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**Aerobic Fitness and Cardiovascular Health Profile  
Two Years after Completion of Cardiac  
Rehabilitation**

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requirements of the University of Chester for the degree  
of Master of Science”

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## Abstract

### Purpose

To evaluate the impact of a 12 week hospital-based phase III cardiac rehabilitation (CR) programme on long-term aerobic fitness and cardiovascular health two years after completion.

### Method

Nineteen male and five female participants (mean age 65 years  $\pm$  2 years) who had completed the CR programme, were randomly recruited to the study. 15 (63%) participants had a diagnosis of MI, 4 (17%) had undergone PCI and 5 (21%) had undergone CABG. The study was a repeated measures design. Participants performed three sub-maximal exercise tests (up to 75% HR<sub>max</sub> and/or RPE 12/13) on a cycle ergometer to assess aerobic fitness (determined by work rate in watts and METs achieved) at baseline, end of CR and at two year follow-up. Secondary measures for cardiovascular health profile (including body anthropometrics, HADS score) were also examined. A one-way (Repeated Measures) ANOVA and the Friedman test examined differences at baseline, end of the programme and at two year follow-up.

### Results

Compared to baseline aerobic fitness improved significantly at the end of CR ( $p = 0.0005$ ) and at two years ( $p=0.0005$ ). At two years there was no significant difference in work-rate ( $p=0.41$ ) or METs achieved ( $p=0.63$ ) compared to levels at the end of CR, indicating that participants maintained their aerobic fitness. The mean work-rate achieved by participants was 56.9 ( $\pm 4.0$ ) watts at baseline, 78.8 ( $\pm 5.5$ ) watts at the end of CR, and 76.8 ( $\pm 5.2$ ) watts at two years. Median METs achieved were 4.3 METs (IQR = 0.9) at baseline, 5.2 METs (IQR = 1.4) at the end of CR and 5.2 METs (IQR = 1.7) at two years.

### Conclusions

A 12 week CR programme can lead to positive health behaviours, an improvement in participant's aerobic fitness and aspects of their cardiovascular health profile, which is maintained two years following completion.

Key words: Cardiac Rehabilitation, Exercise Capacity, Long-Term, Follow-up.

## Declaration

This work is original and has not been previously submitted in support of a Degree, qualification or other course.

Signed.....

Date.....

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## **Glossary of Terms**

<b>CR</b>	Cardiac Rehabilitation
<b>CHD</b>	Coronary heart disease
<b>CVD</b>	Cardiovascular disease
<b>BP</b>	Blood Pressure
<b>SBP</b>	Systolic blood pressure
<b>DBP</b>	Diastolic blood pressure
<b>HR</b>	Heart rate
<b>HR<sub>max</sub></b>	Maximum heart rate
<b>METs</b>	Metabolic Equivalents
<b>RPP</b>	Rate Pressure Product
<b>MI</b>	Myocardial Infarction
<b>CABG</b>	Coronary Artery Bypass Grafts
<b>PCI</b>	Percutaneous Coronary Intervention

## Chapter 1

### Introduction and Literature Review

#### 1.1 Cardiovascular disease and Cardiac Rehabilitation

Cardiovascular disease (CVD) is the leading cause of death globally and in the United Kingdom (UK) (British Heart Foundation, 2009a; WHO, 2009). Premature mortality from CVD is up to six times greater amongst lower socioeconomic groups, but rates vary considerably within the UK geographically, socially and ethnically (Department of Health [DoH], 2008; O'Flaherty et al., 2009). CVD is a major economic burden costing the UK approximately £30 billion annually (Luengo-Fernandez, Leal, Gray, Petersen & Raynor, 2006). This impact demands that initiatives to reduce CHD remain a government and National Health Service (NHS) priority (DoH, 2000).

The cause of CVD is multi-factorial, comprising both non-modifiable (e.g. gender, age, genetic predisposition and ethnicity) and modifiable risk factors. The risk of a first myocardial infarction (MI) is related to the following modifiable risk factors: physical inactivity, tobacco use, elevated blood cholesterol, high blood pressure, obesity, type II diabetes, psychosocial factors and excess alcohol consumption (Yusuf et al., 2004). These modifiable CHD risk factors also contribute to other leading causes of death including an increased risk of stroke, cancer and lung diseases (Cobb, Brown & Davis, 2006). Furthermore, several risk factors are linked. One such example is reduced physical activity, which as well as independently increasing CHD risk, is associated with diabetes, hypertension, obesity and

dyslipidaemia, each further increases the risk of more advanced CHD (Pearson et al., 2002).

Unhealthy dietary and lifestyle behaviours are the major causes of CHD (WHO, 2003). A variety of factors may determine CVD risk in adults including: food production/availability, access to an environment which encourages PA and education (National Institute of Clinical Excellence [NICE], 2010). Lifetime risk of CVD is heavily influenced by diet and levels of physical activity (PA) since childhood (National Heart Forum, 2003).

CR programmes aim to target a number of lifestyle behaviour changes which include: increasing levels of habitual physical activity, improving dietary behaviours, cessation of smoking (if applicable) and helping with patients with their mental well-being following diagnosis of CHD/ a cardiac related event (Smith, Arthur, McKelvie & Kodis, 2004). Amongst these lifestyle changes a number of 'health factors' are also addressed as required, with each CR patient: aerobic fitness, cholesterol levels, obesity, elevated blood pressure, diabetes/impaired glucose tolerance and quality of life (QoL). Both pharmacological treatment and lifestyle modification appear to be of equal value in order to reduce the risk of further mortality and morbidity (Taylor et al., 2004). Although, the most difficult challenge for cardiac patients remain that of motivation and adherence to a long-term healthy lifestyle (Cobb, Brown & Davis, 2006), however, this is to a lesser extent than that of the general population (Gianuzzi et al., 2003). The government continue to emphasise the importance of a lifestyle approach in the management of secondary risk factors, particularly physical activity status (Department of Health, 2000; National Institute for Health and Clinical Excellence, 2006).

Several studies have demonstrated the effectiveness that a reduction of cardiovascular risk factors, and subsequent improvement in cardiovascular health profile, can have on decreasing the number of recurrent coronary events and mortality from cardiovascular disease in patients post MI or revascularisation (Haskell, et al., 1994; Lear, et al., 2006; Willich, et al., 2001). Therefore, full examination of the CR patients' cardiovascular health profile is crucial in order to identify and treat, including lifestyle risk modification, so as to appropriately manage the patient with pre-existing CHD. However, despite public health strategies and campaigns the majority of patients with CHD (85% or more) have at least one modifiable risk factor, defined as: hypertension, cigarette smoking, diabetes or dyslipidaemia (Khot et al., 2003).

It is useful to consider four phases of CR as each represents a different component of the patient's journey of care: (1) inpatient care, (2) early post discharge period, (3) outpatient rehabilitation and (4) long-term maintenance (SIGN, 2002).

The majority of CR programmes typically offer a combination of different interventions including exercise training, patient education and psychological support/intervention. A lack of single-component intervention trials makes it difficult to evaluate the efficacy of individual components. A comprehensive approach to CR employing educational interventions, psychological support and exercise appears to be the most beneficial to cardiac patients, with trials showing that psychological and educational interventions can reduce coronary heart disease risk factors, improve psychosocial wellbeing and patient knowledge and may reduce morbidity and mortality (Joliffe et al., 2001; Dusseldorp et al., 1999; Linden et al., 1996).

## 1.2 The Value of Aerobic Fitness as a measure of outcome

Aerobic fitness is a clinical value which is obtained from exercise testing in order to evaluate an individual's aerobic exercise capacity (also known as exercise tolerance) (Noonan & Dean, 2000). A maximal exercise test is considered the "gold standard" for assessing maximal aerobic capacity ( $VO_{2\max}$ ).  $VO_{2\max}$  is a product of cardiac output (CO) and arterio-venous oxygen difference (a-v O<sub>2</sub> diff), i.e. the ability of the muscles to extract oxygen, at exhaustion. However, the assessment of  $VO_{2\max}$  has its limitations, it typically requires additional monitoring (e.g. electrocardiograph machine), highly trained staff, it is labour intensive and usually requires high levels of motivation from the individual (Noonan & Dean, 2000).

The majority of activities of daily living (ADL) do not require maximal effort but rather sub-maximal exertion and patients with cardiac disease are often unaccustomed to vigorous exercise and have numerous other co-morbidities (e.g. diabetes, asthma) as well as some musculoskeletal limitations. Furthermore, maximal testing is not always safe (i.e. it may be contraindicated in some patients) or impractical to carry out thus a sub-maximal test may be more appropriate. For this reason, although sub-maximal testing involves significant error, it does provide useful information of a person's functional capacity (FC) (Lauer, Froelicher, Williams & Kligfield, 2005).

Aerobic fitness has been demonstrated to be of great importance with greater levels of aerobic fitness related to a reduced relative risk of premature death. Kavanagh et al. (2002) examined over 12,000 male patients with a coronary diagnosis who were referred for CR and assessed their maximal aerobic capacity. The results found that values of 4.3 to 6.3 METs (15-22 ml O<sub>2</sub>/kg per minute,  $p = <.0001$ ) and greater than



6.3 METs (>22 ml O<sub>2</sub>/kg per minute, p = <.0001) led to a 38% and 61% reduction in the risk of cardiac related death over a median of 7.9 (range 4 to 29) years.

Furthermore, the estimated 15 year prognosis improved considerably from the least fit group (average VO<sub>2 peak</sub> of 13 ml O<sub>2</sub>/kg per minute, 35% mortality) to the middle group (average VO<sub>2 peak</sub> of 18.6 ml O<sub>2</sub>/kg per minute, 19% mortality).

Myers et al. (2002) confirmed the protective role of a higher aerobic fitness even in the presence of other risk factors such as hypertension, smoking and diabetes in healthy individuals and those with CVD. The study demonstrated that improvements in cardiovascular fitness over time led to a better prognosis with every one MET increase in treadmill performance associated with a 12 percent improvement in survival. The results suggest that the least fit individuals can achieve the greatest health benefits by increasing their levels of physical activity (Myers et al., 2002). It must be noted that the study's findings are only applicable to men, further investigation is required to evaluate how women's exercise capacity impacts on mortality, especially since evidence suggests exercise test results for females differ significantly to men (Shaw, Hachamovitch & Redberg, 2000). Furthermore, although common practice, the data on exercise capacity was estimated based on the speed and grade of the treadmill, however, directly measured exercise capacity (VO<sub>2 max</sub>) is thought to be both a more accurate and reproducible measure of aerobic fitness and predictor of further outcomes (Myers et al., 1998).

Dunn et al. (1999) examined lifestyle physical activity versus a structured exercise programme in a randomised 24 month trial in previously sedentary healthy adults. The study found that both groups (lifestyle intervention group and structured exercise group) significantly increased their levels of physical activity at six months (p <.001),

with no significant difference in participants' self-reported maintenance of activity (over 18 months), with changes in CVD risk factors (blood pressure, body weight, body fat percentage, lipids) being well maintained or improved over the follow up period. However, at the 24 month follow up there was a significant decline in aerobic fitness in both groups, with the most significant reduction observed in the structured exercise group ( $p < .001$ ). Although, at the 24 month follow up both groups had a similar level of aerobic fitness, which suggests that significant improvements in aerobic fitness, physical activity and CVD risk factors can be achieved without necessarily having to attend a fitness facility but by incorporating lifestyle physical activity.

### **1.3 Sub-Maximal testing as a measure of Aerobic Fitness in Cardiac Rehabilitation**

Patients with cardiac disease often present with a decreased FC and sub-maximal testing can provide a useful means of estimating or predicting the  $VO_{2\max}$  (i.e. aerobic fitness level) of patients in a CR setting (Fleg et al., 2000). When FC is estimated rather than measured directly it is often expressed in metabolic equivalents (METs) which is an indirect measure of oxygen uptake; 1 MET represents resting energy expenditure which is approximately  $3.5 \text{ ml O}_2 \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$  or millilitres of oxygen per kilogram of bodyweight, per minute (Fleg et al., 2000).

Although METs is a common method used to quantify the energy cost and intensity of physical activity, studies suggest that the MET value of  $3.5 \text{ ml O}_2/\text{kg}$  of bodyweight/minute substantially overestimates directly measured values by 30 to 35% (Byrne, Hills, Hunter, Weinseir & Schutz, 2005). Savage, Toth & Ades (2007) suggest that even after adjusting for differences in technique and body composition, the well accepted value for one MET was overestimated by more than 23% in those with CHD. Presently, there is no single definition of how a MET should be measured and further evaluation is needed.

Sub-maximal or predictive testing involves several assumptions: (1) steady-state heart rate (HR) is obtained for each exercise work rate, (2) a linear relationship exists between HR and work rate, (3) the maximal heart rate for a given age is uniform, and (4) mechanical efficiency (i.e. oxygen at a given work rate) is the same for everyone (ACSM, 2006). The selection of an appropriate sub-maximal exercise assessment is of crucial importance in many respects including patient safety and to enable the CR practitioner to provide accurate physical activity guidance. Sub-maximal walking, step and cycle tests are commonly used to provide important

clinical information to the CR practitioner including; assessment of functional capacity, the outcome of interventions, aid in risk stratification for future cardiac events and to assist in appropriate exercise prescription and advice (Gulati & McBride, 2005).

#### **1.4 Impact of Cardiac Rehabilitation on Cardiovascular Health Profile**

Lear et al. (2006) conducted a randomised controlled trial to investigate the effectiveness that long-term modest risk factor and lifestyle intervention can have on individuals after a CR programme over four years. Risk factor and lifestyle counselling sessions were conducted at regular time points over the 4 year (48 month) period by the case manager, with exercise capacity also assessed at six, 12, 24 and 36 months. Recommendations to other health professionals were made as appropriate following each session (i.e. to the dietician, exercise specialist or study cardiologist with regards to medication changes). After completion of the CR programme 302 patients were recruited and randomised to the study. The Extensive Lifestyle Management Intervention (ELMI) trial resulted in a modest non-significant improvement in global risk of ischaemic heart disease in favour of the intervention group with respect to the Framingham risk score:  $-0.60 \pm 2.71$  versus  $0.01 \pm 2.51$  ( $p = .081$ ) for the intervention and usual care groups, respectively. The authors acknowledge a limitation of the study is the use Framingham risk score as measure of global risk of ischaemic heart disease because it was designed to predict risk in primary prevention i.e. individuals without established CHD (Lear et al., 2006). Further, the Framingham risk score does not encapsulate changes in exercise capacity or body mass index (BMI), which are typically targeted in CR programmes (Bethell, Lewin & Dalal, 2009).

Gupta, Sanderson and Bittner (2007) examined which benefits achieved during CR were maintained one year following discharge and whether gender specific differences exist. Two hundred and forty-four patients returned for the evaluation at the one year follow up. The outcome measures were assessed at baseline, CR completion and at the one year follow up and included: six-minute walk distance (6-MWD), BMI, total cholesterol, low density lipoprotein cholesterol (LDL-C), high density lipoprotein cholesterol (HDL-C), triglycerides, self-reported physical activity, physical and mental component scores of the SF-36, depression and current smoking rates. At completion of CR significant improvements were observed in all the outcome measures except HDL-C and smoking ( $p = <.05$ ). However, at the one year follow up visit there was a significant decline in 6-MWD, BMI, diet score and smoking rates in comparison to values at completion of CR, although HDL-C and physical component scores improved. LDL-C, triglycerides, depression score, self-reported physical activity and mental component scores remained the same from completion of CR to one year. Importantly, compared to baseline data, outcome measures at the one year follow up were significantly improved in all clinical, health status and behavioural measures expect for BMI, smoking status and triglycerides. Men who returned for the one year follow up evaluation were typically older, less obese, with lower total cholesterol and better diet scores compared to males who did not choose to return. Women were more likely to be white, have a longer 6-MWD, lower BMI and triglycerides and tended to self-report higher levels physical activity than those women who did not return. Improvements in most outcome measures were similar amongst men and women, with women generally demonstrating a smaller increase in 6-MWD, but a significantly larger reduction in total cholesterol compared with men ( $p < .001$ , comparing baseline to CR completion) and greater

improvements in triglyceride levels and diet scores ( $p < .001$ , comparing baseline and one year follow up).

