The implementation of an intensity regulated exercise programme in coronary artery bypass graft surgery patients: A pilot randomised controlled trial

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AIM: To determine the safety and effect of an intensity regulated exercise programme, compared to a structured usual care mobilisation protocol, on the functional capacity of patients following coronary artery bypass graft (CABG) surgery, at discharge and 10 - 14 days after discharge.

METHODS: Single centre, double-blinded, randomised controlled trial at a private hospital in Cape Town, South Africa. Subjects in the exercise group performed an intensity regulated exercise programme, while subjects in the control group were encouraged to mobilise out of bed. Both programmes were implemented within 24 hours after extubation following uncomplicated CABG surgery. Functional capacity was tested by means of the Six-Minute Walk Test (6MWT) at discharge and 10 - 14 days after discharge.

RESULTS: Eligible patients (n=38) were randomly allocated to an exercise group (n=17) or a control group (n=21). The functional capacity of subjects in the exercise group was significantly higher than that of the control group at hospital discharge, mean difference 103.10 meters (95%CI 23.39 - 182.81) (p=0.01). The exercise group did not further improve after hospital discharge (p=0.3) whereas the control group showed a significant improvement (p<0.01) in walking distance over time. The mean difference in 6MWD at the second test was 44.89 meters (95%CI -84.33 - 174.10) (p=0.47).

CONCLUSION: An intensity regulated exercise programme leads to higher levels of functional capacity on discharge and should be encouraged in the in-patient phase of cardiac rehabilitation following CABG surgery.

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INTRODUCTION

Cardiac rehabilitation is a complex multi-faceted intervention designed to optimise the physical, psychological and social functioning of cardiac patients. In addition, the programme aims to stabilise, slow down, or even reverse the progression of the underlying atherosclerotic processes, thereby reducing morbidity and mortality.[1] The exercise component of the rehabilitation programme is consistently included in clinical guidelines as the core component of the programme.[2] Following a systematic review of the literature which included the data of 1 0794 patients Heran, et al.[3] concluded that exercise-based cardiac rehabilitation is effective in decreasing hospital admissions while improving survival rate and health related quality of life (HRQoL) in patients following a cardiac event. The underlying reason for improvements in clinical outcomes could be based on the physiological effect of exercise training. Exercise training has been shown to have direct benefits on cardiac and coronary vasculature, including myocardial oxygen demand, endothelial function, autonomic tone which protects against fatal dysrythmias, coagulation and clotting factors, inflammatory markers and the development of coronary collateral vessels.[4,5] Cardiac rehabilitation comprises 4 phases, commencing during the in-hospital period (Phase 1) and progressing to the final phase (Phase 4). The final phase aims to assist the patient in identifying and participating in high affinity activities to maintain cardiovascular fitness. This phase does not have an end-date as patients are encouraged to develop routine exercise as a way of life.

Following coronary artery bypass graft (CABG) surgery, physiotherapy intervention during the in-hospital period has aimed to:

- prevent and manage pulmonary dysfunction and
- prevent bed-rest related complications by including a mobilisation programme.[6]

Following a systematic review of 35 papers, Pasquina[7] concluded that the evidence for the routine use of breathing exercises to prevent pulmonary dysfunction in patients following coronary artery bypass graft (CABG) surgery is equivocal. The review highlighted the need to identify the population most at risk for developing pulmonary complications.[8]

Dion, et al.[9] encouraged early exercise (within 24 hours of surgery) to prevent the deleterious effects of bed rest and reduce anxiety and depression that frequently follow cardiac surgery. Early in-patient mobility after CABG surgery reduced length of stay (LOS) and prevented functional loss during hospitalisation.[10] In an attempt to align the 2 stated physiotherapy aims, a new focus of research is developing. This includes the development of interventions to optimise gas exchange, thereby improving pulmonary reserve with the goal of promoting cardiovascular reconditioning.[11]

Recent work has investigated the effect of implementing intensity regulated exercise programmes during phase one to promote cardiovascular conditioning. Mendes, et al.[12] reported improvements in heart rate variability following an exercise programme at 4 metabolic equivalent[4] of task (MET) when compared to a control group who mobilised out of bed. Van der Peijl[13] reported patients reaching higher levels of functional independence when exercising twice daily when compared to a control group exercising once daily. Hirshhoren, et al.[14] reported improved six minute walk distance (6MWD) at discharge in the exercise group who received a moderate intensity exercise programme compared to usual care.

