Design, Implementation and Evaluation of a Reduced Cardiac Rehabilitation Program

by

Alejandra Farias Godoy

M.Sc., Simon Fraser University, 2007
M.D., Catholic University of Chile, 2003
B.M.Sc., Catholic University of Chile, 2001

Dissertation Submitted In Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy in the Department of Biomedical Physiology and Kinesiology Faculty of Science

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Approval

Name: Alejandra Farias Godoy

Degree: Doctor of Philosophy (Biomedical Physiology and Kinesiology)

Title of Thesis: Design, Implementation and Evaluation of a Reduced Cardiac Rehabilitation Program

Examining Committee: Chair: Dr. Angela Brooks-Wilson
Associate Professor, BPK

Dr. Scott Lear
Senior Supervisor
Professor, Faculty of Health Sciences
Professor, BPK

Dr. Victoria Claydon
Supervisor
Assistant Professor, BPK

Dr. Sammy Chan
Supervisor
Cardiologist, Healthy Heart Program,
St. Paul’s Hospital

Dr. Michel Joffres
Internal Examiner
Professor, Faculty of Health Sciences

Dr. Robert Reid
External Examiner
Professor, Faculty of Medicine
University of Ottawa

Date Defended/Approved: February 28th, 2013
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Abstract

**Background:** Cardiac rehabilitation remains under-utilized and novel modes of cardiac rehabilitation delivery are needed to address this concern. **Purpose:** To compare a reduced cardiac rehabilitation program (rCRP) with the standard program (sCRP) in regards to change in exercise capacity and ischemic heart disease risk factors, at program completion and at one-year follow-up. **Methods:** This was a randomized controlled non-inferiority trial. Secondary prevention patients at low and moderate risk were randomized to either the sCRP (n=60) or to the rCRP (n=61). While the sCRP entailed 32 on-site exercise sessions, the rCRP consisted of 10 sessions throughout the four-month program duration. Mixed model analyses of variance were used to test for non-inferiority of the rCRP and repeated measured ANOVA to assess within-group comparisons. **Results:** Baseline data were similar between groups. The rCRP was non-inferior to the sCRP group in regards to exercise capacity at four and 16 months (group estimate=5.25, 95% CI 15.51-26.00 seconds, p=0.62). Exercise capacity improved at program completion for the sCRP and rCRP groups; 524 ± 168 to 630 ± 150 seconds and 565 ± 183 to 655 ± 196 seconds, p< 0.01, respectively, and remained higher than baseline at 16 months; 524 ± 168 to 604 ± 172 seconds and 565 ± 183 to 640 ± 192 seconds, p< 0.01, respectively. The rCRP was non-inferior in regards to HDL-C, triglycerides, TC/HDL-C ratio, fasting glucose, blood pressure, body mass index, waist circumference and waist to hip ratio changes. The rCRP had a higher attendance rate than the sCRP group (97.3 ± 62.6 % vs 70.5 ± 22.0 %, p=0.002) and was non-inferior in terms of self-reported physical activity (group estimate=1.02, 95% CI 0.86-1.21, p=0.8105). These improvements were maintained at one-year follow-up. **Conclusion:** While it utilized less hospital resources, rCRP was “not worse” than the sCRP in terms of exercise capacity and ischemic heart disease risk factor changes as well as program adherence for low and moderate risk patients. Further research is needed to assess if the rCRP helps overcome current CRP utilization barriers.

**Keywords:** Secondary Prevention; Cardiac Rehabilitation; and Cardiac Rehabilitation Programs
Dedication

This thesis was only possible because those whom I love dearly trusted me, loved me and supported me throughout. As Tolstoy said, “Everything that I understand, I understand only because I love”.

This is why I would like to dedicate my thesis to my family, my husband Dan and my son Max. Without their love, support and humour nothing would be possible. I would also like to thank my Father, Mother, Sister and Grandparents for their unconditional love and faith in me.
Acknowledgements

I would like to acknowledge and express my gratitude to the people who contributed in the completion of my thesis.

I would like to thank my supervisor, Dr. Scott Lear, for his guidance, support and patience throughout my work, and for his consistent encouragement.

I would also like to acknowledge the members of my supervisory committee, Dr. Sammy Chan and Dr. Victoria Claydon for their invaluable feedback, advice and guidance. To Dr Joel Singer, who was always available for questions.

In addition, I would like to extend my gratitude to the whole Healthy Heart Program team. This research project also belongs to them.

A special thanks to my fellow graduate students who provided me with invaluable feedback and friendship.
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<th>Description</th>
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<tr>
<td>AACVPR</td>
<td>American Association of Cardiovascular and Pulmonary Rehabilitation</td>
</tr>
<tr>
<td>ACE</td>
<td>Angiotensin converting enzyme</td>
</tr>
<tr>
<td>BP</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>CABG</td>
<td>Coronary artery bypass graft</td>
</tr>
<tr>
<td>CES-D</td>
<td>Centre of Epidemiological Studies Depression Scale</td>
</tr>
<tr>
<td>CRP</td>
<td>Cardiac rehabilitation program</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular Disease</td>
</tr>
<tr>
<td>EQ-5D</td>
<td>European Quality of Life-5 Dimensions</td>
</tr>
<tr>
<td>EQ-VAS</td>
<td>European Quality of Life Visual Analogue Scale</td>
</tr>
<tr>
<td>ER</td>
<td>Emergency Room</td>
</tr>
<tr>
<td>HDL-C</td>
<td>High density lipoprotein cholesterol</td>
</tr>
<tr>
<td>IHD</td>
<td>Ischemic heart disease</td>
</tr>
<tr>
<td>LDL-C</td>
<td>Low density lipoprotein cholesterol</td>
</tr>
<tr>
<td>LTPA</td>
<td>Leisure-time physical activity</td>
</tr>
<tr>
<td>METs</td>
<td>Metabolic equivalents</td>
</tr>
<tr>
<td>MI</td>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>PTCA</td>
<td>Percutaneous transluminal coronary angiography</td>
</tr>
<tr>
<td>rCRP</td>
<td>Reduced Cardiac Rehabilitation Program</td>
</tr>
<tr>
<td>sCRP</td>
<td>Standard Cardiac Rehabilitation Program</td>
</tr>
<tr>
<td>TC</td>
<td>Total cholesterol</td>
</tr>
<tr>
<td>TTT</td>
<td>Time on the treadmill</td>
</tr>
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</table>
1. Introduction

1.1. Cardiovascular Disease

Cardiovascular disease (CVD) is the leading cause of death worldwide [1] and is the second leading cause of death in Canada for both men and women [2]. It is also the leading cause of hospitalizations, accounting for 16.9% of the total, and it costs the Canadian economy, directly and indirectly, more than $22 billion every year [3-5]. Nevertheless, due to improvements in acute care [6, 7], improved risk factor management [6, 8] and increased smoking cessation rates [4, 8], CVD mortality has been declining over the past five decades [4, 5]. As an example, short-term mortality rates due to a myocardial infarction (MI) in the ‘60s approached 30% in developed countries, with a five-year mortality rate that reached 60% [9]. Currently, in-hospital short-term mortality rates due to MI are < 5% for those 65 years old and younger, and the five-year mortality can be as low as 10% [10]. As a result of these improvements, and along with the large aging population, the number of people living with CVD is increasing [11].

There are several risk factors for CVD; some are non-modifiable, such as age, gender, ethnicity and genetics (family history), and some are modifiable, such as physical inactivity, smoking, poor diet and stress. These “unhealthy behaviours” can lead to the so-called traditional risk factors, such as dyslipidemia, hypertension, diabetes and obesity. The interaction of modifiable and non-modifiable risk factors can lead to the development of IHD, which accounts for more than half of CVD deaths [2, 4, 5]. Ischemic heart disease is a chronic inflammatory process with long-term risk for recurrent events, driven by the presence of atherosclerosis, endothelial dysfunction and oxidative stress [12-14].

Although many of these risk factors have been identified as independent predictors of IHD, they tend to cluster together and are rarely found in isolation. There is a synergistic effect amongst these risk factors, and the mechanisms underlying IHD genesis and progression are caused and promoted by the intertwined relationship between them [15].
Table 1 describes the mechanisms by which modifiable risk factors increase the risk of IHD.

**Table 1: Mechanisms underlying the association of modifiable risk factors with IHD risk.**

<table>
<thead>
<tr>
<th>IHD risk factors</th>
<th>Mechanisms that associate risk factors with IHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyslipidemia</td>
<td>Atherogenic dyslipidemia is characterized by the lipid triad: small, dense LDL-C particles, elevated VLDL-C (hypertriglyceridemia) and low HDL-C. This triad confers an elevated total ApoB in plasma [16] and is frequently observed in patients with premature IHD [17]. Each of the components of the lipid triad is independently atherogenic. Together, they represent a set of lipoprotein abnormalities besides elevated LDL-C that promote atherosclerosis [17].</td>
</tr>
<tr>
<td>LDL-C</td>
<td>Low density lipoprotein cholesterol (LDL-C) is recognized as the atherogenic particle of serum lipids given the properties of ApoB which adheres to proteoglycans in the intima [18]. The association of LDL-C with IHD is etiologically demonstrated by the accumulation of modified LDL-C within the fatty streak which causes cell injury through immune and inflammatory mechanisms that leads to arterial disease [14, 19]. A meta-analysis considering over 90,000 patients that participated in statin trials suggested that every 1 mmol/l reduction in LDL-C corresponds to a 23% reduction in cardiovascular events (non-fatal MI, IHD death, any major coronary events, revascularization, and stroke) [20].</td>
</tr>
<tr>
<td>HDL-C</td>
<td>The Framingham Heart Study not only identified low HDL-C as a major risk factor for IHD, but high levels of HDL-C are also protective against the disease [21, 22]. The mechanisms involved are associated with its Apo A1 molecule, which is responsible for reverse cholesterol transport, anti-inflammatory, anti-oxidative and antithrombotic properties. HDL-C is involved in the promotion of endothelial repair, inhibition of LDL-C oxidation, inhibition of the expression of adhesion molecules and increased production of nitric oxide by the endothelium [23, 24]. Circulating HDL-C particles are heterogeneous in size, composition and function, and further research is needed to elucidate its role in IHD [25].</td>
</tr>
<tr>
<td>Hypertension</td>
<td>High BP, both systolic and diastolic, has a strong, independent, etiologically significant relationship with mortality from IHD, stroke and all-cause mortality [26, 27]. Hypertension causes increased arterial wall tension and shear stress, leading to endothelial dysfunction [28] and formation of atherosclerotic plaques [29]. It also causes an elevated afterload, leading to increased myocardial oxygen demand, and concentric hypertrophy, which is a predictor of myocardial infarction and cardiovascular death [30].</td>
</tr>
<tr>
<td>Type 2 Diabetes Mellitus</td>
<td>Type 2 diabetes is an independent risk factor for IHD [21]. The onset of hyperglycemia due to peripheral insulin resistance accelerates atherogenesis, possibly by enhanced formation of glycosylated proteins and advanced glycation products and/or by increasing endothelial dysfunction [31]. Hyperglycemia inhibits endothelial production of nitric oxide impairing vasodilatation [32]. Impaired endothelium-dependant vasodilatation, seen in subjects with type 2 diabetes [31, 33] leads to accelerated atherosclerosis and macrovascular disease [17]. Valmadrid et al [34] reported that patients with microalbuminuria had a relative risk of cardiovascular mortality of 1.84 compared with patients with normoalbuminuria, and those with gross proteinuria had a relative risk of</td>
</tr>
</tbody>
</table>
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2.61, after adjustment for other factors. This suggests that the presence of microalbuminuria and gross proteinuria is also positively associated with cardiovascular mortality. Finally, diabetes is furthermore associated with abdominal obesity, atherogenic dyslipidemia [35] and hypertension [36].

### Smoking

Smoking is the most preventable cause of cardiovascular mortality, and the relative risk of mortality increases with the number of cigarettes and time spent smoking [37]. Cigarette smoking increases pro-inflammatory cytokines which mediate platelet activation and thrombin generation, leading to a hyper-coagulable state and endothelial dysfunction [38, 39]. Carbon monoxide and nicotine adversely alter the myocardial oxygen supply/demand ratio due to oxygen displacement from hemoglobin; they also decrease coronary flow due to coronary vasoconstriction (α-adrenergic stimulation), and increase myocardial work due to increased BP and heart rate [38, 40].

### Obesity

Obesity is an independent risk factor for IHD, an independent predictor of endothelial dysfunction and the second most important modifiable risk factor following cigarette smoking [41]. Abdominal obesity is associated with insulin resistance and atherogenic dyslipidemia which promote the development of IHD [42]. Furthermore, adipocytes are metabolically active cells that produce cytokines called adipokines, and excess adipose tissue leads to the overexpression of TNF-α, IL-6 and plasminogen activator inhibitor 1, and under-expression of adiponectin [43]. These peptides are involved in the pro-thrombotic, pro-inflammatory state of obese patients [43, 44].

LDL-C = Low-density lipoprotein cholesterol, HDL-C = High density lipoprotein cholesterol, VLDL-C = Very low-density lipoprotein cholesterol, MI = Myocardial infarction, IHD = Ischemic heart disease, BP = Blood pressure, TNF-α = Tumor necrosis factor α, IL = Interleukin

Several studies have assessed the importance of modifiable risk factors in the development and health consequences of CVD. A breakthrough study in the subject was the Nurse Health Study. Established in 1976, it evaluated more than 84,000 apparently healthy registered nurses for diet and exercise, and followed them up for 14 years [45]. Participants were classified in different risk categories according to the presence of five variables used to define low risk, such as a) low risk diet, b) non-smoking, c) moderate to vigorous exercise ≥ 30 minutes daily, d) body mass index (BMI) <25, e) alcohol intake ≥ 5 grams daily (equivalent to half a glass of alcoholic beverage). There was a direct association between the number of low risk factors (listed above) and cardiovascular events, with an RR of 17% for developing symptomatic coronary artery disease for the lowest risk group (all five low risk variables present), compared to women with no low risk markers. The authors reported that 82% of the population-attributable coronary event risk was due to lack of healthy lifestyle adherence.

The more recent INTERHEART Study [46] identified nine modifiable IHD risk factors that accounted for and directly contributed to more than 90% of the world population’s risk for
MI. In North America, these nine risk factors contributed to 98.7% of the risk for MI. The nine risk factors identified by the INTERHEART Study were: 1) Smoking, 2) ApoB/ApoA1 ratio, 3) Hypertension, 4) Diabetes, 5) Abdominal obesity, 6) Psychosocial factors, 7) Consumption of fruits and vegetables, 8) Regular alcohol consumption, 9) Physical activity. Most, if not all of these risk factors are associated with lifestyle behaviours.

The above therefore show that IHD is a preventable and treatable chronic condition that requires long-term continuous management through interventions that focus on risk factor modification and positive lifestyle behaviours [47]. Cardiac rehabilitation programs (CRP) offer such prevention and treatment through the involvement of a team of healthcare professionals, all with the common purpose to improve and maintain cardio-metabolic fitness [47]. Cardiac rehabilitation is a key component for the prevention and treatment of CVD, as it remains a proven model of chronic disease care [47].

1.2. Cardiac Rehabilitation

1.2.1. Definition and Description

Cardiac rehabilitation is a systematic process of individualized chronic CVD patient care [47]. The Canadian Association of Cardiac Rehabilitation (CACR) has defined cardiac rehabilitation as “the enhancement and maintenance of cardiovascular health through individualized programs designed to optimize physical, psychological, social, vocational, and emotional status. This process includes the facilitation and delivery of secondary prevention through risk factor identification and modification in an effort to prevent disease progression and the recurrence of cardiac events” [48]. Cardiac rehabilitation is a systematic model of chronic disease care through a multifaceted, multidisciplinary approach, whose depth of services overcomes the resources of family practice as well as cardiovascular specialists.

Standard cardiac rehabilitation programs (sCRP) in Canada provide a multidisciplinary and comprehensive intervention that aims to prolong life, slow or reverse disease progression, reduce recurrent cardiac events and improve functional capacity, all within a prevention-driven environment [47, 49-52]. They aim to improve quality of life through IHD risk-factor management, including lifestyle change (exercise, diet, smoking
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cessation), patient education and medical treatment (dyslipidemias, hypertension). Accordingly, comprehensive sCRPs include five core components:

1. Baseline patient assessment of IHD risk factors, exercise capacity and overall risk and/or ischemic burden (global risk assessment). During the baseline assessment, treatment goals are set.

2. Dietary counselling by a dietician, where the patient’s current diet and possible dietary changes are encouraged through motivational interviewing [53].

3. Risk factor management: a) smoking cessation using motivational interviewing and the transtheoretical model of behaviour change [54], b) weight management, c) blood pressure (BP) control, d) management and treatment of dyslipidemias. Emphasis is placed on positive lifestyle changes to achieve treatment targets that align with current Canadian guidelines [55-58].

4. Psychosocial intervention for those patients that require further psychological assessments. A psychologist and an occupational therapist are available if needed.

5. Exercise training, exercise counselling and education. An exercise specialist assesses the intake stress test with the purpose of planning and implementing an exercise training plan and takes into consideration the patient’s co-morbidities, global risk, baseline exercise capacity and goals and expectations [49].

Patients are continuously assessed throughout program participation by a team of healthcare professionals (nurses, dieticians, exercise specialists and leaders, psychologists and physicians), which works on a treatment plan that is dynamic and individually-tailored to meet patients’ therapeutic goals.

Cardiac rehabilitation delivery differs throughout the developed and developing world based on geographical, economic/resources and health policy considerations [59]. For example, CRPs in the UK follow the British Association for Cardiac Rehabilitation guidelines for phase three outpatient treatments. These programs are led by registered nurses and typically last 6-8 weeks, generally with once-weekly hospital-based exercise sessions and lifestyle counselling [60]. In Germany, the delivery of CRPs is based on regulations set by insurance providers, with an in-patient comprehensive intervention typically lasting 3-4 weeks [61]. Other European countries like Italy and Austria also prefer shorter programs [62]. In contrast, despite the presence of updated technology and treatment for IHD, the availability of cardiac rehabilitation in Latin America is still limited mainly due to a lack of resources [63]. In US and Canada, the current CRP model
Reduced Cardiac Rehabilitation Program encompasses a multidisciplinary intervention that lasts between three to four months, with attendance requirements of two to three hospital-based exercise sessions per week [47, 49]. Program delivery in the US is limited to the availability of health insurance coverage, whereas the healthcare system in Canada is reined by the principle of Universality. Although there are many formats of CRP delivery, several world agencies agree that further research is needed to determine best practices in regards to the frequency of in-hospital exercise sessions and exercise program duration [47, 59, 64, 65].

1.2.2. Cardiac Rehabilitation: Benefits and Challenges

Cardiac rehabilitation involves an evidence-based comprehensive approach that targets exercise fitness, cardio-metabolic fitness and psychosocial factors [66, 67]. There is vast and compelling evidence of CRP’s efficacy and cost-effectiveness, with clear benefits for IHD patients [49, 66-69], making CRP the standard of care for patients with CVD [49, 55, 70]. Cardiac rehabilitation programs improve risk factor profiles by achieving an increase in physical activity and exercise capacity, improved management of diabetes, a reduction of systolic and diastolic BP, reduction of total cholesterol (TC), triglycerides and low density lipoprotein cholesterol (LDL-C), an increase in high density lipoprotein cholesterol (HDL-C) and achievement of higher smoking cessation rates [66, 71]. Cardiac rehabilitation is equally as cost-effective as most drug therapies for high-risk patients, as stated by the American Heart Association [72]. Indeed, cardiac rehabilitation benefits are established as not only achieving successful management of IHD risk factors, but it is also known to decrease all-cause mortality, cardiovascular mortality, non-fatal cardiovascular events and rate of hospitalizations [66, 71, 73-75]. Table 2 describes the evidence behind CRP.

Table 2: Reported CRP benefits from meta-analysis of clinical outcomes in cardiac rehabilitation compared to usual care.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Magnitude of benefit (OR)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality</td>
<td>0.87 (0.71-1.05)</td>
<td>Jolliffe et al 2001 [73]</td>
</tr>
<tr>
<td></td>
<td>0.8 (0.61-0.93)</td>
<td>Taylor et al 2004 [66]</td>
</tr>
<tr>
<td></td>
<td>0.85 (0.77-0.94)</td>
<td>Clark et al 2005 [67]</td>
</tr>
<tr>
<td></td>
<td>0.87 (0.75-0.99)</td>
<td>Heran et al 2011 [71]</td>
</tr>
<tr>
<td>Cardiovascular mortality</td>
<td>0.74 (0.57-0.96)</td>
<td>Jolliffe et al 2001 [73]</td>
</tr>
<tr>
<td>Benefit</td>
<td>Odds Ratio (95% CI)</td>
<td>Reference</td>
</tr>
<tr>
<td>----------------------------------------------</td>
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</tr>
<tr>
<td>Reduced Cardiac Rehabilitation Program</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction of hospital admissions</td>
<td>0.69 (0.51-0.93)</td>
<td>Heran et al 2011 [71]</td>
</tr>
<tr>
<td>Reduction risk for recurrent MI</td>
<td>0.79 (0.50-1.09)</td>
<td>Taylor et al 2004 [66]</td>
</tr>
<tr>
<td>-</td>
<td>0.83 (0.74-0.94)</td>
<td>Clark et al 2005 [67]</td>
</tr>
<tr>
<td>Reduction of total cholesterol (TC)</td>
<td>-0.57 mmol/l (-0.83 to -0.31)</td>
<td>Jolliffe et al 2001 [73]</td>
</tr>
<tr>
<td>-</td>
<td>-0.37 mmol/l (-0.63 to -0.11)</td>
<td>Taylor et al [66]</td>
</tr>
<tr>
<td>Reduction of triglyceride level</td>
<td>-0.23 mmol/l (-0.39 to -0.07)</td>
<td>Taylor et al 2004 [66]</td>
</tr>
<tr>
<td>Reduction of LDL-C</td>
<td>-0.51 mmol/l (-0.81 to -0.19)</td>
<td>Jolliffe et al 2001 [73]</td>
</tr>
<tr>
<td>Smoking cessation</td>
<td>0.64 (0.5-0.83)</td>
<td>Taylor et al 2004 [66]</td>
</tr>
<tr>
<td>Reduction in systolic BP</td>
<td>-3.2 mmHg (-5.4 to -0.9)</td>
<td>Taylor et al 2004 [66]</td>
</tr>
<tr>
<td>Reduction in diastolic BP</td>
<td>-1.2 mmHg (-2.7 to -0.3)</td>
<td>Taylor et al 2004 [66]</td>
</tr>
</tbody>
</table>

CRP: cardiac rehabilitation programs, OR: odds ratio, MI: myocardial infarction, TC: total cholesterol, LDL-C: low density lipoprotein cholesterol, BP: blood pressure

Despite these benefits, there is a large gap between CRP delivery and patients' needs, and many barriers prevent the effective use of these programs. This is partly due to the hospital's limited intake capacity as well as barriers that exist on the part of patients and health-care providers [76-79]. Firstly, the limited availability of program space, which is determined by the hospital's CRP intake capacity [80], is becoming more evident with a growing population of patients living with CVD. As an example, St. Paul’s Hospital has an intake capacity of 480 to 500 patients per year, with a waiting list that ranges between 1-3 months. An expansion of CRP services is needed to attend to a higher number of patients.

A number of patient-centred issues also create barriers to program-use. One main issue is a difficulty in maintaining regular attendance at hospital-based sessions [81]. This is related to the challenges associated with distance and transportation to the CRP facility in terms of time, cost and feasibility [76]. These barriers certainly limit the number of patients that can participate in such programs and warrant the implementation of alternative CRP interventions (ie: programs with less required hospital time). The same
Reduced Cardiac Rehabilitation Program

barriers are also reason for the low physician referral rates; in fact, doctors find that limited resources exist for patients who do not live close to CRP facilities or who have transportation challenges and time constraints (ie: the elderly) [80, 82, 83]. A study by Brown et al [84] studied predictors of CRP referral and the authors recommended overcoming barriers related to treatment cost, shortening travel times to CRP facilities and reducing the time the patient needs to invest in the hospital-based program. These caveats can be improved by implementing more convenient and flexible programs in terms of schedule demands, transportation time and costs, as well as by improving the practicability and convenience of the intervention [85].

Once patients are enrolled, there also exists the problem of poor program adherence, with some reporting drop-out rates as high as 40% [86-88]. Determinants of poor adherence to cardiac rehabilitation include distance to the facility, transportation availability and scheduling, which proves difficult as exercise sessions are usually held during working hours [76, 79, 87, 89]. These barriers affect those patients who do not live close to the CRP facility, who are older, and those who work full time and cannot adjust to the hospital’s schedule [76].