Willich et al. (2001) reported similar findings in cardiac risk factor outcomes following completion of CR demonstrating that an adequate reduction in cardiac risk factors, and improvement in cardiovascular health profile achieved by many patients during in-hospital CR is not being maintained 12 months later. The prospective study, which examined 2441 patients following myocardial infarction (MI), coronary artery bypass graft (CABG) or Percutaneous coronary intervention (PCI) (from admission to, and discharge from CR and at three, six and 12 months later), demonstrated a significant decline in lipid control and a resumption of smoking between completion of CR to one year later. Furthermore, reports suggest that exercise adherence decreases and body weight and serum lipid levels increase as early as six months after CR has finished (Willich et al., 2001). An important observation in this study is the associated decline in the rate of prescription of cardiac medication and a high rate of recurrent clinical events: 886 patients (43% of all patients with complete follow up information) experienced at least one clinical event during the follow up, 69% of those occurred six months after CR discharge. A similar finding was observed by Boesch et al. (2005) with regards to lipid control, total cholesterol ( $p < .05$ ), triglycerides ( $p < .05$ ) and total cholesterol/HDL ratio ( $p < .01$ ) which were all significantly higher at the two year follow up than compared to values on completion of CR. Aldana et al. (2003) found that although participants who received traditional CR demonstrated improvements in HDL-C, most other CHD risk factors remained the same or worse after six months following completion of the programme.

These findings are consistent with other studies on the progression of CHD through increased cardiovascular risk factors, the EUROASPIRE study observed approximately 50% of patients with coronary artery disease were not appropriately controlled for plasma cholesterol and high blood pressure, while 20% of patients did not have adequate management of smoking, BMI or diabetes (EUROASPIRE study group, 1997). The extent to which the results by Willich et al. (2001) can be generalised is limited since the CR policy in Germany incorporates only three to four weeks of in-hospital CR; this is quite different to that observed in UK programmes. The authors acknowledge that the 12 month follow up data was available for 85% of the total patient population and therefore the study may be associated with potential selection and information bias.

## 1.5 Maintenance of Aerobic fitness and Cardiac Rehabilitation

A limited number of studies have reported on the benefits of CR beyond the point of discharge or completion from the formal programme with follow-up typically at one year (Appendix 1). Both observational and randomised controlled trials (RCT) have demonstrated mixed findings; some demonstrated maintained improvements in aerobic fitness through an increased exercise capacity, while others reported a return to baseline measures at follow-up.

Historical evidence has suggested that the convalescent period following MI is associated with spontaneous improvements in functional aerobic capacity that may be because of the normal recovery processes that are unrelated to formal exercise training (e.g. DeBusk, Houston, Haskell, Fry & Parker, 1979). Dressendorfer et al. (1995) performed a randomised controlled trial examining 50, low risk, male patients recovering from acute MI during a five week 'early' CR programme. Patients were randomly assigned to four groups: one was a control group who were restricted to 'very light' (<50%  $VO_{2\max}$ ) physical activity at home, the other three groups performed structured aerobic exercise at a moderate intensity (approximately 70%  $VO_{2\max}$ ), either once, twice or three times weekly at a hospital. The study demonstrated that only the patients in the training group who performed structured exercise showed significant improvements in  $VO_{2\max}$  at follow-up when assessed on a treadmill. It is likely the differences in exercise training, the time of enrolment following MI or other cardiac diagnosis, the differences in the patient population and the impact of counselling may all influence the extent to which CR improves aerobic fitness and individuals' cardiovascular health profile.



Smith, Arthur, McKelvie & Kodis (2004) examined 222 CABG patients randomised to either six months of supervised hospital versus monitored home-based CR. At discharge from the CR patients were advised to continue to exercise a minimum of five times weekly at their prescribed target heart rate with patients also given an exercise log. The study demonstrated that exercise capacity (measured by peak oxygen uptake or  $VO_{2\text{ peak}}$ ), significantly declined in the 'hospital' group from  $1616 \pm 455$  ml/min at 6 months to  $1535 \pm 426$  ml/min at the 12 month follow-up ( $p = 0.002$ ). However, the 'home' group maintained peak  $VO_2$  between CR discharge and the 12 month follow up ( $1567 \pm 430$  ml/min versus  $1565 \pm 437$  ml/min), with the peak METs slightly declining in the 'hospital group at the follow-up ( $p = 0.005$ ). Importantly, the authors observed that both hospital and home groups maintained a significantly higher peak  $VO_2$ , peak METs and peak work rate ( $p = <0.0001$ ) than at baseline (entry to the CR programme). Of note, the study demonstrated that both groups ('Home' and 'Hospital') had significantly higher levels of habitual physical activity compared to the population norms for healthy adults with a mean age of 67 years (ACSM, 2006). The finding that both groups maintained significantly higher levels of aerobic fitness after 12 months of non-intervention than baseline is supported with previous evidence by Dugmore et al. (1999) which also demonstrated improvements in cardio-respiratory fitness, psychological status and vocational status over a five year period following a 12 month CR programme.

In contrast, Stalhe, Mattsson, Ryden, Unden & Nordlander (1999) found that in patients post coronary event (aged 65 years or more), although notable initial improvements in aerobic fitness were observed and remained above baseline levels at the 12 month follow up, the participants' exercise capacity had actually declined considerably to almost baseline levels. This suggests continued structured,

supervised training may be necessary in order to maintain achieved effects in this age population.

Age and location of CR exercise may be an important factor when considering which individuals may benefit the most, not just in terms of maintaining and improving aerobic fitness but with regards to sustaining physical activity levels long-term following completion of CR. A randomised trial by Marchionni et al. (2003) demonstrated that CR post myocardial infarction (MI) enhances exercise tolerance in patients of all ages, with total work capacity (measured in kilograms per minute) consistently improving to a greater extent in middle-aged (45-65 years) and old patients (66-75 years) than in very old patients (> 75 years, traditionally excluded from CR trials). As observed in previous trials such (e.g. Smith, Arthur, McKelvie & Kodis, 2004) most of the initial improvements in exercise capacity with the 'Hospital' CR group was lost over the 12 month follow-up. By comparison the 'Home' group better preserved initial improvements in exercise capacity after 12 months following completion of CR suggesting that home based CR more effectively induces positive changes in lifestyle than hospital based CR in certain patients. Although the study specifies that certain patients were randomised to a 'Home' based CR group, the extent to which they can truly be defined as home-based is questionable since these patients initially participated in up to eight supervised sessions in the CR unit before being provided with a static bike and heart rate monitor for the training period. Arguably, this is not typical practice by National Health Service (NHS) CR programmes due to constraints to both resources and finances. Furthermore, unlike the hospital group, patients in the home group had a bike available to them following the end of the two month training period. This is may have had a considerable

impact on the both the participants' long-term exercise tolerance and adherence to regular physical activity and exercise.

While it is thought that continued exercise is required to sustain most benefits of CR, research demonstrates that just 30-60% of those who complete an outpatient CR programme are still physically active between three and six months later (Holmback, Sawe & Fagher, 1994; Moore, Roland, Pashkow & Blackburn, 1998). Boesch et al. (2005) demonstrated sustained improvements in maximal and sub-maximal exercise capacity following a one month residential CR programme at the two year follow-up. Peak watts and exercise duration were similar to the CR discharge exercise test, exercise capacity remained significantly higher compared to baseline measures at the start of the CR programme ( $p = <0.001$ ). However, the study differed considerably in comparison to the standard CR programmes in the UK in that it was a residential programme; this is uncommon for CR programmes in the UK which are typically supervised, group, outpatient rehabilitation where patients are recommended, by the National Service Framework for Coronary Heart Disease, to attend twice weekly CR (DoH, 2000). Having the study participants living at the rehabilitation centre virtually ensured complete compliance with exercise, educational and dietary components of the programme (Boesch et al., 2005). The study was limited by the lack of a control group, arguably, those who attended the programme and agreed to return at the two year follow up may have been particularly motivated to make positive health/lifestyle changes following their cardiac event (Papageorgiou, Fotinakis, Tsitskari & Giasoglou, 2004) especially since it is more likely that volunteers will adhere to exercise programmes due to their expressed desire to participate (Daltroy, 1994). The exercise volume was also comparatively higher in this study than typically observed in UK CR (SIGN, 2002);

participants performed five times weekly, thirty minute cycling sessions and twice daily 45 minute walks. Notably, more than 54% of the participants in this study were retired, which perhaps made more time available for those individuals to engage in more recreational activity. The high standard deviation in mean energy expenditure at the two year point suggests a considerable variance in the patients' long-term physical activity levels.

Significant improvements in aerobic fitness were also observed by Arrigo, Brunner-LaRocca, Lefkovits, Pfisterer & Hoffman (2008) one year following CR in both the intervention (INT) and usual care (UC) groups at baseline (completion of the CR programme) and at the one year follow-up (INT  $153 \pm 52$  watts at baseline versus  $163 \pm 49$  watts at follow-up; UC –  $144 \pm 52$  at baseline versus  $154 \pm 47$  watts at follow up),  $p = <0.0005$ . Unlike other studies which have involved no intervention after CR completion (e.g. Smith et al., 2004) the intervention group participated in physician supervised exercise once every three months following completion of the formal programme. This contact following discharge from CR may have positively influenced adherence to independent exercise and led to positive health behaviours, since the participants may have been less likely to have wanted to 'let the physician down'. The influence of physician's on health behaviours is an area that requires further evaluation.

## **1.6 Rationale for this project**

Only a limited number of studies have reported on the benefits of CR beyond the point of discharge or completion from the formal programme. Both observational and randomised controlled trials (RCT) have demonstrated mixed findings with regards to improvements in aerobic fitness. While some studies have demonstrated sustained improvements in exercise capacity and improvements in cardiovascular risk factors following completion of CR (e.g. Boesch et al., 2005), other studies have actually shown a considerable decline in aerobic capacity after twelve months of non-intervention following a hospital-based exercise programme (Smith et al., 2004). Protocols from other comparable studies have utilised additional interventions following discharge from the formal CR programme (e.g. Arrigo et al., 2008), therefore, evaluation of the impact that CR alone has on longer-term aerobic fitness and cardiovascular health is difficult and requires further investigation.

Therefore, this proposed study aims to evaluate the impact of a twelve week hospital-based cardiac rehabilitation programme on long-term aerobic fitness and cardiovascular health profile two years after completion of the programme and add to the existing body of research.

### **1.7 Primary research objective**

To determine if aerobic fitness levels achieved prior to discharge from a Phase III (hospital-based) cardiac rehabilitation (CR) programme can be maintained two years after its completion, without further intervention.

### **1.8 Secondary research objective**

The secondary aims are to examine changes in participants' cardiovascular health profile including: blood lipids, blood pressure, smoking status, body anthropometrics (weight and waist circumference), physical activity levels, Hospital Anxiety and Depression score, hospital re-admission rate, quality of life and how these may impact on cardiovascular risk two years after completion of the programme.

## 1.9 STUDY HYPOTHESIS:

**1. Null hypothesis ( $H_0$ ):** There will be no significant difference between aerobic capacity at the end of the cardiac rehabilitation programme and aerobic capacity at the two year follow-up.

**Alternate hypothesis ( $H_1$ ):** There will be a significant difference between aerobic capacity at the end of the cardiac rehabilitation programme and aerobic capacity at the two year follow-up.

**2-6. Null hypotheses ( $H_0$ ):** There will be no significant difference between total cholesterol/body weight/waist circumference/Rate pressure product/HAD score/ at the end of the cardiac rehabilitation programme and total cholesterol/body weight/waist circumference/Rate pressure product/HAD score at the two year follow-up.

**Alternate hypotheses ( $H_{2-6}$ ):** There will be a significant difference between secondary measures: total cholesterol ( $H_2$ )/body weight ( $H_3$ )/waist circumference ( $H_4$ )/Rate pressure product (RPP) ( $H_5$ ) /HAD score at the end of the cardiac rehabilitation programme ( $H_6$ ) and secondary measures at the two year follow-up.

**7. Null hypotheses ( $H_0$ ):** There will be no significant relationship between the volume of physical activity (measured in MET-minutes per week using the IPAQ) and aerobic fitness (estimated METs 75%  $HR_{max}$  at the two year exercise test).

**Alternate hypotheses ( $H_{7-8}$ ):** There will be a significant relationship between the volume of physical activity (measured in MET-minutes per week using the IPAQ) and aerobic fitness (estimated METs 75%  $HR_{max}$  at the two year exercise test).

**8. Null hypotheses ( $H_0$ ):** There will be no significant relationship between waist circumference and total cholesterol measured at the two year follow-up.

**Alternate hypotheses ( $H_8$ ):** There will be a significant relationship between waist circumference and total cholesterol measured at the two year follow-up.



## **Chapter 2**

### **Methodology**

#### **2.1 Participants**

24 participants who fulfilled the inclusion criteria (see section 2.2) were selected at random (using a random number generator) and invited and subsequently agreed to participate in the study (Appendix 2). The study sample consisted of 19 Males and 5 females aged between 46-81 years (see Appendix 7 for recruitment and data collection procedure).

300 patients enrolled onto the cardiac rehabilitation programme. From the total number of patients who initially enrolled on the programme a total of 100 patients completed the 12 week programme of cardiac rehabilitation (including exercise: once or twice weekly and health education (both formally and informally) at Good Hope Hospital between 2008 and 2009.

Ethical approval for this study was acquired from the Birmingham East North & Solihull (BENS) Research Ethics Committee (Appendix 3) and Heart of England NHS Foundation Trust's Research & Development Department (Appendix 4). All participants had given their informed consent prior to participation in the study (Appendix 5). Further support for the study came from the Consultant Cardiologist and Cardiac Rehabilitation Coordinator at Good Hope Hospital (Appendix, 8

## **2.2 Inclusion criteria**

The participants must have completed the CR programme between 2008-2009, been diagnosed and successfully treated for a myocardial infarction (also known as heart attack) or angina and undergone successful coronary revascularisation, as a result of CHD (i.e. coronary artery bypass grafts or percutaneous coronary intervention, also known as coronary angioplasty with/without stenting). Participants also had to be English speaking to participate in the study.

## **2.3 Exclusion criteria**

Proposed participants who have one or more contraindications to exercise testing, both absolute and relative, will be excluded from the proposed study, as suggested by the American College of Sports Medicine (ACSM, 2000) and Gibbons et al. (2002). See 2.3.1 and 2.3.2:

### **2.3.1 Absolute contraindications to exercise testing**

- A significant recent change in the resting electrocardiogram suggesting significant ischaemia, recent myocardial infarction (within 2 days) or other acute cardiac event
- Unstable angina
- Uncontrolled cardiac dysrhythmias causing symptoms or hemodynamic compromise
- Symptomatic severe aortic stenosis
- Uncontrolled symptomatic heart failure
- Acute pulmonary embolus or pulmonary infarction

- Acute myocarditis or pericarditis
- Suspected or known dissecting aneurysm
- Acute systemic infection, accompanied by fever, body aches, or swollen lymph glands

### **2.3.2 Relative contraindications to exercise testing**

- Left main coronary stenosis
- Moderate stenotic valvular heart disease
- Electrolyte abnormalities (e.g. hypokalemia, hypomagnesemia)
- Severe arterial hypertension (i.e. systolic blood pressure of greater than 200 mmHg and/or a diastolic blood pressure of >110 mmHg) at rest
- Tachydysrhythmia or bradydysrhythmia (abnormally elevated resting heart rate >100bpm or abnormally low resting heart rate <60bpm)
- Hypertrophic cardiomyopathy, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
- High degree atrioventricular block
- Ventricular aneurysm
- Uncontrolled metabolic disease (diabetes-blood glucose > 14 mmol/L, thyrotoxicosis or myxedema)
- Chronic infectious disease (e.g. mononucleosis, hepatitis, AIDS)
- Mental or physical impairment leading to inability to exercise adequately

## 2.4 Study Design

The same group of individuals who completed the CR programme (in 2008-2009) performed a sub-maximal exercise assessment (to measure aerobic fitness) on three occasions: at baseline (entry onto the CR programme), at the end of the programme (pre-discharge) and at the two year follow-up point. Therefore the nature of the study was a repeated measures design. Retrospective data from the hospital database and cardiac rehab patient notes was used, this included: exercise assessment data (Watts achieved at 75% HR<sub>max</sub>, estimated METs achieved at 75% HR<sub>max</sub>, blood pressures, rating of perceived exertion scores), blood lipids (cholesterol), body weight, waist circumference, Hospital and Anxiety and Depression (HAD) scores, smoking history and hospital readmission rates. To assess the participants' functional aerobic capacity at the two year follow-up an experimental protocol was used.