During phase one rehabilitation variations in type and intensity level of activities, as well as frequency of application, have been noted.[15] Basic principles in exercise prescription namely specificity, overload and reversibility are not adhered to.[15] We argue that the objective of early mobility of CABG patients should not primarily be prevention of the adverse effects of bed rest, but rather to provide a stimulus sufficient for cardiovascular conditioning. This pilot trial aimed to determine the safety and early effect of an intensity regulated exercise programme, compared to a structured usual care mobilisation protocol, on the functional capacity of patients following CABG surgery, at discharge and 10 - 14 days after discharge.

METHOD

The trial protocol was approved by the Committee for Human Research of Stellenbosch University (N04/04/083). Participation was voluntary and written informed consent was obtained pre-operatively by the principal investigator (PI).

Trail design

Single centre, double blinded, parallel design, randomised controlled trial.

Trial setting

Level II cardio-thoracic unit of a private hospital in Cape Town, South Africa. Two private physiotherapy practices provide a service to the cardio-thoracic unit and all patients that undergo CABG surgery are routinely treated pre- and post-operatively. The physiotherapists use a similar treatment protocol consisting of chest physiotherapy and a structured usual care mobilisation protocol.

Outcome measures

Functional capacity, as measured by the six minute walk distance (6MWD), was the primary outcome of this trial. Functional capacities of both groups were determined at hospital discharge and at the first follow-up appointment (10 - 14 days after discharge). The safety of the intensity regulated exercise programme was a secondary outcome.

Participants

Patients admitted to the hospital for elective CABG surgery between August and November 2004 were eligible for enrollment. Patients were excluded:

- if they could not understand instructions in the local languages;
- presented with a prior non-cardiac disability limiting participation in the exercise programme;
- admitted following emergency surgery or
- required prolonged (>24 hours) post-operative ventilatory support.

Sample size

We did not have data to inform a sample size calculation due to limited published data on 6MWD in the phase one CABG population. The results of this study will be used to inform future studies.

Randomisation

Following successful extubation, patients were allocated to one of two groups by a research assistant based on a computer generated randomisation table. The assistant was blind to group allocation.

Interventions

Patients in both groups received one pre-operative physiotherapy session from the private practitioners. The session consisted of information regarding post-operative management and breathing exercises. Post-operatively all patients were treated individually and patients in both groups received routine chest physiotherapy by the private practitioners. In addition all patients received an exercise programme within 24 hours of extubation provided by the PI. The control group was mobilised following a standardised usual care mobilisation protocol (Table 2). Progression of the activities was guided by the protocol.

The experimental group received an intensity regulated exercise programme (Table 3).

Intensity regulated exercise programme

The medical stability of patients in the experimental group was assessed by the PI (in consultation with the surgeon and nursing staff) before each exercise session. Contra-indications for entry into the programme included[16,17] excessive incisional drainage; resting diastolic blood pressure >100mmHg or resting systolic

TABLE 1: Borg rate of perceived exertion.

Rating	Explanation
6	No exertion at all
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
19	Extremely hard
20	Maximal exertion

TABLE 2: Usual care mobilisation programme.

Days post-op	Treatment received
Day 1 - 3	Mobilise into a chair with assistance of therapist: Sit out once daily for duration of hospital stay.
Day 4 - 5	Mobilise a short distance (e.g. nearby chair, toilet, etc.)
Day 6	Before discharge: Climb 1 x flight of stairs (5 stairs).

blood pressure >160mmHg; tachycardia of >140 beats per minute at rest; atrial or ventricular dysrhythmias; partial pressure of oxygen in arterial blood (PaO_2) of <9kPa (67.5mm Hg); arterial oxygen saturation (SaO_2) of <90% on O_2 support; severe myocardial ischaemia as detected on electrocardiograph (ECG).

Exercise intensity

The exercise programme is aimed at achieving and sustaining specific exercise intensity. Patients exercised at a heart rate of 15 - 20 beats per minute above resting heart rate or a corresponding value of 12 - 13 on the Borg scale[17] for at least 20 minutes (Table 1). If a value of more than 20 beats per minute or 13 on the Borg scale was exceeded, exercise intensity was lowered until the desired values were reached. Exercise was terminated when:[16,17] heart rate (HR) remained >20 beats per minute above resting HR, even if the exercise intensity was lowered;[9,16,17] decrease in oxygen saturation continued; complex ventricular dysrhythmias developed; systolic blood pressure dropped >10 mmHg[16,17] systolic blood pressure >220mmHg or diastolic >120mmHg. In the cardiothoracic ward patients were not monitored and exercise was terminated when a value of more than 13 on the Borg Scale was exceeded; patients complained of dizziness, lightheadedness, dyspnea, anginal symptoms; or confusion, nausea, pallor, excessive sweating was observed by the PI.