The under-utilization of CRP is also influenced by the limited funding of chronic disease care programs. Many times, these funding sources come from the acute care sector, and it is difficult to divert resources from immediately life-threatening diseases to long-term care, especially in acute care hospital settings [47]. Given that 90% of the world’s MI events are attributable to preventable modifiable risk factors (dyslipidemia, poor diet, smoking, hypertension, diabetes, abdominal obesity, inactivity and psychosocial factors) [46], the CACRC [47] has argued that alternative CRP interventions should be better integrated with primary care services in a less centralized manner, thus optimizing the use of chronic disease and hospital resources.

Different ways of CRP delivery services have shown to be effective. A meta-analysis by Clark et al [67] compared three types of cardiac rehabilitation programs: 1) CRP with an exercise component, lifestyle education and counselling, 2) CRP with risk factor education or counselling without an exercise component, 3) Solely exercise-based program. All three types of programs had remarkably similar results with respect to all-cause death (summary risk ratio 0.85) and recurrent MI reduction (summary risk ratio 0.83) compared to usual care. The authors did not find a significant difference in
mortality benefits between exercise-only programs (RR 0.72, CI 0.54-0.95), risk-factor-education- and counselling-only programs (RR 0.87, CI 0.76-0.99), and comprehensive CRPs (RR 0.88, CI 0.74-1.04). This study consequently confirms the benefits of a wider variety of secondary prevention programs. Clark et al [90] subsequently published the results of a systematic review (a total of 46 trials, n=18 821) that further compared mortality benefits between different modalities of secondary prevention programs with usual care. Interestingly, programs that had reduced healthcare professional-patient contact (less than 10 hours) reduced all-cause mortality (RR 0.80, 95% CI 0.68-0.95) as effectively as those with more contact time. Likewise, programs provided in the general practice settings (home-based programs) were effective at reducing all-cause mortality (RR 0.76, 95% CI 0.63-0.92) and compared favourably with the effectiveness of hospital-based programs (RR 0.90, 95% CI 0.79–1.03). These results further support the benefits of different modalities of CRP, especially for relatively short comprehensive secondary prevention programs. This has important implications, as interventions involving less direct patient contact time are also likely to cost less, to require less of the patient’s time and to be more accessible than hospital-based programs.

There is little evidence to support what the “ideal” CRP model should be for the evolving and heterogeneous CRP population and its healthcare needs. Most likely, “ideal” CRP models should be based on current patient needs and healthcare resources, both of which are continually evolving. It is clear that the traditional CRP model is an essential part of CVD treatment and prevention; however, a majority of patients with indications for CRP underutilize these programs due to the barriers discussed above. The Canadian Guidelines for Cardiac Rehabilitation and Cardiovascular Disease Prevention indicate there exists a lack of evidence regarding alternative CRP design and encourage researchers to evaluate and implement CRP models to overcome some of the current CRP barriers [47, 91]. The most recent guidelines of the Canadian Association of Cardiac Rehabilitation (CACR) have stated that “given the large service delivery gap and wide geographic spread of population affected by heart disease in Canada, alternate models of delivery of CR services in combination with enhanced on-site programs must be explored, developed and implemented” [47]
1.2.3. **Alternative Cardiac Rehabilitation Programs**

Alternative CRPs have been evaluated with the aim to implement evidence-based programs and widen access and CRP participation without impairing patient care. For example, home-based exercise programs have the potential to overcome geographical challenges and increase access and participation while limiting the utilization of hospital resources. In comparing home-based to hospital CRPs, they have reported similar improvements in exercise capacity, quality of life and IHD risk factors [92-95]. Notably, it was also reported that sustainability of this effect was better achieved by home-based interventions [96, 97]. Though they show promising results, many caveats exist in relation to these trials, and before implementing home-based interventions, much research is needed to ensure optimal patient care.

In one such trial, Marchionni et al [96] compared the change in exercise capacity and quality of life between a two-month comprehensive hospital-based CRP and a two-month comprehensive home-based CRP in low-risk post-MI patients. The hospital-based group had a total of 40 comprehensive hospital-based exercise sessions and the home-based group had a total of four to eight hospital-based exercise sessions. The home intervention consisted of home exercise with a cycle ergometer (provided to patients), plus biweekly home visits by an exercise therapist. The authors reported that exercise capacity improved for both the hospital-based and the home-based CRP groups at program completion, while the home-based program had better sustainability of exercise capacity at 12 months follow-up. Health-related quality of life had similar improvements for both groups. However, especially considering that the hospital-based CRP had a more comprehensive approach to patient care, a few factors have to be taken into consideration with these results. Firstly, the short duration of this trial might have prevented findings of long-term benefits for the hospital-based group. Furthermore, wider implementation of the home-based intervention would be difficult as it required additional resources such as monthly family support groups, provision of a home cycle ergometer and wristwatch digital pulse monitor. Finally, metabolic variables were not included in the outcomes, which is an important limitation to this study considering their importance in IHD management and CRP success measures [98].

Arthur et al [99] compared the change in exercise capacity as well as self-reported quality of life and social support between a six month hospital-based and a six-month
home-based CRP for low-risk post coronary artery bypass graft (CABG) patients. The hospital-based program entailed three times weekly hospital-based exercise sessions; the home-based intervention entailed a one-hour exercise consultation session with an exercise specialist at baseline and at 3 months, as well as biweekly telephone follow-ups. The authors reported that both programs had similar improvements in exercise capacity at program completion (36% and 31% improvement in VO$_2$max for the hospital-based and home-based programs respectively, p<0.05) and that the home-based program had greater social support than the hospital-based group. Smith et al [97] followed the same study cohort at 12-months follow-up and reported that exercise capacity significantly declined in the hospital-based group only. However, the home-based intervention lacked the multidisciplinary approach which is the standard of care according to guidelines [47]. Furthermore, it required additional telephone follow-ups by the exercise specialist, a feature not part of traditional programs, and included low-risk patients only. Metabolic variables were again not included in the outcomes, which is a limitation considering the importance of risk factor management in cardiovascular patients.

A recent meta-analysis by Taylor et al [100], which included 12 randomized controlled trials (RCTs) published between 2001 and 2008, showed no significant difference between home-based CRP and hospital-based CRP in regards to all-cause mortality, cardiac events, exercise capacity, BP, TC, HDL-C, LDL-C, smoking cessation and health-related quality of life. However, the majority of these studies included low-risk patients younger than 70 years; most trials assessed exercise capacity in the short-term (at program completion); and some of these studies had small sample sizes and problems with study design, with no trial having a non-inferiority trial design. A meta-analysis by Clark et al [101] analyzed a total of 39 RCT that evaluated home-based programs against traditional programs and usual care. Compared with usual care, home-based programs significantly improved some IHD risk factors and quality of life. However, the authors failed to compare home-based programs with traditional CRPs due to small effect sizes and poor quality of trials.

Although there is evidence to support home-based CRPs, traditional supervised CRPs are currently the standard of care given the considerable evidence related to their efficacy, safety and cost effectiveness, especially for moderate- and high-risk patients whose medical complexity warrants supervision during cardiac rehabilitation. There are
still concerns in regards to the safety and adequacy of home-based programs for these higher risk patients; trials that have assessed such programs have had small sample sizes and have been mainly evaluated in low-risk patients, limiting their generalizability and applicability. Home-based interventions have been heterogeneous and independent from the well-established traditional program, with limited educational components and limited participation of a multidisciplinary team of healthcare professionals. The literature is lacking an RCT that evaluates an alternative CRP whose design is derived from the traditional program (i.e. a program which is integrated into the sCRP). There is a lack of non-inferiority trials to assess exercise capacity and IHD risk factor change at program completion, and longer follow-ups are needed to assess sustainability of effect. Ongoing trials are needed as the debate continues regarding the acceptance of alternative CRPs.

1.3. Exercise and the Role of Cardiac Rehabilitation

Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure, and physical fitness refers to the set of attributes that allows one to meet the physical demands of daily living and/or sports performance. Exercise is a subset of physical activity that is planned, structured and repetitive with the goal to achieve physical fitness [102, 103].

Physical inactivity is an independent risk factor for IHD [104]. For patients who are sedentary and/or have had a cardiovascular event, beginning an exercise program at any stage of life can yield significant cardiovascular health benefits [105, 106]. Exercise training reduces the extent of disability, enhances quality of life, and positively influences morbidity and mortality [107]. Exercise benefits have been observed in patients that have participated in traditional CRP, but there is a growing body of evidence that modified program/home-based CRP yield comparable benefits [95, 96, 100]. The benefits of exercise have been observed in survival studies, such that for every 1 metabolic equivalent (MET; 1 MET = 3.5 ml O_2/kg/min) increase in exercise capacity, there is an associated survival benefit of 8% to 35% [108].

The role of functional capacity in determining cardiac outcomes is well-documented. In one of the largest studies with coronary patients, Kavanagh et al [109] reported that exercise capacity measured in VO_2 max was the strongest predictor of cardiovascular
and all-cause mortality, such that the fittest group (VO\textsubscript{2} max > 22 ml/kg/min) had a hazard ratio for cardiovascular and all-cause mortality of 0.39 and 0.45 compared to the least fit group (VO\textsubscript{2} max < 15ml/kg/min). Other studies have reported similar results in terms of survival benefit per MET improvement in primary and secondary prevention in women and men [110-114]. Studies that have assessed physical activity in terms of energy expenditure have shown similar results. An increase in physical activity has been associated with decreased mortality, such that for every 1000 Kcal/week increase in energy expenditure through physical activity (approximately 1 MET), all-cause mortality is reduced by 20% [115]. The effect of exercise on cardiovascular outcomes appears to be graded and to apply to all levels and intensities of physical activity in a dose-response manner. In one study that assessed the effect of low-intensity exercise, the authors reported that older men who walked regularly had a lower mortality rate than sedentary men (RR 0.88), and the distance walked daily was inversely associated with mortality [116]. Lee at el [117] examined the association between physical activity and longevity, comparing non-vigorous (< 6 METS) with vigorous (> 6 METS) physical activity. Energy expenditure from vigorous physical activity was inversely associated with all-cause mortality, demonstrating a graded inverse relationship between total physical activity and mortality.

Taylor et al [118] performed a systematic review that included 19 exercise-only CRPs (n=2984), and examined the reduction in cardiac mortality attributable to risk factor modification and to the direct effect of exercise on the heart and coronary vasculature. The pooled cardiac mortality reduction achieved by exercise-only CRP was 28% (RR 0.72) compared to usual care. From this cardiac mortality reduction, 58% was attributable to risk factor modification (smoking, TC and BP); hence, 42% of mortality reduction was attributable to the beneficial effects of exercise on non-risk factor mechanisms. This study shows that there are multiple mechanisms by which exercise improves survival; one such mechanism includes the effect of exercise on traditional IHD risk factors. For example, exercise training reduces systolic and diastolic BP in both men and women with an average of 11 mmHg and 8 mmHg respectively [119]. This effect happens with low- to moderate-intensity exercise (training intensities < 70% VO\textsubscript{2} max) and happens as soon as after one week of training [119, 120]. Endurance exercise training beneficially impacts the different components of the lipid profile by reducing TC, LDL-C, triglycerides and increasing HDL-C [121, 122]. These changes are mediated
through increased expression and function of lipoprotein lipase in skeletal muscle and adipose tissue, with the consequent decrease in triglycerides and increased HDL-C [123]. Exercise also improves body composition by reducing adiposity and increasing lean mass [124, 125], improves insulin sensitivity and glucose homeostasis [121, 126], and reduces systemic inflammation [127]. In the periphery, exercise training increases muscle blood flow and vascular shear stress, increasing endothelial release of vasoactive substances such as nitric oxide and prostacyclin, which in turn decreases the permeability to plasma lipoproteins [128]. This increased blood flow (increased shear stress and mechanical stretch) mediates changes in endothelium gene expression [128], thus increasing the production of vasodilators and decreasing platelet adhesiveness. This “healthy” endothelial phenotype prevents vascular smooth muscle cell proliferation and migration, and promotes fibrinolysis [129]. Physical activity also results in a higher velocity of rhythmic blood flow, thereby inducing anti-atherogenic molecular pathways and expression of protective gene families [130]. On the other hand, physical inactivity results in insufficient shear stress due to reduced and disturbed flow in arteries, which up-regulates the expression of leucocyte and monocyte adhesion proteins; indeed, exercise has an anti-inflammatory, antithrombotic effect.

The effects of exercise in the heart match the demands of peripheral tissues. As peripheral blood flow in skeletal muscles increases together with increased oxygen extraction, so does venous return, heart rate and cardiac output [131]. The chronic effect of exercise in the heart includes decreased myocardial oxygen demand, increased maximal cardiac output and increased blood flow capacity in skeletal and cardiac muscle [128]. Improved myocardial perfusion has a favourable impact in decreasing the risk of lethal arrhythmias, also mediated by increased vagal tone and decreased adrenergic activity [132].

Peripheral adaptations in skeletal muscles are also important contributors to the overall effect of exercise, especially for CRP patients with documented CVD and the elderly, in whom increases in cardiac output are less evident. Ades et al [133] compared peripheral adaptations of sedentary (control) versus active elderly patients with IHD (mean age 68 years). The authors reported that exercise training resulted in an increase in exercise capacity (minutes on the treadmill) by 47% at both 3 and 12 months (from 8.8 ± 3 to 13.0 ± 4 minutes and from 9.1 ± 4 to 13.3 ± 4 minutes respectively, p< 0.01), while exercise capacity in the sedentary group remained unchanged. This increase was
achieved without a significant increase in cardiac output, but by an increase in arteriovenous oxygen difference at peak exercise of 3 ml/l at both three and 12 months (p<0.05). Changes in skeletal muscles were observed as a 34% increase in capillary density and a 23% increase in succinate dehydrogenase activity (marker of skeletal muscle oxidative capacity) after three months of conditioning (p<.02). At 12 months, individual fiber area increased by 29% compared with baseline (P<.01). These peripheral adaptations allow for much more efficient delivery and utilization of oxygen, therefore requiring less myocardial work [133].

Overall, exercise and the improvement of cardiorespiratory fitness is a key component of cardiac rehabilitation [49]. Exercise capacity is a better predictor of CVD outcomes than other IHD risk factors and is very responsive to traditional and alternative models of CRP. Therefore, exercise capacity is a key outcome when evaluating CRP.
2. **Rationale**

While the current institution-based CRP models in Canada provide efficient treatments for CVD patients [66], these programs are under-utilized, and there is still a large delivery gap between program demand and supply, such that only 15-30% of eligible patients attend cardiac rehabilitation [47]. This inadequate access to CRP warrants a careful evaluation of the current barriers to CRP utilization and the implementation of alternative methods of program delivery. As the population of CVD “survivors” increases, so does the need to expand CRP services, and the traditional hospital-based CRP may not have the resources to meet the increasing demand.

As previously mentioned, main barriers for CRP utilization include geographical difficulties, particularly distance and transportation to CRP facilities, which are mainly located in urban areas [76, 134]; participants’ lack of availability for programs scheduled during work time; and the lack of schedule flexibility of hospital-based exercise sessions [76]. The hospital’s limited intake capacity also results in delays to CRP intake and prolonged wait times for program initiation [135]. These barriers may exacerbate the patient’s lack of motivation to participate and also contribute to the low physician referral rates as physicians are faced with limited resources for patients facing these barriers.

Even once participants are enrolled in a CRP, drop-out rates are as high as 50% [136]. A predictor of CRP attendance is the program convenience and practicability [85]. These are factors that could be improved upon with alternative CRP delivery. If it can improve participant retention, the need for an alternative program is especially emphasized by findings which indicate that CRP “completers” have lower risk of all-cause mortality (HR 0.77, 95% CI 0.71, 0.84) and cardiac hospitalizations (HR 0.68, 95% CI 0.55, 0.83) compared to those that drop-out of the program [136].

To overcome CRP delivery gaps, home-based interventions have been evaluated as treatment alternatives with comparable results to traditional programs in terms of exercise capacity and risk factor management improvements [99, 137, 138]. While a few studies have reported better sustainability of exercise capacity with home-based
Reduced Cardiac Rehabilitation Program

programs versus hospital-based ones [96, 97], these home-based interventions were designed independently from traditional programs; many lacked the comprehensiveness of a standard intervention and were assessed in low-risk patients only, giving rise to safety concerns for those at higher risk. Furthermore, only superiority trials have been reported, which might bias the interpretation of results [139, 140]. Superiority trials aim to show that the experimental group is “superior” to the control group, and they can claim this when there is a significant difference of effect between the groups. When there is a non-significant difference, the conclusion that the experimental group is as good as or not much worse than the control group cannot be made; however, most superiority trials that have non-significant results wrongly interpret this as proof of no difference between the groups [139, 141].

Given the need to increase CRP intake capacity, to improve program adherence and to provide an alternative program for those who feel the standard program is not a good fit, an intervention with the following characteristics warrants evaluation:

Is a hospital-based program with “reduced” hospital time (has a lower number of in-hospital exercise sessions) while maintaining a hospital-supervised intervention within the standard program (an integrated CRP)

  • Is comprehensive in nature
  • Has a supplementary educational component
  • Has a non-inferiority trial design
3. Study Purpose, Hypotheses and Objectives

3.1. Purpose

The purpose of this study was to conduct a non-inferiority trial to evaluate an alternative program called “reduced cardiac rehabilitation program” (rCRP). We wanted to compare the effectiveness of the rCRP with the sCRP in primary and secondary prevention patients in regards to exercise capacity and IHD risk factors change at program completion and at one-year follow-up. The non-inferiority approach to the study allows superiority testing to also be performed using the same p value without statistical penalty [139]. The following research questions were addressed: 1) Is the rCRP “not worse” than the sCRP for improving exercise capacity and IHD risk factors at program completion and at one year follow-up following baseline? 2) Is the rCRP better than the sCRP for improving exercise capacity and IHD risk factors at both four and 16 months following baseline? 3) Will the rCRP have better adherence than the sCRP?

3.2. Reduced Cardiac Rehabilitation Program

To address these questions, the rCRP was designed to be a comprehensive intervention comprising of the same nature of therapies as the sCRP and, therefore, multi-factorial care for chronic disease management. Its difference from the sCRP resided in the total number of hospital-based exercise sessions and the distribution of these sessions throughout the four-month program duration. Typically, the sCRP holds a total of 32 hospital-based exercise sessions at two sessions per week for 16 weeks; in contrast, while the rCRP had a total of 10 sessions, it was spread over four months of intervention (Figure 1). Exercise session distribution was decided in conjunction with the CRP clinical staff; the rCRP hospital-based exercise sessions were concentrated at the start of the program and gradually decreased in frequency with program progression (Figure 1). The purpose of this design was to provide participants with stronger supervision at the beginning learning stages of the program in order for them to build up an appropriate
Reduced Cardiac Rehabilitation Program

exercise routine. The rCRP was a “middle of the road” alternative, in other words, a “hybrid” between a home-based program and a traditional program. It would enable participants to achieve behavioural changes within their own environment, using their own social network, while continuing to be supervised by the CRP clinical staff. Such a design served to address the following CRP challenges: a) to decrease transportation time and cost for patients, b) to decrease “hospital time” and increase program flexibility, c) to increase enrollment of patients who work and/or have time constraints, d) to create an alternative program, thereby increasing the hospital’s intake capacity, e) to redirect hospital supervision to high-risk patients.

3.3. Study Hypotheses

3.3.1. Primary Hypotheses

1. Participation in the rCRP will be non-inferior to a standard hospital-based sCRP with respect to improvements in exercise capacity immediately after completion of the program (four months) and one year after program completion (16 months from baseline).

2. Participation in the rCRP will be better than in a standard hospital-based CRP with respect to improvements in exercise capacity immediately after completion of the program (four months) and one year after program completion (16 months from baseline).

3.3.2. Secondary Hypotheses

1. Participation in the rCRP will be non-inferior to a standard hospital-based CRP with respect to improvements in IHD risk factors immediately after completion of the program (four months) and one year after program completion (16 months from baseline).

2. Participation in the rCRP will be better than in a standard hospital-based CRP with respect to improvements in IHD risk factors immediately after completion of the program (four months) and one year after program completion (16 months from baseline).

3. Adherence to the reduced CRP will be higher than that of the sCRP.
3.4. Objectives

1. To establish a cohort of 118 men and women referred for primary and secondary prevention to the sCRP of the Healthy Heart Program (HHP) at St. Paul’s Hospital. They would be randomized into the sCRP or the rCRP upon meeting inclusion criteria.

2. To compare the effectiveness of the rCRP against the sCRP with respect to exercise capacity change at four months (program completion) and at 16 months from recruitment (one-year follow-up).

3. To compare the changes in other IHD risk factors: lipid profile, fasting glucose, BP, anthropometric measurements and physical activity between the sCRP and the rCRP at four months and 16 months follow-up.

4. To determine and compare exercise adherence between sCRP and rCRP at four and 16 months follow-up.
4. Methods

4.1. Study Design

This study was designed as a prospective, two-group randomized controlled study. Given that the sCRP is an effective treatment for patients with CVD [66, 69], a non-inferiority trial design was chosen to compare the rCRP with the sCRP [139]. The trial followed CONSORT guidelines [142], and it was registered at Clinical Trials, protocol ID 37553.

4.2. Study Outcomes and their Assessment Methods

All outcomes were assessed at baseline (program intake), at four months (program completion) and at 16 months from baseline (one year follow-up).

4.2.1. Primary Outcomes and Methods of Assessment

The primary outcome was the difference in exercise capacity change between the two groups, measured as total time on the treadmill (in seconds) from baseline to program completion and from program completion to 16 months to assess sustainability of effect. Exercise capacity was assessed by a symptom-limited exercise treadmill test using the Bruce protocol [143]. The Bruce protocol remains the most commonly used test [144] due to its convenience, familiarity and widespread use [145].

Since the only difference between the two groups was the number of hospital-based exercise sessions they attended, it was reasonable to measure an exercise variable to compare both programs. Exercise capacity is an important prognostic variable to predict survival [151], and is the stress test variable that exhibits the strongest association with all-cause mortality, cardiac mortality and non-fatal cardiac events after adjustment for clinical and other exercise variables [113, 117, 146-148].
followed healthy middle-aged men and women for up to eight years, the authors reported that those in the lowest quintiles of physical fitness (measured with a symptom-limited stress test) had an increased risk of all-cause mortality compared to those in the highest quintiles of physical fitness (RR 3.4, (CI 2.0-5.8) for men, and RR 4.7 for women (CI 2.2-9.8)) [149]. Myers et al [110] assessed overall mortality among patients that were referred to an exercise stress test for medical reasons with a mean follow-up of six years. After adjustment for age and other IHD risk factors, exercise capacity was the strongest independent predictor of mortality. In fact, the authors found that for every 1 MET increase in exercise capacity, there was a 12% improvement in survival; from these findings, they concluded that exercise capacity is a more powerful predictor of mortality than other IHD risk factors.

The gold standard for the assessment of exercise capacity is VO$_2$ max (product of cardiac output and arterio-venous oxygen difference). It is measured through open circuit spirometry, in which the patient breathes through a low-resistance valve while the nose is occluded. Measures of pulmonary ventilation, expired fraction of oxygen and CO$_2$ are recorded [144]. However, the high cost of equipment, the need for trained personnel and patient discomfort limited the use of VO$_2$ max as a measure of exercise capacity for this study. Furthermore, the clinical evaluation of CRP efficacy is performed by observing differences in treadmill time and/or through estimation of METS if other protocols have been used. Time on the treadmill and the derived estimation of METS are indirect measures of exercise capacity but, nevertheless, have a strong predictive value and are considered to be appropriate estimations of exercise capacity [150, 151]; time on the treadmill is, therefore, a good tool to evaluate the efficacy of a CRP [150].

During the stress test, study participants underwent continuous 12-lead ECG monitoring while supervised by a technician who instructed them on performing the test. The technician indicated increments of workload (every three minutes for the BRUCE protocol) and continuously assessed for possible signs and symptoms (ie: increments of BP, presence of arrhythmias, ST segment changes, presence of angina). The following measurements were assessed before, during and after each exercise stress test: Heart rate, BP, ECG (continuous monitoring), cardiovascular signs and symptoms (ie: fatigue, shortness of breath, chest pain, etc.) and rate of perceived exertion. During the post-exercise period, continuous monitoring of these parameters continued for at least five minutes following exercise. A cardiologist who was blinded to group allocation
interpreted the stress test. All stress tests were carried out in the stress test laboratory at St. Paul’s Hospital.