## **2.5 Primary outcome measures:**

The outcome measures were taken at baseline (beginning of the CR exercise programme), at twelve weeks (prior to discharge from CR) and at the two year follow-up (testing point):

**a)** Aerobic fitness was measured at the two year follow-up by a sub-maximal aerobic exercise cycle assessment (see section 2.8) to assess for changes in aerobic fitness over time. Aerobic fitness was measured by watts achieved at estimated 75% HR<sub>max</sub> and Metabolic Equivalents (METs) attained at 75% HR<sub>max</sub> on the exercise assessment at baseline, the end of CR and at the two year follow-up.

## **2.6 Secondary outcome measures:**

**b)** Hospital Anxiety and Depression Scale (HADS). The HADS has been found to be a reliable instrument to detect states of anxiety and depression in hospital outpatient clinics (Zigmond & Snaith, 1983). Participants' HADS score was measured at three time points: baseline, end of CR and two year follow-up.

**c)** The International Physical Activity Questionnaire-short version (IPAQ-short), to be measured in median MET–minutes/week. Having undergone extensive reliability and validity testing across 12 countries the IPAQ has acceptable measurement properties suitable for use in a variety of settings as a measure of health-related physical activity (Hagstromer, Oja & Sjostrom, 2005). It is currently used by the National Audit of Cardiac Rehabilitation (NACR) as an evaluation tool and is utilised by a number of cardiac rehabilitation programmes to measure health-related physical activity levels nationally. This tool was used at the two year follow-up only.

- d)** The short-form 12 item Health survey (SF-12) is a tool used to measure general health/quality of life. The SF-12 can assess the level of health/ill-health and degree of change overtime. The SF-12 also possesses high test-retest reliability in a cardiovascular setting (Bohannon, Maljanian & Landes, 2004; Jenkinson & Layte, 1997). Quality of life using this tool will be measured at the two year follow-up only.
- e)** Maintenance/change total blood cholesterol (measured in millimoles per litre or mmol/l) using existing data from the hospital database.
- f)** Maintenance/change in pre-exercise blood pressure (measured in millimetres of mercury or mmHg).
- g)** Maintenance/change in body weight measured in kilograms (kg).
- h)** Maintenance/change in abdominal waist circumference measured in centimetres (cm)
- i)** Smoking status (yes or no)
- j)** Hospital readmission rates (for cardiac and non-cardiac reasons) since discharge from the cardiac rehabilitation programme using the hospital database.

## **2.7 Ethical Consideration**

Exercise with CHD brings risks to the cardiac rehabilitation patient. The researcher conducting the study was an experienced Exercise Physiologist within the Cardiac Rehabilitation Team at Good Hope Hospital who has training and competence in exercise testing and immediate life support. Although a sub-maximal exercise assessment may be considered a safe procedure, risks and complications may occasionally arise during the test. These include abnormal blood pressure, fainting, irregular, fast or slow heart rhythms and rarely, heart attack, stroke or death (Fletcher et al., 2001). To minimise potential risks the participants were continually monitored prior to, during and following the exercise assessment with regards to heart rate and rhythm on the electrocardiograph (ECG) monitor, blood pressure and their Rating of Perceived Exertion. Furthermore, prior to assessment each participant was asked a series of health screening questions and was also required to fulfil the criteria for exercise testing (Appendix 6).

## **2.8 Procedure**

### **2.8.1 Exercise Assessment**

The protocol for this sub-maximal stationary cycle assessment (see Appendix 12 for cycle assessment data collection sheet) was adapted from Buckley, Holmes & Mapp (1999).

Each participant was individually assessed in the cardiac rehabilitation department's assessment room. The researcher/exercise physiologist performed a pre-exercise interview to evaluate the participants' current health and cardiac status to ensure the patient was suitable and safe to exercise, i.e. they fulfilled the inclusion criteria (see pre-exercise test checklist, Appendix 6). The participant was informed verbally prior to commencing the exercise assessment as to the exact protocol of the test and the importance was stressed to the participant to immediately inform the exercise physiologist if they experienced any distressing/unusual symptoms, pain anywhere or anginal symptoms, however minor.



## **2.8.2 Equipment**

1. Cycle ergometer that accurately measures pedal work-rate in watts.
2. Electrocardiograph (ECG) monitoring system
3. Rating of Perceived Exertion scale (RPE, Borg, 1998) on a 6-20 graded scale
4. A sphygmomanometer (which is a manual blood pressure meter)
5. Stethoscope
6. Electronic weighing scales
7. Tape measure (to measure abdominal waist circumference)
8. Digital blood glucose monitor

### **2.8.3 Pre-exercise assessment protocol**

Each patient sat quietly for at least 5 minutes prior to the exercise test, before which the following pre-exercise test protocol was performed:

- Seated resting blood pressure was measured (using a manual blood pressure meter known as a sphygmomanometer) and recorded.
- A measurement of body weight (using electronic weighing scales) and waist circumference (by tape measure) was obtained.
- Electrocardiograph (ECG) electrodes were carefully placed and secured on the participant to allow ECG monitoring to be performed throughout the assessment. A pre-exercise ECG trace was recorded and examined (to further assess for participant suitability to perform the test, i.e. no abnormal heart rhythms noted as described in the exclusion criteria)
- If appropriate the participants' blood glucose level was measured pre-exercise using a 'finger prick' glucose monitor.
- The participant then sat on the static bike.
- The seat height of the bike was adjusted so that the participants' legs were almost completely extended when the pedals were at the lowest point.
- A manual blood pressure cuff was placed on the participant' upper arm.
- The RPE scale was described to the participant as per appropriate instructions.

#### **2.8.4 Exercise cycle assessment protocol**

The exercise assessment was conducted by the cardiac rehabilitation exercise physiologist.

- Each test started at 25 watts. For those participants who were felt to be quite unfit the exercise physiologist reduced the workload accordingly where necessary.
- Each stage lasted 2-3 minutes for the cycle test.
- The participant was encouraged to maintain a regular pedalling cadence which was set on an individual basis throughout the test, at 50 or 60 revolutions per minute (rpm).
- Throughout the test participant' symptoms/degree of discomfort (if any) was periodically checked.
- A 3-lead telemetry ECG was continuously monitoring the participant's heart rate/rhythm during the test as means of participant care and safety.
- The work rate on the bike was gradually increased as appropriate during the test from (usually) 25 watts upwards, depending on the participants' heart rate, blood pressure, and RPE.
- Exercise blood pressure was recorded every two minutes, and heart rate was recorded every minute
- The participants were asked to give an RPE (according a 6-20 graded scale) each minute as a means of participant care, but this was only recorded every two minutes, at the end of each stage.
- The test continued until the individual attained either approximately 75% of estimated maximal heart rate (65% heart rate reserve max) and/or an RPE of 11-13, unless the participant became unwell (see stop test criteria, 2.8.5).

- At the end of the test the load on the cycle was reduced and the participant pedalled gently for at least two minutes recovery at a workload which was at least no more than they workload they started the test at. This was to allow for a reasonable recovery and normalisation of the participants' heart rate, blood pressure and breathing rate before getting off the bike.
- If the exercise test is stopped for any of the reasons detailed on the 'stop test criteria' apart from the participants' desire to stop or achieving a heart rate of 75% estimated maximum and/or an RPE of 11-13, which indicate the test should be stopped, the patient will be monitored in the assessment room until symptoms and/or ECG changes have completely resolved. If any symptoms/signs were prolonged appropriate medical attention would be sought from cardiac rehabilitation staff and/or the cardiology team at the hospital.
- Each participant was monitored for a minimum of 10 minutes post-exercise while seated during which time the participants' heart rate, ECG and signs/symptoms were monitored.
- Post-exercise blood pressure was measured at three minutes to ensure that it was returning to pre-exercise levels and also to avoid the risk of postural hypotension.
- As appropriate, blood glucose was also measured to monitor patient safety and check for hypoglycaemia.

### **2.8.5 Stop test criteria for the exercise cycle assessment**

The individual participant attains either 75% of estimated maximal heart rate (65% heart rate reserve max) and/or an RPE of 11-13.

Fatigue defined as an RPE score of  $\geq 15$  ('hard'), reaching a systolic blood pressure greater than/equal to 220mmHg and/or a diastolic blood pressure greater than/equal to 110mmHg (participant specific depending on other previous test results i.e. exercise tolerance test that demonstrated angina or cardiac ischaemia at a specific intensity).

Symptoms such as: 1. acute chest pain/discomfort or other symptom suggestive of angina, 2. sudden pallor, 3. loss of coordination, 4. mental confusion, 5. extreme dyspnoea.

Signs such as:

1. ST segment depression (of more than 1mm) on the ECG
2. T-wave inversion with any of the associated symptoms already mentioned
3. Sustained ventricular tachycardia (dangerously elevated abnormal electrical heart rhythm)
4. A fall in systolic blood pressure by  $> 10$  mmHg from baseline level despite an increase in workload, in the absence of other evidence of ischaemia (inadequate blood and oxygen supply)
5. The participants' desire to stop.

## 2.9 Data Analysis

The following data were collected for statistical analysis at baseline (prior to commencement of the phase III exercise programme), at the end of CR (on completion of the programme) and at the two year follow-up:

- Estimated METs at 75% HR max achieved on exercise testing
- Watts achieved at 75% HR max on exercise testing
- Waist circumference
- Body weight
- Pre-exercise BP's
- BP at 75% HR<sub>max</sub>
- RPP at peak exercise (a clinical measure of the heart's oxygen consumption/demand: which is multiple of heart rate and systolic blood pressure)
- Hospital Anxiety and Depression Scale (HADS) score
- Total blood cholesterol

All statistical data was analysed using PASW version 18 (SPSS) and the alpha values were set to  $p=0.05$ .

The nature of the study was a repeated measures design using the same group of individuals. A parametric test, the One-way (repeated measures) Analysis of Variance (ANOVA) test was performed for the data that met the following assumptions: the data was of interval/ratio level, the same sample was being examined on at least three occasions and the data was normally distributed. A one-way (repeated measures) ANOVA was performed to analyse the data for significant

differences between each assessment (at baseline, end of CR and two year follow-up). As required, post hoc analysis was conducted using multiple T-tests (with Bonferroni adjustment) to see where the differences lay (Coakes & Steed, 2007).

Data concerning the primary outcome measure, aerobic capacity, was analysed using data from each participant from the exercise test performed at baseline, at discharge and at the two year follow-up. The data was tested for significant differences in the watts achieved at 75% HR<sub>max</sub> at each time point. Having met the assumption of normality ( $p > 0.05$ ) a one-way (repeated measures) ANOVA was performed to investigate for differences between data at the three aforementioned time points. To identify where significant differences lay post hoc analysis, with Bonferroni adjustment was performed to reduce the risk of committing a type I error (Williams & Wragg, 2004). Aerobic capacity in watts was converted into estimated METs (achieved at 75% HR<sub>max</sub>). This data failed the assumption of normality, therefore a non-parametric test; the Friedman test was performed to investigate differences between estimated METs achieved at 75% HR<sub>max</sub>. Post hoc analysis was performed on the aerobic capacity data, and on other data where necessary, using multiple Wilcoxon tests to see where any significant differences were apparent (with Bonferroni adjustment) (Coakes & Steed, 2007). All descriptive statistics have been presented for all analyses.

Metabolic Equivalent (METS) is an indirect measure of oxygen uptake (also termed aerobic capacity) used to assess an individual's functional capacity, 1 MET = approximately 3.5 millilitres of oxygen per kilogram of bodyweight per minute. Further data concerning secondary outcome measures including: total blood cholesterol, body weight and waist circumference, were analysed using the one-way (repeated measures) ANOVA was performed to analyse the data for significant

differences between time points (baseline, end of CR and two year follow-up), again where necessary, post hoc analysis was conducted using multiple T-tests (with Bonferroni adjustment) to see where the differences lay (Coakes & Steed, 2007). Health related quality of life (measured by the Hospital Anxiety and Depression Scale) was examined for significant differences in results using the Friedman test due to the data failing the assumption of normality. Post hoc analysis was again performed (with Bonferroni adjustment) to ascertain where the significant differences in results were apparent. To test for relationships Spearman's Rank Correlation Coefficient was performed to investigate for a relationship between total MET-minutes per week and estimated METs at 75%  $HR_{max}$  at the two year follow-up. A Pearson's correlation was performed to test for a relationship between waist circumference and total blood cholesterol at the two year follow-up.



### 3. Results

#### 3.1 Subject characteristics

24 participants, who fulfilled the study criteria (see section 2.2) after being randomly selected, completed the study. The participants were made up of 79% males (n=19), 21% females (n=5). The mean age of all participants (n=24) was 65 years ( $\pm 2$  years). There were no untoward events during sub-maximal exercise testing. Clinical and demographic characteristics are outlined in Table 1. Fifteen (63%) of the participants had a primary diagnosis of MI, 4 (17%) had undergone PCI, and 5 (21%) had undergone CABG. The new or recurring clinical events between CR discharge and the two year follow-up were: angina (n=3), repeat cardiac angiography or CABG surgery (n = 3), or non-cardiac procedure (n=1). The study participants' raw data is presented in Appendix 11.

**Table 1. Participant Characteristics**

<b>N</b>	24
Mean age $\pm$ SD (year)	64.6 $\pm$ 1.7
Male, <i>n</i> (%)	19 (79)
Female, <i>n</i> (%)	5 (21)
MI, <i>n</i> (%)	15 (63)
PCI, <i>n</i> (%)	4 (17)
CABG, <i>n</i> (%)	5 (21)
Previous smoking history, <i>n</i> (%)	16 (67)
Currently smoking (at 2 year follow-up), <i>n</i> (%)	2 (8)
Hospital Readmissions due to cardiac cause (post CR discharge), <i>n</i> (%)	6 (25)

### 3.2 Aerobic Capacity

**Table 2. Exercise Test Responses (mean  $\pm$  SD), at baseline, after training, and after two years following cardiac rehabilitation (CR) completion**

	<b>Baseline</b>	<b>End of CR</b>	<b>2 year follow-up</b>
Watts achieved @ 75% HR <sub>max</sub>	56.9 ( $\pm$ 4)	78.8 ( $\pm$ 5.5)*	76.8 ( $\pm$ 5.2)*
RPP (HR*SBP/100)	160 ( $\pm$ 6)	168 ( $\pm$ 6)	172 ( $\pm$ 7)
Systolic BP (SBP), mmHg @ peak exercise (75% HR max)	129 ( $\pm$ 4)	133 ( $\pm$ 4)	128 ( $\pm$ 3)
Diastolic BP (DBP), mmHg @ peak exercise (75% HR max)	75 ( $\pm$ 2)	74 ( $\pm$ 2)	77 ( $\pm$ 2)

\*  $P < 0.017$  vs. baseline assessment

**Table 3. METs achieved at approximately 75% HR<sub>max</sub> as median values with the interquartile range (IQR), at baseline, the end of CR, and two years after CR completion**

	<b>Baseline</b>	<b>End of CR</b>	<b>2 year follow-up</b>
Estimated METs @ 75% HR <sub>max</sub> , Median (IQR)	4.3 (0.9)	5.2 (1.4)*	5.2 (1.7)*

\*  $P < 0.017$  vs. baseline assessment

### 3.2.1 Watts achieved at estimated 75% HR<sub>max</sub>

Participants with missing aerobic capacity data for one or more assessment were omitted from the analysis, n = 22 in this case.