Progression

Exercise sessions progressed according to each patient's individual cardiovascular response to exercise (Table 3). Successful completion of each level (without termination due to unwanted signs/symptoms) resulted in progression to the next level the following day.The duration of exercise sessions was determined by the individual patient's cardiovascular response to exercise. Once patients reached Level 6, they were not progressed any further, but repeated the Level 6 exercise session daily for the remainder of their hospital stay.

Data collection

Baseline data were extracted pre-operatively from existing unit documentation systems by a research assistant. Intervention and control groups were compared at baseline with regard to age, gender, BMI, co-morbidities and cardiac risk factors. The 6MWD was completed by research assistants (physiotherapists). Testing procedure was standardised by PI before trial commencement, based on ATS guidelines, to ensure data reliability. The following modifications were made: we used a 41 metre circular corridor around the cardio-thoracic unit; a Polar S625X heart rate monitor was used to monitor heart rate and measure the distance walked. Heart rate was monitored continuously and the alarm was set at a value of 20 beats above resting heart rate – if triggered the patient was instructed to rest until the alarm stopped bleeping. The monitor measured and stored the distance covered by the subject by means of a foot pod fitted on the patient's shoe. Polar monitor placement (foot pod and chest strap) was standardised a priori. The monitor was calibrated by PI on a 3km course before trial commencement. To account for the learning effect 2 6MWT were performed. The first test walk was disregarded (termed the "practice walk"). A second test walk was performed after a minimum rest period of 20 minutes when the patient's heart rate and dyspnea levels had returned to baseline. Patients' response to the intensity regulated exercise programme was noted by the PI based on a priori defined criteria.

Blinding

Patients, nurses, doctors and private practitioners were blind to group allocation. In addition to standard physiotherapy, all patients received a daily exercise session by the PI. Individual sessions were supervised by the PI behind closed curtains. The research assistant and statistician were blind to group allocation.

Statistical analysis

Data were analysed with Statistica software version nine by Statsoft TM in consultation with a statistician. For categorical variables, the Chi-square or Fisher exact test was used (as indicated). For continuous variables Student T test, ANCOVA or repeated measures ANCOVA was used to compare groups.

A complete case analysis was done for each test. Due to loss-to-follow-up for second measure we also included an intention to treat analysis. We used "last observation carried forward" analysis. Significant differences between groups, or across time are reported at the alpha level of 0.05. All reported p-values are two-sided.

RESULTS

Thirty eight patients consented to participate in this trial. Five patients were lost before the implementation of the exercise programme due to re-intubation (n=3) and a return to theatre (n=2) Figure 1. There was no difference between the groups in the proportion of patients lost to follow up (p=0.11).

TABLE 3: Intensity regulated exercise programme.

Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Bed exercises: Ankle circulation exercises (circular movements and plantarlexion/ dorsiflexion) 20 repetitions each. Lower limb ROM exercises (knee and hip flexion/extension) 20 repetitions each.	**Bed exercises:** Repeat from level 1.	**Bed exercises:** Repeat from level 1.			
Pedal exercises for 3 minutes on stationary bicycle*.	**Pedal exercises** for 4-5 minutes on stationary bicycle.	**Pedal exercises** for 5-6 minutes on stationary bicycle.			
Sit in chair next to bed for at least 1 hour.	**Sit in chair** for at least 1 hour once/twice per day.	**Sit in chair** for at least 1 hour once/twice per day.	**Sit in chair** for at least 1 hour twice per day.	**Sit in chair** for at least 1 hour twice per day.	**Sit in chair** for at least 1 hour twice per day.
	Walk 1-2 steps to chair with assistance.	**Walk** on the spot for 1-2 minutes next to the bed.	**Walk** 5-10 minutes.	**Walk** 10-15 minutes.	**Walk** 15 minutes.
					Climb one flight of stairs (5) up and down.