4.2.2. Secondary Outcomes and their Assessment Methods

Secondary outcomes tested for non-inferiority

The secondary outcome was the change in IHD risk factor values, from baseline to program completion and from program completion to 16 months follow-up, compared between the two groups. To test for the secondary hypothesis, the following IHD risk factors were assessed for non-inferiority between rCRP and sCRP groups: TC, LDL-C, HDL-C, triglycerides, TC/HDL-C ratio, fasting blood glucose, waist circumference, BMI, waist to hip ratio, systolic and diastolic BP and physical activity.

To measure those secondary outcomes that required blood work testing, blood samples were collected after a 12-hour fast and 72-hour cessation of alcohol. Most laboratory analyses were conducted as part of the CRP at the St. Paul’s Hospital Laboratory, accredited by the Diagnostic Accreditation Program of British Columbia. Some participants, however, already had the required blood tests completed through their physician, and some laboratory analyses were therefore performed in outlying laboratories such as BC Biomedical Laboratories and MDS Laboratory Services. A comparison of these outlying laboratories and St. Paul’s Hospital laboratory methods is done as part of external quality control testing offered by the College of American Pathologists (CAP) Organization, and there is a high agreement (within 2.1%) between these laboratories. The analysis methods used are traceable to the National Cholesterol Education Program (NCEP) designated method [152]. A description of the procedures for the laboratory tests conducted at St. Paul’s Hospital is given in Table 3 below. Table 3 also reviews the IHD risk factors being used for group comparison, and lists their assessment methods and respective cut-point values according to literature.
Table 3: Secondary outcomes, their association with health outcomes and their respective methods of assessment and cut point values to test non-inferiority between rCRP and sCRP groups.

<table>
<thead>
<tr>
<th>Secondary Outcomes</th>
<th>Association with health outcomes</th>
<th>Method of assessment</th>
<th>Cut-point value to test for non-inferiority</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC (mmol/l)</td>
<td>A 1 mmol/l decrease is associated with a decreased risk of IHD mortality for both men and women of 56%, 34% and 17% in the age ranges of 40-49, 50-69, 70-89, respectively [153]. Remains a secondary treatment target according to guidelines [58].</td>
<td>Assessed by Siemens Advia Analyzer 1650 through enzymatic colorimetry.</td>
<td>A decrease of 1 mmol/l [153]</td>
</tr>
<tr>
<td>HDL-C (mmol/l)</td>
<td>An HDL-C increase of 0.33 mmol/l is associated with 1/3 decrease in IHD mortality [153].</td>
<td>The equation was used to calculate LDL-C (LDL-C (calc)= TC – HDL-C – TG/2.2). The use of the Friedewald equation is restricted when triglycerides are above 4.52 mmol/L [154].</td>
<td>An increase of 0.33 mmol/l [153]</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>An increase of 1 mmol/l is associated with 76% and 31% increase in CVD for women and men respectively [155, 156].</td>
<td></td>
<td>A decrease of 1 mmol/l [155, 156]</td>
</tr>
<tr>
<td>LDL-C (mmol/l)</td>
<td>A 1 mmol/l decrease is associated with 20-25% reduction of CVD mortality and non-fatal MI and 12% reduction of all-cause mortality [20]. Is the predominant atherogenic particle and primary treatment target according to guidelines [58].</td>
<td></td>
<td>A decrease of 1 mmol/l [20]</td>
</tr>
<tr>
<td>TC/HDL-C</td>
<td>Predictor of IHD mortality and CVD events [157, 158]. For every 1.33 decrease of TC/HDL-C ratio, there is an associated 1/3 decrease in IHD mortality [153].</td>
<td>The TC/HDL-C ratio was calculated by simple division.</td>
<td>A decrease of 1.33 [153]</td>
</tr>
<tr>
<td>Fasting blood glucose (mmol/l)</td>
<td>A 0.3 mmol/l reduction of fasting blood glucose in individuals at high risk for developing type 2 diabetes.</td>
<td>Assessed by Siemens ADVIA 1650 glucose Hexokinase method. This enzymatic method used.</td>
<td>A decrease of 0.3 mmol/l [159]</td>
</tr>
</tbody>
</table>
| **BP (mmHg)** | A reduction of 10 mmHg systolic BP is associated with 1.17 times decreased risk of all-cause mortality [160].  
A reduction of 5 mmHg diastolic BP is associated with a 42% reduction in the incidence of stroke and a 14% reduction in the incidence of IHD [161-163]. | Recorded as the average of two measures taken 5 minutes apart after 5 minutes of seated rest, using a manual sphygmomanometer and reported in mmHg. An appropriate-sized cuff was used. Participants were instructed to abstain from drinking coffee, smoking and exercising the morning of the assessment. | A decrease of 10/5 mmHg [160-163] |
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<tr>
<td><strong>BMI (kg/cm²)</strong></td>
<td>Dose-response relationship between BMI and risk of incident IHD and diabetes, such that for every 1 unit decrease in BMI, there is a corresponding reduction in risk of IHD and diabetes of 10% [164].</td>
<td>Calculated from weight in kilograms divided by height in metres squared. Weight was assessed with participants in light street clothing, footwear removed and pockets emptied, and measured to the nearest 0.1 kg using a regular scale. Height was measured to the nearest 0.1 cm with the participant standing erect using the L-measure on a regular scale.</td>
<td>A decrease of 1 unit [164]</td>
</tr>
<tr>
<td><strong>Waist circumference (cm)</strong></td>
<td>At a given BMI, a 5 cm increase in waist is associated with 17% and 13% increased mortality risk for men and women respectively [165]. Independent predictor of incident metabolic syndrome in patients with CVD, such that every 5 cm increase in waist is associated with an 87.5% risk of incident metabolic syndrome [166].</td>
<td>Measured to the nearest 0.1 cm, directly over the skin or with a light t-shirt. Measured following normal expiration at the point of maximal narrowing of the trunk as viewed from the anterior position with the participant standing upright [167]. The average of two successive measures was recorded.</td>
<td>A decrease of 5 cm [165]</td>
</tr>
<tr>
<td><strong>Waist to hip ratio (cm)</strong></td>
<td>Has a strong positive association with incident IHD [168], incidence of MI [46], cardiovascular mortality [169] and all-cause mortality [170, 171]. For every</td>
<td>Hip circumference was measured over light street clothing, recorded in centimetres as the average of two measures taken horizontally at the point of</td>
<td>A decrease of 0.1 unit [165]</td>
</tr>
</tbody>
</table>
An increase of 100 kcal/week [102, 115] is associated with a 2% reduction in all-cause mortality [116]. Leisure-time physical activity has been reported to have a negative association with all-cause and IHM mortality [12-17].

<table>
<thead>
<tr>
<th>Physical activity (kcal/week)</th>
<th>An increase of 100 kcal/week of energy expenditure through physical activity is associated with a 2% reduction in all-cause mortality [102, 115]. Leisure-time physical activity has been reported to have a negative association with all-cause and IHM mortality [12-17].</th>
</tr>
</thead>
</table>

0.1 unit increase, the associated risk of all-cause mortality increases by 34% in men and 24% in women [165].... to measures of exercise capacity and use of accelerometers [177].

**CVD =** Cardiovascular disease, **IHD =** Ischemic heart disease, **MI =** Myocardial infarction, **LTPA =** Leisure-time physical activity, **TC =** Total cholesterol, **LDL-C =** Low-density lipoprotein cholesterol, **HDL-C =** High-density lipoprotein cholesterol, **BP =** Blood pressure, **BMI =** Body mass index
Secondary outcomes not tested for non-inferiority

Program adherence

Adherence to the CRP was determined by the LTPA questionnaire as described above, as well as percent attendance to the program. Percent attendance to the program was calculated from the total number of hospital-based exercise sessions attended, with respect to the number of sessions participants were expected to attend according to their group assignment.

Behavioural, psychosocial and global risk score

Behavioural and psychosocial factors are associated with an increased risk for developing symptomatic IHD and convey a poor prognosis for patients with CVD [180, 181]. Global risk scores incorporate a number of IHD risk factors and are used to calculate risk of future cardiovascular events. Table 4 shows the association of these secondary outcomes with health outcomes and their methods of assessment.

Table 4: Behavioural, psychosocial and global risk score outcomes, their association with health outcomes and their methods of assessment

<table>
<thead>
<tr>
<th>Secondary Outcomes</th>
<th>Association with health outcomes</th>
<th>Assessment Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarette Smoking</td>
<td>Major cause of preventable mortality, responsible for 14.54% of all heart disease and stroke deaths in Canada [182]. The relative risk of CVD and all-cause mortality increases with the number of cigarettes and the time smoking [37]. Smoking cessation is the single most cost-effective cardiovascular disease risk factor modification [47, 183].</td>
<td>Determined by self-report. Participants were classified as never smokers, ex-smokers (quit ≤ 6 months ago) or current smokers. Participants were asked about their smoking status at each assessment.</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>Important outcome for cardiac rehabilitation; however, there is not enough evidence to estimate the benefits of CRP in regards to quality of life [184]. Recent meta-analysis reported that although most CRP trials demonstrated an improvement from baseline quality of life, this improvement was comparable to those in usual care [71]. Leung et al [185], however, reported that quality of life was</td>
<td>Assessed by the two components of the European quality of life questionnaire: EQ-5D and EQ-VAS [186](Appendix 2), which is a validated tool for numerous populations [187, 188]. The EQ-5D comprises questions regarding mobility, self-care, usual activities, pain/discomfort, anxiety/depression [188, 189]. The EQ-VAS assessed state of health with a visual analogue scale, which recorded participants’ self-rated health on a vertical scale.</td>
</tr>
</tbody>
</table>
**Reduced Cardiac Rehabilitation Program**

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<tbody>
<tr>
<td><strong>Self-efficacy</strong></td>
<td>Defined as the belief in our own ability to succeed at certain tasks. Is an important determinant of behavioural changes and their maintenance. There is a lack of evidence regarding the role of self-efficacy in association with cardiac rehabilitation, as well as for its importance in the maintenance of healthy behavioural changes [190].</td>
</tr>
</tbody>
</table>

| **Depression** | Among acute coronary syndrome survivors, 15-30% also have concomitant depression which persists over time [192]. Depression is associated with lower CRP attendance and low psychosocial support [193]. Depressed patients are susceptible to being undertreated [193]. Major systematic reviews of cardiac rehabilitation have not reported significant improvements in depression scores [66, 71]. | Assessed with the CES-D Scale based on Likert scoring [194] (Appendix 4). It is a validated screening questionnaire designed to measure general symptomatology but is not a diagnostic tool. It is a valid, reliable and consistent scale with high consistency and adequate test-retest repeatability [194, 195]. It comprises of 20 questions, and the score can range from 0-60. The higher the score, the stronger the symptomatology. Participants with a score of 16 or more were considered to have symptoms of depression, and were therefore excluded from the study. |

| **Global Risk Scores** | Global IHD risk assessments reflect the multi-factorial nature of IHD [49, 56-58]. The Framingham risk score is the most commonly used global risk score in Canada. It was developed from the Framingham Heart Study, based on 2489 men and 2856 women aged 30 to 74 years without previous IHD. Its purpose is to predict the risk of a coronary event occurring in the next 10 years [196]. This risk score was found to be reliable in predicting IHD outcomes in a population of 1700 men and women in the United Kingdom [197]. The Progression of Disease score was derived from the Framingham risk score, but it considers those with documented IHD and therefore adds an additional CVD mortality risk [91]. | The Framingham risk score was calculated for primary and secondary prevention participants, used as a quantitative variable only, not as a predictor of CV events. It incorporated age, TC, HDL-C, smoking status, BP and presence of diabetes [21]. A total score was calculated from the points assigned to each risk factor, with a different scoring system existing for men than for women. Age at baseline was held constant and carried through to ensure that the scores were comparable between subjects. Results of variables that fell outside of the provided categories were given the score of the closest category. For example, those categorized as “ex-smokers” were placed as smokers. Participants with undiagnosed diabetes were considered diabetic if fasting plasma glucose exceeded 7.0 mmol/l or if they were taking diabetes-related medications. |

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CVD = Cardiovascular disease, IHD = Ischemic heart disease, EQ-5D = European Quality of Life-5 Dimensions, EQ-VAS = European Quality of Life Visual Analogue Scale, CES-D = Centre of Epidemiological Studies Depression scale

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Reduced Cardiac Rehabilitation Program
4.3. **Study Population**

The following is a list of inclusion/exclusion criteria for study participation according to the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) [198] risk stratification.

### 4.3.1. **Inclusion Criteria**

1. Men and women (equal distribution) with risk factors for IHD (primary prevention) or documented IHD (secondary prevention) accepted in the CRP of St. Paul's Hospital.

2. Secondary prevention patients classified as low- and moderate-risk according to the AACVPR risk stratification criteria for cardiac patients (Table 5).

### 4.3.2. **Exclusion Criteria**

1. Secondary prevention patients at high risk according to the AACVPR risk stratification criteria for cardiac patients (Table 5)

2. Presence of poorly-controlled metabolic factors (renal failure, poorly-controlled diabetes, other endocrinopathies). Refers to patients who have difficulty managing their medical condition, either due to advanced disease, lack of therapy compliance and/or the presence of co-morbid conditions that require close follow-up by their physician. Such conditions would have been discussed with the treating physician.

3. Scheduled revascularization procedures

4. Inability to provide informed consent

5. Unlikely to survive due to non-cardiac causes

6. Psychiatric diagnosis that would interfere with compliance (psychosis, severe addiction problems other than smoking, cognitive impairment, diagnosed depression and/or CES-D screening score ≥ 16)

7. Those coming to the CRP due to congenital heart disease with no IHD risk factors
Table 5: American Association of Cardiovascular and Pulmonary Risk Stratification Criteria.

<table>
<thead>
<tr>
<th>Low risk patients</th>
<th>Moderate risk patients</th>
<th>High risk patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No significant left ventricular dysfunction (ejection fraction of &gt; 50%)</td>
<td>• Moderate risk is assumed for patients who do not meet the classification for either low or high risk</td>
<td>• This category was excluded from the study</td>
</tr>
<tr>
<td>• No resting or exercise-induced complex arrhythmias (second degree AV block, third degree AV block, PVC strings, VT)</td>
<td>• Moderately impaired left ventricular function (ejection fraction = 40-49%)</td>
<td>• Decreased left ventricular function (ejection fraction of ≤ 40%)</td>
</tr>
<tr>
<td>• Uncomplicated MI; CABG; angioplasty; atherectomy; or stent (absence of CHF or signs/symptoms of post event ischemia)</td>
<td>• Signs or symptoms, including angina, at moderate levels of exercise (5-6.9 METs) or in recovery</td>
<td>• Low functional capacity (&lt; 5 METs)</td>
</tr>
<tr>
<td>• Normal hemodynamics with exercise or recovery</td>
<td>• High or low risk. Functional capacity of ≥ 7 METs</td>
<td>• Complex arrhythmias at rest, or complex ventricular dysrhythmias during exercise or recovery (second and third degree AV block, strings of PVC, VT)</td>
</tr>
<tr>
<td>• Asymptomatic, including absence of angina with exertion or recovery</td>
<td>• Absence of clinical depression</td>
<td>• History of cardiac arrest or complicated MI (cardiogenic shock, CHF)</td>
</tr>
</tbody>
</table>

4.4. Sample Size Calculation

Sample size was calculated using preliminary data on the primary outcome from 61 subjects. Based on these data, the mean improvement in total stress test time after completion of St. Paul's Hospital CRP was 126 ± 103 seconds. A non-inferiority power calculation (Study Size Software) was used, with a standard deviation of 103 seconds, a confidence interval (CI) of 0.95, power at 80%, alpha at 0.025 (to allow for two
comparisons of the primary outcome, at four and 16 months follow-up) and a clinically relevant difference of 60 seconds between the two groups. A difference of 60 seconds or more between groups is considered clinically relevant according to expert opinion, because 60 seconds on the treadmill is equivalent to a 1 MET improvement, and this has been associated with increased survival [110, 115]. As this is a non-inferiority trial, the primary hypothesis will be accepted if the average improvement in exercise treadmill test time of the rCRP cohort is no less than 60 seconds or better than the sCRP cohort time, with an upper bound CI of less than 60 seconds (non-inferiority margin) [140].

Using these parameters, sample size was calculated at 47 patients per group. Consistent with preliminary data, the anticipated dropout rate was 25% of the study population. Considering a 25% dropout, a total of 118 patients were needed for the trial.

4.5. Recruitment and Randomization

Recruitment and randomization took place in the CRP intake clinic at the HHP in St. Paul’s Hospital, which was held on a weekly basis. St. Paul’s Hospital is a tertiary care centre part of Providence Healthcare, and its CRP falls under the auspices of the Vancouver-wide HHP. As a tertiary acute care centre, revascularizations and other cardiovascular surgical procedures take place in St. Paul’s Hospital. The sCRP at the HHP in St. Paul’s Hospital receives automated in-hospital patient referrals after acute cardiac events or revascularization procedures, as well as receiving referrals through family physicians and/or cardiologists. Once referred, patients attend the intake clinic, which consists of an appointment with the CRP cardiologist, nurse, dietician and exercise specialist. Lifestyle and pharmacological management of their CVD risk factors based on current Canadian guidelines takes place when appropriate [56-58].

The study manager screened potential study participants prior to their intake by reviewing charts of patients attending the CRP intake clinic. Potential participants were identified according to inclusion/exclusion criteria, and eligible candidates were approached during the intake clinic. This included those with IHD risk factors (primary prevention) and those with documented IHD (secondary prevention) at low and moderate risk, as defined by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) (Table 5) [198]. High-risk patients were not asked to participate
in the study due to safety concerns. Those patients that initially consented to participate in the study were evaluated with the CES-D depression questionnaire prior to randomization (Appendix 4) [194], as the presence of depression was part of the exclusion criteria [195]. In order to minimize drop-outs, participants were advised that due to the randomization process, they would not know which group they would be assigned to prior to giving consent; therefore, if one or both groups of the study were unacceptable to them for any reason, they were advised not to participate. Eligible participants were asked to read and sign an informed consent (Appendix 5), approved by Providence Healthcare and the Simon Fraser University Research Ethics Committees. Eligible and consenting patients signed the informed consent prior to their randomization and baseline assessment. Following consent, participants were stratified by gender and randomized using a computer-generated block randomization (blocks of four, six and eight). Randomization by this procedure ensured that at the end of each block, an equal number of participants were assigned to each group. This block list was incorporated into a telephone randomization system, which had been previously developed by Dr. Joel Singer, Programme Head, CIHR Canadian HIV Trials Network, PhD, a third party who was blinded to the recruitment process. The study manager was given a unique authorization code to allow entry into the system. The date and time of the call, patient identifiers and randomization codes were automatically maintained in a transaction file. Due to the nature of the study, participants were not blinded to their group assignment. The CRP clinical staff was also notified of the randomization status for each recruited participant.

4.6. Baseline Assessment

Consenting participants underwent a baseline assessment by the study manager at the CRP intake clinic. The assessment consisted of recording participants’ medical history, including past medical history; history of present illness, including current cardiovascular symptoms; history of revascularization procedures (PTCA and CABG); and list of medications, including their dosage. This information was first reviewed from participants’ charts, then further corroborated with the patient at the time of assessment. Exercise capacity information was taken from the intake stress test in the chart, as were blood work values (lipid profile and fasting glucose). Systolic and diastolic BP and anthropometric measurements (weight, height, waist circumference, hip circumference,
BMI and waist to hip ratio calculations) were performed by the study manager. Smoking status was assessed by self-report. Other lifestyle and psychosocial variables were assessed through questionnaires which were thoroughly explained to participants who further filled them out during the assessment time (physical activity, depression, quality of life, health-related and exercise self-efficacy). In the rare occasion that the participant needed help to complete the questionnaires (ie: poor vision, poor understanding), the study manager read the questions in the questionnaires, and the participant answered them accordingly. There was no answer guidance or prompting on the part of the study manager. If participants did not have enough time to complete the questionnaires during the allotted assessment time, questionnaires were given to participants to take home and bring back to the study manager at their next visit.

4.7. Study Groups

4.7.1. Standard Cardiac Rehabilitation Program

The sCRP is a multidisciplinary and comprehensive four-month intervention in which the CRP clinical staff works with each participant to achieve positive lifestyle behaviours and risk factor management, following the Transtheoretical Model of Change [199, 200], Motivational Interviewing [201] and current Canadian guidelines [55-58]. The CRP clinical staff is composed by registered nurses, registered dieticians, American College of Sports Medicine certified exercise specialists and exercise leaders, occupational therapists, psychologists for stress management, and a team of three cardiologists. This program is currently in practice at St. Paul’s Hospital, and none of its interventions were changed for research purposes.

First contact with the sCRP participant occurred at the intake clinic where a baseline assessment and medical evaluation were performed by a registered nurse, registered dietician and a cardiologist. Lifestyle counselling and pharmacological management of lipids, blood glucose and BP, if appropriate, were performed based on current Canadian guidelines [55-58]. Dietary counselling was provided based on the Adult Treatment Panel III of the National Cholesterol Education Program [202]. Smoking cessation and detection of psychosocial problems were part of the initial assessment, and appropriate referrals were made if needed.
The participant was asked to perform an intake exercise stress test to evaluate his/her baseline exercise capacity. A medical-based exercise was prescribed by an exercise specialist, and target heart rate (THR) was determined according to a calculation of heart rate reserve (HRR) [198]. Generally, THR was prescribed at 50-70% of HRR, and further adjustments were made in class. Age, prior exercise capacity, prior level of activity and severity of disease were considered when prescribing exercise. The goal of treatment was to improve exercise capacity and to achieve and maintain an exercise program of moderate-intensity physical activity for at least 30 minutes most days of the week [49, 203]. As hospital-based exercise sessions were scheduled twice weekly, participants were encouraged to exercise outside of the hospital setting to achieve their treatment goals.

During the in-hospital exercise sessions, CRP clinical staff also held educational sessions and discussed the following weekly topics: 1) Basic heart overview, 2) IHD risk factors and atherosclerosis, 3) Nutrition, 4) Hypertension, 5) Angina, 6) Irregular heart beats, 7) Exercise (benefits and different exercise components), 8) Drug therapy, 9) Stress management, 10) Motivation for lifestyle changes. These topics were chosen by the CRP healthcare team in conjunction with feedback from participant surveys that addressed the utility and importance of educational sessions.

Throughout the program, patients received ongoing risk factor management, nutritional counselling, medical care by a cardiologist, psychological support and smoking cessation aid, if needed. Each in-hospital exercise session consisted of a warm-up (10-15 minutes), aerobic activity within the prescribed THR (30-45 minutes), resistance training (10-20 minutes) and a cool down (10-15 minutes). At program completion (week 17), participants were assessed by a cardiologist; an exit stress test and blood work were evaluated with the purpose to further achieve treatment targets and evaluate goal achievement during the program. The participant graduated and was encouraged to continue practicing the acquired lifestyle changes, as well as to continue with the pharmacological treatment prescribed by the cardiologist. The patient then returned to the usual care provided by their general practitioner.
4.7.2. Reduced Cardiac Rehabilitation Program

The intervention group took part in the rCRP; this program was designed to have the core elements of the sCRP [49], with the only difference being the total number of hospital-based exercise sessions it consists of (10 sessions for the rCRP vs. 32 sessions for the sCRP). The number of hospital-based sessions and their distribution during the four-month program was established in collaboration with CRP clinical staff and was the same for all rCRP participants. The program was based on patient safety and the sustainability of a comprehensive therapy, and was conducted simultaneously with sCRP sessions. Before randomization, patients underwent the same process at the CRP intake clinic (evaluation by a nurse, dietician, cardiologist and an exercise specialist). After randomization, those who were allotted to the rCRP group were informed of their group assignment and their hospital-based exercise schedules (Figure 1). The CRP staff was notified of participants’ in-site exercise schedule, and a copy of this schedule was placed in their charts.

Participants randomized to the rCRP group received a logbook and an educational package with weekly topics. The rCRP logbook contained a schedule of hospital-based exercise sessions and a section where the patient was able to record the following for each day of the next four months: 1) Type of exercise, 2) Intensity of exercise (maximum heart rate and perceived exertion of exercise), 3) Presence of symptoms (angina, shortness of breath, palpitations), 4) Medication compliance, 5) Diet compliance (Appendix 6). The logbook also had a section where participants could record questions and concerns to be addressed with the CRP staff during the following in-hospital session. The purpose of the logbook was to serve as a motivational tool, not as an outcome tool.