The data for participants' aerobic capacity measured by watts at 75% HR<sub>max</sub>, met the assumption of normality because  $p \geq 0.05$  (Appendix 10), the Shapiro-Wilk statistic was consulted because the sample size was less than 100 (Coakes & Steed, 2007). A parametric test, the one-way repeated measures ANOVA (Table 4) was therefore performed due to the repeated measures design of the study. The data met the assumption of sphericity (Appendix 10),  $p = \geq 0.05$ , therefore, the 'sphericity assumed' statistic was used for the remainder of the analysis.

**Table 4. One-way (repeated measures) ANOVA to test for differences in watts at peak exercise at baseline, end of CR and two year follow-up.**

<b>Trial</b>	<b>F-ratio</b>	<b>Sig.</b>
Sphericity Assumed	38.797	.000

Observation of the results (Table 4) indicates there is a significant difference between the three trials ( $p = 0.0005$ ). To find out where the differences lay post hoc analysis was performed by conducting three paired samples *t*-tests, with Bonferonni adjustment ( $p=0.05/3 = 0.017$ ). This was done to reduce the risk of committing a type I error, since multiple tests were conducted on the same sample (Williams & Wragg, 2004). The new significance level was therefore set at  $p = 0.017$  for the analysis of the aerobic capacity data (i.e. watts at 75% HR<sub>max</sub>).

**Table 5. Post hoc analysis using Paired samples t-test's to examine for differences in watts at 75% HR max between assessments (baseline, the end of CR, at two year follow-up)**

	<i>t</i>	<b>Sig. (2-tailed)</b>
Pair 1: watts @ baseline & watts @ end of CR	-7.39	.000
Pair 2 : watts @ baseline & watts @ 2 years	-8.97	.000
Pair 3 : watts @ end of CR & watts @ 2 years	.84	.409

The results (Table 5) of the post hoc analysis revealed that there was a significant difference between the participants' watts achieved (at 75% HR<sub>max</sub>) between both baseline and the end of CR (p=0.0005), and baseline and the two year follow-up assessment (p=0.0005). However, there was no significant difference in aerobic fitness (measured in watts) at the end of CR and the two year follow-up, p = 0.41. The mean watts achieved by participants at 75% HR<sub>max</sub> (Table 2) were 56.9 (±4) watts at baseline, 78.8 (±5.5) watts at the end of CR, and 76.8 (±5.2) watts at the two year follow-up.

### **3.2.2 METs attained at estimated 75% HR<sub>max</sub>**

Participants with missing aerobic capacity data for one or more assessment were omitted from the analysis, n = 22 in this case. Estimated METs were calculated using published tables and calculations based on participants' body weight, revolutions per minute and watts attained at approximately 75% HR max achieved on sub-maximal exercise testing (ACSM, 2006). The term METs achieved will be used to identify METs achieved at 75% HR max (i.e. sub-maximal exercise intensity).

The data concerning METs achieved (at 75% HR<sub>max</sub>) at the three time points: baseline, CR discharge and two year follow-up were tested for normality (Appendix 10). The data failed the assumption of normality and therefore a non-parametric test, the Friedman test was performed. The results in Table 6,  $p = 0.0005$  ( $p \leq 0.05$ ) indicate a significance difference in the participants' METs at 75% HR<sub>max</sub> achieved between baseline, end of CR and at the two year follow-up assessment. Post hoc analysis was performed by way of three Wilcoxon tests to ascertain where significant differences lay between the three testing points (at baseline and the end of CR, baseline and two year follow-up, and the end of CR and two year follow-up). The results of post hoc analysis is displayed in Table 7, Bonferroni adjustment set the new level of significance at 0.017 ( $p = 0.05 / 3$ ), this was performed to reduce the risk of committing a type I error (Williams & Wragg, 2004).

**Table 6 – Friedman Test to analyse for significance differences in the METs at 75% HR<sub>max</sub> achieved at three time points: baseline, end of CR and at the two year follow-up**

<b>N</b>	<b>22</b>
<b>Chi<sup>2</sup></b>	29.301
<b><i>p</i></b>	.000

**Table 7 – Results of post-hoc analysis using Wilcoxon tests to assess for significant differences between in aerobic capacity (METs at 75% HR<sub>max</sub>) at three time points; baseline, end of CR and two year follow-up.**

	<b>METs @ end of CR – METs @ baseline</b>	<b>METs @ 2 year follow-up – METs @ baseline</b>	<b>METs @ 2 year follow up – METs @ end of CR</b>
<b>Z</b>	-4.020	-3.967	-.488
<b>p</b>	.000	.000	.626

The results in Table 7 demonstrate that there is a significant difference in aerobic fitness as measured by METs at 75% HR<sub>max</sub>, between the baseline assessment and discharge assessment (p=0.0005), and baseline assessment and the two year follow-up assessment (p=0.0005). There was no significant difference between the METs at 75% HR<sub>max</sub> achieved by patients at the end of CR and the two year follow-up assessment (p=0.63). Therefore the null hypothesis (1) cannot be rejected.

The median aerobic capacity is presented in (Table 3) at the end of CR was 5.2 METs (IQR = 1.4) vs. 4.3 METs (IQR = 0.9) at baseline, the median aerobic capacity at the two year follow-up was 5.2 METs (IQR = 1.7) vs. 4.3 METs (IQR = 0.9) at baseline, at the two year follow-up: 5.2 METs (IQR = 1.7) vs. 5.2 METs (IQR = 1.4) at the end of CR.

### 3.3 Anthropometrics

#### 3.3.1 Abdominal Waist Circumference

Participants with missing waist circumference data for one or more assessment were omitted from the analysis, n = 13 for the analysis of this data.

Data was tested for normality (Appendix 10),  $p = >0.05$  in the Shapiro-wilk statistic which indicated the data was normality distributed. Consequently, a one-way repeated measures ANOVA (Table 8) was performed. The data also met the assumption of sphericity (Appendix 10), and therefore the 'Sphericity Assumed' statistic was consulted to identify for significant results in the one-way ANOVA (Table 6).

**Table 8. One-way Repeated Measures ANOVA to evaluate for differences in waist circumference at baseline, the end of CR and two year follow-up**

<b>Trial</b>	<b>F-ratio</b>	<b>Sig.</b>
Sphericity Assumed	2.39	0.11

The results from the one-way repeated measures ANOVA (Table 8) demonstrate that there is no significant difference in abdominal waist circumference between the three assessments (at baseline, end of CR and two year follow-up)  $p = 0.11$  ( $p = > 0.05$ ). The mean abdominal waist circumference was  $100.3\text{cm} \pm 3.6\text{cm}$  at baseline,  $99.5\text{cm} \pm 3.3\text{cm}$  at the end of CR and  $102.5\text{cm} \pm 3.3\text{cm}$  at the two year follow-up.

### 3.3.2 Body weight

**Table 9. Anthropometrics (mean  $\pm$  SD), at baseline, after training, and after two years following cardiac rehabilitation (CR)**

	Baseline	End of CR	2 year follow-up
Weight (kg) ( $n=24$ )	81.2 $\pm$ 2.6	81.3 $\pm$ 2.5	82.1 $\pm$ 2.2
Waist Circumference (cm) ( $n=13$ )	100.3 $\pm$ 3.6	99.5 $\pm$ 3.3	102.5 $\pm$ 3.3

The data concerning participants body weight met the assumption of normality ( $p = >0.05$ ) and sphericity  $p = 0.16$  ( $p = >0.05$ ) (Appendix 10), therefore, a One-way Repeated Measures ANOVA was performed (Table 10).

**Table 10. One-Way Repeated Measures ANOVA examining for differences in participants' bodyweight: at baseline, the end of CR and two year follow-up**

Trial	<i>F-ratio</i>	Sig.
Sphericity Assumed	.84	.44

The results revealed no significant difference in body weight (Table 10) when measured at baseline, discharge and two year follow-up assessments ( $p=0.44$ ). Therefore the null hypothesis ( $H_0$ ) cannot be rejected. The mean body weight at



baseline assessment was 81.2 ( $\pm$  2.6) kg, 81.3 ( $\pm$  2.5) kg at the end of CR, and 82.1 ( $\pm$  2.2) kg at the two year follow-up, respectively.

### 3.4 Total blood cholesterol

Participants with missing total cholesterol data for one or more assessment were omitted from the analysis,  $n = 19$  for the analysis of this data. The total cholesterol data (measured in mmol/l) was recorded at baseline, the end of CR and two year follow-up assessments. Because of the ratio level data and repeated measures study design a One-Way Repeated Measures ANOVA was performed because it met the assumptions of normality ( $p=>0.05$ ) (Appendix 10). The data however failed the assumption of sphericity ( $p=<0.05$ ) and therefore the 'Greenhouse-Geisser' statistic was used in the rest of the analysis (Appendix 10).

**Table 11. Blood Lipid Values (mean  $\pm$  SD) at baseline, after training and at the two year follow-up**

	<b>Baseline</b>	<b>End of CR</b>	<b>2 year follow-up</b>
Total Cholesterol (mmol/l), $n=19$	4.4 $\pm$ 0.2	4.0 $\pm$ 0.2	4.1 $\pm$ 0.2

**Table 12. One-Way repeated measures ANOVA test to analyse for differences in total blood cholesterol measures (at baseline, end of CR and two year follow-up)**

<b>Trial</b>	<b><i>F-ratio</i></b>	<b>Sig.</b>
Greenhouse-Geisser	.75	.42

Observation of the results (Table 12) revealed no significant difference between total cholesterol level at baseline, the end of CR or at the two year follow-up,  $p = 0.42$  ( $p > 0.05$ ). Therefore the null hypothesis ( $H_0$ ) cannot be rejected. The mean total cholesterol was  $4.4 (\pm 0.2)$  mmol/l at baseline,  $4.0 (\pm 0.2)$  mmol/l at the end of CR and  $4.1 (\pm 0.2)$  mmol/l at the two year follow-up, respectively.

### 3.5 Rate Pressure Product (RPP)

**Table 13. One-way (Repeated Measures) ANOVA to test for differences in Rate Pressure Product between exercise assessments (at baseline, end of CR, and two year follow-up).**

<b>Trial</b>	<b><i>F-ratio</i></b>	<b>Sig.</b>
Sphericity Assumed	1.64	.21

Data concerning participants RPP ( $HR \times SBP$  at 75%  $HR_{max} / 100$ ) met the statistical assumptions in order to perform a one-way (repeated measures) ANOVA (Appendix 10) to investigate for differences in RPP between the three exercise assessments (at baseline, end of CR and two years following CR). Table 13 demonstrates that  $p=0.21$  ( $p>0.05$ ) which is not significant. Therefore the null hypothesis cannot be rejected. The mean RPP at 75%  $HR_{max}$  at each assessment point was: 160 ( $\pm 6$ ) at baseline, 168 ( $\pm 6$ ) at the end of CR, and 172 ( $\pm 7$ ) at the two year follow-up.

### 3.6 Health Related Quality of Life

#### 3.6.1 Assessment of Hospital Anxiety and Depression Scale (HADS) scores

HADS score was assessed at baseline, end of CR and at the two year follow-up using a repeated measures design. Participants with missing data for one or more assessment were omitted from the analysis, n = 20 for the analysis of this data.

The data failed the assumption of normality (Appendix 10) and the Friedman test was therefore performed to test for significant differences between the data at the three aforementioned time points.

**Table 14. Friedman Test to investigate for significant differences in HADS score at baseline, end of CR and two year follow-up**

<b>N</b>	<b>20</b>
<b>Chi<sup>2</sup></b>	21.73
<b><i>p</i></b>	.001

**Table 15. Post hoc analysis using Wilcoxon tests to examine for differences between HADS score for Anxiety subscales and Depression subscales between three time points (baseline, CR discharge and at the two year follow-up)**

	HAD Anxiety score @ end of CR – HAD Anxiety score @ baseline	HAD Anxiety score @ 2 year follow-up – HAD Anxiety score @ baseline	HAD Anxiety score @ 2 year follow up – HAD Anxiety score @ end of CR	HAD Depression score @ end of CR – Depression score @ baseline	Depression score @ 2 year F-up – Depression score @ baseline	Depression score @ 2 year F-up – Depression score @ end of CR
<b>Z</b>	-2.09	-2.01	-.34	-2.60	-1.50	-1.75
<b>p</b>	.036	.044	.731	.009	.135	.081

**Table 16. HADS scores for Anxiety and Depression subscales as Median (and IQR) scores at Baseline, the End of CR and after Two Years**

	Baseline	End of CR	2 year follow-up
HADS score-Anxiety	4 (6)	2 (7)	2.5 (6)
HADS score-Depression	2 (3)	1 (2)*	1 (4)

\* $P < 0.017$  vs. baseline assessment

The results (Table 14) demonstrate that a significance difference existed in HADS score,  $p=0.001$  ( $p < 0.05$ ) between measures taken at baseline, end of CR and at the

two year follow-up. Results of the post hoc analysis (Table 15) with Bonferonni adjustment ( $p = 0.05/3 = 0.017$ ) revealed the following for the anxiety subscale: there was no significant difference between baseline and the assessment at the end of CR ( $p=0.04$ ) or between baseline and the two year follow-up ( $p=0.04$ ). There was also no significant difference in anxiety scores between the end of CR and the two year follow-up ( $p=0.73$ ). With regards to the depression subscale, a significant difference, was observed between measures at baseline and the end of CR,  $p=0.009$  ( $p<0.017$ ). No significant difference was found between depression scores at baseline and at the two year follow-up ( $p=0.14$ ) or between scores at the end of CR or the two year follow-up ( $p=0.08$ ). Therefore the null hypothesis cannot be rejected. Descriptive statistics are presented as median values (and interquartile range, IQR) in Table 16 for the anxiety subscale: at baseline 4 (6), 2 (7) at the end of CR and 2.5 (6) two years after CR. Median scores for the HADS depression subscale were 2 (3) at baseline, 1 (2) at the end of CR, and 1 (4) two years after completion of CR.

### 3.6.2 Health related quality of life (HRQoL) assessed using the SF-12 questionnaire

**Table 17. Health Related Quality of Life at the Two Year Follow-up assessed using the SF-12 questionnaire**

<b>SF-12 Health questionnaire</b>	<b>Mean (<math>\pm</math>SD)</b>
Physical component summary score (PCS)	50.5 ( $\pm$ 1.6)
Mental component summary score (MCS)	53.6 ( $\pm$ 1.7)

The results of participants HRQoL, measured using the SF-12 (Table 17), reveal both physical and mental component summary scores were above average levels at the two year follow-up, since scores are calibrated so that 50 is the average score or norm (Ware, Kosinski & Keller, 1996).

### 3.7 Independent Physical Activity

**Table 18. Total Physical Activity levels (in MET-minutes per week) and Participant Levels of Physical Activity measured by the IPAQ Two Years after CR**

Total MET-mins/week (mean $\pm$ SD)	3101 (2159)
<u>Level of Physical Activity</u>	
Low, <i>n</i> (%)	3 (13)
Moderate, <i>n</i> (%)	14 (58)
High, <i>n</i> (%)	7 (29)

Participants total MET minutes per week are demonstrated in Table 18, the majority of the participants' (58%) participated in moderate intensity activities, either: three or more days of vigorous intensity activity lasting at least 20 minutes per day, five or more days of moderate intensity activity and/or walking of a minimum of 30 minutes daily, or a combination of walking, moderate or vigorous intensity activity on five or more days achieving at least 600 MET-minutes per week.



### 3.8 Investigation for relationships between variables

#### 3.8.1 Investigation of relationships between physical activity and aerobic fitness

**Table 19. Spearman's Correlation test to examine for a significant relationship between total MET-minutes per week and estimated METs at 75% HR<sub>max</sub> at the two year follow-up assessment**

Correlation Test Between	Spearman (r)	<i>p</i>
IPAQ score (Total MET-mins per week) & METs achieved (75% HR <sub>max</sub> )	.267	.21

The data concerning IPAQ scores and METs at 75% HR<sub>max</sub> at the two year follow-up failed the assumption of a normal distribution (see Appendix 10) therefore a non-parametric test was performed using Spearman's correlation. Table 19 demonstrates that no significant relationship was evident between participants' level of physical activity and their aerobic fitness  $p=0.21$  ( $p>0.05$ ). Therefore the null hypothesis cannot be rejected.