**The adapted bicycle was fixed at a set resistance for the duration of the trial, enabling patients to exercise at a moderate intensity without getting out of bed.*

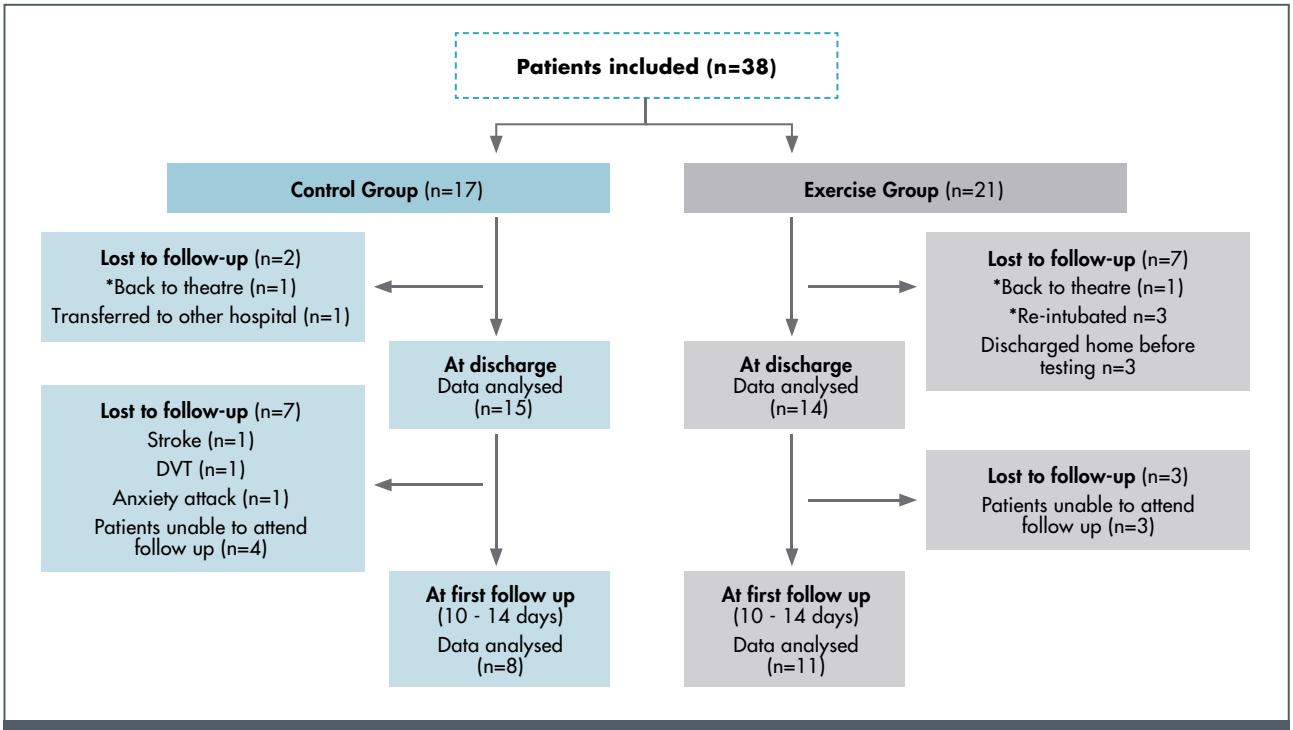

FIGURE 1: Consort diagram of patient participation.

TABLE 4: Baseline characteristics.

	Experimental group n=21	Control group n=17	p-values
Anthropometric factors			
Sex (M/F)	20/1	15/2	0.43
Age mean ± SD (y)	57 ± 8.3	57 ± 10.9	0.81
BMI mean ± SD (kg/m^2)	29.4 ± 3.5	28.4 ± 4.6	0.49
Co morbidities			
Myocardial Infarction n(%)	9 (43%)	5(29%)	0.39
Previous cardiac surgery n(%)	1(5%)	0	-
Cerebral Vascular Accident n(%)	0	1 (6%)	-
Cancer n(%)	1(5%)	1 (6%)	-
COPD n(%)	1(5%)	1 (6%)	-
Cardiac risk factors			
Smoke till CABG n(%)	8(38%)	3 (18%)	< 0.01*
Previous smoker n(%)	13(62%)	9 (53%)	< 0.01*
Never smoked n(%)	0	5 (6%)	< 0.01*
High blood lipid value n(%)	12 (57%)	9 (29%)	9.7
Family history of CAD n(%)	15(71%)	15 (88%)	0.42
Diabetes Mellitus n(%)	4 (5%)	6 (35%)	0.26
Hypertension n(%)	13 (62%)	13 (76%)	-
Self reported activity level			
Low n(%)	5 (24%)	5 (29%)	0.54
Average n(%)	9 (43%)	9 (53%)	0.54
High n(%)	7 (33%)	3 (18%)	0.54
Employment yes	9 (43%)	8 (47%)	0.80