Since rCRP participants only attended 1/3 of the regular sCRP classes, they missed 2/3 of the spoken educational sessions. Written educational information was instead provided to this group in an educational package at time of randomization. This package was meant to serve as the educational component of the program, teaching participants about their condition, and cardiovascular health in general. It contained the same topics as were covered in the sCRP (previously described section IV. 7. 1.); each topic consisted of about three to five pages, written using language that was easy to understand. The educational package was also developed in collaboration with CRP.
clinical staff to assure the quality and quantity of the information provided. Since the format of this information might have had an impact on how much participants learned, an anonymous mini-quiz was answered by a sample of volunteer participants from each group at program completion (four month assessment). The quiz contained 16 questions, one for each of the 16 topics, and tested participants’ general knowledge about their disease (Appendix 7).

Patients randomized to the rCRP participated in the standard hospital exercise sessions as per their schedule, with exercise guidelines adjusted to their needs. The treatment goal did not differ from those randomized to the sCRP; it was to achieve a moderate-intensity level of physical activity for at least 30 minutes, most days of the week [49, 203]. Because in-hospital sessions were less frequent for the rCRP group, participants were highly encouraged to exercise outside of the hospital setting. The first two weeks were the same for both groups (a total of two in-hospital exercise sessions/week), and during this time, rCRP participants were able to learn exercise routines and were evaluated by the CRP staff. If, during this period, the CRP staff considered the patient more suitable for the sCRP for safety reasons, or if the patient decided he/she preferred being in the sCRP, the exit strategy was applied (explained subsequently). If they stayed in the rCRP, the schedule of these patients consisted of an in-hospital exercise session in each, week three, four, six, eight, 12 and 16 (Figure 1).

4.7.3. Exit Strategy

There were two reasons for exiting the rCRP: 1) patient safety and 2) patient choice. As the rCRP consisted of a lower number of in-hospital exercise sessions than the standard program, CRP clinical staff had the discretion to transfer patients from the rCRP to the sCRP only in cases where patient safety was at risk. A participant was considered at risk if he/she exhibited the appearance of new arrhythmias, such as strings of premature ventricular contractions; ventricular tachycardia; second or third degree AV block; a new diagnosis of atrial fibrillation; fast ventricular response with exercise; syncope or other acute coronary event during exercise; worsening angina; or other health concerns raised by the CRP clinical staff, the patient had to be re-evaluated by a cardiologist for a possible move to the sCRP in light of safety concerns. As part of the exit strategy, the patient could also make the choice be transferred to the sCRP.
4.7.4. Follow-up Assessments

All follow-up assessments were performed by the study manager at the HHP, St. Paul’s Hospital. The exit assessment was performed at four months (program completion), and the one-year follow-up was performed at 16 months from baseline. Every effort was made to obtain final data on the primary outcome from subjects, regardless of the extent of their participation to that point; lack of compliance to the sCRP or rCRP was not a reason for removal from the study.

Participants were contacted by the study manager either in-person at the CRP site (for the exit assessment) or through telephone calls. In case a participant was not contacted successfully through these means, the listed next of kin was contacted via telephone. A total of six to 10 telephone calls to the participant, completed at different times of the day throughout a 1-3 month period, were attempted before classifying them as lost-to-follow-up. A valid attempt of contact was considered as an answered phone call by the patient or a returned phone call from the patient after having left six messages on the answering machine.

Follow-up assessments did not differ from the previously-described baseline assessment. Participants were asked about cardiovascular symptoms and new cardiovascular events, including revascularization procedures. A list of medications and changes in medication type and dosage were recorded. An exit stress test and blood work were completed at program completion, and this information was gathered from participant charts by the study manager. Following four months of the program, all participants were graduated from the HHP and returned to usual care (this follows standard practice), which in most cases meant return to the care of their primary care provider. At one-year follow-up, participants were contacted again by the study manager and asked to come to the HHP for an assessment appointment, a stress test to re-measure exercise capacity and for blood work to measure their lipid profile and fasting glucose.

On six occasions, the study manager was not available for participant follow-ups, in which case another graduate student previously instructed by the study manager performed the assessment. However, the majority of assessments were performed by Alejandra Farias-Godoy, MD, MSc, who fulfilled the role of study manager and research coordinator throughout the study. Dr Farias-Godoy completed her MSc under Dr. Scott
A. Lear’s supervision in the HHP of St. Paul’s Hospital, and during this time, she gained experience in the CRP through observerships with different CRP clinical staff.
Figure 1: Diagram of study design
4.7.5. Data Quality

Study data were stored in Excel datasheets. Charts were placed in a secured storage area. Separate checklists created in Word 2007, which were continually updated, were used to remind the study manager of data that needed collection and participants to be contacted. An electronic calendar was used to schedule participant assessment appointments.

A total of 20 participant charts were randomly selected, and their data were matched with the information previously entered into the database. Extreme data scores as well as outliers were identified, double-checked and matched with the previous database to ensure data quality.

4.7.6. Statistical Analyses

Prior to analysis, group assignment identifiers within the dataset were removed by a third person so that data was blinded to the study manager and the statistician, both of whom performed the statistical analyses of this study. All variables were tested for normality pre-analysis using QQ plots. Non-normally distributed continuous variables were then log-transformed and reported as median and inter-quartile ranges. The presence of outliers was noted for further sensitivity analyses. The normality of residuals was also assessed before analyses. Variables whose residuals were not normally distributed were log transformed before analysis.

Differences between those lost-to-follow-up and those who remained in the study were explored with an independent sample t-test and Pearson chi-square test for continuous and categorical variables, respectively.

To test for the primary outcome, that is, for the difference in exercise capacity change (seconds on the treadmill) between the sCRP and rCRP groups at four and 16 months follow-up, a Mixed Model Analysis of Variance was performed. A fitted piecewise model was built based on the pattern of exercise capacity over time. In order to adjust for baseline time on the treadmill, the model considered exercise capacity change (time on the treadmill, in seconds) as the outcome variable (dependent variable) and baseline exercise capacity as a covariate (independent variable). The model was also fitted in a piecewise fashion to take two time periods into consideration, therefore allowing for
comparison of exercise capacity across three time points (baseline, exit and one-year follow-up). The first period was defined as zero to four months, and in this case, baseline exercise capacity was taken as the value at program start. The second period was defined as four to 16 months, in which case baseline exercise capacity was taken as that at four months. As there were two time periods, the term “period” was introduced in the model as a covariate and was set as an outcome variable.

To test for the secondary hypothesis, that is, for non-inferiority of secondary outcomes between the two groups (IHD risk factors), the same analyses were used as for the primary hypothesis. Non-inferiority cut-points for each variable were decided upon based on an updated literature review.

To conduct within-group comparisons of continuous variables such as exercise capacity and IHD risk factors, a two (group) by three (time) repeated measures ANOVA was performed. When appropriate, post hoc multiple comparisons were done using the Bonferonni correction. To test for within-group comparisons of categorical variables, McNemar tests with multiple testing corrections were performed.

The P value was set at 0.05 for all analyses. Analyses were governed by an intent-to-treat and per-protocol analysis [139, 204] to assess for non-inferiority of each outcome. Intent to treat analyzed patients as randomized, whereas per-protocol analyses excluded those that used the exit strategy. Imputation of missing data was not performed as the method of analysis allowed missing data [205, 206]. No Interim analyses were planned due to the reasonable safety of the population involved and the type of intervention. These analyses were performed by the study manager using SPSS version 17 and by the statistician, Julie Park, using SAS.
5. Results

5.1. Participants’ Logistics

Between May 2006 and May 2010, a total of 121 men and women who met the study inclusion criteria were recruited and randomized. A total of 2016 charts were screened for eligibility, of which approximately 61% (1163 patients) were non-eligible. Of those not eligible, approximately 38% (445 patients) had a history of or current CHF (either documented low ejection fraction, diastolic dysfunction, current history of CHF or remote history of CHF), 22% (256 patients) had low baseline exercise capacity (< 5 METS), and 15% (174 patients) had diagnosed depression and/or during further baseline evaluation, scored high (≥ 16 points) in the CES-D depression questionnaire. The remainder of ineligibility was attributed to other reasons, such as: cardiologist preference, chronic renal disease, inability to do a BRUCE protocol stress test, psychiatric disorders, poor english, etc. From a total of 853 eligible participants, 732 did not participate in the study; of these, approximately 65% (476 patients) refused to participate, 15% (105 patients) were approached and consented but did not show up to the first class and were therefore not randomized, 7.5% (55 patients) did not give a reason for non-participation and 5% (96 patients) were not approached due to patients’ lack of time for an appointment or missed appointments with unsuccessful subsequent contact attempts. Of the 476 patients who refused to participate, the main reasons given were: 1) A preference to be in the standard program (274 patients total, approximately 60% of those who refused) due to anxiety about exercising, a perceived “lack of self-discipline” and/or the need for group support and 2) A preference to be in the reduced program (182 patients total, approximately 40% of those who refused) due to time constraints, geographical barriers and/or a perceived feeling of good health and therefore of “not needing to come as much”. A small portion refused for other reasons, including the preference to not participate in research and a lack of commitment to follow-ups.

Of the 121 participants taking part in the study, 60 were randomized to the sCRP program and 61 to the rCRP. A total of four participants that were randomized to the
rCRP used the exit strategy and switched to the sCRP. The reasons for using the exit strategy were the following: 1) symptomatic new-onset atrial fibrillation, 2) perceived insufficient self-efficacy to carry through with the rCRP, 3) chronic fatigue and medical advice to switch to the sCRP, 4) anxiety due to atypical chest pain. A total of 57 participants randomized to the rCRP therefore received the intended intervention.

A total of three participants from both groups underwent revascularization procedures shortly after randomization. After undergoing the revascularization procedures, these patients came back to the CRP intake clinic for a baseline evaluation and repeat stress test, and completed a repeat baseline assessment with the study manager. As they had already been randomized, they maintained their randomized status, started the program, and were therefore included in analyses. Another two participants had revascularization procedures during the program, and these were not included in the analyses. A total of 119 participants were therefore analyzed for study outcomes (intent to treat).

Six CRP exit assessments could not be completed at the four-month follow-up, of whom three had been randomized to the rCRP. These participants received six to 10 phone calls and were left several telephone messages at different times of day, but they did not return the calls. One next of kin was contacted successfully, informing the study manager that the participant was out of the country. Another rCRP participant informed the study manager he wanted to withdraw from the study due to an uncomfortable experience in the program, and asked not to be followed.

Another seven participants, of whom two had been randomized to the rCRP, successfully completed the exit assessment but did not perform a four-month stress test. While two of them had mechanical problems (back pain and knee pain), two did not show up for three consecutive stress test appointments, and another three participants refused the stress test for non-medical reasons. One such participant expressed concerns over not being fit enough, and refused even after being assured that data was kept confidential. Another participant informed the study manager that his state of health was “good enough”, and he therefore refused the stress test despite being aware of its importance. Lastly, one participant left a written message expressing his refusal of going through another stress test. Including lost to follow-up participants, a total of 14 participants therefore did not complete an exit stress test.
A total of 12 participants, 7 of whom had been randomized to the rCRP, were lost to follow-up at 16 months (one year after CRP completion). Six of them had also been lost to follow-up at their four-month assessment. These participants did not reply to any of the six to 10 telephone call attempts that were made or messages that were left at different times of day. Two participants were said by next-of-kin contacts to be out of the country. Another five participants withdrew from the study at follow-up; four of them informed the study manager that they were not going to participate in the assessment due to personal difficulties, i.e., grief. One of them had already asked not to be followed due to an unpleasant experience in the program.

Another four participants, two of whom had been randomized to the rCRP, completed the 16-month follow-up assessment with the study manager; however, they did not perform a 16-month stress test due to the following reasons: 1) Two participants failed to show up for the stress test on three different occasions, 2) One participant had mechanical problems (back pain), 3) One participant felt that he did not need a stress test due to health improvements in the last year, and refused one even after the importance of performing the test was thoroughly explained to him. There were no reported deaths throughout the duration of the study.

Only those participants who had complete data (baseline, four- and 16-month follow-up) for a specific outcome were included in the statistical analyses. With respect to exercise capacity change (primary outcome), a total of 47 participants in each group had complete stress test data at baseline, four- and 16-month follow-up.

Figure 2 shows a flow diagram detailing the study progress from participant screening to data analysis; all procedures were carried out in accordance with Consort Guidelines [142]. Figure 3 outlines study sample numbers, starting with the total number randomized, to the final number of participants analyzed within each group.
Reduced Cardiac Rehabilitation Program

Figure 2: Flow diagram of study progress through different phases of enrollment, allocation, follow-up and analysis.
Figure 3: Flow diagram showing participant numbers, from randomization to analysis
5.2. Baseline Comparisons

Tables 6 through 9 outline the baseline characteristics of the sCRP and rCRP groups, and show that demographic characteristics, exercise capacity, IHD risk factors, lifestyle and psychosocial variables were similar between the two groups.

**Table 6: Baseline comparison of participant demographics between sCRP and rCRP groups (means with SD and totals with percentages)**

<table>
<thead>
<tr>
<th></th>
<th>sCRP (n= 60)</th>
<th>rCRP (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>48 (80%)</td>
<td>50 (82%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>60.6 ± 10.7</td>
<td>61.6 ± 10.5</td>
</tr>
<tr>
<td>Primary prevention</td>
<td>14 (23%)</td>
<td>19 (31%)</td>
</tr>
<tr>
<td>Family History of IHD</td>
<td>30 (50%)</td>
<td>26 (43%)</td>
</tr>
<tr>
<td>IHD presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td>17 (28%)</td>
<td>19 (31%)</td>
</tr>
<tr>
<td>CABG</td>
<td>20 (33%)</td>
<td>18 (30%)</td>
</tr>
<tr>
<td>PTCA</td>
<td>24 (40%)</td>
<td>28 (46%)</td>
</tr>
<tr>
<td>Hx of Angina</td>
<td>40 (67%)</td>
<td>42 (69%)</td>
</tr>
<tr>
<td>Hx of Angiogram</td>
<td>51 (85%)</td>
<td>53 (87%)</td>
</tr>
<tr>
<td>Presence of Diabetes</td>
<td>7 (12%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Post-menopausal</td>
<td>11/12 (92%)</td>
<td>10/11 (90%)</td>
</tr>
</tbody>
</table>

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group, IHD = Ischemic heart disease, MI = Myocardial infarction, CABG = Coronary artery bypass graft, PTCA = Percutaneous transluminal coronary angiography
### Table 7: Baseline comparison of exercise capacity and metabolic risk factors between sCRP and rCRP groups (means with SD medians with inter-quartile range)

<table>
<thead>
<tr>
<th></th>
<th>sCRP (n=60)</th>
<th>rCRP (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Exercise Capacity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time on treadmill</td>
<td>532 ± 162</td>
<td>544 ± 182</td>
</tr>
<tr>
<td>(in seconds)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Exercise Capacity</strong></td>
<td>9.1 ± 2.1</td>
<td>9.2 ± 2.3</td>
</tr>
<tr>
<td>(METS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TC (mmol/L)</strong></td>
<td>4.14 ± 1.07</td>
<td>4.16 ± 1.17</td>
</tr>
<tr>
<td><strong>LDL-C (mmol/L)</strong></td>
<td>2.28 ± 0.89</td>
<td>2.25 ± 0.86</td>
</tr>
<tr>
<td><strong>HDL-C (mmol/L)</strong></td>
<td>1.19 ± 0.30</td>
<td>1.27 ± 0.32</td>
</tr>
<tr>
<td><strong>Triglycerides</strong></td>
<td>1.24 (0.93-1.90)</td>
<td>1.38 (0.94-1.65)</td>
</tr>
<tr>
<td>(mmol/L) †</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TC/HDL-C</strong></td>
<td>3.59 ± 1.00</td>
<td>3.41 ± 1.03</td>
</tr>
<tr>
<td><strong>Fasting glucose</strong></td>
<td>5.6 (5.3-6.2)</td>
<td>5.5 (5.1-6.1)</td>
</tr>
<tr>
<td>(mmol/L) †</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BP (mmHg)</strong></td>
<td>118/69 ± 16/10</td>
<td>120/72 ± 16/10</td>
</tr>
</tbody>
</table>

† = Log-transformed variables, sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group, METS = Metabolic equivalents, TC = Total cholesterol, LDL-C = Low-density lipoprotein cholesterol, HDL-C = High-density lipoprotein cholesterol, BP = Blood pressure

### Table 8: Baseline comparison of anthropometric measurements, lifestyle and psychosocial variables between sCRP and rCRP groups (means with SD, totals with percentages and medians with inter-quartile ranges)

<table>
<thead>
<tr>
<th></th>
<th>sCRP (n=60)</th>
<th>rCRP (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td>28.1 ± 3.7</td>
<td>28.4 ± 4.6</td>
</tr>
<tr>
<td><strong>Waist circumference</strong></td>
<td>97.4 ± 11.0</td>
<td>98.2 ± 12.8</td>
</tr>
<tr>
<td>(cm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Waist to hip ratio</strong></td>
<td>0.92 ± 0.07</td>
<td>0.92 ± 0.08</td>
</tr>
<tr>
<td>(cm)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Smoking status
Never Smokers 51 (85%) 56 (92%)
Ex Smokers 2 (3%) 2 (3%)
Current Smokers 7 (12%) 3 (5%)

LTPA (kcal/week) † 1700 (900-2685) 1464 (806-3423)

Quality of life
EQ-5D 5.9 ± 0.9 5.8 ± 1.1
EQ-VAS 71.3 ± 13.6 73.2 ± 13.9

Self-efficacy
Health-related 42.2 ± 4.4 42.4 ± 4.0
Exercise-related 67.9 ± 10.1 69.5 ± 10.5

CES-Depression score 5.3 ± 4.1 5.2 ± 4.2

† = Log transformed variables, sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group, BMI = Body mass index, LTPA = Leisure time physical activity, EQ-5D = European Quality of Life-5 Dimensions, EQ-VAS = European Quality of Life Visual Analogue Scale, CES-D = Center for Epidemiologic Studies Depression Scale

**Table 9: Baseline comparison of global risk scores between sCRP and rCRP groups (means with SD)**

<table>
<thead>
<tr>
<th></th>
<th>sCRP (n=60)</th>
<th>rCRP (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Framingham Risk Score</td>
<td>12.9 ± 5.1</td>
<td>12.8 ± 4.3</td>
</tr>
<tr>
<td>sCRP (n=45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progression of disease risk score</td>
<td>8.2 ± 2.4</td>
<td>7.6 ± 1.8</td>
</tr>
<tr>
<td>rCRP (n=42)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group, Framingham Risk Score = Calculated for primary and secondary prevention participants, Progression of disease risk score = Calculated for secondary prevention participants

Table 10 shows the proportion of participants in each group taking cardiac- and diabetes-related medications at baseline; these proportions are shown to be similar between the two groups.
Table 10: Comparison of the promotion of participants in sCRP and rCRP groups taking cardiac- and diabetes-related medications at baseline. (Totals and Percentages)

<table>
<thead>
<tr>
<th></th>
<th>sCRP (n=60)</th>
<th>rCRP (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statins</td>
<td>49 (82%)</td>
<td>48 (79%)</td>
</tr>
<tr>
<td>Lipid-lowering medications</td>
<td>50 (83%)</td>
<td>48 (79%)</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>39 (65%)</td>
<td>45 (74%)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>8 (13%)</td>
<td>10 (16%)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>8 (13%)</td>
<td>15 (25%)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>30 (50%)</td>
<td>31 (51%)</td>
</tr>
<tr>
<td>Angiotensin receptor blockers</td>
<td>7 (12%)</td>
<td>6 (10%)</td>
</tr>
<tr>
<td>Diabetes-related medications</td>
<td>5 (8%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Nitrates</td>
<td>5 (8%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>51 (85%)</td>
<td>50 (82%)</td>
</tr>
</tbody>
</table>

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group,
ACE = Angiotensin converting enzyme
Diabetes-related medications = Hypoglycemic medications
Lipid-lowering medications = Statins, fibrates, niacin

A total of six participants, three of which had been randomized to the rCRP group, were lost to follow-up at the four-month assessment. Those that were lost to follow-up at four months (program completion) were significantly younger (52.7 ± 9.4 vs 61.6 ± 10.5 years, p < 0.05), had a significantly higher baseline BMI (34.8 ± 5.9 vs 27.8 ± 3.7, p < 0.01), higher baseline waist circumference (117.0 ± 11.7 vs 96.8 ± 11.0 cm, p < 0.01) and higher baseline waist to hip ratio (1.00 ± 0.09 vs 0.92 ± 0.07 cm, p < 0.05) than those who remained in the study.
A total of 12 participants, seven of which had been randomized to the rCRP group, were lost to follow-up at 16 months (one year after program completion). This portion of participants had a significantly higher baseline BMI (30.1 ± 6.2 vs 27.9 ± 3.8, p < 0.05), higher waist circumference (106.6 ± 16.4 vs 96.8 ± 10.9 cm, p< 0.05) and a higher waist to hip ratio (0.96 ± 0.07 vs 0.96 ± 0.08 cm, 0< 0.05) than those who remained in the study. Other baseline variables were not significantly different.

There was no difference in the mean follow-up period between the rCRP and sCRP groups between baseline and exit assessments (4.9 ± 1.2 vs 5.2 ± 0.9 months, p=0.173, respectively). There was also no difference in the mean follow-up period between the rCRP and sCRP groups between baseline and one-year follow-up assessments (16.8 ± 2.3 vs 17.6 ± 1.8 months, p=0.100).

5.3. Results for the Primary Outcomes

To test for differences between the rCRP and sCRP groups in regards to change in exercise capacity (seconds on the treadmill) at the four and 16-month follow-up, a Mixed Model Analysis of Variance was performed. A fitted piecewise model was built based on the pattern of exercise capacity over time, as shown in Figure 4. The difference between two periods (first period = zero to four months; second period = four to 16 months) was set as an outcome variable. Since randomization was based on sex and there was no significant difference in age between the rCRP and sCRP groups at baseline, the model was not adjusted for age or sex. Since group-by-time interaction was not significant, it was not included in the model.

Model

1. Time on the treadmill (4 months) = B0 + baseline time on the treadmill + baseline time on the treadmill x first period + group assignment

2. Time on the treadmill (16 months) = B0 + baseline time on the treadmill (4 months) + baseline time on the treadmill (4 months) x second period+ group assignment
Reduced Cardiac Rehabilitation Program

A.

B.

Figure 4: sCRP and rCRP mean time on the treadmill across time. A: Intent to treat, B: Per protocol analysis. First period = 0-4 months; Second period = 4-16 months.
Table 11 shows the results based on the intent-to-treat and per-protocol analyses respectively. An outlier was identified and was included in the model since sensitivity analyses showed that it did not alter the results.

As shown by the per-protocol analysis, baseline time on the treadmill had a significant impact such that for every one-second increase in baseline time on the treadmill, there was a 0.87 second increase in time on the treadmill at four months. For every one-second increase in time on the treadmill at four months, there was a one-second increase at 16 months \((0.16 + 0.87)\). The difference in time on the treadmill between the second period (4-16 months) relative to the first period (0-4 months) was a decrease of 37 seconds \((171.55 - 208.71)\). There was no significant difference between the groups in regards to the change in exercise capacity for the two time periods \((p=0.6171)\), as was shown by the lack of significance in the group estimate and group-by-period interaction. Since the upper value of one-sided 97.5% CI (or two-sided 95% CI) for the group estimate was 26 seconds (lower than the 60-second cut-point), the rCRP is non-inferior to the sCRP. Based on the intent-to-treat analysis, as there was no significant difference between the groups in regards to exercise capacity change across time, and there was a non-significant group-by-period interaction, the rCRP is not superior to the sCRP.

**Table 11: Mixed Models analysis for exercise capacity change across two time periods (baseline to four months and four to 16 months) for the rCRP and sCRP groups. Intentions-to-treat and per-protocol analyses given.**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Intent to treat</th>
<th>Per protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B coefficient</td>
<td>Standard Error</td>
</tr>
<tr>
<td>Intercept</td>
<td>174.74</td>
<td>27.04</td>
</tr>
<tr>
<td>Baseline TTT</td>
<td>0.86</td>
<td>0.05</td>
</tr>
<tr>
<td>Period</td>
<td>-208.02</td>
<td>45.98</td>
</tr>
<tr>
<td>Baseline TTT x Period</td>
<td>0.16</td>
<td>0.07</td>
</tr>
<tr>
<td>Group</td>
<td>0.85</td>
<td>10.42</td>
</tr>
<tr>
<td></td>
<td>95% CI:</td>
<td>(-19.82-21.52)</td>
</tr>
</tbody>
</table>

Reference group for the categorical variables: First period (0-4 months) and rCRP  

TTT = Time on the treadmill
5.4. Results for Secondary Outcomes

To test for differences in IHD risk factor changes across two time periods between the rCRP and sCRP groups, a Mixed Model Analysis of Variance was performed. A fitted piecewise model was built and the difference between the two time periods (first period = zero to four months; second period = four to 16 months) was set as an outcome variable. Since randomization was based on sex and there was no significant difference in age between the rCRP and sCRP groups at baseline, the model was not adjusted for age or sex. Since the group-by-time interaction was found to be non-significant, it was not included in the model. All secondary outcomes were tested for non-inferiority using the same model.