### 3.8.2 Investigation of relationships between waist circumference and total cholesterol

**Table 20. Pearson's Correlation to examine for a relationship between waist circumference (at the two year follow-up) and total cholesterol (at the two year follow-up)**

<b>Correlation Test Between</b>	<b>Pearson (r)</b>	<b><i>p</i></b>
Waist circumference @ 2 year F-up & Total blood cholesterol @ 2 year F-up	-.082	.712

The data concerning participants' waist circumference and total cholesterol at the two year follow-up met the assumption of normality (Appendix 10) and therefore a Pearson's correlation test was performed to test for a relationship. Analysis revealed (Table 20) that at the two year follow-up, there was no significant relationship between participants' waist circumference and the level of total cholesterol level,  $p=0.71$  ( $p>0.05$ ). Therefore the null hypothesis cannot be rejected.

## **4. Discussion**

Whilst the benefits that CR have on patients following MI and revascularisation has been well documented, there is less documented studies that have evaluated the longer term benefits of CR beyond the point of discharge from the formal programme. Observational and randomised controlled trials have demonstrated mixed findings; with regards to sustained improvements in aerobic fitness in the longer time. The impact that a twelve week hospital-based CR programme can have on patients' long-term aerobic fitness and cardiovascular health profile two years after completion of the programme, is an area which demands further investigation. The CR was typical of many programmes in England in that it was short, 12 weeks in the case of this study, where patients generally attended twice weekly exercise sessions, with the emphasis on cardiovascular conditioning. The CR also provided patients with both formal and informal education on their condition and how to manage it, along with dietary and lifestyle guidance and counselling.

### **4.1 Discussion of results**

During the CR programme patients demonstrated typical benefits in aerobic exercise capacity, with an overall 38.5% increase in work rate (or 21.9 watts improvement from baseline fitness levels) ( $p < 0.017$ ), with a 0.9 MET increase in estimated peak METs achieved between baseline and end of CR exercise tests ( $p < 0.017$ ). Although, overall the peak work rate was slightly reduced at the two year follow assessment, participants' still demonstrated both a significantly higher work rate (with a 35% improvement from baseline levels) and aerobic capacity compared to baseline levels. The salient finding was that the gains achieved in exercise capacity after completion of the CR programme were maintained two years following completion of the programme (Table 2), with watts and METs achieved at 75%

HR<sub>max</sub> at the end of CR, both similar at the two year follow-up ( $p > 0.05$ ).

Consequently the null hypothesis cannot be rejected. There was no significant difference between aerobic capacity at the end of the CR programme and aerobic capacity at the two year follow-up.

#### **4.2 Discussion in relation to previous studies**

The current study's finding that participants' aerobic fitness remained significantly above baseline (entry to the CR programme) after two years following CR is consistent with evidence from other studies including, Smith et al. (2004), who demonstrated that the 'hospital group' maintained improvements in exercise capacity at the one year follow-up in peak  $V_{O_2}$ , peak METs and peak work-rate above baseline levels. Dugmore et al. (1999) reported improvements in cardio-respiratory fitness, psychological and vocational status, which was maintained from one to five years following discharge from CR following 12 months without intervention. Additionally, Boesch et al. (2005) also demonstrated sustained improvements in sub-maximal exercise capacity following a one month residential CR programme. Both peak watts and exercise duration remained similar to the exercise test at end of CR, as well as demonstrating a significantly higher exercise capacity compared to baseline levels ( $p = <0.001$ ). Furthermore, consistent with the current study, Marchionni et al. (2003) also reported that improvements in exercise capacity as a result of CR were maintained up to 12 months following discharge in patients post MI. This was significantly different to those who did not participate in CR.

However, unlike the current study which demonstrated that participants maintained their level of aerobic fitness two years following completion of CR other studies have reported notable declines in exercise capacity following completion of the CR programme. Smith et al. (2004) and Stahle et al. (1999) observed considerable declines in exercise capacity to almost baseline levels, between the period from the end of the CR programme to follow-up at 12 months. Evidence has demonstrated that just 30 to 60% of those who complete an outpatient CR programme are still physically active between three to six months later (Holmback, Sawe & Fager, 1994; Moore et al., 1998). Possible reasons to explain this contrast compared to findings in the current study may lie in differences in the levels of habitual physical activity in study participants. The significant decline in exercise capacity in a study by Smith et al. (2004), reported that those who were in the 'hospital exercise' group demonstrated substantial declines in the levels of habitual independent physical activity compared to the 'home exercise group'. This resulted in those who had been in the 'hospital CR' group having a lower exercise capacity at the one-year follow-up.

In the current study, the majority of participants were performing more than approximately 3,000 total MET-minutes per week (Table 18) which is enough to produce substantial health benefits (Meusel, 2008). Independent physical activity prior to finishing CR was not measured, therefore comparisons of any change in habitual physical activity independent from CR was not possible. Furthermore, the majority of participants in the current study (58%) participated in moderate intensity activities, classified using the IPAQ. Given that participants in the current study maintained their aerobic fitness two years after completion of CR it is perhaps surprising that no significant relationship was observed between the volume of independent physical activity and aerobic capacity ( $p \geq 0.05$ ). Therefore the null

hypothesis could not be rejected. There is no significant relationship between the volume of physical activity (measured in MET-minutes per week) and aerobic fitness (estimated peak METs at two years). It must be noted that the IPAQ is a subjective tool used to assess physical activity levels so it is possible that some participants may have interpreted their physical activities at a higher intensity and/or on a more frequent basis than may have actually been the case. Following the end of CR, participants in the current study were advised and encouraged to maintain and improve on their future level independent physical activity/exercise levels through walking, cycling etc. In some cases, if available, participants were also offered the option of undertaking phase IV CR exercise at a local leisure centre if they so wished. In the current study it was apparent that a number of participants had independently continued to exercise at a gym based facility and/or at home following completion of CR, this is likely to have had a notable bearing on the results and is likely to have helped them to maintain their aerobic fitness at the two year follow-up. A possible mechanism for the maintenance in aerobic capacity at two years after completion of CR, was that an element of self-monitored hospital-based CR (i.e. patients monitoring their own heart rate and RPE and self-pacing during exercise) may have helped foster greater independence when it came to leaving the CR programme and exercising independently, without supervision. The CR programme at the hospital where the current study took place, tried to foster self-management of the exercise programme in the early stages of CR and perhaps it is this that helps stimulate a more permanent lifestyle change which has long-term benefits to participants' aerobic fitness. Further evaluation of this is warranted to understand what can best motivate patients to continue to maintain exercise/physical activity independently following a cardiac event.

Another reason for the maintenance in aerobic capacity after two years following completion of the CR programme in the current study is that it is possible that those participants who agreed to attend for the study (at the two year point) may have been more motivated to make and sustain positive health behaviours following their cardiac event, since volunteers are more likely to adhere to an exercise regime due to their expressed desire to participate (Daltroy, 1994). It could be speculated, that perhaps those who chose not to participate in the study were less physically active, had not maintained their previously more positive health behaviours and did not want to know what they might have been already aware of with regards to their health. A reason for individuals with a cardiac history not participating in the study, their level of aerobic fitness and volume of habitual physical activity, is an area which requires further examination in order for these individuals to also gain long-term improvements in aerobic fitness and cardiovascular health.

An important and encouraging finding in the current study was that participants demonstrated approximately a 0.9 MET improvement overall in aerobic capacity (Table 3) between testing at baseline (prior to starting CR exercise) and at the two year follow-up. A higher level of aerobic fitness even in the presence of other risk factors such as hypertension, diabetes and smoking, provides a protective role to the individual, since every one MET increase in performance is associated with a 12 percent improvement in survival (Myers et al., 2002).

### 4.3 Secondary measures relating to Cardiovascular Health Profile

The study demonstrates that a number of benefits of CR are sustained at two years, although this is to an extent attenuated compared with the level of improvement attained at the end of CR (completion of the CR programme). When compared with levels at the start of CR; total blood cholesterol and HADS score (both anxiety and depression subscales) demonstrated improvements at two years.

The current study found that there was no significant difference in body anthropometrics (body weight and abdominal waist circumference) between the three time points: baseline, end of CR and at two years ( $p>0.05$ ). Therefore the null hypotheses cannot be rejected. There is no significant difference between waist circumference at the end of CR and at the two year follow-up, and there is no significant difference between body weight at the end of CR and body weight at the two year follow-up. Following completion of the CR programme there was a minimal non-significant reduction in waist circumference by approximately 0.8cm at the end of CR. However, after two years after completion of CR abdominal waist circumference increased by approximately 3 centimetres since the end of CR, this was not statistically significant ( $p>0.05$ , Table 10). Changes in waist circumference relate closely to intra-abdominal fat mass (Pouliot et al., 1994) and changes in waist circumference reflect changes in cardiovascular risk factors (Wing & Jefferey, 1995). Waist circumference cut-off's have been proposed by Lean et al. (1995) as  $\geq 102$ cm in men,  $\geq 88$ cm in women. These cut-offs have been endorsed by consensus conferences on obesity and the metabolic syndrome (National Institutes of Health, 1998; Expert panel on detection, evaluation, and treatment of high blood cholesterol in adults [Adult Treatment Panel III], 2001). Clinically the mean 3cm increase in



waist circumference observed in participants between the end of CR to two years was significant, waist circumference rose from 99.5 to 102.5cm at the two year follow-up. In the current study at the two year follow-up participant's had an increased risk of developing more cardiovascular risk factors and/or further progression of already established risk factors (such as elevated total cholesterol, insulin resistance syndrome and insulin dependent diabetes mellitus).

The study participants' body weight increased from the end of CR to the two year follow-up by 0.8 kilograms, again this was not statistically significant. Both waist circumference and body weight values were found to be higher at the two year follow-up than they were at baseline levels. The findings from the current study were consistent with previous findings, Willich et al. (2001) suggests that body weight and serum lipid (cholesterol) levels increase as early as six months after CR has finished, Gupta et al. (2007) also reported small but statistically non-significant increases in body weight (measured by body mass index) at one year follow-up compared to baseline. Following completion of CR it is possible that without the weekly face-to-face contact provided by the multi-disciplinary CR team during the programme, participants were slightly less strict in terms of eating the same portion sizes and exercising to the same extent. This may have had some impact on the participants' follow-up body weight and also waist circumference two years following CR completion.

Total cholesterol was recorded at three time points: baseline, at the end of CR and at two years following CR. The results (Table 11) demonstrated no significant difference between cholesterol levels either time point, with a small but non-significant increase in total cholesterol from 4.0 ( $\pm$  0.2) mmol/l at the end of CR to 4.1 ( $\pm$  0.2) mmol/l two years following CR completion. Therefore the null hypothesis

cannot be rejected. There is no significant difference in total cholesterol at the end of the CR programme and total cholesterol at the two year follow-up. Encouragingly, in the current study, the participants' total cholesterol levels collectively, remained slightly below baseline levels, with a 0.3 mmol/l mean reduction in total cholesterol. This overall reduction could have a considerable positive impact on CHD related mortality since it has been reported that a 0.4 mmol/l decrease in total cholesterol can reduce CHD deaths by approximately 25% (Prospective Studies Collaboration, 2008). Gupta et al. (2007) reported that total cholesterol levels were largely maintained at follow-up (one year following CR completion) with no significant change observed, although, consistent with the current study, a slight increase was seen. However, unlike the present study, at the follow-up, total cholesterol levels were significantly lower than baseline levels. In contrast, Boesch et al. (2005) observed a significant increase in total cholesterol at the two year follow-up compared to levels at the end of CR, this was likely due to the careful control of diet and lifestyle whilst the participants resided at the CR centre, which perhaps was not sustainable long-term. However, participation in CR has generally resulted in small but statistically significant improvements in blood lipids (Lavie & Milani, 2000).

It is recommended that in individuals diagnosed with CHD, total cholesterol should fall below 4 mmol/l (NICE, 2008). In the current study the mean total cholesterol was 4.1 ( $\pm$ 0.2) mmol/l, inadequate cholesterol control was observed in 54.2% of the study's participants who were noted to have a total cholesterol of greater than 4 mmol/l at the two year follow-up. This is consistent with other studies that have observed that approximately 50% of patients with coronary artery disease were not appropriately controlled for elevated plasma cholesterol (EUROSPIRE study group, 1997). It is plausible that reasons for the differences in total cholesterol between the

current study's participants were due to differences in pharmacological treatment and/or the adherence of the participant to their medication regime. One of the aims of CR is to reduce the risk of short and long-term mortality from coronary artery disease and therefore appropriate long-term management of individuals' weight and abdominal waist circumference is of great importance, by both the individual themselves and appropriate health professionals (e.g. general practitioner, CHD nurse etc). This is an area of secondary prevention which requires further attention in order to reduce potential risk of future hospital readmissions and earlier CHD related mortality and morbidity.

There was no significant difference in participants' RPP (a clinical measure of myocardial oxygen demand) at any time point (baseline to two year follow-up). There was no significant difference between the participants RPP at the end of CR and RPP at the two year follow-up and therefore the null hypothesis (5) could not be rejected. A small, non-significant rise in RPP was observed at the two year follow-up compared to at the end of CR despite the lower mean systolic blood pressure at the two year follow-up. This increase in RPP was due to higher overall mean heart rates achieved by the participants at 75%  $HR_{max}$  at the two year follow-up test which was on average within 1bpm higher at the two year follow-up compared to the exercise test at the end of CR (mean  $106 \pm 10.1$  bpm at the end of CR vs.  $107 \pm 10.7$  bpm at two years). This suggests that participants in the current study on tended to work at a harder level on average overall, which was reflected in an increase in myocardial oxygen consumption through a higher RPP at the two year follow-up. Typically, after regular aerobic training patients experience a reduction in RPP which is largely due to reduction in sub-maximal heart rate and blood pressure. This leads to reduction in myocardial oxygen consumption at sub-maximal

workloads because of a lower myocardial oxygen demand at sub-maximal workloads (Thompson, 2005).

HADS scores were measured at baseline, the end of CR and at the two year follow-up. The important finding with regards to quality of life measures through use of HADS was that at the two year follow-up, both the anxiety subscale (HADS-A) and depression subscale (HADS-D) were reduced from baseline levels (Table 16). This may suggest that the CR programme positively influenced participants' overall quality of life through reductions in overall anxiety and depression levels. A statistically significant reduction was observed between the HAD-D at the end of CR compared to baseline ( $p < 0.017$ ), and this lower depression score was maintained at the two year follow-up (Table 16). No significant difference was observed between participants' anxiety specific and depression specific scores between the end of CR and the two year follow-up ( $p > 0.017$ ). Therefore, the null hypothesis could not be rejected. There was no significant difference between HADS scores at the end of the CR programme and the HADS score at the two year follow-up. HADS scores (for anxiety subscales and depression subscales) of 0-7 are clinically within the 'normal' range, with scores of 8-10 indicating 'mild' cases, scores of 11-15 'moderate cases' and greater than 16 'severe cases' (Snaith & Zigmond, 1994). Interestingly, in the current study the median scores from baseline through to two year follow-up were all clinically non-significant with scores for both anxiety and depression subscales remaining on average, within the clinically 'normal' range.

Although not the main focus of the study, whether the overall 'normal' HADS score is typical of the wider CR population requires further investigation. Although the mean HADS-A and HADS-D scores were not presented in the results due to the non-

normal distribution of statistical data, the mean scores perhaps offer a better clinical clarification of the overall change in HADS scores at each time point. HADS-A was 5.4 ( $\pm 4.4$ ) at baseline, 4.1 ( $\pm 4.4$ ) at the end of CR, and 3.7 ( $\pm 3.3$ ) at the two year follow-up. HADS-D: 3.3 ( $\pm 4.0$ ) at baseline, 1.7 ( $\pm 2.8$ ) at the end of CR, and 2.4 ( $\pm 2.7$ ) at the two year follow-up.

