COMPARING THE EFFECTIVENESS OF A TRADITIONAL VERSUS AN ALTERNATIVE OUTPATIENT CARDIAC REHABILITATION MODEL

by

Jacqueline Brigitte Monique Gabelhouse

B.Sc., The University of Saskatchewan, 2000

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Abstract

It has been demonstrated that participation in cardiac rehabilitation (CR) elicits improvements in health related quality of life (HRQOL), exercise tolerance, cardiac risk factors, and all-cause mortality rates in patients with cardiovascular disease (CVD). Despite the aforementioned benefits associated with CR, enrollment and participation rates remain low (30%) due to a number of barriers including accessibility, financial constraints, time conflicts, the referral process, and participant interests. Due to the sub-optimal enrollment of CR programs, alternative CR models have been developed to provide greater flexibility for patients in terms of accessibility, interests, affordability and preferences. However, little is known about the effectiveness of this alternative model, or more specifically, whether these alternative models result in similar positive benefits associated with traditional cardiac rehabilitation models (TM). Thus, the purpose of this study was to compare the effectiveness of a traditional model (TM) to an alternative, hybrid model (HYM) for CR in terms of health related quality of life and secondary outcome measures (i.e., physical activity, resting blood pressure, cholesterol profile, blood sugars, metabolic equivalents, smoking status, fruit and vegetable intake, depressive symptoms, and anthropometrics). This study was a prospective, two-armed non-randomized intervention consisting of 125 cardiac patients from the Central Okanagan. Participants choose to enroll in a TM (n=72) or an alternative HYM (n=53) CR program. Of 125 participants, 88% completed the programs. Mean age of the participants was 67.1±10.6 years and 70.4% were male. The results of the two way-analysis of variance (ANOVA) showed no significant interaction between models. However, statistically significant improvements were observed over time in HRQOL (p<.001). The secondary outcome measures found statistically significant improvements over time for physical activity (p<.001), systolic blood pressure (p<.001), total
cholesterol (p<.001), low density lipoprotein (p<.001), METs (p<.001), reductions in smoking status (p=.043), dietary behaviors (p<.001), depressive symptoms (p<.001), and waist circumference (p<.001). Study results indicate that an 8 week HYM in a CR setting may be as effective as a TM for changing health promoting behaviours specific to those with CVD.
Preface

Ethical approval for this project was obtained from the University of British Columbia Okanagan’s Behavioral Research Ethics Board (H15-00023).
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Glossary of Terms

*Acute coronary syndrome* (ACS) refers to a group of conditions due to decreased blood flow in the coronary arteries as part of the heart muscle is unable to function properly or dies. This typically occurs with unstable angina, which occurs suddenly with minimal exertion or new onset angina (Stone et al., 2009).

*Arrhythmias* refer to a group of conditions in which the heartbeat is irregular, too fast, or too slow. A heartbeat that is too fast (greater than 100 bpm) is called tachycardia and a heartbeat that is too slow (less than 60 bpm) is called bradycardia (Stone et al., 2009).

*Atherosclerosis* is a disease in which plaque builds up inside the artery wall and can lead to a heart attack, stroke or even death. Arteries are blood vessels that carry oxygen rich blood to your heart and other parts of the body (Wilmore & Costill, 1998).

*Cardio-protective therapies* are cardiovascular medications that prevent and protect the progression of cardiovascular disease (CVD). With appropriate medication, patients with CVD or those at risk of the disease can improve their quality and quantity of life. Cardiovascular medications include but are not limited to, statins, beta-blockers, anti-coagulants, anti-platelets and ACE-inhibitors (Stone et al., 2009).

*Cardiorespiratory fitness* refers to the ability of the circulatory and respiratory systems to supply oxygen to skeletal muscles during sustained physical activity (Martin et al., 2013).

*Cognitive behavioral therapy* (CBT) is a short-term psychotherapy designed to reduce symptoms of anxiety and depression. It works to solve current problems and change unhelpful thinking and behavior (Aldcroft et al., 2011).

*Cardiac Rehabilitation* is a professionally supervised chronic disease management program which provides education and exercise classes to increase physical fitness, reduce cardiac
symptoms, improve health, and reduce the risk of future cardiac events and foster self-management (Stone et al., 2009).

*Ischemia* is an insufficient supply of blood to an organ, typically a blocked artery (Wilmore & Costill, 1998).

