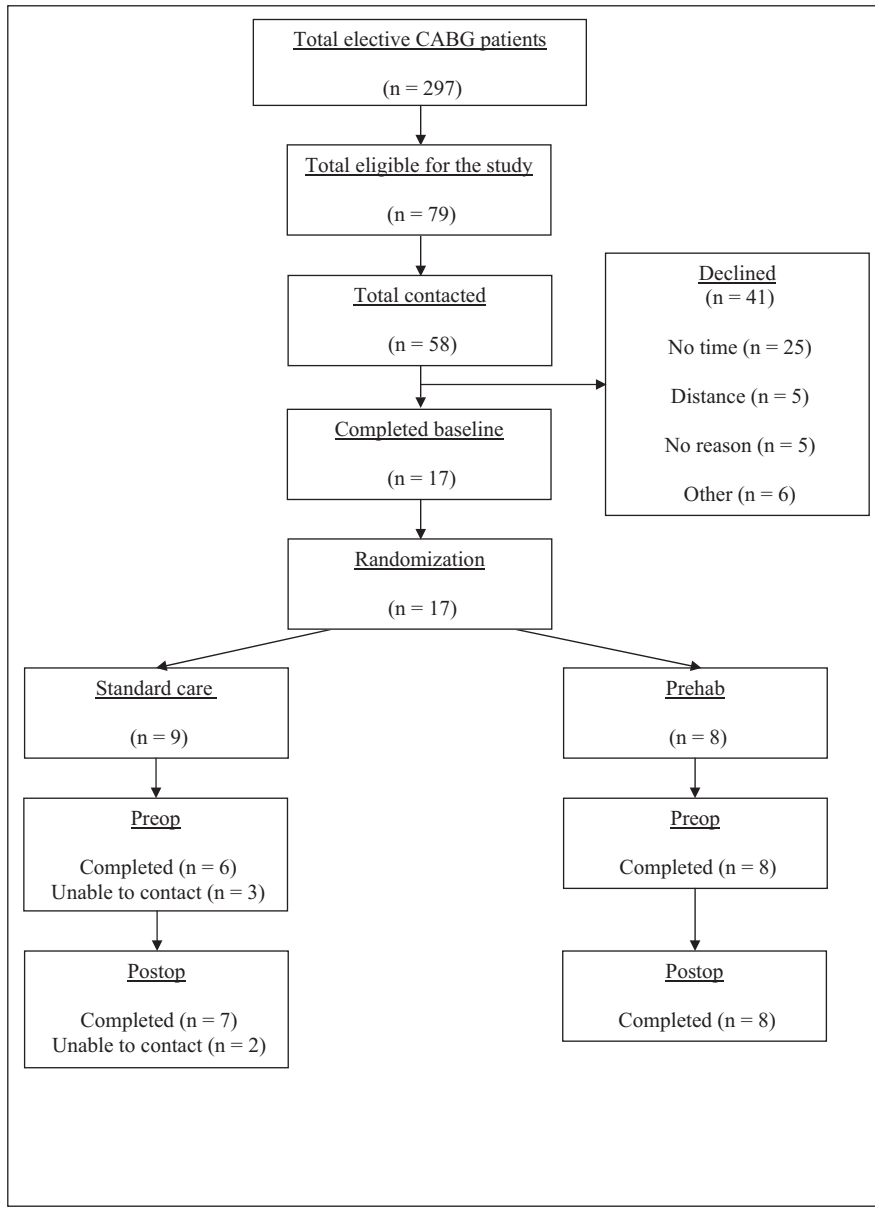

Figure 1. Flow diagram: participant recruitment.
CABG, coronary artery bypass graft; Preop, one week pre-operatively; Postop, three months post-operatively.

university, regional, and hospital research review committees.

This study was conducted at a 500-bed tertiary center in Western Canada. A research assistant at the tertiary center collected data from all study participants at baseline, preoperatively, and three months postoperatively. After baseline data collection, the research assistant randomly assigned patients to receive standard care ($n = 9$) or the Prehab intervention ($n = 8$) by opening a sealed envelope

containing a third party, computer-generated random group assignment. The research assistant was aware of which patients were randomly assigned to standard care and Prehab, thus increasing the risk of detection bias.

As a part of standard care, all participants attended a three-hour cardiac preassessment meeting, where a nurse practitioner and anesthetist assessed each patient's cardiac status and other underlying conditions that may have affected their surgical outcomes. Participants were counselled on healthy lifestyle behaviors during their preassessment visit.