#### **4.4 Limitations of the study**

This study was limited by the absence of a control group. It is possible that those participants who attended the CR programme and agreed to return for this research study were particularly motivated to make health and lifestyle changes such following their respective cardiac event. Reason's for participant's not responding to mailings during the follow-up period and subsequently not returning for the two year follow-up was not available. This could have potentially biased the results, furthermore, it is likely that patients who returned for follow-up differ in a number of characteristics compared to those who chose not to; further research is required to ascertain if this is the case. It is also possible that the cardiac event itself may have influenced health-related behaviours without participating in a CR programme. Of note, 62.5% of the study's participants were retired, and therefore, may have had more time available to engage in leisure and recreational activities following their cardiac event. Finally, the generalisability and interpretation of the current study's findings require some caution due to the small sample size used. Furthermore, the study sample consisted exclusively of Caucasian individuals, the majority of which were male (79%). This represents a national trend of CR programmes in the UK, whereby women are typically less likely to be referred or join a CR programme (Rees et al., 2005; British Heart Foundation, 2009b).

## **4.5 Conclusion**

After two years following a cardiac event and participation in a structured twelve week CR programme that included exercise and health education, patients maintained their aerobic fitness and improved aspects of their cardiovascular health profile. These findings suggest that CR can act as a catalyst to help motivate, guide and support individuals following a cardiac event to adopt and maintain positive health behaviours, maintain their aerobic fitness and reduce their long-term cardiovascular risk. This is still evident two years after completion of CR. Further secondary prevention research is needed to guide interventions for long-term health benefits that will address not only the needs of Caucasian males, but females and other individuals from different ethnic backgrounds in order to improve patients' long-term well-being.

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2. Cardiac Rehabilitation Coordinator at Good Hope Hospital

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**APPENDIX 1: TABLE TO SUMMARISE COMPARABLE STUDIES EXAMINING EXERCISE CAPACITY & TYPICAL FOLLOW-UP PERIOD**

<b>Author</b>	<b>Study Design</b>	<b>Sample</b>	<b>Methods</b>	<b>Measures used</b>	<b>Main findings</b>	<b>Typical follow-up</b>
Boesch et al.(2005)	Repeated Measures	78 CR patients (post MI, CABG, PCI)	<ul style="list-style-type: none"> <li>• 1 month residential programme</li> <li>• 5x 30 mins per week indoor cycling sessions</li> <li>• 2 daily 45 mins walk,</li> <li>• subjects divided into 3 training groups</li> </ul>	<ul style="list-style-type: none"> <li>• Maximal exercise test at baseline, post rehab, at 2 years</li> <li>• Physical Activity Questionnaire</li> <li>• Blood Lipid testing</li> </ul>	<ul style="list-style-type: none"> <li>• At 2 years exercise capacity was maintained</li> <li>• At 2 years, peak workload (watts) remained significantly higher compared to baseline.</li> </ul>	Two years
Smith, Arthur, McKelvie & Kodis (2004)	Repeated Measures	222 CABG patients	<ul style="list-style-type: none"> <li>• Six months hospital vs. monitored home-based CR</li> <li>• Patients advised to exercise 5 x per week after CR discharge</li> </ul>	<ul style="list-style-type: none"> <li>• Maximal exercise test at baseline and 12 months</li> <li>• Habitual physical activity</li> <li>• HRQoL (SF-36)</li> <li>• Anthropometrics</li> <li>• Social support</li> </ul>	<ul style="list-style-type: none"> <li>• At follow-up peak VO<sub>2</sub> declined in hospital group</li> <li>• Home group maintained peak VO<sub>2</sub></li> <li>• Both groups maintained higher peak VO<sub>2</sub> vs. baseline</li> </ul>	One year

Stalhe et al. (1999)	Repeated Measures	101 patients post acute coronary event aged $\geq 65$ yrs	<ul style="list-style-type: none"> <li>• Randomised into 2 groups: Intervention (I) &amp; control (C)</li> <li>• (I) 50 min aerobic outpatient exercise programme , 3 x p/w for 3 months</li> <li>• (C) resume usual physical activity when able</li> </ul>	<ul style="list-style-type: none"> <li>• Maximal exercise capacity at baseline, 3 &amp; 12 months</li> <li>• HRQoL</li> <li>• Self-graded level of physical activity &amp; well-being</li> </ul>	<ul style="list-style-type: none"> <li>• (I) Increased Exs. Capacity at 3 months but this declined to near baseline at one year</li> <li>• Exs. Capacity significantly higher than baseline at 1 year follow-up</li> </ul>	<ul style="list-style-type: none"> <li>• One year</li> </ul>
Arrigo et al. (2008)	Repeated Measures	261 patients enrolled following 4-week inpatient or 12 week outpatient CR programme	<ul style="list-style-type: none"> <li>• Two groups (intervention-INT and control- UC)</li> <li>• Physician supervised 3 monthly exercise sessions &amp; keep a physical activity diary</li> <li>• UC-no instruction, only return at 1 year.</li> </ul>	<ul style="list-style-type: none"> <li>• Exercise test at baseline and 1 year</li> <li>• Physical activity</li> <li>• Risk factors</li> <li>• HRQoL</li> </ul>	<ul style="list-style-type: none"> <li>• Significant improvement in exercise capacity at follow-up in both groups</li> <li>• More patients in INT group adhered to regular physical activity</li> </ul>	<ul style="list-style-type: none"> <li>• One year</li> </ul>
Marchionni et al. (2003)	Repeated Measures	270 patients post MI	<ul style="list-style-type: none"> <li>• Randomised into 3 groups: hospital CR, home CR or no CR</li> <li>• Divided into 3 aged groups 45-65, 66-75, &gt;75 years. 2 month period.</li> </ul>	<ul style="list-style-type: none"> <li>• Total work capacity (TWC) in watts at baseline, 6 months and 12 months</li> </ul>	<ul style="list-style-type: none"> <li>• Improvement in TWC in each age group with Hosp-CR and Home-CR, unchanged with no CR.</li> <li>• TWC declined to almost baseline by 12 months in Hosp-CR but not Home-CR</li> </ul>	<ul style="list-style-type: none"> <li>• One year</li> </ul>



## Appendix 2

Version 1. 01/03/2011

Dear Sir/Madam

**Re: Title of Project: Aerobic Fitness and Cardiovascular Health Profile Two Years after Completion of Cardiac Rehabilitation, REC Ref: 11/WM/0072**

**Principal Researcher: Steve Padmore, Exercise Physiologist in Cardiac Rehabilitation (Good Hope Hospital – Heart of England NHS Trust)**

I would like to ask for your assistance with a research study that I am conducting as part of my Master of Science (MSc) degree in Cardiovascular Rehabilitation. The study aims to investigate whether a cardiac rehabilitation programme can be effective in maintaining aerobic fitness. Please read the information sheet enclosed for more details.

Please read the enclosed information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you of any kind and I thank you for considering our request.

Once you have read the information sheet if you are interested in taking part in the research or finding out more about it, I would be grateful **if you would contact me, Steve Padmore on the number below within fourteen days of receiving this letter.**

Cardiac Rehabilitation Department (Good Hope Hospital): - Tel: **0121 424 7465**

Yours Sincerely

**Steve Padmore – Exercise Physiologist-Cardiac Rehabilitation**

**Student Researcher**



**National Research Ethics Service  
Birmingham, East, North and Solihull Research Ethics Committee**

REC Offices  
Prospect House  
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B97 6EW

Telephone: 01527 582534  
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Dear Mr Padmore

**Study title:** Aerobic Fitness and Cardiovascular Health Profile Two  
years after completion of Cardiac Rehabilitation  
**REC reference:** 11/WM/0072

Thank you for your letter of 10 April 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Ethical review of research sites**

**NHS sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Non-NHS sites**

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Protocol	1	01 March 2011
Response to Request for Further Information		10 April 2011
Letter of invitation to participant	1	01 March 2011
GP/Consultant Information Sheets	1	21 February 2011
GP/Consultant Information Sheets	1	10 April 2011
REC application	1	01 March 2011
Supervisor CV		01 March 2011
protocol for exercise cycle assessment	1	01 March 2011
Participant Debriefing Sheet	2	10 April 2011
Participant Information Sheet	2	10 April 2011
Questionnaire: Validated questionnaire		
Evidence of insurance or indemnity		01 March 2011
Letter from Statistician		01 March 2011
Investigator CV		01 March 2011
Participant Consent Form	2	10 April 2011
Summary/Synopsis	1	01 March 2011
Letter from Sponsor		01 March 2011
Student CV		01 March 2011
Per-exercise assessment Health screening form	1	01 March 2011

This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Rating of perceived exertion scale (validated tool)		01 March 2011
Letter of support to the line manager (Cardiac rehab coordinator)		01 March 2011

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

**11/WM/0072**

**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



RP

**Dr Rex J Polson**  
Chair

Email: [karen.green@westmidlands.nhs.uk](mailto:karen.green@westmidlands.nhs.uk)

**Enclosures:** "After ethical review – guidance for researchers"

**Copy to:** Professor Sarah Andrew  
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This Research Ethics Committee is an advisory committee to West Midlands Strategic Health Authority  
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England



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**Research & Development Directorate**



*Medical Innovation Development Research Unit*  
*Office Hours (Mon-Fri): 09.00 – 17.00*  
*Tel: 0121 424 1633*  
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Head of Research & Innovation: Bethan Bishop  
R&D Manager - Governance & Operations: Elizabeth Adey  
R&D Manager - Finance & Facilities: Rachel Ward  
Please send e-mails via [firstname.surname@heartofengland.nhs.uk](mailto:firstname.surname@heartofengland.nhs.uk)

**Re: Aerobic Fitness and Cardiovascular Health Profile Two years after Completion of Cardiac Rehabilitation**

I am writing to confirm that our department has received details of the above project and it has been entered onto the Trust Research and Development database. The R&D project code is 2010177CD. Please use this reference in any correspondence relating to this project.

The project review process will now be initiated and we will be in touch with you shortly to raise any outstanding queries and/or inform you that the project has been formally approved. The Trust R&D Directorate aims to issue approval within 56 days of receipt of a fully signed and completed "Site Specific Information" form. To help us achieve this target we ask that any requests for further information either from R&D or support services are dealt with in a timely manner in order to prevent delays in study start up.

Review of this project is based on the understanding that you have understood and are fully compliant with the NHS SSI Declaration by Principal Investigator.

May I remind you that the project must not commence until formal R&D approval has been given on behalf of the Trust, regardless of whether you receive ethical approval (if applicable) in the meantime.

Please note that R&D approval will not be granted until a copy of the ethics approval letter has been received by us. You must ensure this is faxed/sent to us as soon as approval is granted to ensure that delays are not incurred.

If you have any queries prior to receiving project approval, do not hesitate to contact us.



Yours sincerely

*J. Delarue*

Mrs June Delarue  
R&D Coordinator

Version 4.0 October 2010

**CONSENT FORM FOR PARTICIPANTS**

Title of Project: Aerobic Fitness and Cardiovascular Health Profile Two Years after Completion of Cardiac Rehabilitation

**Please tick each box to confirm you agreement**

- I confirm I have read and understood the Participant Information Sheet concerning the above study.
- I have had the opportunity to consider the information and ask questions all of which have been answered to my satisfaction. I understand that I am free to request further information at any stage.
- I consent to the researcher informing my GP of my participation in this study.
- My participation in the study is entirely voluntary and I am free to withdraw from the study at any time, up until the project is submitted, without any reason and without my medical care or legal rights being affected.
- The information I provide and all data collected from the study, in accordance with the Data protection Act 1998, will be treated as confidential and anonymous.
- I agree that Steve Padmore can access my medical information for consultant letters, previous blood results, results concerning my cardiac investigations (e.g. echocardiogram results), and demographic information (your GP address, home address and date of birth). All this information will be used to confirm your identity for the purpose of the study and to ensure appropriate action can be taken if anything demands further medical assistance or investigation.
- I agree to undertake an exercise assessment as part of study which will involve (1) a full health screen covering my cardiac and medical history, medication, joint/muscular problems and current physical activity/exercise. (2) I agree to participate in an exercise test on a stationary exercise bike while having my heart rhythm, blood pressure, and Rating of Perceived Exertion monitored by the researcher, Steve Padmore.
- Parts of the data collected during the study may be examined by the research supervisors of Steve Padmore or regulatory authorities and I give permission for this.
- In keeping with University of Chester policy any data or results on which the project depend will be retained in secure storage for ten years, after which it will be destroyed; the results of the study for this MSc Dissertation may be published on the ChesterRep, which is the University of Chester's online repository but my anonymity will be preserved. I agree to this.
- I understand that I will receive a written summary of the findings of the study.

I therefore give my consent to take part in this research study. Please sign and date:

Participant Name	Date	Signature
Name of researcher taking consent	Date	Signature

**PARTICIPANT INFORMATION SHEET**

Title of Project: **Aerobic Fitness and Cardiovascular Health Profile Two Years after Completion of Cardiac Rehabilitation**

Principal Researcher: Steve Padmore, Exercise Physiologist in Cardiac Rehabilitation

I would like to ask for your assistance with a research study that I am conducting as part of my Master of Science (MSc) degree in Cardiovascular Rehabilitation. The study aims to investigate whether a cardiac rehabilitation programme can be effective in maintaining aerobic fitness. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you of any kind and I thank you for considering our request.

**Why have I been invited to take part?**

Because you have previously completed the Cardiac Rehabilitation programme.

**How many others will be in the study?**

You will be among at least 25 other people who will also participate in the study.

**What is the purpose of the study?**

The purpose of the study is in part educational and in part service evaluation: the project will be submitted as part of an MSc in Cardiovascular Rehabilitation at the University of Chester. The main purpose of the study is to determine if a standard cardiac rehabilitation programme (lasting three months) can be effective in maintaining aerobic fitness two years after completion of the programme. Though this is standard it is a relatively short period. The secondary aims of the study are (1) to examine changes in the participants' cardiovascular health profile two years after completing cardiac rehabilitation (blood cholesterol, resting blood pressure, smoking status, body weight, waist circumference) (2) The study will also investigate changes in Hospital Anxiety and Depression scores, examine current physical activity levels, quality of life status and the number of



hospital re-admissions (cardiac and non-cardiac related causes) since finishing the rehabilitation programme.

### **Do I have to take part?**

Your involvement in this study is voluntary. Your decision will not affect your medical care or disadvantage you in any way.

### **What will I be asked to do?**

Should you agree to take part in this study, you will be asked to complete three short questionnaires. These questionnaires assess your current physical activity levels, mood and your quality of life. You will also be invited to the hospital's cardiac rehabilitation department to perform an exercise assessment which consists of a full health screen and a static bike ride which will last about six to eight minutes while having your blood pressure, heart rate/rhythm and your Rating of Perceived Exertion assessed. This is exactly the same test you performed previously approximately two years ago. The appointment for the exercise assessment will last approximately 60 minutes in total. Should anything untoward be noted on the heart monitor (i.e. ECG machine) during the assessment you will be advised to be referred via your GP back to a consultant cardiologist for a clinical review.

### **What are the benefits of taking part?**

Participating in this study may help evaluate your cardiovascular health, how fit you are and what type of physical activity/exercise is suitable for you. Your participation in this study may help to identify aspects of cardiac rehabilitation which require greater focus or change, helping to improve the benefits of rehabilitation for future patients.

### **What are the risks of taking part?**

The risks are no different to what you previously experienced when attending the cardiac rehabilitation programme. We will carry out another health-screen to identify any changes since we last saw you. The researcher is an experienced Exercise Physiologist within the Cardiac Rehabilitation Team at Good Hope Hospital who has training and competence in exercise testing. Although a sub-

maximal exercise assessment may be considered a safe procedure, risks and complications may occasionally arise during the test. These include abnormal blood pressure, fainting, irregular, fast or slow heart rhythms and rarely, heart attack, stroke or death, however, you will be continually monitored throughout to minimise any potential problems to yourself.