*Heart Failure* occurs when the heart is unable to pump sufficiently to maintain blood flow to meet the body’s needs, causing limitations such as, shortness of breath, excessive tiredness and leg swelling (Heart & Stroke, 2013).

*Metabolic equivalents* is a physiological measure describing the energy cost of physical activities and is defined as the ratio of metabolic rate during a specific physical activity to a reference set by convention to $3.5 \text{ ml } O_2 \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ (ACSM, 2014).

*Modifiable Risk Factor* is a risk factor that can be controlled, treated or modified, without genetic predisposition, such as high blood pressure, cholesterol, overweight/obesity, tobacco use, lack of physical activity and type 2 diabetes (Wilmore & Costill, 1998).

*Myocardial Infarction* occurs when a decrease in blood flow is seen in the coronary arteries and a part of the heart muscle dies. This is also referred to as a heart attack (Stone et al., 2009).

*Psychosocial health* include such factors as depression, anxiety, psychological stress, social isolation, socioeconomic status, personality and alcohol abuse in addition, if poorly managed results in an increased risk of cardiovascular disease (Stone et al., 2009).

*Peripheral vascular disease* a common circulatory problem affecting the arteries towards your extremities (usually limbs) where limited blood flow reduces oxygen received causing pain (Wilmore & Costill, 1998).

*Self-management* skills aims at helping patients to maintain a wellness from their perspective, concentrating knowledge delivery on three sets of tasks for people living with chronic
conditions, which include medical or behavioral management, role management, and emotional management (Lorig & Holman, 2013).

*Stroke* is known as cerebral vascular accident (CVA) and is due to poor blood flow to the brain resulting in cell death. There are 2 main types of stroke 1) ischemic; due to lack of blood flow or 2) hemorrhagic; due to bleeding (Heart and Stroke, 2013).
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Dedication

In 1974, preliminary Cardiac Rehabilitation commenced in Kelowna, BC, spear-headed by Dr. Dorrance Bowers and later guided by Dr. Kevin J. Pistawka and Mr. Bert Webb. There were several volunteer Board of Directors who supported COACH’s Mission and Vision statements; Doug Kaulbach, Cam Bonell, Don Cocar, Bea Kline, Dr. Micheal Koss, Tracy Moench, Jennifer Charles, and Roy Buckler. It was their belief in quality care and life after a cardiac event that has produced the outcomes we observe within the Central Okanagan Association of Cardiac Health (COACH) today. Thank you for believing in the COACH team.
Chapter 1 Introduction

1.1 Layout of Thesis

This thesis has been organized into six sections. Chapter one provides an overview and introduces the overall purpose for the current research. Chapter two provides a review of the research literature, presenting the groundwork for the thesis by focusing on the literature pertaining to cardiovascular disease (CVD), modifiable cardiac risk factors, the evolution of cardiac rehabilitation (CR) and the need for alternative CR programming. Chapter three details the methodology of a prospective cohort study designed to examine health related quality of life and cardiac risk factors (i.e., physical activity, resting blood pressure, cholesterol, metabolic fitness, depressive symptoms and anthropometric indicators) in CR patients enrolled in two CR program models. Chapters four and five present and discuss the results of the research, respectively. The sixth and final chapter provides a summary of conclusions, strengths, and limitations, as well as outlines future research recommendations concerning CR models.

1.2 Overview

Approximately 1 out of 3 Canadians will die of CVD, of which many will die before the age of 65 years (Wielgosz, Arango, Bancej, Bienek, Johansen, Lindsay, … Webster, 2009). Research has found that CVD deaths are preventable as the majority are attributed to modifiable risk factors such as obesity, physical inactivity, hypertension, hyperlipidemia and smoking. Furthermore, two out of five Canadians over the age of 20 years are living with 3 or more modifiable risk factors (Wielgosz et al., 2009), and approximately 90% of first heart attacks are related to nine modifiable risk factors (Yusuf, Hawken, Ounpuu, Dans, Avezum, Lanas, …
Aggressive modifiable risk factor management will help reduce this epidemic and subsequent cardiac event occurrence (Thomas et al., 2007; Stone et al., 2009).