Patients randomized to the Prehab group received standard care plus a Prehab intervention at a medical fitness facility. Key healthcare providers at the medical fitness facility (i.e. CEO, Director of Health and Fitness, cardiologists, nurses, and exercise specialists) were involved in facilitating the participation of Prehab participants in the study in order to address the practical aspects of the study. Accordingly, the Prehab participants joined a larger group of patients attending the facility's 16-week CRP. Prehab participants completed a minimum of two 60-minute structured exercise sessions/week until their surgery date or for the duration of the 16-week Prehab intervention. Prehab participants also attended additional voluntary exercise sessions at the facility. Care providers prescribed the Prehab program by following standardized procedures at the medical fitness facility for their CRP. Aerobic exercise intensity was prescribed at 85% of their maximal oxygen consumption based on their stress test results. The intensity and duration of aerobic exercise was progressively increased based on close communications between the healthcare providers and participants enrolled in Prehab. Types of exercises were prescribed by healthcare providers based on individual interests and abilities, which included walking (8/8 participants), stationary cycling (2/8 participants), light resistance exercise with body weight and resistance bands (2/8 participants), and stretching (2/8 participants). Prehab participants also attended 12 class-based education sessions concerning medication use, exercise, stress, diet, and cardiovascular risk factor management.

To address patient safety, all Prehab participants underwent a standardized exercise stress test prior to the initiation of the Prehab program.[9] Additionally, during the Prehab program, trained medical staff, including a cardiologist, nurses, and an exercise specialist monitored the participants. Data related to Prehab safety outcomes were collected from patient charts at the medical fitness facility after patients had completed the Prehab program and included fatal or non-fatal myocardial infarctions, exercise-induced arrhythmias, unstable angina, and hospitalization owing to Prehab participation. In addition, data on operative and postoperative complications were collected from hospital chart reviews and included 30-day mortality, atelectasis, atrial fibrillation, stroke, renal failure requiring dialysis, prolonged ventilation, sternal wound infection, reoperation, and re-hospitalization.

The primary study outcome was a change in walking distance assessed using the 6-minute walk test (6MWT), based on standardized guidelines.[10] The 6MWT correlates with physical fitness as assessed by a maximal graded exercise test.[11] In accordance with standardized guidelines, gait speed was measured using a 5-m gait speed test, a predictor of mortality and morbidity in patients undergoing cardiac surgery.[12]

Physical activity was objectively measured using an actical accelerometer (Phillips–Respironics[13]). Accelerometer data were analyzed utilizing the protocol described by Colley et al.[13] Specifically, physical activity intensity was measured in counts/min (light activity = 100–750 counts/min; moderate to vigorous physical activity (MVPA) ≥750 counts/min), which was subsequently analyzed in minutes/week. Participants wore an accelerometer during their waking hours for seven-day periods. A valid day of accelerometer data was defined as >10 hours of wear time. Accelerometer data were analyzed in ≥10-minute intervals (i.e. $MVPA_{10min}$, $TotalPA_{10min}$), as well as sporadically in bouts of ≥30 seconds (i.e. $MVPA_{spor}$, $TotalPA_{spor}$,). Physical activity accumulated in 10-minute bouts or more is currently recommended by the *Canadian Physical Activity Guidelines* for health benefits.[14] We chose to analyze physical

activity in sporadic bouts owing to emerging evidence suggesting that even very short activity bouts are associated with health physical fitness.[15]

Quality of life was assessed using the validated short-form health survey (SF-36) questionnaire.[16] Symptoms of depression were assessed using the Patient Health Questionnaire-9 (PHQ-9).[17] The 18-item Cardiac Anxiety Questionnaire (CAQ) was utilized to assess participants' perceptions of their anxiety related to their heart health.[18] Participant exercise self-efficacy was measured using the 16-item Cardiac Exercise Self-Efficacy Index (CESEI).[19]

Based on previous research showing a 40% increase in 6-minute walking distance in CABG patients after participation in a CRP,[20] we determined a sample size of 20 (10 participants per arm) would have sufficient power (0.8) with an alpha = 0.05 to detect a change in walking distance from baseline to preoperatively. Based on our preliminary analysis preoperatively (standard care, $n = 6$; Prehab, $n = 6$), we found the mean difference in 6-minute walking distance was statistically different between the standard care and Prehab groups ($p < 0.05$). Therefore, to account for 10%–15% attrition, a drop-out rate used in previous literature utilizing a Prehab program,[8] we completed participant recruitment with nine patients in the standard care group and eight patients in the Prehab group.