**Will Medical Staff know I am involved in the study?**

Yes. Both a Dr Richard Watkin (Consultant Cardiologist) and Harry Dranginis (Cardiac Rehabilitation Nurse Co-ordinator) based at Good Hope Hospital are aware of the study and your eligibility to take part.

**Can Participants Change their Mind and Withdraw from the Project?**

Yes. You may withdraw from the study at any time up until the point where the research project has been submitted, without giving a reason and without it affecting your medical care. This can be done through contacting me or Dr John Buckley.

**Will my participation in the study and data be kept confidential?**

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence in accordance with the Data protection Act 1998. For the purpose of the research your medical information will be accessed by only me (the researcher). All information collected about you during the course of the research will be kept strictly confidential and anonymous.

**Who is organising/funding the research?**

The research is in partnership the University of Chester and with the permission of the Heart of England NHS Foundation Trust. This research is supported and supervised by Dr John Buckley, BASES Accredited Sports and Exercise Scientist, University of Chester.

**Who has reviewed the study?**

All research in the NHS is examined by an independent group of people called a Research Ethics Committee (REC) to ensure your safety, rights, dignity and wellbeing. The study has been approved

by the Birmingham East North & Solihull REC and the hospital Trust's Research and Development department.

### **What if I have any questions or concerns?**

If you have any questions or would like further information about any aspect of the study or regarding participating, please contact the researchers using the contact details below. If at any point you remain unhappy and wish to make a formal complaint, you can do so through the University of Chester complaints procedure, details of which can be obtained from the University. You should contact me, the principal researcher, in the first instance.

### **What do I do now?**

If you are interested in taking part in the research or finding out more about it, I would be grateful if **you would contact me, Steve Padmore on the number below within fourteen days of receiving this information sheet.** I will then send you some short questionnaires to complete and organise an appointment for the exercise assessment. If you have any further questions about the study please do not hesitate to contact me. Contacting me about the study does not mean you are obliged to take part.

### **Researcher contact details:**

#### **Principal Researcher:**

Steve Padmore

Exercise Physiologist

Cardiac Rehabilitation

Good Hope Hospital

Cardiac Rehabilitation Department Telephone Number: - [0121 424 7465]

**Academic Supervisor**

Dr John Buckley

University of Chester

Department of Clinical Sciences

Parkgate Road

Chester

CH1 4BJ

University Telephone Number: - [01244 511 692]

It may not be possible for us to take your call immediately but please give us details of how we may contact you and we will return your call as soon as possible.

**Patient Advice and Liaison Service (PALS):**

Office Address

Patient Advice & Liaison Service

Office Telephone Number: - [0121 255 0707]

**Pre-exercise assessment Health screening form****Participant number/code:****Participant age:****Date:**

Chest Pain (Including recent use of GTN spray)	
Breathlessness	
Palpitations	
Dizziness/Fainting/Blackouts	
Orthopnoea	
Ankle swelling	
Claudication	
Wound problems	
Musculoskeletal limitations/problems	

**Current medication:**

Name	Dose

**Current physical activity/exercise:****Is the participant a smoker (please circle): Yes / No****Ex-smoker (please circle): Yes/ No - If yes, how long have they not smoked?**

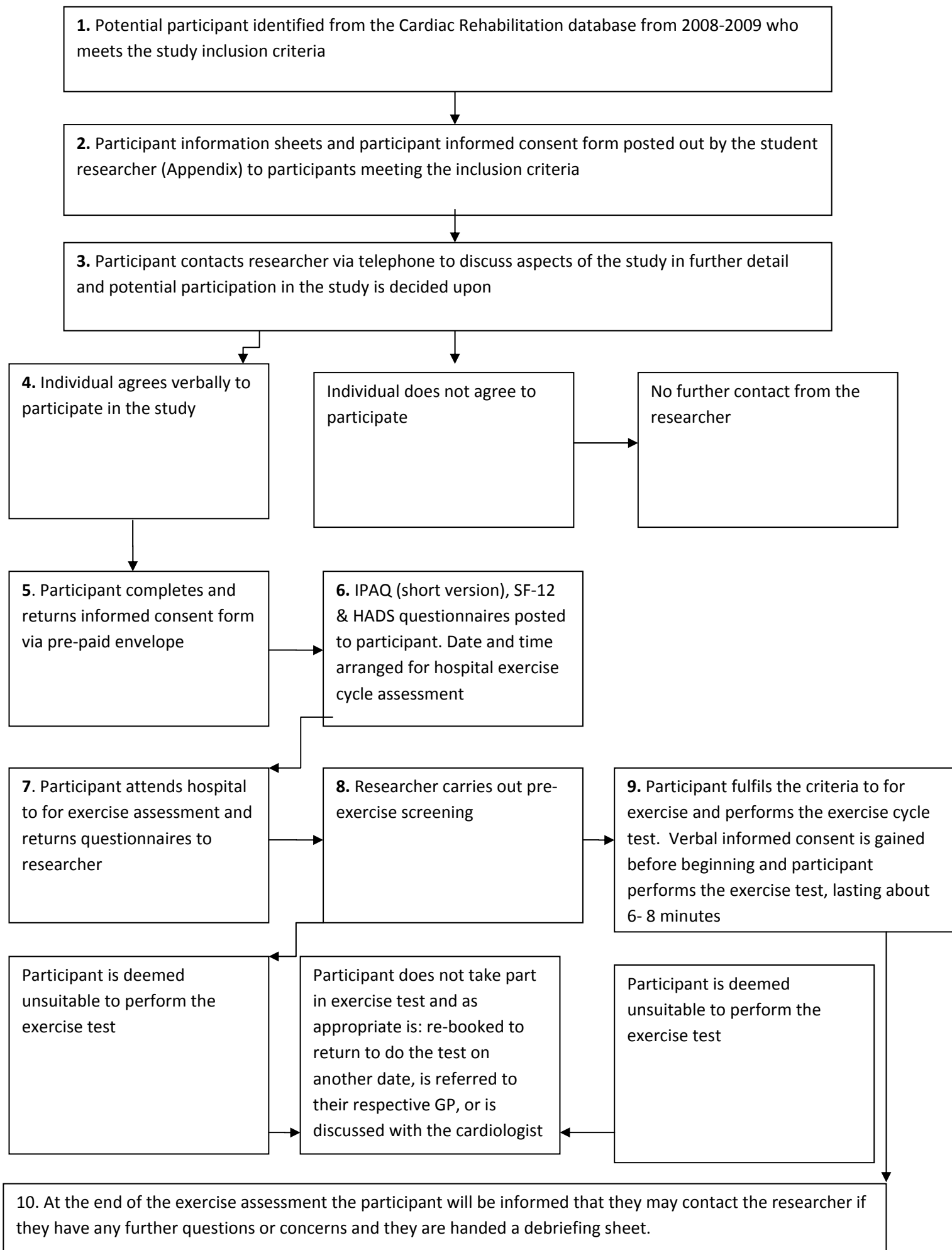
## Pre – Exercise Test Checklist

Medical consent gain	<input type="checkbox"/>
Participant gives informed consent	<input type="checkbox"/>
BP controlled (SBP <180) (DBP <100)	<input type="checkbox"/>
Client taken all prescribed medication	<input type="checkbox"/>
Client free from cold, sore throat or other temporary illness	<input type="checkbox"/>
Client no on antibiotics	<input type="checkbox"/>
No other hospital admissions in the past 4 weeks which indicate unstable cardiac status	<input type="checkbox"/>
No musculoskeletal problems that could be exacerbated by the exercise test	<input type="checkbox"/>
If the participant is diabetic, no hypoglycaemic episodes in the past seven days	<input type="checkbox"/>
No acute signs of heart failure	<input type="checkbox"/>
No excessive alcohol consumption in the past 24 hours	<input type="checkbox"/>
No caffeine consumption in the past two hours	<input type="checkbox"/>
No heavy meal in the past two hours	<input type="checkbox"/>
No strenuous physical activity 24 hours prior to the test	<input type="checkbox"/>
Client is wearing suitable clothing/footwear.	<input type="checkbox"/>

Access to telephone and cardiologist/Cardiology Doctor in emergency	<input type="checkbox"/>
Resuscitation equipment accessible and checked	<input type="checkbox"/>
Tester competent in basic/immediate life support	<input type="checkbox"/>

Appendix 7

## Flow Chart of Recruitment and Data Collection Procedure



21<sup>st</sup> February 2011

To whom it may concern,



NHS Foundation Trust

Good Hope Hospital  
Rectory Road  
Sutton Coldfield  
West Midlands  
B75 7RR

Tel: 0121 424 2000

I am aware that Stephen Padmore, Exercise Physiologist in Cardiac Rehabilitation, is to carry out a research project within the Cardiac Rehabilitation Department at Good Hope Hospital. I understand that this project will be subject to Research Ethics Committee (REC) and Research and Development (R&D) department approval from the Heart of England NHS Foundation Trust, prior to commencement.

I have seen and discussed the research proposal with Stephen Padmore and I am aware that this research dissertation will be undertaken as part of an MSc degree in Cardiovascular Rehabilitation with the University of Chester.

I agree with the proposed exercise assessment protocol, the contraindications to exercise testing, the pre-exercise assessment screening checklist and the stop-test criteria. I agree that the study participants are suitable to perform the exercise test provided they meet the criteria determined by the by pre-exercise checklist and the exercise assessment interview, failure of which may indicate an unstable cardiac status. The study participants should have no anginal symptoms, no shortness of breath on minimal exertion, no orthopnoea (difficulty breathing whilst laying flat), no ankle swelling, and no significant dizziness/fainting/blackouts and be on the prescribed cardiac medication.

I agree to offer cardiology assistance and support for the aforementioned student researcher with this research project.

Yours Sincerely

28/2/11

Dr Richard Watkin

Consultant Cardiologist – Heart of England NHS Foundation Trust (Good Hope Hospital)





NHS Foundation Trust

Good Hope Hospital  
Rectory Road  
Sutton Coldfield  
West Midlands  
B75 7RR

Tel: 0121 424 2000

21<sup>st</sup> February 2011

To whom it may concern,

I agree that Stephen Padmore can carry out a research project within the Cardiac Rehabilitation Department at Good Hope Hospital. I understand that this project will be subject to Research Ethics Committee (REC) and Research and Development (R&D) department approval from the Heart of England NHS Foundation Trust, prior to commencement. I am aware that this research dissertation will be undertaken as part of an MSc degree in Cardiovascular Rehabilitation with the University of Chester.

Yours Sincerely

**Harry Dranginis**

**Cardiac Rehabilitation Co-ordinator**

**PARTICIPANT DEBRIEFING SHEET**

Title of Project: **Aerobic Fitness and Cardiovascular Health Profile Two Years After Completion of Cardiac Rehabilitation**

Principal Researcher: Steve Padmore, Exercise Physiologist in Cardiac Rehabilitation

**Thank you for taking part in the above study. You may find the following information useful.**

**What is the purpose of the study?**

The purpose of the study is in part educational: the project will be submitted as part of a research project for a Master of Science degree in Cardiovascular Rehabilitation at the University of Chester. The main purpose of the study is to determine if a short-term cardiac rehabilitation programme (lasting three months) can be effective in maintaining aerobic fitness two years following completion of a hospital-based cardiac rehabilitation programme. The secondary aims of the study are (1) to examine changes in the participants' cardiovascular health profile two after completing cardiac rehabilitation (blood cholesterol, resting blood pressure, smoking status, body weight, waist circumference) (2) The study will also investigate changes in Hospital Anxiety and Depression scores examine current physical activity levels, quality of life status and the number of hospital re-admissions (cardiac and non-cardiac related causes) since finishing the rehabilitation programme.

**What if I wish to withdraw from the study?**

You may withdraw from the study at any time up until the point the research project has been submitted, without giving a reason and without it affecting your medical care. This can be done through contacting me or Dr John Buckley. In this instance any personal data collected as part of the study will be removed and destroyed.

**Will my participation in the study and data be kept confidential?**

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence in accordance with the Data protection Act 1998. For the purpose of the research your medical information will be accessed by only me (the researcher). All information collected about you during the course of the research will be kept strictly confidential and anonymous. Some aspects of this data may be accessed by authorised individuals from the University of Chester or representatives from regulatory authorities to check the study is being correctly carried out. These individuals all have a duty of confidentiality to you as a research participant. Your data will be stored in a confidential locked cabinet within the Cardiac Rehabilitation Department during the study; this will only be accessed by me. When the study is complete, all of your personal information will be destroyed immediately except any data on which the results of the project depend: this will remain anonymous and be retained in secure storage for ten years, as required by the University's research policy.

### **Who is organising/funding the research?**

The research is in partnership the University of Chester and with the permission of the Heart of England NHS Foundation Trust. This research is supported and supervised by Dr John Buckley, BASES Accredited Sports and Exercise Scientist, University of Chester.

### **What will happen to the results of the study?**

After participating in the study you will receive no further contact from the researcher with regards to the study. Although a summary of the findings will be sent to you: if you do not wish to receive this information please contact Steve Padmore. Your future medical care will not be affected

### **Contact Information**

If you have any questions or concerns regarding this study or you feel you need to speak to a professional concerning anything raised by the research, you may contact Steve Padmore, the principal researcher. If at any point you remain unhappy and wish to make a formal complaint, you can do so through the University of Chester complaints procedure, details of which can be obtained from the University. The Cardiac Rehabilitation Coordinator is aware the research is taking place but is separate to the research team and can be contacted if needed. Participation in the study is separate to the medical care you receive, for queries

regarding your medical care please see your GP or medical professional involved in your care.

**Contact details:**

**Principal Researcher:**

Steve Padmore

Exercise Physiologist

Cardiac Rehabilitation

Good Hope Hospital

Cardiac Rehabilitation Department Telephone Number: - [0121 424 7465]

**Academic Supervisor**

Dr John Buckley

University of Chester

Department of Clinical Sciences

Parkgate Road

Chester

CH1 4BJ

University Telephone Number: - [01244 511 692]

**For Further Support**

British Heart Foundation (BHF) Heart Support Groups - To find your nearest support group call the [HeartHelpLine](http://www.bhf.org.uk/heart-help-line) on **0300 330 3311** (local rate number) or email: [supporterservices@bhf.org.uk](mailto:supporterservices@bhf.org.uk).

A heart support group offers the chance for patients to share their experiences in a friendly and mutually supportive environment and provides a range of benefits and activities for their members.