Risk reduction through CR can reduce morbidity and mortality in CVD patients by approximately 25%. (Taylor, Brown, Ebrahim, Jolliffe, Noorani, Rees, … Oldridge, 2004). The Canadian Association of Cardiovascular Prevention and Rehabilitation (CACPR) describe CR programs as providing secondary prevention treatment options to enhance chronic disease management that foster behavioral improvements and self-management (Stone, Arthur & Suskin, 2009). Similarly, the American Association of Cardiovascular Prevention and Rehabilitation (AACVPR) assert that the adoption and completion of an evidenced-based CR program facilitates life-long behavior change (Thomas et al., 2007). Overall, participating in CR results in considerable benefit for those who have had a cardiac event, including improved health related quality of life (Yu, Lau, Chau, McGhee, Kong, Cheung, & Li, 2004; Taylor et al., 2004; Leung, Keerat, Gravely-Witte, Suskin, Stewart, & Grace, 2011; Janssen, De Gucht, van Exel & Maes, 2012), reduced cardiac death (Lawler, Filion, & Eisenberg, 2011; Taylor, Brown, Ebrahim, Jolliffe, Noorani, Rees, … Oldridge, 2004), reduced all-cause mortality (Goel et al., 2011), reduced health care costs (Papadakis et al., 2005), and improved modifiable cardiac risk factors (Gupta, Sanderson & Bittner, 2007; Magelhaes, Ribeiro, Barreira, Fenandes, Torres, Gomes & Viamonte 2013) compared to usual care.

Despite the benefits associated with CR participation, only 30% of eligible participants are referred to CR programs (Grace, Abbey, Shnek, Irvine, Franche & Stewart, 2002) and of that, only 30% choose to participate (Dafoe, Arthur, Stokes, Morrin & Beaton, 2006; Candido, Richards, Oh, Suskin, Arthur, Fair, & Alter, 2011). These low participation rates are due to a number of barriers including: lack of referral, demographic characteristics (e.g., older age,
gender, ethnic origin), financial concerns, clinical condition of the patient, transportation, and time conflicts (Chan et al., 2006; Suaya et al., 2007; Grace et al., 2009; Brual et al., 2010). Due to the sub-optimal uptake of evidence-based CR, alternative CR models have been proposed (Stone et al., 2009; Leung et al., 2011) to address some of these reported barriers (Redfern, Briffa, Ellis & Freedman, 2008; Stone et al., 2009; Leung et al., 2011). These new models have been developed to provide greater flexibility for patients in terms of accessibility, interests, affordability and preferences.

In Kelowna, British Columbia, the CR program (Central Okanagan Association for Cardiac Health, [COACH]) offers both a traditional (TM) and hybrid model (HYM) of CR. The active phase of each CR model is eight weeks in which patients choose to participate in the TM or HYM. Although the selection of the program model is patient driven, the TM model is encouraged if the participant is risk stratified as high risk i.e heart failure, previous cardiac arrest, medically managed coronary artery disease (>70% blockage), diagnosed with depression and metabolic equivalent level <5.0 (Thomas et al., 2007; Stone et al., 2009). The HYM is tailored to reduce the amount of on-site participation required in the TM, reducing travel time, transportation concerns and return to work barriers. However, evaluation of this HYM has been limited and little is known about the effectiveness of this alternative model, or more specifically, whether this alternative model results in similar positive benefits associated with the TM. This thesis provides valuable insight concerning the effectiveness of these models, helping to inform the delivery of CR programming for cardiac patients.
1.3 Purpose

The overarching purpose of this thesis is to compare two CR models to determine whether participation in the TM model exhibits greater positive changes in health related quality of life (primary outcome) and secondary measures. Specifically, these secondary measures include: physical activity, resting blood pressure, cholesterol profile, blood sugars, metabolic equivalents, smoking status, fruit and vegetable intake, depressive symptoms, body mass index, and waist circumference. These measures will be assessed at baseline (pre-CR programs) and at completion of the CR programs (8 weeks).

1.4 Research Question and Hypothesis

The research question guiding the current study is: Does participation in an HYM elicit the improvements in health related quality of life and secondary outcomes as seen in the TM? Guided by research demonstrating the effectiveness of a TM (Balady et al., 2007; Thomas et al., 2007; Stone, et al., 2009), the hypotheses of this research are as follows:

Hypothesis 1: The change in health related quality of life will be greater in the TM compared to the HYM.