Model

1. Secondary Outcome (4 months) = B0 + baseline secondary outcome + baseline secondary outcome x first period + group assignment + group-by-time interaction
2. Secondary Outcome (16 months) = B0 + baseline secondary outcome (4 months) + baseline secondary outcome (4 months) x second period + group assignment + group-by-time interaction

A total of 12 secondary outcomes were tested for non-inferiority comparisons. Table 12 shows the group estimates with the CI for each outcome. Intent-to-treat and per-protocol analyses were performed to test for non-inferiority and superiority, respectively, of the rCRP compared to the sCRP. Log transformations of TC, LDL-C and LTPA were necessary to fit the linear mixed model. Data, however, was presented as raw data (i.e., was converted back).

A comparison of secondary outcomes showed that the rCRP group was non-inferior compared to the sCRP group in regards to the change over time for the following IHD risk factors: HDL-C, triglycerides, TC/HDL ratio, fasting blood glucose, systolic and diastolic BP, BMI, waist circumference, waist to hip ratio and physical activity (LTPA score). Because the upper bound of the confidence intervals for TC and LDL-C were slightly higher than their specific cut-points, non-inferiority between rCRP and sCRP groups was not shown for these two risk factors. The intent-to-treat analysis also did not show superiority of either group.
The only risk factor that had a significant group-by-period interaction was HDL-C ($p=0.0108$), and group differences were therefore assessed separately in each period for this factor. For the first period, there was a non-significant group difference of $-0.05$ mmol/l, 95% CI $-0.12$ to $0.02$. For the second period, there was a non-significant group difference of $0.11$ (group estimate + group-by-period estimate), 95% CI $0.03$ to $0.19$. Since the upper bound of both CIs was less than the specific cut-point to test for non-inferiority ($0.33$ mmol/l), the rCRP was shown to be non-inferior to the sCRP for HDL-C.
Table 12: Change of IHD risk factors across two time periods, compared between rCRP and sCRP groups. Mixed model Analysis of Variance, per-protocol and intent -to-treat analyses were used.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Per Protocol</th>
<th>Intention to Treat</th>
<th>Cut-point value to test for non-inferiority</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B coefficient of group estimate</td>
<td>95% CI</td>
<td>P-value</td>
</tr>
<tr>
<td>TC (mmol/l)</td>
<td>0.98</td>
<td>0.95-1.01</td>
<td>0.1935</td>
</tr>
<tr>
<td>LDL-C (mmol/l)</td>
<td>0.99</td>
<td>0.94-1.04</td>
<td>0.5962</td>
</tr>
<tr>
<td>HDL-C (mmol/l)</td>
<td>-0.05</td>
<td>-0.12-0.02</td>
<td>0.1891</td>
</tr>
<tr>
<td>Group difference in First Period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HDL-C (mmol/l)</td>
<td>0.11</td>
<td>0.03-0.19</td>
<td>0.1891</td>
</tr>
<tr>
<td>Group difference in Second Period</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triglycerides mmol/l</td>
<td>-0.03</td>
<td>-0.12-0.07</td>
<td>0.5479</td>
</tr>
<tr>
<td>TC/HDL-C</td>
<td>-0.05</td>
<td>-0.17-0.08</td>
<td>0.0573</td>
</tr>
<tr>
<td>Fasting glucose (mmol/l)</td>
<td>-0.02</td>
<td>-0.14-0.12</td>
<td>0.7858</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>-1.09</td>
<td>-4.06-1.87</td>
<td>0.4670</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>-0.005</td>
<td>-1.996-1.987</td>
<td>0.9963</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>0.07</td>
<td>-0.16-0.29</td>
<td>0.5669</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>0.16</td>
<td>-0.76-1.09</td>
<td>0.7247</td>
</tr>
<tr>
<td>Waist to hip ratio (cm)</td>
<td>0.003</td>
<td>-0.005-0.011</td>
<td>0.4771</td>
</tr>
<tr>
<td>LTPA (kcal/week)</td>
<td>0.99</td>
<td>0.83-1.18</td>
<td>0.9122</td>
</tr>
</tbody>
</table>

Reference for the categorical variables: First period (0-4 months) and sCRP.
Reference for HDL-C was rCRP group. TC = Total cholesterol, LDL-C = Low-density lipoprotein cholesterol, HDL-C = High-density lipoprotein cholesterol, BP = Blood pressure, BMI = Body mass index, LTPA = Leisure-time physical activity.
5.5. Exercise capacity and IHD risk factors change within the sCRP and rCRP groups

Using intent-to-treat and per-protocol analyses respectively, tables 13 and 14 show exercise capacity and IHD risk factor changes within each group across time (at baseline, four and 16 months). The between-groups comparison testing for non-inferiority is shown in the last column.

Both groups had a significant improvement in exercise capacity at program completion, with a significant decline in exercise capacity for the sCRP group at 16-months follow-up. Both groups had a significant improvement or a non-significant trend of improvement for physical activity and most IHD risk factors at CRP completion compared to baseline, with further deterioration of these variables at 16-months follow-up. Fasting blood glucose, BP and anthropometric measurements did not have a significant change across time for either group.

The rCRP was non-inferior compared to the sCRP group in regards to exercise capacity change, physical activity and most IHD risk factors change at program completion and 16-months follow-up. Non-inferiority was not demonstrated for TC and LDL-C. Superiority was not shown for either group.
Table 13: Exercise capacity and IHD risk factor changes at four to 16 month follow-up for both sCRP and rCRP groups (means with SD and medians with inter-quartiles ranges). The last column shows the results for the non-inferiority testing between groups. Intent-to-treat analysis was used.

<table>
<thead>
<tr>
<th>Variables</th>
<th>sCRP</th>
<th>rCRP</th>
<th>Non-inferiority results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (n=52) Four Months (n=52) 16 Months (n=52) Multiple comparison</td>
<td>Baseline (n=50) Four Months (n=50) 16 Months (n=50) Multiple comparison</td>
<td>NS NI</td>
</tr>
<tr>
<td>Exercise capacity (seconds)</td>
<td>524 ± 168 630 ± 150 604 ± 172</td>
<td>565 ± 183 655 ± 196 640 ± 192</td>
<td>B≠4* B≠16* 4≠16</td>
</tr>
<tr>
<td>Exercise Capacity (METS)</td>
<td>8.9 ± 2.1 10.1 ± 1.8 9.8 ± 2.0</td>
<td>9.5 ± 2.3 10.6 ± 2.5 10.4 ± 2.4</td>
<td>B≠4* B≠16* NI</td>
</tr>
<tr>
<td>TC (mmol/l)</td>
<td>4.13 ± 1.11 3.91 ± 0.84 4.30 ± 1.07</td>
<td>4≠16*</td>
<td>1.03 NS</td>
</tr>
<tr>
<td>LDL-C (mmol/l)</td>
<td>2.24 ± 0.88 2.13 ± 0.67 2.33 ± 0.89</td>
<td>NS</td>
<td>2.23 ± 0.75 2.09 ± 0.67 2.27 ± 0.79 NS</td>
</tr>
<tr>
<td>HDL-C (mmol/l)</td>
<td>1.20 ± 0.32 1.22 ± 0.29 1.32 ± 0.33</td>
<td>1.27 ± 0.33 1.36 ± 0.36 1.35 ± 0.35</td>
<td>B≠4* B≠16* NI</td>
</tr>
<tr>
<td>Triglycerides (mmol/l) †</td>
<td>1.25 (0.93-1.91) 1.10 (0.86-1.50) 1.38 (0.89-1.76)</td>
<td>B≠4* 4≠16*</td>
<td>1.25 (0.94-1.63) 1.22 (0.81-1.42) 1.11 (0.91-1.47) NS NI</td>
</tr>
<tr>
<td>TC/HDL-C</td>
<td>3.56 ± 0.99 3.28 ± 0.67 3.34 ± 0.80</td>
<td>B≠4i</td>
<td>3.36 ± 0.88 3.08 ± 0.84 3.21 ± 0.74 NS NI</td>
</tr>
<tr>
<td>Fasting glucose (mmol/l) †</td>
<td>5.6 (5.3-6.4) 5.7 (5.1-6.2) 5.8 (5.4-6.2)</td>
<td>NS</td>
<td>5.5 (5.1-6.3) 5.7 (5.2-6.1) 5.8 (5.4-6.2) NS NI</td>
</tr>
<tr>
<td></td>
<td>Systolic BP (mmHg)</td>
<td>Diastolic BP (mmHg)</td>
<td>BMI (kg/m²)</td>
</tr>
<tr>
<td>-------------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td>-------------</td>
</tr>
<tr>
<td></td>
<td>118 ± 16</td>
<td>119 ± 14</td>
<td>121 ± 15</td>
</tr>
<tr>
<td></td>
<td>120 ± 15</td>
<td>117 ± 14</td>
<td>120 ± 17</td>
</tr>
<tr>
<td></td>
<td>69 ± 10</td>
<td>70 ± 10</td>
<td>68 ± 10</td>
</tr>
<tr>
<td></td>
<td>71 ± 10</td>
<td>69 ± 9</td>
<td>69 ± 10</td>
</tr>
<tr>
<td></td>
<td>69 ± 10</td>
<td>70 ± 10</td>
<td>68 ± 10</td>
</tr>
<tr>
<td></td>
<td>69 ± 10</td>
<td>70 ± 10</td>
<td>68 ± 10</td>
</tr>
</tbody>
</table>

Reference for the categorical variables: First period and sCRP. Reference for HDL-C: rCRP group.

Multiple comparisons: B = Baseline, 4 = Four-month assessment, 16 = Sixteen-month assessment, NS = Non-significant comparison

† = Log transformed variables, NI = rCRP is non-inferior to sCRP

TC = Total cholesterol, LDL-C = Low-density lipoprotein cholesterol, HDL-C = High-density lipoprotein cholesterol,

BP = Blood pressure, BMI = Body mass index, LTPA = Leisure-time physical activity.
Table 14: Exercise capacity and IHD risk factor change at four and 16 months follow-up within the rCRP and sCRP groups (means with SD and median with inter-quartile ranges). The last column shows the results of the non-inferiority testing. Per-protocol analysis was used.

<table>
<thead>
<tr>
<th>Variables</th>
<th>sCRP Baseline (n=52)</th>
<th>Four Months (n=52)</th>
<th>16 Months (n=52)</th>
<th>Multiple comparison</th>
<th>rCRP Baseline (n=46)</th>
<th>Four Months (n=46)</th>
<th>16 Months (n=46)</th>
<th>Multiple comparison</th>
<th>Non-inferiority results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exercise capacity (seconds)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>524 ± 168</td>
<td>630 ± 150</td>
<td>604 ± 172</td>
<td>B&lt;4*, B&lt;16*, 4&lt;16I</td>
<td>574 ± 176</td>
<td>663 ± 189</td>
<td>644 ± 189</td>
<td></td>
<td>NI</td>
</tr>
<tr>
<td>Exercise capacity (METS)</td>
<td>8.9 ± 2.1</td>
<td>10.1 ± 1.9</td>
<td>9.9 ± 2.1</td>
<td>B&lt;4*, B&lt;16*</td>
<td>9.6 ± 2.2</td>
<td>10.6 ± 2.4</td>
<td>10.4 ± 2.4</td>
<td>B&lt;4*, B&lt;16*</td>
<td>NI</td>
</tr>
<tr>
<td>TC (mmol/l)</td>
<td>4.13±1.11</td>
<td>3.9 ± 0.84</td>
<td>4.29 ± 1.07</td>
<td>4&lt;16*</td>
<td>4.12 ± 1.02</td>
<td>4.01 ± 0.78</td>
<td>4.22 ± 0.95</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>LDL-C (mmol/l)</td>
<td>2.24 ± 0.88</td>
<td>2.13 ± 0.67</td>
<td>2.33 ± 0.89</td>
<td>NS</td>
<td>2.22 ± 0.74</td>
<td>2.12 ± 0.67</td>
<td>2.30 ± 0.80</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>HDL-C (mmol/l)</td>
<td>1.20 ± 0.32</td>
<td>1.22 ± 0.29</td>
<td>1.32 ± 0.33</td>
<td>B&lt;16*, 4&lt;16I</td>
<td>1.25 ± 0.33</td>
<td>1.34 ± 0.36</td>
<td>1.32 ± 0.34</td>
<td>B&lt;4*</td>
<td>NI</td>
</tr>
<tr>
<td>Triglycerides mmol/l †</td>
<td>1.25 (0.93-1.91)</td>
<td>1.10 (0.86-1.50)</td>
<td>1.38 (0.89-1.76)</td>
<td>B&lt;4*, 4&lt;16I</td>
<td>1.41 (0.94-1.65)</td>
<td>1.22 (0.65-1.42)</td>
<td>1.11 (0.96-1.48)</td>
<td>B&lt;4*</td>
<td>NI</td>
</tr>
<tr>
<td>TC/HDL-C</td>
<td>3.56 ± 0.99</td>
<td>3.28 ± 0.67</td>
<td>3.34 ± 0.80</td>
<td>B&lt;4i</td>
<td>3.41 ± 0.89</td>
<td>3.15 ± 0.83</td>
<td>3.29 ± 0.73</td>
<td>NS</td>
<td>NI</td>
</tr>
<tr>
<td>Fasting glucose mmol/l †</td>
<td>5.6 (5.3-6.4)</td>
<td>5.7 (5.1-6.2)</td>
<td>5.8 (5.4-6.2)</td>
<td>NS</td>
<td>5.5 (5.2-6.1)</td>
<td>5.7 (5.2-6.1)</td>
<td>5.8 (5.2-6.2)</td>
<td>NS</td>
<td>NI</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>118 ± 17</td>
<td>119 ± 14</td>
<td>121 ± 15</td>
<td>NS</td>
<td>119 ± 145</td>
<td>117 ± 14</td>
<td>119 ± 19</td>
<td>NS</td>
<td>NI</td>
</tr>
<tr>
<td></td>
<td>BMI (kg/m²)</td>
<td></td>
<td>Waist circumference (cm)</td>
<td></td>
<td>Waist to hip ratio</td>
<td></td>
<td>LTPA (kcal/week)†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------</td>
<td>----------------------</td>
<td>--------------------------</td>
<td>----------------------</td>
<td>-------------------</td>
<td>----------------------</td>
<td>------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>28.1 ± 3.7</td>
<td>27.9 ± 3.7</td>
<td>28.1 ± 4.2</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>1590 (653-2905)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>28.1 ± 10.9</td>
<td>28.1 ± 12.5</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>2180 (1181-3542)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2115 ± 2117</td>
<td>2115 ± 2117</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>2115 (1326-4288)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2115 ± 2117</td>
<td>2115 ± 2117</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>1493 (803-3885)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2115 ± 2117</td>
<td>2115 ± 2117</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>2115 (1227-3166)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1928 ± 1928</td>
<td>1928 ± 1928</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>1928 (1348-4790)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2115 ± 2117</td>
<td>2115 ± 2117</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>2115 (1326-4288)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2115 ± 2117</td>
<td>2115 ± 2117</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>1493 (803-3885)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2115 ± 2117</td>
<td>2115 ± 2117</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>2115 (1227-3166)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1928 ± 1928</td>
<td>1928 ± 1928</td>
<td>96.8 ± 10.9</td>
<td>NS</td>
<td>0.91 ± 0.07</td>
<td>0.92 ± 0.07</td>
<td>1928 (1348-4790)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* <0.01, † < 0.05. Repeated measures ANOVA.

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group.
Reference for the categorical variables: First period and sCRP. Reference for HDL-C: rCRP group.
Multiple comparisons: B = Baseline, 4 = Four-month assessment, 16 = Sixteen-month assessment.
NS = Non-significant comparison
† = Log transformed variables, NI = rCRP is non-inferior to sCRP.
TC = Total cholesterol, LDL-C = Low-density lipoprotein cholesterol, HDL-C = High-density lipoprotein cholesterol, BP = Blood pressure, BMI = Body mass index, LTPA = Leisure-time physical activity.
5.6. Behavioural, psychosocial and global risk scores factors change within the sCRP and rCRP groups

Table 15 below shows behavioural, psychosocial and global risk score changes within each group across time (with an intent-to-treat analysis). The number of current smokers was dismal, and there was no significant change in the proportion of current smokers across time. The European Quality of Life Visual Analogue Scale score increased for the rCRP group at four-months follow-up and increased for both groups at 16-months follow-up. At 16-months follow-up, exercise self-efficacy declined for the rCRP group. Both groups had an increase in the CES-D depression score at 16-month follow-up. The Progression of Disease risk score decreased significantly at program completion and at 16-months follow-up for the rCRP and sCRP group respectively. A per-protocol analysis showed the same findings.
Table 15: Behavioural, psychosocial and global risk scores change at four –and- 16- months follow-up with the rCRP and sCRP groups (means with SD and counts with percentages). Intent-to-treat analyses was used.

<table>
<thead>
<tr>
<th>Variables</th>
<th>sCRP</th>
<th>rCRP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (n=52)</td>
<td>Four Months (n=52)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non smoker</td>
<td>44 (85%)</td>
<td>43 (83%)</td>
</tr>
<tr>
<td>Ex-smoker</td>
<td>1 (2%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>7 (13%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EQ-5D</td>
<td>5.8 ± 0.9</td>
<td>5.9 ± 1.1</td>
</tr>
<tr>
<td>EQ-VAS</td>
<td>71.6 ± 14.6</td>
<td>74.7 ± 14.7</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health-related</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise-related</td>
<td>42.4 ± 4.6</td>
<td>42.1 ± 4.3</td>
</tr>
<tr>
<td>CES-Depression</td>
<td>68.5 ± 10.5</td>
<td>66.8 ± 11.5</td>
</tr>
<tr>
<td>Framingham risk score</td>
<td>5.4 ± 3.9</td>
<td>7.2 ± 5.4</td>
</tr>
<tr>
<td>Progression of disease risk score</td>
<td>13.4 ± 4.5</td>
<td>12.8 ± 3.9</td>
</tr>
</tbody>
</table>

*< 0.01, †< 0.05. Repeated measures ANOVA and McNemar tests with multiple testing correction.

Multiple comparisons: B = Baseline, 4 = Four-month assessment, 16 = Sixteen-month assessment, NS = Non-significant comparison

† = Log-transformed variables, rCRP = Reduced cardiac rehabilitation group, sCRP = Standard cardiac rehabilitation

Ex-smoker = Defined as those that quit smoking < 6 months ago.

EQ-5D = European Quality of Life-5 Dimensions, EQ-VAS = European Quality of Life Visual Analogue Scale, CES = Center of epidemiologic studies depression score
Table 16 shows the proportion of participants taking cardiac- and diabetes-related medications at baseline, four- and 16-months follow-up in both groups. The proportion of rCRP participants taking beta-blockers decreased by 14% at four-months follow-up compared to baseline. The proportion of rCRP participants taking angiotensin receptor blockers increased by 14% at 16-months follow-up compared to baseline. There was no significant change in the proportion of rCRP participants taking other cardiac- and diabetes-related medications. A per-protocol analysis showed the same findings.
Table 16: Comparison of the proportion of sCRP and rCRP participants taking cardiac – and – diabetes –related medication at baseline, four- and -16 months follow-up (totals and percentages).

<table>
<thead>
<tr>
<th>Medications</th>
<th>sCRP</th>
<th>rCRP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (n=52)</td>
<td>Four Months (n=52)</td>
</tr>
<tr>
<td>Statins</td>
<td>42 (81%)</td>
<td>42 (81%)</td>
</tr>
<tr>
<td>Lipid-lowering</td>
<td>43 (83%)</td>
<td>43 (83%)</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>33 (63%)</td>
<td>29 (56%)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>6 (12%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>8 (15%)</td>
<td>9 (17%)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>27 (52%)</td>
<td>29 (56%)</td>
</tr>
<tr>
<td>Angiotensin receptor blockers</td>
<td>6 (12%)</td>
<td>8 (15%)</td>
</tr>
<tr>
<td>Diabetes-related medications</td>
<td>4 (8%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Nitrates</td>
<td>5 (10%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>43 (83%)</td>
<td>40 (77%)</td>
</tr>
</tbody>
</table>

p<0.017, McNemar tests with multiple testing correction.

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group
ACE = Angiotensin converting enzyme

Multiple comparisons: B = Baseline, 4 = Four-month assessment, 16 = Sixteen-month assessment, NS = Non-significant comparison

Diabetes-related medications = Hypoglycemic medications Lipid-lowering medications = Statins, fibrates, niacin
Table 17 shows the comparison of the proportion of participants in the sCRP and rCRP groups who either had medication dosages increased or decreased between baseline and four months, and baseline and 16 months. There was no significant difference between the groups in regards to the proportion of patients who had medication adjustments (either an increase or decrease in dosage) for any cardiac- or diabetes-related medications.
Table 17: Comparison of medication dosage adjustments between the sCRP and rCRP groups, at baseline – four months and baseline-16 months follow-up.

<table>
<thead>
<tr>
<th>Medications</th>
<th>sCRP [52]</th>
<th>rCRP (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline-four months</td>
<td>Baseline-16 months</td>
</tr>
<tr>
<td></td>
<td>Increased</td>
<td>Decreased</td>
</tr>
<tr>
<td>Statins</td>
<td>6 (12%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Lipid-lowering</td>
<td>7 (13%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Beta blockers</td>
<td>4 (8%)</td>
<td>9 (17%)</td>
</tr>
<tr>
<td>Calcium channel blockers</td>
<td>0</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Diuretics</td>
<td>1 (2%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>17 (32%)</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Angiotensin receptor blockers</td>
<td>3 (6%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Diabetes-related medications</td>
<td>2 (4%)</td>
<td>0</td>
</tr>
<tr>
<td>Nitrates</td>
<td>0</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>1 (2%)</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>

p<0.05, Pearson chi square tests between groups comparisons.

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group
ACE = Angiotensin converting enzyme
Diabetes related medications = Hypoglycemic medications
Lipid lowering medications = Statins, fibrates, niacin
5.7. **Program Adherence**

Table 18 shows the number and rate of hospital-based exercise sessions attended by the sCRP and rCRP participants (using intent-to-treat analysis). The attendance rate was significantly higher for the rCRP group.

**Table 18: Mean number of hospital-based exercise sessions attended, and attendance rate for the sCRP and rCRP groups.**

<table>
<thead>
<tr>
<th></th>
<th>sCRP (n=59)</th>
<th>rCRP (n=60)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of exercise</td>
<td>22.5 ± 7</td>
<td>9.7 ± 6.3</td>
<td>NA</td>
</tr>
<tr>
<td>sessions attended</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attendance rate</td>
<td>70.5 ± 22.0 %</td>
<td>97.3 ± 62.6 %</td>
<td>0.002</td>
</tr>
<tr>
<td>Number of participants</td>
<td>8</td>
<td>7</td>
<td>NA</td>
</tr>
<tr>
<td>with low attendance</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

sCRP = Standard cardiac rehabilitation group, rCRP = Reduced cardiac rehabilitation group, NA = Not applicable

Attendance rate: calculated based on 32 and 10 hospital-based exercise sessions for the sCRP and rCRP groups respectively.

Low attendance: defined as attendance to ≤ 1/3 of the expected number of sessions; number of sessions based on group assignment.

From the eight sCRP participants with low hospital-based exercise-session attendance, three were lost to follow-up, and the study manager was informed by a next of kin contact that one of these three was out of the country. From the other five sCRP participants, four of them informed the study manager that they were unable to attend hospital-based exercise sessions due to work and time constraints. One of these four participants also lived far from St. Paul’s Hospital and faced transportation difficulties. The fifth participant felt that he was in a good state of health and physical fitness, and decided he did not want to continue attending the program.
From the seven rCRP participants who had low hospital-based exercise-session attendance, five participants reported work and time constraints. Three of these five participants were lost to follow-up. One participant was lost to follow-up without informing the study manager of the reasons for his low attendance. Finally, one participant informed the study manager that he preferred to exercise at home and, after attending a total of three in-hospital sessions, did not wish to continue attending the hospital-based exercise sessions.