**Patient Advice and Liaison Service (PALS):**

Office Address

**Appendix 10: PASW outputs for statistical analysis on study participants**

**Output to interpret normal distribution of aerobic capacity measured by watts achieved at 75% HR<sub>max</sub> at each assessment: CR baseline, End of CR and at two years after CR**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Peak Watts @ baseline	.115	22	.200*	.972	22	.754
Peak Watts @ discharge	.151	22	.200*	.949	22	.302
Peak Watts @ 2 years	.208	22	.014	.911	22	.050

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

**Assessment of sphericity for peak watts data**

**Mauchly's Test of Sphericity<sup>b</sup>**

Measure: MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Trial	.878	2.607	2	.272	.891	.968	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept  
Within Subjects Design: Trial

**Output to interpret normal distribution of the Aerobic Fitness (measured by METs achieved at 75% HR<sub>max</sub>) for the different assessment time points (CR baseline, End of CR and at two year post completion CR).**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
peak METs @ baseline	.113	22	.200 <sup>*</sup>	.960	22	.480
peak METs @ CR discharge	.100	22	.200 <sup>*</sup>	.968	22	.675
peak METs @ 2 year follow-up	.202	22	.020	.869	22	.007

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

**Test for normality of Rate Pressure Product (RPP) values at est.75% HR<sub>max</sub> baseline, discharge and two year follow-up.**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
rate pressure product (HR x SBP/100) @baseline	.107	22	.200 <sup>*</sup>	.945	22	.251
rate pressure product (HR x SBP/100)@CR discharge	.109	22	.200 <sup>*</sup>	.977	22	.867
rate pressure product (HR x SBP/100)@2 year F-up	.209	22	.013	.932	22	.138

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

### Test of Sphericity for RPP data

**Mauchly's Test of Sphericity<sup>b</sup>**

Measure:MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Tests	.972	.562	2	.755	.973	1.000	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept  
Within Subjects Design: Tests

**Waist Circumference – Test of normal distribution of data**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
waist circumference @ baseline (cm)	.194	13	.194	.916	13	.221
waist circumference @ CR discharge (cm)	.174	13	.200 <sup>*</sup>	.941	13	.470
waist circumference @ 2 year follow-up (cm)	.137	13	.200 <sup>*</sup>	.919	13	.245

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

**Test of sphericity for abdominal waist circumference data**

**Mauchly's Test of Sphericity<sup>b</sup>**

Measure:MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Trial	.923	.881	2	.644	.929	1.000	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept  
Within Subjects Design: Trial

**Test for normal distribution of body weight data**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
body weight @ baseline (kg)	.095	24	.200 <sup>*</sup>	.972	24	.705
body weight @ CR discharge (kg)	.080	24	.200 <sup>*</sup>	.975	24	.797
body weight @ 2 year follow-up (kg)	.075	24	.200 <sup>*</sup>	.991	24	.997

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

**Test of sphericity for body weight data**

**Mauchly's Test of Sphericity<sup>b</sup>**

Measure: MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
trial	.845	3.704	2	.157	.866	.930	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept  
Within Subjects Design: trial

**Test of normal distribution for total blood cholesterol data**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
total blood cholesterol (mmol/l)@baseline	.147	19	.200 <sup>*</sup>	.940	19	.268
total blood cholesterol (mmol/l)@discharge	.136	19	.200 <sup>*</sup>	.954	19	.457
total blood cholesterol (mmol/l)@ 2 years	.098	19	.200 <sup>*</sup>	.959	19	.552

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

**Test of sphericity for total cholesterol data**



**Mauchly's Test of Sphericity<sup>b</sup>**

Measure: MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Trial	.372	16.832	2	.000	.614	.636	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept  
Within Subjects Design: Trial

**Normal distribution interpretation for pre-exercise systolic blood pressure data (at baseline, CR discharge and two year follow-up).**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Pre exercise Systolic BP (mmHg)	.130	24	.200 <sup>*</sup>	.950	24	.271
Pre exercise Systolic BP (mmHg)	.164	24	.095	.959	24	.420
Pre exercise Systolic BP (mmHg)	.101	24	.200 <sup>*</sup>	.974	24	.774

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

**Output for Mauchly's test of Sphericity for SBP data**

**Mauchly's Test of Sphericity<sup>b</sup>**

Measure: MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Time	.838	3.900	2	.142	.860	.923	.500

## Results of One-way (repeated measures) ANOVA to test for differences in pre-exercise SBP

Tests of Within-Subjects Effects

Measure: MEASURE\_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Time	Sphericity Assumed	287.194	2	143.597	1.105	.340
	Greenhouse-Geisser	287.194	1.721	166.922	1.105	.333
	Huynh-Feldt	287.194	1.847	155.534	1.105	.336
	Lower-bound	287.194	1.000	287.194	1.105	.304
Error(Time)	Sphericity Assumed	5975.472	46	129.902		
	Greenhouse-Geisser	5975.472	39.572	151.002		
	Huynh-Feldt	5975.472	42.470	140.700		
	Lower-bound	5975.472	23.000	259.803		

## Test of normal distribution of data for participants' diastolic blood pressure (DBP) at three time points (baseline, end of CR and at two years)

Tests of Normality

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Pre exercise Diastolic BP (mmHg)	.146	24	.200*	.938	24	.146
Pre exercise Diastolic BP (mmHg)	.127	24	.200*	.947	24	.238
Pre exercise Diastolic BP (mmHg)	.083	24	.200*	.979	24	.883

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

## Results of test for sphericity of pre-exercise DBP data

**Mauchly's Test of Sphericity<sup>b</sup>**

Measure: MEASURE\_1

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon <sup>a</sup>		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Tests	.991	.192	2	.908	.991	1.000	.500

Tests the null hypothesis that the error covariance matrix of the orthonormalized transformed dependent variables is proportional to an identity matrix.

a. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

b. Design: Intercept  
Within Subjects Design: Tests

**Results of One-way (repeated measures) ANOVA to test for differences in pre-exercise DBP**

**Tests of Within-Subjects Effects**

Measure: MEASURE\_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Tests	Sphericity Assumed	171.361	2	85.681	2.352	.107
	Greenhouse-Geisser	171.361	1.983	86.425	2.352	.107
	Huynh-Feldt	171.361	2.000	85.681	2.352	.107
	Lower-bound	171.361	1.000	171.361	2.352	.139
Error(Tests)	Sphericity Assumed	1675.972	46	36.434		
	Greenhouse-Geisser	1675.972	45.604	36.751		
	Huynh-Feldt	1675.972	46.000	36.434		
	Lower-bound	1675.972	23.000	72.868		

**Interpretation of normality for Hospital Anxiety and Depression Scale (HADS) score questionnaire data at baseline, CR discharge and two year follow-up**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
HAD - Anxiety score @ baseline	.175	20	.110	.874	20	.014
HAD - Depression score @ baseline	.241	20	.003	.760	20	.000
HAD - Anxiety score @ CR discharge	.285	20	.000	.817	20	.002
HAD - Depression score @ discharge	.356	20	.000	.614	20	.000
HAD - Anxiety score @ 2 year F-up	.235	20	.005	.857	20	.007
HAD - Depression score @ 2 year F-up	.253	20	.002	.797	20	.001

a. Lilliefors Significance Correction

**Test for normality of data of Total physical activity MET-minutes per week and peak METs at the two year follow-up**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
peak METs @ 2 year follow-up	.190	24	.025	.885	24	.011
IPAQ score (Total MET-mins per week)	.222	24	.003	.867	24	.005

a. Lilliefors Significance Correction

**Test of normality for two year follow-up waist circumference and total cholesterol data**

**Tests of Normality**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
waist circumference @ 2 year follow-up (cm)	.098	23	.200*	.940	23	.179
total blood cholesterol (mmol/l)@ 2 years	.103	23	.200*	.968	23	.644

a. Lilliefors Significance Correction

\*. This is a lower bound of the true significance.

# Appendix 11 – Raw Data

Participant No.	Cardiac condition/diagnosis	Age (years)	peak METs	peak METs	peak METs	HR @ peak	HR @ peak	HR @ peak	RPE @ peak	RPE @ peak	RPE @ peak	peak watts1	peak watts2	peak watts3
1	STEMI & P.PCI	56	3.5	5.2	3.5	98bpm	114	112	13	12	12	40	84	40
2 F	elective PCI to LAD x 2	80	3	3.7	3.5	100	93	103	10 to 11	13	13	25	35	35
3	Ant MI & P.PCI	64	4.3	5.5	5.4	87	100	91	12 to 13	13.5	13	60	84	84
4	Ant MI & thrombolysis	64	n/a	5.5	4.8		133	123	n/a	11.5	15		84	72
5 F	TCABG	68	4.5	5.7	5.7	112	111	98bpm	12	11.5	13	45	72	72
6	NSTEMI	46	n/a	4.6	5		108	114	n/a	13	13		90	90
7	NSTEMI & PCI	70	4.8	5.2	5.6	85	99	88	11 to 12	12	14	78	90	102
8 F	Inferior MI & P.PCI	55	4.2	4.6	5	108	106	107	13	14	14	50	60	72
9	Elective PCI	67	4.5	5.1	5.2	86	97	95	13 to 14	12	13	72	90	96
11	QCABG	63	4.3	6.5	5.5	107	96	97	12	13	13	60	120	90
12	NSTEMI	56	3.3	4	4	100	108	122	13	13	13	40	55	55
13 F	NSTEMI	63	4	4.3	5	113	101	107	13	13	13.5	50	60	72
14	DCABG & (M) AVR	62	6	6.6	6.1	109	100	113	13	13	14	84	96	96
15	QCABG	70	4.6	5.6	6	103	110	114	13	12	14	60	84	90
16	PCI	81	3.8	4.2	3.7	101	95	106	13	14	14	50	60	50
17	Inferio-Lateral MI & VF arrest	64	4.5	5.6	5.5	109	112	107	11	13	12	75	100	102
18	Inferior MI & P.PCI	62	4.6	6	5.7	103	109	110	13	13	15	60	90	90
19	PCI	65	3.7	4.8	5.1	91	103	91	11	11	10	50	85	90
20	NSTEMI	65	4.1	4.6	4.8	98	98	102	13	12	15	65	78	84
21	DCABG	79	3.2	3.5	3.4	98	85	97	13	12	15	35	45	40
22	NSTEMI	62	4.5	5.7	5.5	114	109	120	14	14	13	60	90	90
23 F	Ant MI & P.PCI	73	3.4	3.7	3.7	122	112	119	14 to 15	11.5	15	25	35	35
24	A-L MI	54	4.9	4.9	5.2	110	115	106	12	12	13	65	75	84
25	NSTEMI & PCI	62	5	6.1	5.9	105	121	125	13	13	14	102	145	120

Participant No.	Cardiac condition/diagnosis	Age (years)	RPP1	RPP2	RPP3	pSBP1	pSBP2	pSBP3	SBP1	DBP1	SBP2	DBP2	SBP3	DBP3	RPP1	RPP2
1	STEMI & P.PCI	56	135	194	164	138	170	146	122	72	139	85	130	83	120	158
2 F	elective PCI to LAD x 2	80	110	134	175	110	144	170	125	74	144	88	131	77	125	134
3	Ant MI & P.PCI	64	113	130	122	130	130	134	104	65	104	59	106	65	120	104
4	Ant MI & thrombolysis	64		213	199		160	162	122	88	140	100	130	96		162
5 F	TCABG	68	157	162	127	140	146	130	105	70	126	68	97	62	118	140
6	NSTEMI	46		119	114	92	110	110	102	64	100	58	103	67		110
7	NSTEMI & PCI	70	156	196	167	184	198	190	153	74	147	68	146	80	130	146
8 F	Inferior MI & P.PCI	55	168	151	161	156	142	150	140	88	154	85	110	71	151	163
9	Elective PCI	67	146	182	165	170	188	174	137	74	112	60	138	78	118	109
11	QCABG	63	201	184	175	188	192	180	168	94	140	84	133	89	180	134
12	NSTEMI	56	134	156	181	134	144	154	105	64	96	56	123	73	105	104
13 F	NSTEMI	63	203	168	178	180	166	166	142	86	166	76	136	79	160	168
14	DCABG & (M) AVR	62	198	170	221	182	170	196	143	73	148	68	146	66	156	148
15	QCABG	70	159	200	225	154	182	184	150	81	159	84	156	89	155	175
16	PCI	81	186	144	159	184	152	150	142	64	122	60	149	85	143	97
17	Inferio-Lateral MI & VF arrest	64	164	199	167	150	178	156	99	67	121	76	114	75	108	136
18	Inferior MI & P.PCI	62	185	194	207	180	178	188	146	83	150	80	146	83	150	164
19	PCI	65	135	165	118	148	160	130	120	80	117	81	116	79	109	121
20	NSTEMI	65	155	157	163	158	160	160	130	64	160	60	116	70	127	157
21	DCABG	79	180	119	149	184	140	154	153	72	143	69	158	74	150	122
22	NSTEMI	62	162	164	180	142	150	150	110	60	109	65	115	68	125	119
23 F	Ant MI & P.PCI	73	173	161	179	142	144	150	133	76	133	73	122	79	162	149
24	A-L MI	54	110	136	136	100	118	128	96	61	115	77	120	75	106	132
25	NSTEMI & PCI	62	202	225	258	192	186	206	141	95	141	84	140	89	148	171

Participant No.	Cardiac condition/diagnosis	Age (years)	RPP3	Body Wt (kg)	Body Wt (kg)	Body Wt (kg)	Waist Circ.	Waist Circ.	Waist Circ.	TC (mmol/l)	TC (mmol/l)	TC (mmol/l)	smoker (Yes/no)	smoker	smoker
1	STEMI & P.PCI	56	146	80.2	84.4	82.2		99	96	3.5	3.5	4.6	no	no	no
2 F	elective PCI to LAD x 2	80	135	66	67.8	70.8		88	87	3.2	4.2	4.7	no	no	no
3	Ant MI & P.PCI	64	96	80.4	74.4	77	88	90	90	5.1		2.4	no	no	no
4	Ant MI & thrombolysis	64	172	77.2	77.2	78			89.5	4.7	4.1	3.5	stopped at MI	no	no
5 F	TCABG	68	95	57.4	59.2	61		85	85.5	5.2	4.7	4.9	ex stopped 2yrs ago	no	no
6	NSTEMI	46	117	106.6	104.6	104.2	116.9	117.5	114.3	5.7	1.8	1.6	ex stopped 2yrs ago	no	no
7	NSTEMI & PCI	70	128	87.8	86.8	87.8	97.5	100	102.7	4.2	4.8	4.8	ex stopped 40yrs ago	no	no
8 F	Inferior MI & P.PCI	55	118	71.2	68	73.6	88	87	92.3	5.7	5.4	5.6	ex stopped 15yrs	no	no
9	Elective PCI	67	131	93	92	93.2	103	106.4	107.4	5.3	5.2	5	ex stopped 40yrs ago	no	no
11	QCABG	63	129	80.8	82.2	82.8		93	98.6	3.5	3.9	4.4	no	no	no
12	NSTEMI	56	150	95	87.6	86	118	113.2	110.5	4	4.7	5.4	stopped at MI	no	yes (20/day)
13 F	NSTEMI	63	146	78.2	80.2	75.2		97	95	4.7	3.8	3.7	ex stopped 35 yrs	no	no
14	DCABG & (M) AVR	62	165	66	66.8	70.2	81	81	83.3	2.9		3	no	no	no
15	QCABG	70	178	70.6	70	70.2		86	85.8	3.6	3.2	3.3	no	no	no
16	PCI	81	158	85.4	85.2	89	105	110	113.8	4.1	4	4	no	no	no
17	Inferio-Lateral MI & VF arrest	64	122	92.8	88.4	93	110	100	115.3	4.1	4.7	4.1	ex stopped 24 years	no	no
18	Inferior MI & P.PCI	62	161	70.2	71.4	76.8	85	86.4	85				ex stopped 9 yrs	no	no
19	PCI	65	106	89.6	95.4	88.2		102.5	102.5	4.4	4.9	3.6	stopped on admission	no	yes
20	NSTEMI	65	118	93	94.8	94.8	112	111	117.2	4.1	3.4	4.1	stopped on admission	no	yes (2 per month)
21	DCABG	79	153	84	86	89.8		99	104.1	3.1	2.6	2.6	no	no	no
22	NSTEMI	62	138	75.4	75.8	79.6	89	89	99	4.4		5	stopped at MI	no	no
23 F	Ant MI & P.PCI	73	145	67.2	66.4	65.6		86	86	3.4	4.2	5.4	ex stopped 36 yrs ago	no	no
24	A-L MI	54	127	72	78.8	83		93	93			3.5	stopped at MI	no	no
25	NSTEMI & PCI	62	175	108.2	107.4	98.8	110.5	102.5	102	6.3	3.7	3.1	ex stopped 37 yrs ago	no	no

**GOOD HOPE HOSPITAL - CARDIAC REHAB - 6 - MINUTE BIKE ASSESSMENT**

Minutes	Workload (Watts)	Heart Rate (bpm)	BP (mmHg)	RPE (6-20 scale)	Symptoms (CP/Dys/Leg fatigue)
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

Current Activity/Goals/Comments:

Name: _____ DOB: _____ Est. 75% HRmax (200-age): _____ Assessment No: _____ Cardiac Condition/Diagnosis: _____	Age: _____ Date: _____ Assessor: _____ Date: _____
Exercise Considerations (MSK/joint problems etc): _____ Medication: _____ Pre-Exs HR: _____ (Reg/Irreg)      Resting BP: _____ Body Weight: _____      Time/Temp: _____	
Post Exercise HR: 3 mins: _____      5 mins: _____ Post Exercise BP: 3 mins: _____      5 mins: _____ TARGET HR: _____	