Data were expressed as mean ± SD and frequency (%). Continuous variables were analyzed using a two-way analysis of variance (ANOVA), using one repeated measure (time) and one between-group comparison. An independent *t*-test was used to compare group differences in baseline characteristics. An intent-to-treat analysis was utilized for drop-outs/missing data points. A *p*-value <0.05 was considered statistically significant. A Neuman–Kuels post-hoc analysis was used to identify differences between specific means.

Results

During the study period, 79/297 patients referred for CABG surgery during the conduction of the study met our recruitment criteria (see flow diagram, Figure 1). Of the 17 participants who enrolled in the study at baseline, 7/9 in the standard care group and 8/8 participants in the Prehab group completed the study. Baseline characteristics between standard care and Prehab participants did not differ except for beta-blocker use, which was significantly higher in the standard care group (Table 1).

Patients in the Prehab group attended a mean ± SD 19 ± 7 exercise sessions over a mean exposure time of 8.2 ± 2.2 weeks. Based on chart reviews at the medical fitness facility after Prehab completion, no adverse events occurred during participation in the Prehab program. Neither surgery parameters nor prevalent postoperative complications differed between the two groups (Table 1).

No differences were observed at baseline for total distance walked on the 6MWT between the standard care and Prehab groups (Table 2). In contrast, compared with baseline, participants in Prehab walked significantly further preoperatively and three months postoperatively ($p < 0.05$) than standard care. Similarly, baseline gait speeds (Table 2) between the standard care and Prehab groups were non-significant. Over time, standard care participants did not improve gait speed preoperatively or three months postoperatively. However, in the Prehab group, an interaction effect was observed ($p < 0.05$), where gait speed was improved preoperatively and three months postoperatively, respectively, as compared with the standard care group.

We attempted to capture accelerometer data at all time points (i.e. baseline, preoperatively, and three months postoperatively); however, 11 of 15 participants in the study had their surgeries within 1–3 days of receiving notification, which was less than the minimum required accelerometer wear time of 4 days. Based on this limitation, we analyzed accelerometer data for the baseline and three month postoperative time points only (Table 3). When physical activity was assessed in 10-minute bouts, no differences were found for any intensity of physical activity at any time. Additionally, no differences between groups were observed when physical activity was analyzed in sporadic bouts for $\text{TotalPA}_{\text{spor}}$ at any time. However, a main effect of time was observed for both groups, where

Table 1. Comparison of baseline characteristics and surgery parameters between groups.

	Standard care (n = 7)	Prehab (n = 8)	p-value
Demographics			
Age (years)	63 ± 9	64 ± 7	0.63
Gender (% female per group)	1 (14%)	2 (25%)	0.99
Height (cm)	172.6 ± 6.1	173.0 ± 11.7	0.79
Weight (kg)	89.4 ± 6.2	94.1 ± 15.5	0.46
BMI	30.0 ± 2.7	31.5 ± 4.4	0.43
Preoperative summary			
Ejection fraction	62% ± 10%	58% ± 11%	0.51
CCS class angina score*	2 (1–3)	2 (1–3)	1.00
Previous MI	4 (57%)	4 (50%)	1.00
Arrhythmia	3 (43%)	2 (25%)	1.00
Hypertension	6 (86%)	6 (75%)	1.00
CVA/TIA	1 (14%)	1 (13%)	1.00
Psychiatric diagnosis	2 (29%)	1 (13%)	1.00
Diabetes	1 (14%)	3 (38%)	1.00
Hyperlipidemia	7 (100%)	6 (75%)	1.00
Medications			
Beta-blocker	7 (100%)	2 (25%)	0.02
ACEI/ARB	4 (57%)	3 (75%)	1.00
ASA	7 (100%)	8 (100%)	1.00
Statin	7 (100%)	7 (88%)	1.00
Antiplatelet	3 (43%)	2 (25%)	1.00
Nitrate	5 (71%)	4 (50%)	1.00
Antidepressant	2 (29%)	0 (0%)	0.46
Surgery parameters			
Time on wait list (days)	66 ± 15	92 ± 25	0.46
2–3× CABG	5 (71%)	5 (63%)	0.99
4–5× CABG	2 (29%)	3 (38%)	0.99
Cardiopulmonary bypass time (minutes)	64 ± 17	69 ± 15	0.92
ICU length of stay (hours)	25 ± 7	24 ± 12	0.80
Length of hospital stay (days)	5.3 ± 1.0	5.1 ± 1.4	0.81
Operative complications†			
Atelectasis	0 (0%)	2 (25%)	0.47
Atrial fibrillation	4 (57%)	2 (25%)	0.31