Hypothesis 2. The change in secondary outcomes (cardiac risk factors) would be greater in the TM compared to the HYM.

1.5 Significance and Contribution

The significance of this research is essential given the clinical relevance for those in the community setting which provide CR. Health professionals continue to refine and develop alternative CR models in an attempt to address some of the participation and maintenance
barriers that this population faces, however, little is known about the effectiveness of these models. This preliminary research provides a look at the effectiveness of these models. More specifically, this research examines whether alternative HYM provides benefits as in the TM, particularly concerning health related quality of life and the important risk factors relevant to this population. Moreover, the outcomes of this research will provide insight into best practice approaches for CR programming. Understanding which type of model provides the greatest benefit will inform the refinement and development of future CR programming. Most importantly, this research specifically draws on the outcomes of a specific community (Okanagan cardiac population), which has ‘real world’ implications for the local CR program (COACH) and thus the findings can be used to specifically tailor CR models to the needs of this particular community.
Chapter 2 Review of Literature

2.1 Cardiovascular Disease

Cardiovascular disease (CVD) is a set of conditions that impede the heart and blood vessels surrounding the heart. These conditions reduce blood flow (ischemia) or produce a clot (thrombosis) which limits blood flow to vital organs, often leading to a myocardial infarction-MI (heart attack) or stroke (Mendis, Pusk, & Norrvig, 2011). There are many conditions associated with CVD due to the progressive and chronic nature of this disease, including: hypertension, peripheral vascular disease (PVD), cerebral vascular accident (stroke), heart failure, irregular heart rhythms (arrhythmias), and coronary artery disease (CAD). CAD is the narrowing of the vessel lumen, typically caused by accumulation of fatty deposits called atherosclerosis (Mendis et al., 2011; Wilmore & Costill, 1998). The atherosclerosis process of CVD can be aggressive when modifiable cardiac risk factors are not managed and this disease process is typically advanced by the time cardiac symptoms occur (De Backer, Ambrosioni, Borch-Johnsen, Brotons, Cifkova, Dallongeville, … Wood, 2003). As CVD progresses, angina symptoms begin, signaling reduced blood supply to the heart (Finks, 2010). When blood supplies to a part of the heart (myocardium) are restricted, this ischemia can lead to a MI (heart attack).

The prognosis after acute coronary syndrome (ACS) depends on the interventions available within local hospitals, wait-times, on-set of medications (thrombolytic/clot busters), age, multiple co-morbidities and disease severity. Approximately 90% of MIs are related to nine modifiable risk factors, including; poor psychosocial health, physical inactivity, high blood pressure, abdominal obesity, smoking, diabetes, reduced fruit and vegetable intake, alcohol consumption, and inflammation for both men and women of all cultural backgrounds (Yusuf,
Hawken, Ounpuu, Dans, Avezum, Lanas, McQueen…& Lisheng., 2004), thus prevention and management of CVD is crucial.

2.2 Prevalence of CVD

In Canada, CVD is the second leading cause of mortality, following cancer, for both women and men (Statistics Canada, 2014). In 2005-2006, rates of CVD hospitalizations in Canada for both women and men doubled each decade of age increase; 494.3 (45-54 years), 1202.8 (55-64 years), and 2952.5 (65-74 years) per 100,000 for women and 1155.2 (45-54 years), 2854.6 (55-64 years), and 5502.8 (65-74 years) per 100,000 for men (Public Health Agency of Canada, 2009). Moreover, CVD mortality rates for men were 1.6 times higher than for women (288 per 100,000 versus 175 per 100,000) (Manuel, Leung, Nguyen, Tanuseputro, & Johanse, 2003) and are anticipated to increase 120 and 137 percent for women and men, respectively (Gaziano, 2007).