The total number of hospital-based exercise sessions held was 32, and no sCRP participant exceeded this attendance number. On the other hand, there were four rCRP participants who attended more than the allotted 10 classes. They did this for the following reasons:

- One participant had hernia repair surgery during CRP participation and felt that he had lost his fitness level during his absence. He attended two extra in-hospital exercise sessions.
- Two participants informed CRP staff that they needed more exercise sessions for reassurance. One of them wanted to improve their diabetes management, and the other wanted to improve her exercise routine as she suffered from chronic back pain. They attended two extra hospital-based exercise sessions.
- One participant lost track of his exercise sessions and attended three extra classes by mistake.

Aside from the above examples, most in-hospital sCRP and rCRP exercise sessions were carried out according to the intervention algorithm, in other words, they followed the schedule appropriately (Figure 1).

Figure 5 shows the change in exercise capacity (time on the treadmill in seconds) from baseline to exit assessment (A) and from baseline to one-year follow-up (B) in relation to the total number of hospital-based exercise sessions attended. The Pearson correlation test for attendance (total number of hospital-based exercise sessions) and exercise capacity change from baseline to four-months follow-up was $r=0.213$, $p=0.03$. For baseline to 16-months follow-up, the test results were $r=0.161$, $p=0.11$. 
Figure 5: Exercise capacity change from baseline to four months (A) and from baseline to 16 months (B) from rCRP and sCRP groups in relation to the total number of hospital-based exercise sessions. A per-protocol analysis was used.
5.8. Educational Quiz

An educational quiz was performed by 25 and 24 sCRP and rCRP volunteer participants, respectively, at program completion. The sCRP group had a mean of 12 ± 2 correct answers out of a total of 16 questions; the rCRP group had a mean of 13 ± 2 correct answers out of a total of 16. There was, therefore, no significant difference in the educational quiz scores between the sCRP and rCRP groups (p=0.062).

5.9. Self Reported Hospitalization and Emergency Room Visits

Table 19 shows the rate of occurrence of self-reported all-cause hospitalizations and emergency room visits during study participation; there was no statistical difference between the groups. A total of two participants (one from each group) had revascularization procedures. There were no reports of MI, stroke or exercise-related events (injuries, syncope, MI).

Table 19: Comparison of self-reported all-causes hospitalizations and ER visits between the sCRP and rCRP groups (total with percentages)

<table>
<thead>
<tr>
<th>Self-reported events</th>
<th>sCRP (n=57)</th>
<th>rCRP (n=56)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause hospitalizations</td>
<td>3 (5%)</td>
<td>9 (16%)</td>
<td>0.062</td>
</tr>
<tr>
<td>All-cause ER visits</td>
<td>11 (19%)</td>
<td>6 (11%)</td>
<td>0.202</td>
</tr>
</tbody>
</table>

A Pearson chi-square comparison was used. sCRP= standard cardiac rehabilitation group, rCRP= reduced cardiac rehabilitation group, ER= emergency room
6. Discussion

Cardiac rehabilitation is an efficient and cost-effective intervention for patients with CVD; however, only a small proportion of patients that would benefit from such programs attend them [47, 207]. The gap between CRP demand and utilization can be explained by geographical barriers such as distance to the CRP facility and transportation/parking difficulties [207, 208], as well as the time- and schedule-related challenges of attending in-hospital exercise sessions regularly [88]. The CACR emphasises the need for more accessible rehabilitation by stating that “alternate models of delivery of Cardiac Rehabilitation services in combination with enhanced on-site programs must be explored, developed and implemented”. [47]. Certain home-based CRPs have been evaluated in response to this need. However, such interventions have been independent from the traditional program, sometimes lacking a multi-disciplinary and comprehensive approach, and many have been assessed in low-risk patients, which limits the generalizability of their results [100]. As the population of those who could benefit from the CRP grows, so does the need to improve cardiac rehabilitation delivery and to decrease the treatment gap that currently exists [209].

The purpose of this study was to evaluate a reduced cardiac rehabilitation program (rCRP) and compare its effectiveness to the standard program (sCRP) with respect to exercise capacity, IHD risk factors and psychosocial variables change in primary- and secondary-prevention patients who are of low and moderate risk. The difference between the two programs was that the rCRP had a lower number of hospital-based exercise sessions than the sCRP for the same program duration. However, it retained a comprehensive nature of treatment, making it a “middle of the road alternative”. In other words, the rCRP was a “hybrid” intervention because it combined elements of a traditional program and a “home-based” program. The rCRP demanded less hospital, travel and transportation time, thereby providing flexibility and convenience while promoting and encouraging home-based exercise and independent behavioural changes. Likewise, it kept the comprehensive and multidisciplinary nature of CRP services as rCRP participants kept coming to hospital-based exercise sessions.
throughout the duration of the program. The rCRP is a novel mode of CRP delivery, and we therefore wanted to add to the current body of knowledge surrounding alternative programs, and evaluate its effectiveness when comparing it with the traditional CRP.

In regard to program effectiveness, the results confirm our primary hypothesis: the rCRP group was non-inferior to the sCRP group with respect to improvements in exercise capacity at program completion and at one-year follow-up. Superiority of either group was not shown. With regard to secondary outcomes, the results confirm our secondary hypothesis: the rCRP group was non-inferior to the sCRP for IHD risk-factor changes at program completion and at one-year follow-up, except in the case of TC and LDL-C, where neither non-inferiority nor superiority of either group was shown. The results also confirm our third hypothesis; the rCRP had a better attendance of scheduled on-site sessions than the sCRP. Finally, the rCRP was non-inferior in regard to self-reported physical activity at program completion and at one-year follow-up.

### 6.1. Primary Outcomes

The rCRP was non-inferior to the sCRP group in regard to exercise capacity improvement at program completion and at one-year follow-up. In other words, there was no significant difference in exercise capacity change between the two groups, and the upper bound confidence interval of the group estimate was lower than 60 seconds, the cut-point value to test for non-inferiority. Exercise capacity improved significantly in both groups at program completion: by 106 seconds in the sCRP group (from 524 ± 168 to 630 ± 150 seconds, p<0.01) and by 90 seconds in the rCRP group (from 565 ± 183 to 655 ± 196 seconds, p<0.01). This translates into a 20% and 16% improvement of exercise capacity in the sCRP and rCRP groups, respectively. At 16-months follow-up, exercise capacity remained above baseline by 80 seconds in the sCRP group (524 ± 168 at baseline to 604 ± 172 seconds at follow-up, p<0.01) and by 75 seconds in the rCRP group (565 ± 183 at baseline to 640 ± 192 seconds at follow-up, p<0.01). This translates into a 15% and 13% improvement of exercise capacity in the sCRP and the rCRP groups, respectively, at one-year follow up compared to baseline.

A number of studies have previously investigated alternative CRPs and compared their effectiveness with traditional programs in regard to exercise capacity change. Most trials
have reported short-term exercise capacity changes (with three- to six-month follow-ups) [99, 138, 210, 211], but fewer studies have performed longer follow-ups [96, 97, 212].

Arthur et al [99] compared a six-month home-based intervention with a traditional six-month hospital-based CRP in low-risk post-CABG patients and reported no significant difference in the improvement of exercise capacity between the two groups at program completion measured as peak VO$_2$ max in a cycle ergometer (difference of 5% between the groups; peak VO$_2$ max improved by 36% in the hospital group and 31% in the home group, p > 0.05). These results are comparable to the rCRP trial as the difference in exercise capacity change between the sCRP and rCRP was 4% (20% and 16% exercise capacity improvement respectively). In terms of METS, the rCRP trial reported improvements of 1.2 and 1.1 METS for the sCRP and rCRP group respectively, which is higher than that reported by the mentioned study. This can be explained by the fact that treadmill testing provides a more common form of physiological stress (walking) in which subjects are more likely to attain a slightly higher oxygen consumption (VO$_2$) than a cycle ergometer. In contrast with the rCRP intervention, the home-based program in the mentioned study was designed for low-risk patients, was longer in duration, was a completely hospital-independent intervention and required an additional one-hour exercise specialist consultation at baseline and at three months. In the time between these in-person consultations, specialists performed periodic assessments of patients' exercise plans and conducted telephone follow-ups every two weeks. Unlike this home-based program, the rCRP was integrated into the traditional program and had no additional intervention requirements other than those offered by the sCRP for a higher-risk population (i.e., an exercise specialist was not required for completion of telephone follow-ups). The rCRP intervention had the additional advantage of making use of existing hospital and CRP staff resources without requiring additional home interventions. Furthermore, it was able to assess IHD risk factors in addition to exercise capacity change, evaluating the rCRP as a comprehensive treatment. Our findings show that low- and moderate-risk patients participating in “hybrid” programs (i.e., not fully home-based programs) are able to achieve non-inferior exercise capacity improvements to those that participate in a traditional CRP. They are also able to achieve results comparable to comprehensive fully home-based programs.

Carlson et al [213] evaluated a six-month “modified” home-based CRP and compared it with a six-month traditional hospital-based CRP in a low- to moderate-risk population.
This “modified” program had more similarities to the rCRP intervention as it had an initial one-month period of hospital-based exercise sessions. These consisted of three weekly on-site exercise sessions that were identical to the traditional program. Patients were subsequently slowly weaned to twice-weekly hospital sessions. This was complemented with educational meetings (once-weekly) and telephone follow-ups throughout program duration. The “modified” program showed similar improvements in exercise capacity at program completion compared to the traditional program (exercise capacity change of 7.2 % versus 6.3% respectively, p=0.08). Compared to the rCRP group, this intervention had a longer hospital-based “run-in” period and a higher total number of hospital-based exercise sessions (twice-weekly), which might have attenuated any difference between the traditional and the modified CRP. Also when comparing the two studies, the percent improvement for the sCRP and rCRP groups was higher than that reported by the above study, which might be explained by the difference in measurements used - i.e., treadmill time tends to overestimate aerobic fitness [214]. Nonetheless, both studies reported favourable results for alternative CRPs that use a step-down approach with a gradual reduction of on-site exercise sessions. The rCRP trial extended the findings by Carlson et al by showing exercise capacity improvements for low- and moderate-risk CRP patients without a long initial run-in period and without an extensive in-hospital intervention.

Gordon et al [138] compared three types of cardiac rehabilitation interventions in low- and moderate-risk patients: 1) a 12-week traditional CRP with three weekly hospital-based exercise sessions 2) a 12-week physician-supervised, nurse-managed home-based CRP 3) a 12-week community-based, exercise-specialist-managed CRP. All three programs had the same educational components (one-on-one, written information and audiotapes). The home-based intervention consisted of a baseline and a six-week evaluation by a physician, as well as a total of four telephone calls from a nurse manager. The community-based program consisted of a total of 12 centre-based exercise sessions. All three programs reported improvements in exercise capacity, but the authors reported that the home-based program was the least effective in improving maximal oxygen uptake; VO₂ max change of 0.9 ± 1.9 versus 1.6 ± 2.1 ml/kg/min, which translates into a 4% and a 7% improvement in exercise capacity respectively. The change in exercise capacity observed in the rCRP trial at the four month follow-up was more pronounced for both the sCRP and rCRP groups with a treadmill time change of
106 and 90 seconds, which translates into a 20% and 16% improvement in exercise capacity respectively. This can be explained by the different method used to assess exercise capacity (i.e., treadmill time overestimates VO$_2$ max) and perhaps by the longer duration and comprehensive nature of the rCRP trial intervention. These results suggest that for low- and moderate-risk patients, the in-hospital sessions demanded by traditional programs may not be completely necessary, but home-based interventions that are not comprehensive enough and/or do not achieve an appropriate level of intensity might run short in terms of fitness improvements. According to our results, the rCRP design had an appropriate “dose” of hospital-based sessions for low- and moderate-risk patients.

There are several studies with longer follow-ups that, like the rCRP trial, have investigated the long-term effect of home-based CRPs in regard to improvements in exercise capacity. One such study by Marchionni et al [96] compared a two-month home-based CRP with a two-month hospital-based CRP in low- and moderate-risk post-MI patients. The hospital CRP group had a total of three weekly endurance exercise sessions and twice-weekly flexibility and stretching exercise sessions. Alternately, participants in the home-based group received a cycle ergometer and a heart rate monitor and were advised to exercise at least three times weekly, with biweekly visits from a physical therapist. The authors reported that the home-based CRP achieved a similar total work capacity (TWC Kg*m) improvement compared to the hospital CRP at program completion, and better sustainability of improvement for those older than 65 years at 12-months follow-up. Although the rCRP trial did not conduct between-age-group comparisons, our findings were consistent with these results in terms of rCRP exercise capacity improvements being non-inferior to the sCRP at program completion and at 16-months follow-up. The within-group comparison also showed that the sCRP and rCRP both achieved significant improvements in exercise capacity at program completion, and both maintained above-baseline exercise capacity levels at the 16-month follow-up. This differs from findings by Marchionni et al [96], who reported that exercise capacity returned towards baseline at six months and at one-year follow-up for those older than 65 years in the hospital-based group. These results suggest that a two-month hospital-based CRP may perhaps be too short to obtain perdurable benefits. Although the rCRP trial did not perform a sub-analysis of different age groups (as it was not part of our research questions), age would not have been a predictor of exercise capacity improvement given its equal distribution in both intervention groups. However,
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for all combined age groups (which ranged from 34 to 84 years), the rCRP trial showed that a four-month program attained long-term exercise capacity benefits for low- and moderate-risk patients. In comparing study design between the rCRP and the above trial, the rCRP has the advantage of being tested as a comprehensive therapy by assessing IHD risk factors in addition to exercise capacity. The feasibility of implementing a home intervention, as described in the former study, is also limited since participants not only received biweekly home visits from an exercise therapist, but also received a cycle ergometer and heart rate monitors, thereby increasing the cost and required resources of such an intervention.

Smith et al [97] also observed long-term CRP effects by performing a one-year follow up of the participants in the study by Arthur et al [99] described earlier in this section. Exercise improvement was sustained in the home-based CRP, but declined in the hospital-based group at 12-months follow-up compared to program completion (1567 ± 430 to 1565 ± 437 ml/min, and 1616 ± 455 to 1535 ± 426 ml/min, respectively, p=0.002). This translates into a 5% exercise capacity decline for the hospital-based group versus 0.1% for the home-based group. These are comparable to our results, which showed that the rCRP group “sustained” their exercise capacity improvement better at the one-year follow-up compared to program completion (655 ± 196 to 640 ± 192 seconds, p>0.05; 2.3% decline), compared to the sCRP group (630 ± 150 to 604 ± 172, p<0.05; 4.1% decline). Although parallels can be drawn between that study and the rCRP trial, further conclusions of “superiority” of sustainability of effect cannot be made. If home-based programs do indeed produce more sustained exercise capacity improvements, a reason for this may be that a higher level of self-management implicit in home-based or “reduced” programs may induce more permanent changes than hospital-based programs. There may be factors in the home environment that promote the adoption and maintenance of healthy behaviours, and the rCRP probably enhanced the utilization of these factors to achieve comparable health improvements to the traditional program [215]. Exercise capacity maintenance and predictors of fitness sustainability after cardiac rehabilitation warrant further research.

In the UK, Dalal et al [210] compared a two-month hospital-based CRP (once-weekly sessions), versus a home-based CRP based on the Heart Manual (a self-help rehabilitation program) in a low-risk, post-MI population. Exercise capacity was assessed at three- and nine-months follow-up. At nine months, there was no difference between
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the hospital and self-help groups in regard to exercise capacity improvement after adjusting for age, sex and baseline exercise capacity (7.36 ± 2.8 to 7.68 ± 2.8 METS, delta 0.32 for hospital-based; and 8.69 ± 2.87 to 9.66 ± 3.1 METS, delta 0.87 for self-help; p =0.23). According to these findings, low-risk, post-MI patients would benefit equally from even less-monitored, less-intensive interventions than the above-described home-based models. Although hopeful, these results have to be interpreted with caution, as the authors failed to conduct a baseline assessment of exercise capacity. Without baseline values for comparison, we cannot speculate that exercise capacity at three months reflects changes achieved by the programs; for example, if Heart Manual users had lower baseline values, results would favour this home-based program. Furthermore, in the UK, the Heart Manual is a popular method of rehabilitation and has been used widely since 2004; however, this intervention is not directly transferable to other societies, as it may not stand up to cultural, economic and social differences. The rCRP was better designed for a Canadian population, as it was integrated into the sCRP and maintained a hospital component, which is the standard of care for CVD patients in Canada. Exercise capacity was also assessed in the rCRP trial before program initiation, at program completion and then one year after program completion; exercise capacity changes can therefore be attributed to cardiac rehabilitation.

Given the extensive health benefits associated with exercise, as discussed in section I.3., the change in exercise capacity with program completion was chosen as the primary outcome. Exercise capacity is also the most powerful predictor of survival, more so than are other IHD risk factors, especially for secondary-prevention patients [110, 115, 146]. Time on the treadmill in a symptom-limited exercise stress test provides a good estimate of VO2max, which is the gold standard for measuring cardio-respiratory fitness, for both active and sedentary men and women [216, 217]. Although measuring fitness based on time on the treadmill can overestimate aerobic capacity [151], we were only interested in the change in exercise capacity over a period of time, regardless of the absolute values. Furthermore, exercise capacity improvement in a CRP setting is evaluated as the observed change in endurance in any exercise testing modality that a given patient requires. To standardize and be able to compare exercise capacity with different exercise testing modalities, exercise capacity is normally compared in METS; however given that all participants in the rCRP trial were evaluated using the BRUCE protocol, no standardization was needed. A total of 60 seconds on the treadmill (equivalent to 1
MET) was chosen as the cut-point to compare non-inferiority of the rCRP with the sCRP, as this improvement has been associated with increased survival [110, 115] and is a clinically relevant value according to expert opinion.

As previously mentioned, the rCRP group was non-inferior to the sCRP group in regards to exercise capacity improvement at both program completion and at one-year follow-up. It is important to discuss possible factors that could have attenuated a significant difference in exercise capacity change between the two groups. One possible confounder could have been differing dropout rates, but these were not a factor in this case since rates were similar between the groups at both program completion and follow-up. Another possible confounder might have been a dissimilar use of beta blockers, which can blunt improvements in exercise capacity [144]. However, while beta blockade decreases endurance exercise capacity [218], it does not alter the response to an exercise training program in patients with CVD; in other words, it does not influence exercise capacity change over time [110, 219]. Between-group differences may occur with disproportional medication changes, which can happen with increased exposure to CRP physicians (e.g. closer follow-up for those in the sCRP) or due to an overall improvement in health and fitness level. However, in this case, the proportion of patients that had dosage adjustments for any cardiac- and diabetes-related medications was the same for both groups, and there were also no baseline differences between them. In any case, medication changes and dosage adjustments are an integral part of the comprehensive nature of CRP interventions, and exercise capacity changes should be attributed to the program as a whole.

6.2. Secondary Outcomes

The rCRP group was non-inferior compared to the sCRP group in regard to the change over time for HDL-C, triglycerides, TC/HDL-C ratio, fasting blood glucose, systolic and diastolic BP, waist circumference, waist-to-hip ratio and self-reported physical activity (LTPA score). Although group differences in TC and LDL-C levels were non-significant, the upper bound confidence interval of the group estimates was slightly higher than the specific cut-points, and non-inferiority of the rCRP was therefore not shown for these variables. No group superiority was present for any IHD risk-factor changes.
The within-group comparisons showed that both groups had a significant improvement or a non-significant trend of improvement of the following IHD risk factors at program completion: TC, LDL-C, HDL-C, triglycerides and TC/HDL-C ratio. Most of these IHD risk factors deteriorated at one-year follow-up for both groups, except for HDL-C, which further improved in the sCRP group. Self-reported levels of physical activity (LTPA score) significantly improved at program completion and were maintained above baseline levels at one-year follow-up for both groups. Anthropometric measurements, BP and fasting blood glucose showed no significant changes over time for either group.

Among studies that have compared alternative programs with traditional CRPs, only a few have assessed IHD risk-factor changes. Carlson et al [138] reported that a "modified" CRP achieved similar improvements for TC, LDL-C, HDL-C, triglycerides and TC/HDL-C ratio compared to the traditional CRP at program completion. Our results are consistent with these findings, as the positive changes in IHD risk factors achieved by the rCRP group were non-inferior to those achieved by the sCRP group. However, non-inferiority was not shown for TC and LDL-C, and some IHD risk factors had a non-significant trend of improvement across time. This can be explained by the differences in lipid profile baseline values. For example, baseline LDL-C in the former study was 3.41 ± 1.00 mmol/l and 3.18 ± 0.85 mmol/l in the traditional and modified program respectively, while baseline LDL-C in the rCRP trial was 2.28 ± 0.89 and 2.25 ± 0.86 for the sCRP and rCRP groups respectively. These baseline differences between the two study populations can contribute to the milder changes observed in the rCRP trial since our study population had less room for improvement. Furthermore, Carlson et al [213] reported significant decreases in anthropometric measurement values for their entire cohort (BMI decreased by -1.8 and -2.2 for the traditional and modified programs respectively; p<0.05), whereas the rCRP study population did not achieve anthropometric changes. This might be due to the longer and more intense intervention in the former study. Significant changes in anthropometric parameters can further accentuate the differences seen in IHD risk-factor improvements between the two studies. Nevertheless, rCRP trial participants had significant improvements in HDL-C, triglycerides and the TC/HDL-C ratio over time, which, given the negligible changes in anthropometric measurements, was most likely the result of increased exercise capacity and physical activity. Exercise has been shown to consistently lower triglyceride levels; increase skeletal muscle and lipoprotein lipase activity in adipose tissue and skeletal
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muscle [220, 221] translate into increased uptake of circulating triglycerides for utilization or restoration of intracellular lipid stores [221]. Furthermore, increased lipoprotein lipase activity is associated with a decreased TC/HDL ratio, while a higher lipoprotein lipase/hepatic lipase ratio is associated with a subsequent increase in HDL-C particles, even in the absence of weight loss [222].

A study by Gordon et al [138], described in the previous section, assessed three models of CRP delivery: a traditional CRP; a physician-supervised, nurse-managed CRP; and a community-based CRP. They reported significant improvements in BP, TC, LDL-C and significant weight loss at CRP completion for all three programs, with no significant difference between them. Our findings are consistent with the mentioned study, as the rCRP achieved non-inferiority for most of these risk-factor changes over time, and superiority of the sCRP was not shown. However, the extent of risk-factor improvements achieved by both the sCRP and rCRP groups was lower than those reported by Gordon et al [138]. This may be attributed to differences in IHD risk-factor baseline values; for example, baseline LDL for secondary-prevention rCRP trial participants was 2.07 ± 0.81 mmol/l, while participants in the mentioned study had a baseline value of 2.95 mmol/l. The same applies to other lipid and BP values; for example, the rCRP trial population had a baseline systolic BP of 119 ± 16 mmHg, while those in the mentioned study had a baseline systolic BP above 130 mmHg. Therefore, the rCRP trial population had IHD baseline values that were closer to the targets outlined by current treatment guidelines [56-58], resulting in a narrower treatment gap and less room for improvement. When comparing the proportion of patients taking cardiovascular medications at baseline, the Gordon et al study population had a lower proportion of patients on lipid-lowering medications (70% vs 80%), beta blockers (40% vs 69%) and ACE inhibitors (24% vs 50%) than the rCRP-trial population, which helps explain the differences in baseline IHD values between these two studies.

It is apparent that the IHD risk factors of the rCRP study population were well managed at intake; for example, secondary-prevention rCRP-trial participants had a baseline TC/HDL ratio of 3.48 ±1.09, LDL-C of 2.07 ± 0.81 and systolic BP of 119 ± 16 mmHg. These baseline values meet, or are very close to meeting, treatment targets set by current treatment guidelines [56-58]. Since patients in a CRP are referred to the program by family physicians or cardiologists and, further, need to be willing to participate, it is possible that there is a selection bias towards patients who are better-treated than the
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rest of the CVD population. This idea is further corroborated by the EUROASPIRE II survey [223], which reported that cardiovascular patients who participate in a CRP have a better risk factor profile and a higher proportion of cardiovascular medications than those who do not participate in a CRP. Indeed, Yusuf et al [224], reported that among CVD patients in Canada, approximately 40% are taking beta blockers, 60% are taking statins and 60% are taking antiplatelet agents; compared to this, the rCRP-trial population had a higher proportion of patients taking cardiovascular medications at baseline (69% beta blockers, 80% statins and 83% antiplatelet agents). These population discrepancies may be partly explained by physician referral biases, as younger (< 60 years), male, post-revascularized patients are more likely to be referred; this is in contrast with women and the elderly, who might be under-treated [223, 225]. Furthermore, patients that subsequently agree to participate in the CRP are likely to be more aware of their health problems and have a higher adherence to treatment than those who do not attend. Likewise, there might be a study selection bias; those that consented to participate in the rCRP trial might have had higher self-efficacy and confidence in achieving favourable lifestyle changes (volunteer bias).