SD: Standard Deviation, BMI: body mass index, PMH: past medical history, COPD: chronic obstructive pulmonary disease, CABG: coronary artery bypass graft, CAD: coronary artery disease.

Sample characteristics

The majority of patients were male. More than half (57%) the patients in the experimental group described themselves as retired. There were significantly more smokers and previous smokers in the experimental group. For all other variables the groups were similar at baseline (Table 4).

Safety of the intervention

All patients in the experimental group could successfully complete the programme. No exercise session was terminated based on pre-defined criteria.

Completion of 6MWD

All patients completed the 6MWD without interruption when tested at hospital discharge. During the follow-up visit, two tests were terminated before the six minutes were over. One patient (experimental group) developed excessive leg pain due to femoral artery claudication and one patient (control group) stopped due to fatigue.

Six Minute Walk Distance

At hospital discharge the exercise group walked significantly (p=0.01) further compared to the control group. The mean difference in the 6MWD between the exercise group and the control group was 103.10 meters (95%CI 23.39 - 182.81).

There was a significant improvement in the 6MWD of subjects in the control group (p<0.01) from hospital discharge to follow-up visit (Figure 2). The exercise group did not improve further after hospital discharge (p=0.3). At the 2 week follow-up visit the mean difference in the 6MWD between the exercise group and the control group was 44.89 meters (95%CI -84.33 - 174.10). The difference did not reach statistically significance in this sample (p=0.47).

With an intention to treat analysis of the data, mean difference in the 6MWD between the exercise group and the control group was 79.89 meters (95%CI -33.56 - 193.31). The difference did not reach statistically significance in this sample (p=0.16)

Length of hospital stay

The mean difference in length of hospital stay was 1 95%CI 0.078 - 1.922 (p=0.034) days. Patients in the intervention group were discharge within a mean of 8SD1 days and patients in the control group were discharged within a mean of 9SD1.4 days.

DISCUSSION

Trial findings indicate that it is safe for patients to participate in an intensity regulated exercise programme implemented within 24 hours of CABG surgery. In addition, participation in this programme improved patients' functional capacity at discharge when compared to patients who were mobilised following a standardised mobilisation protocol. However, the sustainability of the initial improvement in functional exercise capacity remains open to discussion.

The importance of considering the risk: benefit ratio of any intervention remains a cornerstone of evidence based-practice.[18] When considering the risk of an intensity regulated exercise programme, our data suggests that it is safe to incorporate activities that increase the demand on myocardial function. No adverse effects were noted. The exercise intensity was patient specific and progression through the different levels of the programme was dependent on physiological responses to exercise. Our findings concur with Mendes, et al.[12] who also reported no difference in atrial fibrilisation (AF) rates when comparing a MET-regulated physiotherapy-supervised structured walking programme with an early mobility programme. Based on the effect of these two programmes we argue that an intensity regulated exercise programme for phase one cardiac patients seems safe. Whether the cardiovascular stimulus offered by an intensity regulated exercise programme is sufficient for optimal benefit is less clear.

Our data – which is confirmed by Hirshhoren, et al.[14] – suggests that the initial cardiovascular stimulus offered by performing the exercise at a specific intensity was sufficient. There was a significant improvement in functional exercise capacity at hospital discharge of the exercise group when compared to the control group. However, in both studies the initial improvements were not sustained over time. The reasons for this finding require further investigation. The finding could be indicative of (1) a ceiling effect to exercise or (2) exercise intensity not maintained after discharge. During the design of the study we hypothesised that if patients in the experimental group had a higher functional capacity at discharge, they would be more active than their counterparts in the control group. However, it could be that patients in the experimental group did not feel safe to continue with exercise at the same intensity level at home. In hospital, contrary to the home environment, exercise took place in a safe environment where patients were constantly monitored during exercise. These results highlight the importance of teaching patients "how much is too much" when it comes to the resumption of activities of daily living and getting back to their normal routine. Patients should be taught how to monitor their exercise intensity and which signs to look for when exercising to stay within a safe intensity. The most common information needs of men and woman after CABG surgery, included clarity regarding the resumption of pre-illness activities.[19] It has also been proposed that patients will return to their pre-surgery default activity levels if not held accountable.[15] The poor adherence of patients with CR programmes supports this proposition. It will be valuable to investigate whether earlier enrollment into a CR programme, supported by predefined requirements from medical insurance companies, could improve long-term patient outcome.