In 2007, 4.8% of Canadians 12 years of age and older (1.3 million) reported having heart disease, and after 75 years of age, 23.5% reported having heart disease diagnosed by a health care professional (Public Health Agency of Canada, 2009). Moreover, it has been confirmed that particular modifiable risk factors grossly contribute to the prevalence of CVD. For example, 40% of Canadians have elevated cholesterol, 60% are overweight or obese, 20% have elevated blood pressure, 16% suffer from nicotine addiction (Statistics Canada, 2012) and 85% are not meeting the guidelines of 150 minutes per week of physically activity (Colley, Garriguet, Janssen, Craig, Clarke, & Tremblay, 2011). As CVD is highly preventable, targeting CVD risk factor reduction is a global priority and has led to the development and implementation of Cardiovascular Prevention and Rehabilitation programs worldwide (Giannuzzi, Saner, Bjornstad, Fioretti,

2.3 The Evolution of Cardiac Rehabilitation

   In nearly a century, the therapy following ACS has evolved from complete bed rest in the 1930’s (Certo, 1985; Levine and Lowe, 1952) to a comprehensive health promotion program integrating rigorous exercise and health education, supported by a multi-disciplinary team of health professionals (i.e. cardiologists, general physicians, exercise physiologists, psychologists, nurses, social workers, registered dietitians, and pharmacists) (Stone, Arthur, & Suskin, N., 2009). The Canadian Association of Cardiovascular Prevention and Rehabilitation (CACPR) describe CR programs as a systematic process of chronic CVD patient care which provides health behavior interventions for cardiac patients with the objective of patients achieving self-management (Stone, Arthur & Suskin, 2009).

   In 1953, Dr. Louis Katz exposed the medical community to a new form of rehabilitation for cardiac patients, and the application of “work physiology” ensued. Work physiology referred to the capability of people to function optimally at the workplace without placing the heart under undue stress or strain (Davis, Faulkner, & Miller, 1969). By the 1960’s, CR programs were based on physical activity (PA) energy requirements, exercise capacity and evaluation of cardiac function post-MI. The evaluation tools were developed from engineers, psychologists, physiologists and those practicing medicine (Davis et al., 1969). These components, in addition to education, were soon recognized to be essential CR protocols positively impacting CR patients return to work and normal activities of daily living (ADL’s) (Certo, 1985).
CR in Canada was formerly described in phases. Phase one is now termed “in patient” and occurs in hospital. "In patient” is an early ambulation and counselling period (Murphy, George, & Driscoll, 2007) where patients may be assisted with self-care duties, such as taking medications, basic hygiene and meals; and provided with instructions concerning medications along with strategies for managing CVD. The “in patient” period is also the time when patients are referred to an outpatient CR program. (Murphy, 2007; Grace, Chessex, Arthur, Chan, Cyr, Dafoe, Juneau, … Suskin, 2011). Outpatient (formerly Phase 2-3) CR is a supervised ambulatory program, traditionally three months in duration, which consists of monitored exercise, and an emphasis on the continued development of self-management skills and education concerning lifestyle change and risk factor reduction (Grace et al., 2011). Finally, the Maintenance (formerly Phase 4) CR program is community-based and promotes lifelong physical fitness and continued risk-factor self-management (Pinto, Goldstein, Papadonatos, Farrell, Tilkemeier, Marcus & Todaro, 2011). Inpatient, outpatient and maintenance CR programs form a continuum of care to facilitate recovery and prevent further cardiac events.

Today, cardiac patients in-hospital stay has reduced significantly over the years and patients can be discharged within 24-48 hours due to early detection, cardiac disease screening, and technologically advanced interventions such as coronary stenting, which reduces symptoms of CVD and prevents MIs or the re-occurrence of MIs. Coronary stenting, medically-termed percutaneous coronary interventions (PCI), is the most common interventional procedure which places a stent in the coronary artery to prevent blood vessel closure. This procedure has reduced the incidence of angiographic restenosis (the return of abnormal narrowing or clot) by 30-40% (Sigwart, Puel, Mirkovitch, Joffre & Kappenberger, 1987) however, this procedure alone is not enough as many percutaneous transluminal coronary angioplasty patients often experience a
repeat coronary event due to continued poor lifestyles behaviours, including physical inactivity, unhealthy eating, smoking, and discontinuing protective cardiac medications (Lisspers, Hofman-Bang, Ryden, Sundin, Ohman & Nygren, 2005).