Continuous variables expressed as mean ± SD. Categorical variables expressed in frequencies (percentage of group).
*CCS class expressed as median (interquartile range).
†Only data on complications that were prevalent are presented.
ACI, angiotensin converting enzyme inhibitor; ARB, angiotensin receptor blocker; ASA, acetylsalicylic acid; BMI, body mass index; CABG, coronary artery bypass graft; CCS, Canadian Cardiovascular Society; CVA, cerebrovascular accident; ICU, intensive care unit; MI, myocardial infarction; TIA, transient ischemic attack.

$MVPA_{spor}$ increased three months postoperatively, as compared with baseline ($p < 0.05$).

The SF-36 scores did not improve from baseline to preoperatively in either group. However, six of eight quality of life subscales (i.e. general health, physical functioning, role limitations owing to physical health, role limitations owing to emotional problems, energy/fatigue and social functioning) improved postoperatively in both groups, as compared with baseline and preoperatively ($p < 0.05$). Similarly, baseline PHQ-9, exercise self-efficacy (i.e. CESEI), and the total CAQ score,

Table 2. Comparison of functional walking tests between groups.

	Baseline	Preop	Postop	Differences between group means (95% CI)	
				Preop minus baseline	Postop minus baseline
6-min walking distance (meters)				136 (61 to 209)	123 (62 to 209)
Standard care	337 ± 52	332 ± 27	357 ± 27		
Prehab	342 ± 79	474 ± 101*†	487 ± 106*†		
5-meter gait speed (seconds)				–1.6 (–0.5 to –2.7)	–1.2 (0.26 to –2.6)
Standard care	5.3 ± 0.9	5.3 ± 1.0	4.7 ± 0.2		
Prehab	5.5 ± 1.7	4.0 ± 0.7*†	3.7 ± 0.9*†		

Values are means ± SD; standard care, $n = 7$; Prehab, $n = 8$.
Two-way repeated measures ANOVA revealed significant differences: *different than baseline: $p < 0.05$; †different than standard care: $p < 0.05$.
CI, confidence interval; Postop, postoperatively Preop, preoperatively.

Table 3. Comparison of physical activity as measured by accelerometry between groups at baseline and postoperatively in minutes per week.

	Baseline	Postop	Differences between group means (95% CI)
			Postop minus baseline
10 minute bouts			
$MVPA_{10min}$			78 (–135 to 291)
Standard care	82 ± 58	130 ± 51	
Prehab	21 ± 15	147 ± 53	
$TotalPA_{10min}$			75 (–221 to 370)
Standard care	103 ± 66	198 ± 89	
Prehab	23 ± 150	193 ± 65	
Sporadic bouts			
$MVPA_{spor}$			–37 (–274 to 198)
Standard care	132 ± 64	281 ± 72	
Prehab	139 ± 64	250 ± 53	
$TotalPA_{spor}$			–91 (–700 to 518)
Standard care	576 ± 89	872 ± 197	
Prehab	574 ± 100	780 ± 84	

Values are means ± SD; standard care, $n = 6$; Prehab, $n = 7$.
CI, confidence interval; MVPA, moderate-to-vigorous physical activity; Postop, three months post-operativley.

fear, and avoidance CAQ subscales were not different between groups, but all showed a main effect of time, where the three month postoperative time point was significantly lower than baseline and preoperatively ($p < 0.05$). Three (43%) of the standard care and eight (100%) of the Prehab group participants chose to enrol in cardiac rehabilitation postoperatively ($p < 0.05$).

Discussion

We have demonstrated the feasibility of utilizing preoperative exercise therapy for patients waiting for first time elective CABG. Notably, no patients enrolled in Prehab experienced an adverse event, suggesting that a Prehab program may be a safe therapy for patients waiting for a first time elective CABG. Our novel data also shows for the first time that patients who are on a waiting list for elective CABG surgery improve their physical fitness as assessed by the 6MWT before surgery, and that this outcome is maintained postoperatively, as compared with a group that received standard care. Similarly, Prehab improved 5-meter gait speed preoperatively and was maintained postoperatively; whereas, participants in the standard care group had no change in 5-meter gait speed over time. Interestingly, while only three (43%) of the standard care participants chose to enroll in cardiac rehabilitation postoperatively, all eight (100%) participants in the Prehab group had chosen to attend. Collectively, our data suggests that there is an opportunity to utilize a Prehab program to significantly improve the health status of patients waiting for elective CABG. However, the results of our study should be interpreted with caution, and a larger study is needed to establish the safety and efficacy of Prehab.