Given the above considerations, that IHD risk factors can be managed well with the use of statins, beta blockers and other cardiovascular medications and interventions that were not available before, the goals of a modern CRP are challenged. Given the better risk factor profile of those attending the program versus those who do not, one also wonders what benefits can be gained from cardiac rehabilitation. Recent meta-analyses that have compared CRP with usual care in terms of different health outcomes have reported that modern, comprehensive CRPs achieve lower all-cause and cardiovascular mortality, lower hospital admissions, higher smoking cessation rates, greater reductions in BP and better management of dyslipidemias than usual care [66, 71]. A recent statement was released by the American Heart Association [72], where cardiac rehabilitation was reported to be as cost-effective as most technologies and drug therapies. This is further emphasized by a recent analysis that suggested that cardiac rehabilitation contributed to the significant reduction in IHD mortality observed in the United States between 1980 and 2000, and that risk reduction attributed to cardiac rehabilitation was comparable to reductions seen with the use of aspirin, beta blockers, ACE inhibitors and statin therapies [226]. To add to the list of CRP benefits, an RCT published in 2004 compared a 12-month CRP with PTCA for patients with single vessel
disease. The CRP group had higher event-free survival rates (88% versus 70%, p=0.023) and exercise capacity improvements (+16% mL O2/kg, P<0.001) compared with the PTCA group. These outcomes were additionally accomplished at a lower cost than PCI [227].

Current evidence supporting CRP benefits for CVD patients is robust, as advances in interventional and preventative cardiology (statin era) have not offset the benefits associated with cardiac rehabilitation. Therefore, the challenge going ahead is not to question the efficacy of these programs, but to further expand the opportunities for patients to attend and adhere to the CRP. In this sense, the evaluation and implementation of alternative modes of CRP delivery, which improve access and utilization, is warranted. As such, our results show that the rCRP is a feasible alternative, as it was demonstrated to be a non-inferior program in regards to important health outcomes such as exercise capacity and IHD risk factor improvements. The implementation of this alternative program has the potential to increase program intake capacity, program adherence and choices for patients that would not participate in the program otherwise.

### 6.3. Program Adherence

Cardiac rehabilitation adherence has been, and continues to be, a challenge. Daly et al [76] reviewed the barriers to CRP adherence and described that over the first three to six months of CRP participation, only 30 to 60% of entering participants continued to adhere to an exercise routine. The discussion of adherence in cardiac rehabilitation is complex, is intertwined with motivation and self-efficacy, and has many different components, from behavioral (diet, smoking, exercise, risk-factor management) to psychosocial (stress, anxiety and depression management). This makes the assessment of program adherence difficult, with different CRP trials having different definitions of adherence [76]. Given the importance of improving and maintaining exercise capacity in cardiac rehabilitation, the rCRP trial measured program adherence as a percentage of program attendance to scheduled hospital-based exercise sessions and adherence to physical activity, measured as kcal/week energy expenditure from physical activity, as reported in the LTPA questionnaire. The percent of attended hospital-based exercise sessions was higher for the rCRP group than sCRP (84% versus 71.5%, p< 0.01). This might be
explained by the fact that it is more feasible and easier to attend a less demanding program; the rCRP was less time-consuming and required less transportation and hospital time than the standard program. This is consistent with literature, which states that many CRP participants perceive the effort to attend hospital-based sessions as a barrier for program participation and adherence [88, 228].

The decreased number of hospital-based exercise sessions for the rCRP group did not translate into reduced amounts of physical activity (which were reported in the LTPA questionnaire), as was evidenced by rCRP’s non-inferiority to the sCRP group and the significant increase in physical activity for both groups at program completion. These findings are consistent with those of Carlson et al [213], who reported no difference in self-reported physical activity between the home-based and hospital-based groups at program completion (3.8 ± 1.3 versus 4.3 ± 1.2 exercise sessions/week, respectively; p>0.05). In contrast, Marchionni et al [96] reported in his study that the number of self-reported exercise sessions completed were significantly higher for the home-based group. Similarly, Arthur et al [99] reported higher physical activity levels at program completion for the home-based group (6.5 ± 4.6 versus 3.7 ± 2.6 exercise sessions/week, respectively; p<0.01). Both of these latter studies, however, measured the total number of completed self-reported exercise sessions, whereas the rCRP trial measured physical activity as weekly energy expenditure; comparison between these is therefore difficult.

Hamill et al [229] reported that among Medicare beneficiaries attending CRP, there was a dose-response relationship between the number of hospital-based exercise sessions attended and risk of MI and mortality. These findings contrast ours, as the rCRP trial found that the absolute number of attended sessions did not have an impact on health outcomes. However, there were some differences between the two studies that makes comparison difficult. For starters, the outcomes themselves differed since we did not measure cardiovascular events or mortality; on the other hand, exercise capacity is strongly associated with both [110, 146]. In the mentioned study, all patients were expected to attend the same number of exercise-based hospital sessions, and a lower program attendance in absolute numbers therefore served as a measure of program adherence. In contrast, rCRP-trial participants were expected to attend less hospital-based exercise sessions than the standard group, and as such, a comparison of the
absolute number of sessions attended was not a measure of adherence and/or commitment to the program.

There are also a number of limitations to the Hamill et al study. For example, Medicare beneficiaries were reimbursed for diagnoses or events associated with IHD only, and socioeconomic status may therefore well have been a confounder. Furthermore, more frequent attendance is not the sole mechanism in reducing mortality or MI risk, because early adherence to a CRP may be a proxy for other factors (i.e., general health, long-term exercise adherence, medication adherence, socioeconomic status, etc.). It is unknown to what extent these factors influence program attendance, and causation, therefore, cannot be determined. Instead, the question that arises from the study by Hamill et al is: is less attendance making patients sicker, or are “sicker” or more disadvantaged patients attending less? Less healthy patients may not tolerate CRPs as well as healthy ones, and are therefore likely to attend less frequently and be at increased risk of MI and mortality. As was seen in the rCRP trial, it is possible for participants to attend less hospital-based exercise sessions and still see improvements in exercise capacity and self-reported physical activity levels comparable to those attending more sessions. This shows that the concept of program adherence entails more than just attending a certain number of on-site exercise sessions. In any case, further research is warranted to explore determinants of successful and perdurable lifestyle changes, of risk factor management and maintenance of exercise capacity by CRP participants.

With regard to the decreased numbers of on-site sessions associated with alternative CRPs, a common criticism is that these result in less, or complete lack of, social support and group camaraderie that is inherent with more hospital time. Group support can provide encouragement and reinforces self-discipline to achieve behavioural changes. It can also decrease stress and anxiety by providing participants the opportunity to share common experiences with peers along with providing continuous health-care professional support. This might be true for many CRP attendees; in fact, those that prefer a traditional program also tend to seek social support from their CRP “classmates” [230]. However, as previously mentioned, there is vast heterogeneity in the CVD population. Among CVD patients, there are different personality traits, psychosocial needs, environmental needs and barriers to CRP attendance. In fact, those that prefer home-based or “reduced” programs usually have higher self-efficacy, have
transportation and geographical barriers to attending a traditional program, have personality traits that make them dislike groups, or feel that they benefit most from the social support provided within their own environment [228, 230]. Therefore, the concept of social support becomes relative to every patient’s needs and preferences. In this regard, the rCRP trial population consented to participate because they either preferred the rCRP to the sCRP (by participating, they at least had a 50% chance of being randomized to the rCRP as opposed to none), or they had no group preference. While this might bias the study sample, it was found that those who felt amenable to participate in a reduced program showed short- and long-term improvements in exercise capacity that were non-inferior to those in the traditional program. In fact, the rCRP program works for self-selected patients who would prefer this type of CRP delivery for reasons listed above.

6.4. Study Strengths and Limitations

6.4.1. Study Strengths

The following are important strengths of the rCRP trial that contribute to the current body of knowledge:

- The rCRP is a novel intervention, as it combined elements of a home-based program while maintaining the multidisciplinary services of the sCRP. To our knowledge, no other “hybrid” intervention of this nature has been previously evaluated.

- The rCRP was an RCT that measured exercise capacity change as the primary outcome and IHD risk factors change as the secondary outcome. Randomized trials control for unmeasured variables that might confound the results and the measurement of multiple outcomes reflects the multifactorial nature of cardiac rehabilitation.

- Exercise capacity and IHD risk factors (some assessed through blood work) were measured by technicians working in St. Paul’s Hospital who were blinded to group randomization. Therefore, although the study manager and participants were aware of group assignments, the primary and many secondary outcomes were measured by blinded third parties (single-blinded study).

- To our knowledge, this is the only study that has compared an alternative CRP delivery mode to the traditional program using a non-inferiority trial design. Previous studies have assessed differences between home-based or alternative CRPs and hospital-based CRPs using superiority trials, in which case non-significant results can be wrongly interpreted as proof that there is
Reduced Cardiac Rehabilitation Program

no difference between two groups [139]. Therefore, previous studies whose interpretations are based on superiority trials, and who have reported no significant differences between home-based and hospital-based programs, can provide tentative conclusions at most. Our study adds to the body of knowledge surrounding alternative CRPs, as non-inferiority is the most appropriate trial design with which to test a new intervention and compare its effectiveness to a previously proven treatment [139, 140]. We can conclude that the rCRP is not worse than the sCRP in regards to exercise capacity and most IHD risk factor changes at CRP completion and at one-year follow-up. With non-inferiority shown, further research is needed to explore group differences with superiority trials.

- Exercise capacity and IHD risk factor changes were assessed at both program completion and at one-year follow-up. The incorporation of a longer follow-up showed non-inferior maintenance of the wide array of CRP benefits, not only of exercise capacity but also IHD risk factors. This provides a comprehensive longitudinal comparison that no previous studies have reported. Furthermore, our study population included moderate-risk patients, which further adds to current research as most trials have assessed these variables in low-risk patients.

- The rCRP intervention was derived from and was incorporated into the sCRP, which is the current gold standard of treatment for CVD patients [47]. To our knowledge, only one study reported the effectiveness of a “step-down” CRP design that was incorporated into the traditional program [213]. This study assessed a modified CRP in which participants started a traditional program and were gradually weaned off from the hospital site. However, the intervention was longer and the step-down approach was milder, as those randomized to the modified program still had to attend on-site exercise sessions twice per week for the six months of program duration. Additionally, that was a superiority trial, and yet the intensity of such a program might have attenuated any significant differences between the groups. The results of our study further expand these findings, since we showed that a much less intense program with a more drastic step-down approach achieved non-inferior outcomes compared to the traditional program in a higher risk population. To our knowledge, the rCRP is a novel way of CRP delivery, is realistic and easy to incorporate into current practice. It requires no additional interventions, other than an educational package and logbook, as compared to some above-mentioned trials that have required additional staff for home visits and telephone follow-ups, among other requirements [96, 97, 99, 138].

6.4.2. Study Limitations

However, the generalizability of our findings may be restricted because of the following possible limitations:

- Exercise capacity was measured indirectly through time on the treadmill in seconds using the BRUCE protocol. Although VO2max is the gold standard for
measuring exercise capacity, its measurement would have added a cost that was not justified for the purposes of this study. Time on the treadmill is directly associated with cardiovascular events and all-cause mortality [115], and positively associated with increases in VO₂ max [151]. In the CRP setting, exercise capacity improvement values are based on the exercise testing modality used. Since all patients underwent exercise testing with the BRUCE protocol, the use of METS for standardization of exercise capacity was not necessary. Therefore, time on the treadmill using the BRUCE protocol was a feasible and appropriate tool to assess and compare exercise capacity change.

• The study had a high exclusion rate, which resulted from the selection of patients who could safely exercise at home. High-risk patients were excluded from the study, and therefore our results cannot necessarily be extrapolated to this population. However, we believe the eligibility criteria prevented exercise-related events. Furthermore, the study results can be generalized to a wide population of CRP attendees as the inclusion criteria was broad including primary prevention patients and secondary prevention at low and moderate risk. This further expands the body of knowledge in terms of study population as most trials have evaluated low-risk only.

• Exercise adherence was based on on-site exercise session attendance and self-reported physical activity questionnaires (LTPA questionnaire). These are indirect means to assess lifestyle changes in regards to exercise; however, the modified Minnesota LTPA questionnaire has been validated through comparisons to results from exercise capacity measurements and the use of accelerometers [177].

• Diet analyses were not incorporated in the results. Had they been done, they may have shown a dietary effect on changes in the lipid profile and could also have been used to assess dietary goals as a lifestyle change at program completion and at one-year follow-up. Three-day food records [231] were, in fact, collected at baseline, program completion and at one-year follow-up, and analyses of these are therefore warranted in the near future.

• A number of secondary outcomes were measured by the study manager, who was not blinded to group randomization. This might potentially introduce a bias through a differential assessment of outcomes between the groups. However, exercise capacity and IHD risk factors change were measured by blinded laboratory technicians, preventing this form of bias for the primary outcome and secondary outcomes measured through blood samples.

• Participants from both groups attended the same exercise sessions introducing a potential for between-group contamination. However, this is also considered a study strength as this type of study design allowed for rCRP utilization of existing hospital resources and an equivalent comprehensive treatment of patients by the CRP staff.

• Our study population consisted of mainly middle-aged men and very few women, which precludes the assessment of gender differences. This can be partly due to a CRP population bias, as the majority of those referred to the CRP are men. In any case, this warrants further exploration of CRP utilization barriers for women and of alternative forms of program delivery, including the
effect of the rCRP and its potential to increase the uptake of women to these programs.

• As with every RCT, there might have been a selection (volunteer) bias. Given the nature of the study, allocation concealment was not possible.

• In a non-inferiority trial, a non-inferior margin (effect size) has to be chosen a priori for primary and secondary outcomes. The selection of this margin is critical because the wider the margin the higher the risk of accepting a smaller sample size and of wrongly accepting non-inferiority of the rCRP compared to the sCRP. In this study, non-inferior margins were chosen with caution based on clinically relevant outcome changes after an extensive literature review and upon consultation with experts in the area.

• It is reasonable to think that patient preference may have an impact on program uptake and adherence. As this was an RCT, it was not possible to assess the effect of patient preference on study outcomes. In this respect, Dalal et al [210] compared a home-based and hospital-based CRP, and employed a comprehensive cohort design in addition to the randomized population. In this design, patient-preference arms were included to assess if patients' preference affected the outcomes. They found no difference between the groups in regard to exercise capacity improvement, and interestingly, patient preference did not affect the outcomes. Program adherence was also similar between the randomized (75%) and preference arms (73%). This finding does not support the hypothesis that participants who can choose program allocation will have better outcomes and adherence rates. Therefore, randomization remains a viable approach to test for non-inferiority of the rCRP compared to the traditional program.

• This study was not powered to test for non-inferiority of secondary outcomes. However, the sample size was calculated to test for non-inferiority of the rCRP using a clinically significant difference in the change of exercise capacity between the two groups. Exercise capacity is the variable that exhibits the strongest association with all-cause mortality and cardiac events after adjustment for IHD risk factors and other exercise variables [113, 117, 146-148].

• Cardiovascular events were recorded through self-report and were not part of our outcomes. Further research is required to assess for differences in mortality and cardiovascular events between groups.
7. Study Implications and Conclusion

7.1. Study Implications

The results of this study have important implications for the use and delivery of CRP services. Current practice dictates that primary- and secondary-prevention, low- to high-risk patients participate in on-site, hospital-based CRPs given the vast evidence regarding their safety, efficacy and cost-effectiveness [71]. However, traditional programs are associated with accessibility challenges, extended travel time [76], low intake capacity and increased cost [232]. Though the population of CVD “survivors” is increasing, cardiac rehabilitation availability is not [209]. Therefore, alternative models of the CRP are needed to help overcome current utilization barriers [47]. Evaluation of such programs is the initial step for the changes to come in the way CRP services are delivered.

Our study showed that patients who participated in the rCRP achieved and maintained exercise capacity and IHD risk factor improvements, and, most importantly, that these changes were non-inferior to those achieved by the traditional program. These findings imply that a CRP does not need to be as resource- and time-consuming to achieve comparable health benefits in a selected population of patients. In fact, a total of 10 in-hospital exercise sessions spread over four months of program duration was enough for patients to achieve health benefits which were not “unacceptably” worse than the traditional program (which, conversely, consisted of 32 in-hospital exercise sessions in four months). The rCRP also had better on-site exercise session attendance and non-inferior self-reported physical activity improvement and maintenance.

As cardiac rehabilitation continues to be underfunded [47, 209], in-hospital time needs to be used efficiently. Our study shows that the rCRP was not unacceptably worse than the traditional program for low- and moderate-risk patients in regard to exercise capacity and IHD risk factors change. This would allow for hospital resources to be directed to high-risk patients who need it most.
7.2. Study Conclusions

Previous studies suggest that, although cardiac rehabilitation is a class I indication for IHD patients, it remains under-utilized, with accessibility being a major issue [233, 234]. Given the large unmet need for CRPs, alternative modes of delivery need to be evaluated so they can be implemented in an attempt to decrease this treatment gap. Our study evaluated the rCRP among low- and moderate-risk patients, comparing its effectiveness to the traditional program in regard to exercise capacity and IHD risk factor changes. Non-inferiority between the two programs was shown at program completion and at one-year follow-up, suggesting that low- and moderate-risk patients benefit from a reduced program at least not less than they benefit from a standard program in terms of the tested health factors. Our findings were consistent with previous studies [96, 97, 213] and add to the current body of knowledge in the following ways: the rCRP was a novel intervention, as it was a “hybrid” program incorporating traditional program elements; it consisted of a higher-risk population than was used in previous studies; both exercise capacity and IHD risk factors were evaluated; and improvements were measured at one-year follow-up, in addition to program completion, in order to assess the sustainability of effect. The rCRP trial results suggest that it is feasible to implement an rCRP in parallel with a traditional program. This type of alternative program also has the potential to increase hospital intake capacity, to offer an alternative to patients that would prefer this type of CRP delivery due to time/distance/travel constraints, and to allow for better utilization of resources, with more hospital spaces being available for high-risk patients. However, the potential to overcome CRP utilization barriers, and rCRP’s effectiveness in doing so, needs further evaluation. Demonstrating that the rCRP is not worse than the traditional CRP in terms of relevant health outcomes was the first step.

Based on our findings, several conclusions can be stated:

1. The rCRP was well accepted by study participants, given the higher percentage of in-hospital attendance rate and a similar number of drop-outs compared to the sCRP
2. The rCRP did not require many additional resources other than those provided by the sCRP: rCRP participants were required to attend 1/3 of the exercise sessions and had an additional educational package and exercise logbook.
3. Although participation in it was voluntary, the results of the educational quiz suggest that there was no difference in information
uptake between the rCRP and sCRP groups. Further exploration of this component of the CRP is necessary before drawing conclusions.

4. Results in regard to exercise capacity and IHD risk factor changes are comparable to previous studies that have evaluated alternative CRPs. Our results are therefore consistent with current literature.

5. The rCRP was non-inferior to the sCRP group in regard to improvements in exercise capacity and most IHD risk factors at program completion and one-year follow-up. Superiority of either group was not shown. This finding has important implications in terms of bridging the gap between CRP need and delivery.

6. The rCRP was non-inferior to the sCRP in terms of self-reported physical activity improvement at program completion and physical activity maintenance at one-year follow-up. Superiority of either group was not shown. Therefore, both programs significantly achieved and maintained improvements in physical activity, and these changes were at least “not worse” in the rCRP group as compared to those in the traditional program.

7. Although a cost analysis was not included, it is reasonable to presume that the rCRP is a less costly intervention compared to the sCRP, as participants only attended 1/3 of the in-hospital CRP exercise sessions. However, other healthcare utilization costs have to be taken into consideration when assessing and comparing interventions. Further research is needed to explore whether any differences exist among “other” healthcare utilization such as rates of cardiovascular events, hospital visits and rates of hospitalizations among others.

7.3. Future Research

- Demonstrating non-inferiority of the rCRP intervention to the sCRP is the first step. The following are possible areas that require further research:
  - The next step would be to evaluate whether there are significant differences between the rCRP and the sCRP in regard to cardiovascular outcomes such as mortality rates, hospitalization rates, cardiovascular events and healthcare-resource utilization. Such information would provide vital knowledge in terms of the long-term effectiveness and safety of this alternative mode of CRP delivery, with clear implications for clinical practice.
  - Further research is required in order to determine the mechanisms by which the non-inferior benefits achieved by the rCRP group occurred. Predictors of CRP “success” need further evaluation in order to foresee which patients would benefit from either type of CRP delivery. Elucidating mechanisms of CRP success can further guide clinical practice decisions regarding the optimal mode of delivery for low-, moderate-, and high-risk patients.
  - Although we did not specifically evaluate the elderly, the rCRP and other alternative modes of CRP delivery might improve CRP utilization by this population, which tends to have mobility and transportation difficulties that
may limit participation in the sCRP [235]. Further research is therefore required to evaluate if alternative programs can help improve CRP access and participation for the elderly.

- The low recruitment and randomization of women in our cohort prevented the opportunity to assess sex differences. The rCRP can potentially improve CRP access for women, who may prefer home-based or hybrid programs in order to minimize distance, transportation requirements and travel time to the CRP facility [230, 235]. Further research is needed to assess for predictors of CRP participation among women and evaluate if the rCRP or other alternative modes of delivery can improve women’s CRP access and participation.

- Although there was a statistically non-significant difference between the groups in regard to all-cause hospitalizations, there is at least some indication that the rCRP group participants had more hospitalizations than participants in the sCRP group, and that this difference might be clinically relevant (Table 19). Therefore, it is important to further our research and identify causes of hospitalizations as it has health implications for patients and cost implications for the healthcare system. Exploring these differences between the groups and accounting these in a cost-analysis is warranted.

In summary, the duration of a formal in-hospital CRP and the intensity of its interventions (i.e., the number of sessions and the depth of therapeutic emphasis) have to be dictated by patients’ needs, while achieving efficient utilization of available resources. For these reasons, less intensive, more convenient, less-costly hybrid programs should be evaluated and implemented into current practice. Results from one such program, the rCRP, demonstrated that exercise capacity and IHD risk factor improvements, as well as program adherence rates, were “not worse” compared to the traditional program. These results warrant additional research to assess long-term cardiovascular outcomes of the program, which will allow for future implementation of the rCRP and/or other alternative modes of CRP delivery. This study has important implications for policy makers, as the availability of service options is of utmost importance to meeting patients’ needs.

### 7.4. Publications Arising from this Thesis

None of this data has been published so far. It is anticipated that the results of this thesis project be published in the near future.
References


47. CACRC. *Canadian Guidelines for Cardiac Rehabilitation and Cardiovascular Disease Prevention:* 3rd ed; 2010.


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234. Thomas RJ, King M, Lui K, Oldridge N, Pina IL, Spertus J, AACVPR/ACCF/AHA 2010 Update: Performance Measures on Cardiac Rehabilitation for Referral to Cardiac Rehabilitation/Secondary Prevention Services Endorsed by the American College of Chest Physicians, the American College of Sports Medicine, the American Physical Therapy Association, The Canadian Association of Cardiac Rehabilitation, the Clinical Exercise Physiology Association, the European Association for Cardiovascular Prevention and Rehabilitation, the Inter-American Heart Foundation, the National Association of Clinical Nurse Specialists, the Preventive Cardiovascular Nurses Association, and the Society of thoracic Surgeons. *J Am Coll Cardiol.* 2010 Sept; 56(14): p. 1159-1167.

Appendices
Appendix A.