2.4 Components of Cardiac Rehabilitation

CR services include a number of program components aimed at improving patient care and reducing further cardiac events and hospitalization. The core components of an established CR program include: an assessment of psycho-social health status, physical fitness assessment, cardiac risk factor assessment and management (i.e., blood pressure, lipids, anthropometrics), smoking status, diabetes, nutrition, cardio-protective therapies and discharge information as described by the American Heart Association (Balady, Williams, Ades, Bittner, Comoss, Foody, ... Southard (2007) and CACPR (Stone et al., 2009). The baseline assessment should take place within 1 to 3 weeks from hospital discharge dependent upon the patients’ health status (Dafoe, Arthur, Stokes, Morrin, & Beaton, 2006). During this baseline assessment, a health care professional who specializes in CR conducts a review of the patient’s CV health history (i.e., medical interventions, cardiac tests such as electrocardiograms, echocardiograms, stress tests) and initiates discussion concerning the importance of medication compliance and risk factor reduction. In particular, attention is focused on reviewing the benefits of engaging in PA and other healthy lifestyle behaviors (e.g., healthy eating, tobacco cessation) for CR patients (Wenger, 2008). Further details regarding the baseline assessments are detailed below.

Psychosocial status should be screened individually for psychological distress, especially depressive symptoms, unhealthy coping strategies and family/social support status. If a person has a diagnosis of depression or rates high on the assessment tool measuring depressive
symptoms, an individual counseling session should be made and group education sessions may also be provided to address stress management and coping strategies (Thomas, King, Lui, Oldridge, Pona, & Spertus, 2007; Balady et al., 2007; Stone et al., 2009). This support service is provided by a licensed psychologist, counselor or social worker, to deliver effective cognitive behavioral therapy internal or external to the program (Aldcroft, Taylor, Blackstock, & O’Halloran, 2011).

PA status is evaluated using a graded exercise test, utilizing a treadmill or cycle ergometer. Based on the outcomes of this test and on the risk stratification tools described by the American Heart Association (AHA) and American Association of Cardiovascular Prevention and Rehabilitation (AACVPR), an exercise prescription is given to the participant (Taylor et al., 2004; Thomas et al., 2007). In addition, PA management is addressed and includes instruction on risks associated with a CV event based on previous PA, comorbid conditions, and a review of any previous musculoskeletal or neuromuscular concerns. Each participant is encouraged to engage in PA on non-CR days to achieve the recommended guidelines of 150 minutes of moderate to vigorous PA per week.

Blood pressure status is assessed and monitored during each exercise session. At the time of measurement, values should be discussed with patients, specifically highlighting goals of \(<140/90\) or \(<130/85\) for diabetics to reduce heart, kidney or brain injury (Anderson, Gregoire, Hegele, Couture, Mancini, McPherson, … Stone, 2012). Lipid status is discussed and reviewed based on most recent values and includes targets for low density lipoprotein (LDL) of \(<2.0\text{ mmol}\) or \(50\%\) less from baseline (Anderson et al., 2012) along with increased consumption of plant-based foods, reduced animal fats and medication compliance (Wenger, 2008).
Weight status is assessed by measuring waist circumference (<102 cm/men, <88 cm/women), and calculating body mass index (height in cm and weight in kg), and goals for weight management are made at the baseline appointment and reviewed throughout the program (Balady et al., 2007; Thomas et al., 2007). Tobacco consumption should be assessed, with smoking cessation support, aids and resources provided as applicable (Selby, Brosky, Cote-Meek, Els, O’Loughlin, Ordean & Reid, 2011). Behavioral interventions to promote long-term smoking-cessation should be provided, including small group or telephone hotline support (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009).

Nutritional status is assessed through a review of eating habits, including how much the individual consumes fruit and vegetable, fiber, sodium and heart healthy fats; ensuring participants understand basic principles of healthy dietary sources and label reading. Cardio-protective medication status is reviewed to inform the patient has been prescribed preventative medications and understands the importance of adherence. Diabetes status requires particular instruction on physical activity (PA), monitoring blood glucose pre and post exercise for safety for individuals with diabetes, especially those with Type 1 diabetes. Lastly, a discharge plan is provided to participants and includes participant pre and post assessments outcomes and short and long term goals in partnership with the primary care physician (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009). Patient education is provided regarding lifestyle and medication management, this may include a referral to a diabetes program or educator (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009). Once patient information has been documented and the goals and expectations of the CR program have been discussed, the patient/family will take part in group education classes or one-to-one sessions. The education classes include topics such as: healthy eating (lipid and diabetes management), stress management, medication management,
exercise safety and progression, heart anatomy and procedures, and cardiovascular risk management. At the post assessment, promotion of participants to transition to a community exercise setting is encouraged in larger centers and includes a progressive exercise prescription. Primary care physicians and specialists receive a completed discharge plan which includes risk factor status, symptom management and exercise prescription. This communication is critical in the enforcement of the CR discharge plan.