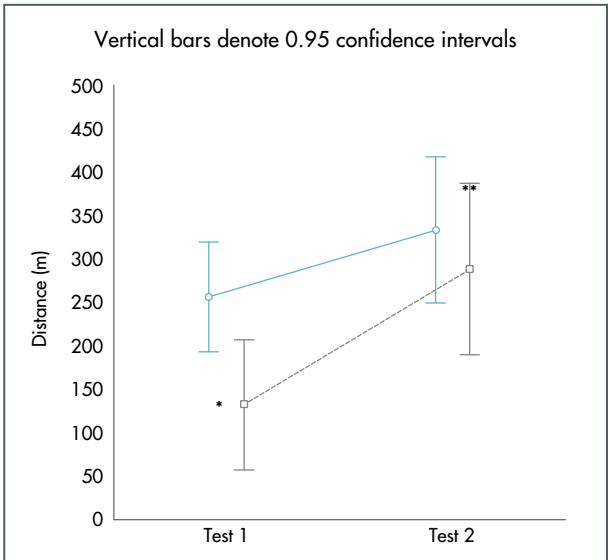

FIGURE 2: The mean 6MWD of the exercise and control groups at hospital discharge and at follow-up visit.

* *Significant difference p<0.01 between average walking distance of the exercise and control group on discharge from hospital.*

** *Significant improvement p<0.01 of average walking distance for control group between Test 1 and Test 2.*

This pilot trial highlighted specific design limitations which need to be addressed in planning future trials.The large proportion of patients lost to follow up in this trial is problematic. Four patients included into the study were re-intubated (n=3) or returned to theatre (n=1) before the exercise programme was initiated. Criteria to define trial entry needs to be revisited. In addition, testing could not be concluded due to early transfer/discharge of patients. When planning future trials, investigators must develop clear communication guidelines regarding the logistical management of patients. In this trial intervention group patients were discharged earlier than control group patients. Whether this difference can be related to the intervention needs to be investigated. Functional capacity testing of the intervention group patients was thus completed one day earlier than control group patients. Patients were also unable to attend the follow-up visit at the hospital. Consultation with surgeons regarding the post-operative care of patients from distant geographical areas is needed. Imputing the last 6MWD observation in an intention-to-treat analysis for the patients who were lost to follow up did not affect the results. Whether the observed mean difference (78 meters) in 6MWD between the 2 groups at the follow-up visit was merely by chance will need to be established in a sufficiently powered trial. This data can inform the design.

The clinical significance of the observed mean difference in 6MWD between the groups needs clarification. While the 6MWD is regarded as predictive of mortality in the COPD population, data on the clinical significance of 6MWD in the cardiac surgery population is imprecise.[20] One study reported that slow gait speed defined as 5 meters/6 seconds is predictive of in-hospital complications in elderly patients after cardiac surgery.[21]

We contend that it is safe and potentially beneficial to use an intensity regulated exercise programme within 24 hours of CABG surgery. Further work is needed to define parameters of exercise prescription in the CABG population. The potential to use exercise as a non-pharmaceutical intervention to facilitate autonomic cardiac function in the CABG population has been reported.[12] The development and evaluation of exercise prescription models based on exercise physiology needs to be investigated.

CONCLUSION

Participating in an intensity regulated exercise programme within 24 hours of CABG surgery is safe and will improve patients' functional exercise capacity at discharge from hospital. Moving beyond the implementation of a structured early mobility protocol, the inclusion of a patient specific intensity regulated exercise programme during the in-hospital phase has the potential to facilitate cardiovascular conditioning in the CABG population. The development and evaluation of a physiologically based exercise prescription model for CABG patients during phase one CR needs further investigation.

All authors have read and approved submission of the manuscript and the manuscript has not been published and is not being considered for publication elsewhere in whole or part in any language except as an abstract.

Conflict of interest: none declared.

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