Leisure Time Physical Activity Questionnaire

Study number: ____________________________
Birthdate: ________________________________

Date Completed: ________________________

Design, Implementation and Evaluation of a Reduced Cardiac Rehabilitation Program
Leisure Time Physical Activity Questionnaire

This is a questionnaire to assess your recent participation in physical activity. Please check only those activities that you have participated in during the last 4 weeks. If you have any questions please contact Alejandra Farias Godoy at ________________

<table>
<thead>
<tr>
<th>Activity</th>
<th>Check each week in which you performed the activity.</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Average times/week</th>
<th>Average Duration (min)</th>
<th>MET Values</th>
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<tbody>
<tr>
<td><strong>Section A: Walking and miscellaneous.</strong></td>
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<td>Walking for Pleasure (slowly)</td>
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<td>Walking to and from work</td>
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<td>Walking during work break</td>
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<td>Stairs when elevator available</td>
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<td>Cross country hiking</td>
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<td>Backpacking</td>
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<td>Mountain climbing</td>
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<td>Bicycling (work/pleasure)</td>
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<td>Dancing (ballroom/square)</td>
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### Reduced Cardiac Rehabilitation Program

#### Section B: Conditioning Exercise.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Check those activities that you have done in the past 4 weeks.</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Average times/week</th>
<th>Average Duration (min)</th>
<th>MET Values</th>
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<tr>
<td>Home exercise</td>
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<td>Health club</td>
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<td>Jogging and walking (briskly)</td>
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<td>Running</td>
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<td>Weight lifting</td>
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</table>

#### Section C: Water Activities.

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<tr>
<th>Activity</th>
<th>Check those activities that you have done in the past 4 weeks.</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Average times/week</th>
<th>Average Duration (min)</th>
<th>MET Values</th>
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<td>Water skiing</td>
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<td>Sailing</td>
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<td>Canoeing/rowing (pleasure)</td>
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<td>Canoeing/rowing (competition)</td>
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<td>Canoeing (camping)</td>
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<td>Swimming (&gt;50' pool)</td>
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<td>Swimming (beach)</td>
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<td>Scuba diving</td>
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<td>Snorkeling</td>
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</table>

#### Section D: Winter Activities.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Check those activities that you have done in the past 4 weeks.</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Average times/week</th>
<th>Average Duration (min)</th>
<th>MET Values</th>
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<tbody>
<tr>
<td>Snow skiing (downhill)</td>
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<td>Snow skiing (x-country)</td>
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<td>Ice/roller skating</td>
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<td>Tobogganing</td>
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</tr>
</tbody>
</table>

Check each week in which you performed the activity.

#### Section E: Sports.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Check those activities that you have done in the past 4 weeks.</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Average times/week</th>
<th>Average Duration (min)</th>
<th>MET Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowling</td>
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<td>Volleyball</td>
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<tr>
<td>Table tennis</td>
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<tr>
<td>Tennis (singles)</td>
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<tr>
<td>Tennis (doubles)</td>
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<tr>
<td>Softball</td>
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<td></td>
</tr>
<tr>
<td>Badminton</td>
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<tr>
<td>Paddle ball</td>
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<tr>
<td>Racketball</td>
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<tr>
<td>Basketball (non-game)</td>
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<tr>
<td>Basketball (game)</td>
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<tr>
<td>Basketball (officiating)</td>
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<tr>
<td>Touch football</td>
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<tr>
<td>Handball</td>
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<tr>
<td>Squash</td>
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<tr>
<td>Soccer</td>
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<tr>
<td>Golf (riding cart)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Golf (walking with clubs on cart)</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Golf (walking carrying clubs)</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**Section F: Lawn and Garden Activities.**

<table>
<thead>
<tr>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mowing lawn (riding mower)</td>
</tr>
<tr>
<td>Mowing lawn (power mower)</td>
</tr>
<tr>
<td>Mowing lawn (push mower)</td>
</tr>
<tr>
<td>Weeding and cultivating garden</td>
</tr>
<tr>
<td>Digging/filling/spading garden</td>
</tr>
<tr>
<td>Raking lawn</td>
</tr>
<tr>
<td>Snow shovelling by hand</td>
</tr>
</tbody>
</table>

**Section G: Home Repair.**

<table>
<thead>
<tr>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpentry (power tools/workshop)</td>
</tr>
<tr>
<td>Paint/wallpaper/waxing/plumbing</td>
</tr>
<tr>
<td>Carpentry/fences/porch (outside)</td>
</tr>
<tr>
<td>---------------------------------</td>
</tr>
<tr>
<td>Painting/windows/drains (outside)</td>
</tr>
</tbody>
</table>

**Section H: Fishing and Hunting.**

- Fishing from river bank
- Fishing wading in river
- Hunting (birds)
- Hunting (small game)
- Hunting (large game)

**Section I: Other Activities.**

- Other 1
- Other 2
- Other 3
Appendix B.

Euro Quality of Life Questionnaire

Design, Implementation and Evaluation of a Reduced Cardiac Rehabilitation Program

EuroQOL Quality of Life Questionnaire

Please turn the page over to begin the questionnaire.
By placing a check-mark in one box in each group below, please indicate which statements best describe your own state of health today.

**Mobility**
- I have no problems in walking about
- I have some problems in walking about
- I am confined to bed

**Self-Care**
- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

**Usual Activities** *(e.g. work, study, housework, family or leisure activities)*
- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/Discomfort**
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

**Anxiety/Depression**
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed
To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0. We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.
Appendix C.

Self –Efficacy Questionnaire

Design, Implementation and Evaluation of a Reduced
Cardiac Rehabilitation Program
Self-efficacy Questionnaire

Date Completed: ________________________

This questionnaire assesses how confident you are in making healthy lifestyle changes. Please answer the following questions as accurately as possible by circling one of the four numbers below such that ‘1’ means ‘Not at all true’ and ‘4’ means ‘Very much true’. If you have any questions please contact Dr. Alejandra Farias Godoy at 6822344 local 63570.

1. If I intend to take up a healthy diet, I know that I can stick to it.

2. When I understand why a medication is needed, I know that I will take it as instructed.

3. I doubt that I can manage to really carry through with a low fat, healthy diet.
4. Often I am unable to organize my day so that I can take all my pills on time.

5. I usually can’t resist the temptation of delicious but unhealthy food.

6. Often I am unable to find the patience necessary for cooking a healthy meal.

7. I often get confused about how to take my medication.

8. I know for sure that I can stick to my medication routine.

9. I know for sure that I can stick to a healthy diet when I really want to.

10. Often I don’t succeed to take the time necessary for buying fresh, healthy groceries.

11. I doubt that I can take all my medications exactly when and how I am supposed to take them.

12. I know for sure that I can take all my prescribed medication at the right times.

More questions…
I am confident that I can perform a planned exercise even if...

<table>
<thead>
<tr>
<th></th>
<th>Not confident at all</th>
<th>Maybe</th>
<th>Very confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I am tired.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. I feel depressed.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. I have worries.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. I am angry about something.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. I feel tense.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. friends are visiting.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. others want me to join them in an activity.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. my family/my partner takes up much of my time.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. I find no one to exercise with.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. the weather is bad.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11. I still have a lot of work to do.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12. There is an interesting program on TV.</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
### Appendix D.

## CES-D Centre of Epidemiological Studies Depression Scale

Below is a list of some of the ways you may have felt or behaved. Please indicate how often you have felt this way during the past week: *(circle one number on each line)*

<table>
<thead>
<tr>
<th>During the past week...</th>
<th>Rarely or none of the time (less than 1 day)</th>
<th>Some or a little of the time (1-2 days)</th>
<th>Occasionally or a moderate amount of time (3-4 days)</th>
<th>All of the time (5-7 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I was bothered by things that usually don’t bother me.........................</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. I did not feel like eating; my appetite was poor.............................</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. I felt that I could not shake off the blues even with help from my family..............</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. I felt that I was just as good as other people</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. I had trouble keeping my mind</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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1 Version Date: Dec27-2005
2. I felt lonely................................................ 0 1 2 3
3. I enjoyed life.............................................. 0 1 2 3
4. I had crying spells........................................ 0 1 2 3
5. I felt sad.................................................. 0 1 2 3
6. I felt depressed........................................... 0 1 2 3
7. I felt that everything I did was an effort........... 0 1 2 3
8. I felt hopeful about the future....................... 0 1 2 3
9. I thought my life had been a failure................. 0 1 2 3
10. I felt fearful............................................. 0 1 2 3
11. My sleep was restless................................. 0 1 2 3
12. I was happy.............................................. 0 1 2 3
13. I talked less than usual............................... 0 1 2 3
14. I felt lonely............................................. 0 1 2 3
15. People were unfriendly................................ 0 1 2 3
16. I enjoyed life............................................ 0 1 2 3
17. I had crying spells...................................... 0 1 2 3
18. I felt sad................................................ 0 1 2 3
19. I felt that people disliked me....................... 0 1 2 3

---

2 Version date: Dec 27-2005
20. I could not “get going”.......................... 0  1  2  3
Appendix E.
Consent Form

Design, Implementation and Evaluation of a Reduced Cardiac Rehabilitation Program

Consent form

INVESTIGATORS:
Dr. Scott Lear
Dr. Alejandra Farias Godoy (Primary Contact)

The above investigators would like to invite you to participate in the following research study as you have heart disease and are currently beginning the Healthy Heart Program cardiac rehabilitation program. Participation is entirely voluntary and you may decide to refuse to participate or withdraw from the study at any time.

Purpose

The purpose of this research is to design and implement a Reduced Cardiac Rehabilitation Program (rCRP) and compare it to the standard CRP of the Healthy Heart Program, St Paul’s Hospital). We hope will allow us to improve services to a greater number of patients. We hope that this will lead to: Equivalent exercise capacity, modification of cardiac risk factors and lifestyle behaviours, and quality of life with less visits to the hospital for exercise sessions.
What is the Reduced Cardiac Rehabilitation Program (rCRP)?

The rCRP is a comprehensive program that offers the core elements of the standard cardiac rehabilitation program, that is, a multidisciplinary approach to optimize patient’s physical, psychological, social and emotional status:

- Patient referral and assessment
- Exercise and activity counseling
- Nutritional assistance
- Risk factor management (manage and control all the risk factors for having a cardiac condition such as diet, smoking, weight, etc.)
- Medical Care by a cardiologist
- Psychological screening
- Education with Question of the week education series.
- Smoking cessation if needed

The only difference with the standard cardiac rehabilitation program is the number of hospital based exercise sessions. 10 hospital exercise sessions for the rCRP compared to 32 sessions for the standard program (sCRP) over the period of 16 weeks.

What does your participation involve?

If you decide to participate, you will undergo a standard physical including blood pressure measurement, weight, height, waist circumference, waist to hip ratio. Blood tests consisting of lipid measurements (cholesterol levels, fats in your blood), and blood sugar. Also, an exercise stress test conducted in St. Paul’s hospital under the cardiologist’s supervision. All these tests will be done twice: at intake and at graduation from the program and they are part of a standard procedure when you join the cardiac rehabilitation program. However, since this information will be used for research purpose, if you have had a blood test done beyond a month from intake, or a stress test done beyond 2 weeks from intake, we may ask you to repeat these tests. You will also have to answer the following questionnaires twice: at intake and at graduation from the program: a) A questionnaire to assess symptoms of depression. b) A questionnaire to assess your current level of physical activity. c) EuroQol questionnaire to assess your current quality of life. d) A 3-day food record to assess your diet to be completed at home. e) A questionnaire to assess how you perceive yourself at performing certain tasks. The total time for these questionnaires is approximately 60. If you meet inclusion criteria and safety requirements, you will be randomly assigned to one of two groups: 1. An intervention group that consists of a reduced cardiac rehabilitation program (you will have to come to 10 hospital exercise sessions in total over a period of 16 weeks) and 2. The standard cardiac rehabilitation program group (you will have to come to 32 hospital exercise sessions in total over a period of 16 weeks). The only difference between these two groups is the number of hospital based exercise sessions.
After completing the program there will be a third follow up, where the case manager will contact you 1 year after graduation and ask you to come for an appointment to assess your weight, waist circumference, hip circumference, blood pressure and answer the same questionnaires, along with a blood test and a stress test.

If you wish to give us your permission to be contacted for a follow up appointment and possible future research studies, please read the consent paragraph below (print and sign your name in the appropriate places).

**Control Group: Standard Cardiac Rehabilitation Program**

This is the usual cardiac rehabilitation program of St. Paul’s Hospital. It is a 4-month program where you will receive 32 hospital exercise sessions (twice a week), nurse assistance, medical care by a cardiologist, risk factor management, nutritional counseling, social worker, psychological support and smoking cessation if needed.

**Intervention Group: The Reduced Cardiac Rehabilitation Program**

The Reduced CRP is designed to be a multidisciplinary intervention too that will keep the same nature of therapies as the sCRP. The difference with the standard program resides in the number of hospital exercise sessions; there will be 10 sessions spread throughout 4 months of participation in the program instead of 32 hospital exercise sessions for the sCRP. You will still be expected to exercise as much as the sCRP but with emphasis on home exercise. The reduced cardiac rehabilitation program includes an individualized exercise guideline according to your exercise prescription. During the first two weeks of participation you will be asked to come for hospital exercise sessions twice a week to be evaluated by the staff and learn your exercise program. An exercise specialist will show you how to do the exercises at home. You will be given an educational package with questions to be answered on a weekly basis. You will also receive a diary to record exercise sessions at home and to answer the questions of the week. During the 4 months of program you will be given a schedule with your hospital exercise sessions.

If you participate in the study, all of the above questionnaires will be assessed again at the end of the program (4 months after intake). If you had a blood collection done beyond a month from intake the procedure will have to be repeated. If you had a stress test done beyond 2 weeks from intake it will have to be repeated at St. Paul's Hospital.
How will we protect your confidentiality?

Ensuring your confidentiality is very important to us. Only the project investigators, your nurse and the other health care professionals of the Healthy Heart Program will have your name. Your name and any personally identifying information, such as date of birth or address, will be removed from any data collected and stored separately. Data will be labeled with an anonymous code number at the time it is entered into the database. Your completed questionnaires will be identified by
number only, not with your name. The database will be protected by a password. Only the principal investigator and co-investigator will have access to the database.

**What are the costs of participation?**

The Standard cardiac rehabilitation program has a cost of $100/month. If you decide to participate in the study and are randomized to the reduced program it will have a cost of $50/month. However, regardless of the group you are randomized in you will be asked to pay what you can without imposing any additional financial burden. This will be discussed in your interview with the nurse at the intake clinic.

Transportation and parking expenses will not be covered.

**What are the benefits of participation?**

The purpose of the rCRP is to do less exercise in St. Paul’s Hospital and more exercise at home. Participation in cardiac rehabilitation has been proven to result in improvements in fitness levels and reduction in future risk of heart disease events. Regardless of which group you are assigned to, we anticipate that your participation will result in these improvements. In addition, if you are assigned to the reduced program you will spend less time attending the hospital for cardiac rehabilitation because you will receive guidelines for a home based cardiac rehabilitation program. This may result in a reduction in expenses for you (ie: parking, transportation). Results of this research can be obtained by contacting Dr. Alejandra Farias Godoy at 604-6822344 ext. 63570.

**What are the risks of participation?**

The risks are those associated with participating in non-medically supervised exercise (home exercise). These are rare and will be minimized by appropriate safety screening and prescription of target exercise heart rate ranges, but may include chest pain or shortness of breath with exertion and in extremely rare instances may lead to a heart attack, disorders of the heart rhythm and stroke.

If you have any questions about your rights as a research subject you may contact the Director of Research Services, University of British Columbia at (604) 822-8598. Alternatively you may contact Dr. Hal Weinberg, Director of Research Ethics at Simon Fraser University at 604-268-6593, or the Director of the School of Kinesiology at Simon Fraser University at 604-291-4062.
Authorization: I, __________________________, have read the above information and I have had an opportunity to ask questions to help me understand what my participation would involve. I freely consent to participate in the study and acknowledge receipt of a copy of the consent form. I also understand that I may refuse to participate in the study or withdraw from the study AT ANY TIME. My refusal to participate or withdraw from the study will not affect my medical care at St. Paul’s Hospital or Providence Health.

I consent to the research team notifying my family physician and cardiologist about my participation in this study: Yes____ No____

____________________ ________________ Date:_______________
participant’s signature name (please print)

____________________ ________________ Date:_______________
witness’ signature name (please print)

____________________ ________________ Date:_______________
co-investigator’s signature name (please print)
Consent for 1 year follow-up

I, ________________________________ (print name), do hereby grant the investigators of the Reduced Cardiac Rehabilitation Program Study permission to contact me regarding a follow up appointment and future research studies. I understand that signing this permission form is voluntary and I may refuse to do so. Refusal to sign this form will in no way affect the care I receive from Providence Health Care. I also understand that by signing this form I am in no way consenting to participate in any future research studies. If I am asked to participate in future research studies, I will be asked to provide consent at the time. I have had all of my questions answered to my satisfaction and received a copy of this form for my records.

________________________________________________________________________
participant’s signature

________________________________________________________________________
today’s date

Yours sincerely,

Alejandra Farias-Godoy, MD

Scott Lear, PhD
Design, implementation and evaluation of a reduced cardiac rehabilitation program

Contact Information

Phone | E-Mail
---|---

Investigators
Dr. Scott Lear |  
Dr. Alejandra Farias |  

Study Coordinator
Dr. Alejandra Farias

Dietitian

Exercise Specialist

Nurse

Healthy Heart Program Website: www.healthyheart.org
Design, implementation and evaluation of a reduced cardiac rehabilitation program

Appointment Instruction Sheet

Exercise Stress Test:
Location: ECG Lab (Rm. 2450)-2nd floor Providence Wing.
1. Light meal (allow 2-3 hours before the test). No coffee/tea/cigarettes before test.
2. Medications as usual.
3. Light comfortable clothing and comfortable shoes (athletic shoes preferable).
4. Refrain from exercise the morning of your test.

Blood (Cholesterol/Lipid) Test:
Location: St. Paul’s Lab-2nd Floor Providence Wing (HR. 730 AM-530 PM)
No appointment required.
1. Please take white requisition with you.
2. Fasting (No food/drinks except water) for 12 hours.
3. No alcohol for 3 days before test.
4. Blood test should be done at least 2 weeks before your appointment date.

Exercise Session Days:
Location: Healthy Heart Program Upper Gym (2nd Floor Comox Bldg).
1. Abstain from exercise for 6-12 hours prior to your exercise session, as blood pressures will be measured before/after exercise.
2. Wear light comfortable clothing and comfortable shoes (athletic shoes preferable).
3. If you are Diabetic, bring your Glucometer and be prepared to test your blood sugar before/after exercise.
Leisure Time Physical Activity Questionnaire

Location: To be completed at the intake clinic if you have time or at home.

1. Complete the questionnaire before your exercise stress test appointment.
2. Consider only those activities that you have participated in, in the past 4 weeks only.
3. If you complete the questionnaire at home, bring it with you next time you come to the Healthy Heart Program and hand it in to Dr. Alejandrar Farias Godoy

Three Day Dietary Record
Location: To be completed at home.

1. Record all food that you have eaten for 3 consecutive days, one of which must be a weekend day (Thu-Fri-Sat, or Sun-Mon-Tue).
2. Record all food and beverages consumed and the amounts as accurately as possible.

Tips: size of deck of cards = 3 oz. cooked meat
size of a closed fist = 1 cup (e.g. vegetables, grains)
size of a thumb = 1 Tbsp (e.g. spreads, sauces, dips)
3. Include all snacks eaten through out the day.
4. Include the amount of butter, margarine, oil and amount and type of mayonnaise, salad dressing, sauces, etc. you have used in preparing foods.
5. Specify the kind of milk (skim, 1%, 2%, etc.), yogurt (diet, 0.5% MF, etc), cheese (low fat, cheddar, etc).
6. Indicate any foods eaten outside of the house by a “*”.

EuroQol questionnaire
Location: To be completed at the intake clinic (if you have time) or at home.

Read the questions carefully and take your time to answer them.
The questionnaire takes about 5 minutes to answer.
If you have any questions about the questionnaire, please contact Dr. Alejandra Farias Godoy at 604-682-2344 extension 63570.
If you complete the questionnaire at home, bring it with you the next time you come to the Healthy Heart and hand it in to Dr. Alejandra Farias Godoy

Self Efficacy questionnaire
Location: To be completed at the intake clinic or at home

1. Read the questions carefully and take your time to answer them.
2. The questionnaire takes about 10-15 minutes to answer.
3. If you have any questions about the questionnaire, please contact Dr. Alejandra Farias Godoy at 604-682-2344 extension 63570.
4. If you complete the questionnaire at home, bring it with you the next time you come to the Healthy Heart and hand it in to Dr. Alejandra Farias Godoy.
Depression questionnaire

Location: To be completed at the intake clinic or at home

1. Read the questions carefully and take your time to answer them
2. The questionnaire takes about 10 minutes to answer.
3. If you have any questions about the questionnaire, please contact Dr. Alejandra Farias Godoy at 604-682-2344 extension 63570.
4. If you complete the questionnaire at home, bring it with you the next time you come to the Healthy Heart and hand it in to dr. Alejandra Farias Godoy.

Exercise schedules for the next 4 months.
Appendix F.
Exercise Logbook

Week of:___________________

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
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Example and Instructions

(This is an example only, in order to provide guidance in completing the logbook. Please follow the recommendations made by your health care professional.)

Target HR: 105 to 110 beats/minute
Week of: Feb 22, 1998

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Instructions
Every time you exercise enter in the following information: Date, Activity, Peak HR, Peak RPE, Symptoms, Diet and check for Medicine use.

Activities:  W = walking
              W/R = jogging
              R = running
              S = swimming
              B = bicycling
              H = health club
              WL = weight lifting

Other activities: ________________________

Symptoms:  0 = none
            1 = angina
            2 = shortness of breath
            3 = dizziness
            4 = leg cramps/claudication
            5 = nausea
            6 = irregular heart beats
            7 = excessive fatigue
            8 = other: ________________________
            9 = other: ________________________

Diet:  1 = Excellent (no concerns, following a healthy heart diet today)
       2 = good (generally following a healthy heart diet today)
       3 = satisfactory (slightly strayed from a healthy heart diet today)
       4 = I did not follow my diet (unable to follow a healthy heart diet today)

RPE Scale:

1 = Very easy
2 = Easy
3 = Moderate
4 = Somewhat hard
5 = Hard
6
7 = Very strong
8
9
10 = Very, very hard
* = Maximal
Questions and Concerns

Please use this space to write down any questions or concerns that you may have so that they can be addressed upon next contact with the staff. Please write down the date
Appendix G.
Educational Quiz

Educational questionnaire

1. The following are heart disease risk factors, except for:
   a) High fat diet
   b) High blood pressure
   c) Smoking
   d) Lack of exercise
   e) None of the above

2. Cholesterol is:
   a) A waxy substance that carries fat through the blood for storage
   b) Involved in making hormones
   c) Required for the body to function normally
   d) All of the above

3. How can you decrease your high blood pressure?
   a) By taking your medications
   b) By exercising
   c) By smoking
   d) Only a and b

4. How can you manage angina?
   a) Stop smoking
   b) Controlling blood pressure
   c) Manage stress effectively
   d) All of the above

5. What are NOT benefits of exercising?
   a) Elevates your metabolism
   b) Increases the good cholesterol (HDL)
   c) Increases flexibility and muscular strength
   d) Makes you look younger and more beautiful
6. To monitor exercise intensity, you can use:
   a) The talk test
   b) Rating of perceived exertion
   c) Heart rate
   d) Any of the above

7. Which of the statements below is a good reason for stopping exercise?
   a) You are experiencing a lot of joint and muscle pain
   b) You are experiencing light headedness
   c) You are experiencing jaw pain
   d) All of the above

8. How can you increase your intake of fruits and vegetables?
   a) Include 1-2 servings of fruit and/or vegetables at all 3 meals and snacks
   b) Ensure that half your plate at supper time contains vegetables
   c) I do not have to increase fruits and vegetables because I take vitamins
   d) a and b only

9. Which statement is true?
   a) frozen yogurt is fat free and I can eat all I want
   b) if a product is fat free it will not affect my blood sugar
   c) fat free does not equal calorie free
   d) if I follow a low fat diet I will lose weight

10. If you are starting to experience overtraining you might feel:
    a) elated
    b) emotional
    c) energetic
    d) exhilarated

11. Free weights are advantageous because:
    a) It is easy to figure out how to exercise each different muscle group
    b) It takes less time to use free weights than machine weights
    c) Safety is a key feature
    d) More likely to transfer over to everyday activities better than machine weights.
12. What is important to remember about your medications?
   a) the name of the medication
   b) what does it do
   c) when should you take it
   d) how much should you take
   e) all of the above.

13. What side effects from medications would you seek immediate medical attention?
   a) swelling of the throat and limbs
   b) difficulty breathing
   c) a rash over most of the body
   d) all of the above

14. What are the goals of drug therapy?
   a) to control symptoms
   b) to slow or reverse disease
   c) to accumulate different coloured pills
   d) to prevent further damage
   e) all but c

15. What is ablation?
   a) A way to fix an arrhythmia
   b) It is done by putting a catheter in your vein
   c) A way to fix high blood pressure
   d) a and b

16. How do I know I have atrial fibrillation?
   a) irregular heart beats
   b) palpitations of “flutter” in the chest
   c) shortness of breath
   d) get tired more easily when exercising
   e) all of the above