Physical fitness is an important prognostic factor for predicting adverse cardiac events and mortality. Patients with stable coronary artery disease who walk <419 meters on a 6MWT have a two-fold increased risk of experiencing an adverse cardiac event, as compared with patients who walk >481 meters.[21] In our patient cohort, all patients walked <419 meters at baseline, which did not change in the standard care group. However, after the Prehab intervention, patients were able to walk >481 meters. Therefore, our innovative study data makes an important contribution to this body of literature, because it is the first to demonstrate that a Prehab program enhances physical fitness among a cohort of patients waiting for elective CABG surgery.

Our data did not show a difference in length of hospital stay between standard care and Prehab participants. Over the past decade, length of stay following elective cardiac surgery has declined from an average seven days to five days,[22] which coincides with the average length of hospital stay in our study. Therefore, recent advances in surgical procedures, as well as a small sample size in the current study, could account for the differences observed in our study, as compared with the cardinal study by Arthur et al. published in 2000, where they found a reduction in the length of hospital stay of one day.

Our data shows that all eight (100%) of the Prehab patients chose to enroll in cardiac rehabilitation postoperatively, which was significantly different from the three (43%) standard care patients who chose to enroll. These data add to the previous literature, where Arthur et al.[8] found that CRP attendance rates postoperatively were 70% among Prehab participants, and only 57% among standard care participants. Collectively, a Prehab intervention for elective CABG surgery patients could enhance CRP attendance postoperatively because current estimates indicate that only 15%–20% of North Americans of the referred cardiac population chooses to enroll.[23] However, we acknowledge that only 29% of the eligible elective CABG surgery patients who were contacted chose to participate in the study (Figure 1).

This pilot study has several limitations. The research assistant was not blinded to which participants were in each group, thus increasing detection bias. However, data collection by the research assistant was conducted in accordance with standardized procedures for each outcome variable. In the context of generalizability, beta-blocker use was significantly higher in the standard care group compared with the Prehab group. Furthermore, our recruitment criteria limited us to 79/297 (27%) of the elective CABG surgery cohort. We also did not recruit patients scheduled for other surgeries (i.e. valve repair/replacement, combination surgeries); however, this was a safety feature of our study based on the consensus of cardiac surgeons and cardiologists at the hospital site, that the lack of supportive evidence concerning the safety of a Prehab intervention warranted the exclusion of more complex procedures.

Antiplatelet use was quite low in our patient cohort. However, medications were prescribed by the referring doctor (a cardiologist) to the patients' respective cardiac surgeon and were not altered at the time of their surgery. Finally, several characteristics, including stage of behavior change for a healthier lifestyle,[24] socioeconomic status,[25] and type A personality,[26] which could have influenced our results, were not collected.

In conclusion, our study demonstrates the feasibility of exercise Prehab to improve the health status for patients waiting for elective CABG surgery. Importantly, no Prehab participants developed cardiac symptoms as a result of participation. However, a larger sample size is required to demonstrate the safety and efficacy of this approach. Based on our data, 25% of Prehab patients went from walking <419 meters at baseline to >544 meters, which is suggested to be associated with a three-fold decreased risk (in comparison to a two-fold decreased risk among participants who walked between 419–543 meters) in cardiac morbidity and mortality.[21] Thus, in order to establish the efficacy, as well as the safety of Prehab, a power analysis with an alpha of 0.01, a beta of 0.8, and an anticipated 15% drop-out rate, indicates that 92 elective CABG patients should be recruited (standard care, $n = 46$; Prehab, $n = 46$) for our future Prehab study.

Clinical messages

- Exercise prehabilitation for patients waiting for elective CABG surgery is feasible within this patient cohort and can improve physical fitness preoperatively.
- We will recruit 92 patients in a future randomized controlled trial to demonstrate the efficacy and safety of exercise prehabilitation in patients waiting for elective CABG surgery.

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Conflict of interest

Authors report no conflicts of interest.

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