Offering these components in CR provides participants with the opportunity to be empowered to self-manage their chronic CVD. Self-management refers to a person’s ability to confidently implement resource utilization, partnership building with care providers, develop an action plan, solve problems, make decisions, self-tailor and implement these skills appropriately (Lorig & Holman, 2003; Stone, 2009). Evidence has indicated that the adoption, participation and completion of the prescribed CR components, as outlined above, provide elements for lifelong behavior change (Balady et al., 2007; Thomas et al., 2007; Stone, 2009) and greater positive health outcomes compared to those undergoing usual care (e.g., routine physician care) (Piepoli, Davos, Francis, & Coats, 2004; Taylor et al., 2004; Papadakis, Oldridge, Coyle, Mayhew, Reid, Beaton, …Angus, 2005; Grace et al, 2006).

2.5 Benefits of Cardiac Rehabilitation

Extensive research has been conducted on the benefits of CR, including reduction of mortality and morbidity (Piepoli et al., 2004; Taylor et al., 2004; Papadakis et al., 2005; Kingsbury & Oh, 2014), as well as improved health related quality of life (Yu et al., 2004; Leung, Keerat, Gravely-Witte, Suskin, Stewart, & Grace, 2011) and reduced CV risk. Specific, physical and psycho-social benefits associated with CR are outlined below.
2.5.1 Physical Health Benefits

There are a number of physical health benefits that are particularly relevant to CVD. In a meta-analysis of randomized control trials (RCTs) on CR programs (comprehensive and exercise arm only), Taylor et al., (2004), compared usual care patients with patients who engaged in CR and found significantly reduced all-cause and cardiac mortality (OR=0.80; 95% CI: 0.68 – 0.93 and OR=0.74; 95% CI: 0.61 – 0.96), respectively. Lawler, Filion, & Eisenberg (2011) systematically reviewed 34 RCTs on exercise based CR and found similar results indicating a reduction in cardiac mortality (OR 0.64, 95% CI 0.46-0.88), all-cause mortality (OR 0.74, 95% CI 0.58-0.95), and lower risk of re-infarction (OR 0.53, 95% CI 0.38-0.76).

Regarding cardiac risk factors, Gupta, Sanderson & Bittner’s (2007) evaluated a 12 week CR program (2-3 x week monitored exercise and education core components) on 289 CR patients at baseline and post-intervention, results indicated significant improvements for 6-min walk test (1,319 ft to1,579 ft, p<.01), BMI (28.8 to 28.4, p<.01), total cholesterol (177 mg/dL to 164 mg/dL, p<.01), LDL (108 mg/dL to 96 mg/dL, p<.01), PA (8.9 METhrs to 22.8 METhrs, p<.01), and depression (9.4 to 5.8, p<.01), assessed by the Beck Inventory Index. There were significant improvements in all clinical, behavioral, and health status measures except for triglycerides and smoking status. Taylor et al., (2004) also reported in the RCT’s that modifiable risk factors were associated with significant reductions in total cholesterol (weighted mean difference, -0.37 mmol/L [-14.3 mg/dL] 95% DI: -0.63 to -0.11 mmol/L [-23.4 to -4.2 mg dL]), triglycerides (-0.23 mmol/L [-20.4 mg/dL]; 95% CI: -0.39 to -0.07 mmol/L [-34.5 to -6.2 mg/dL]) and systolic blood pressure with CR (weighted mean difference, -3.2 mmHg; 95% CI: -5.4 to 0.9 mmHg). Significant reductions in smoking status were also reported at follow up with CR participation (OR=0.64; 95% CI: 0.50 to 0.83). Lawler et al., (2011) systematic review
found a favorable reduction in smoking, BP and total cholesterol. Minimal changes were seen in body weight. When modifiable risk factors are managed they are associated with reduced risks of future events and repeated physician visits.

In another CR study which included one year follow up, Magelhaes, Ribeiro, Barreira, Fenandes, Torres, Gomes & Viamonte (2013) found the effects of a 12 week CR program (2 x week monitored exercise and core education components), on 256 adults significantly improved elevated cholesterol and other measures. From baseline to 3 months total cholesterol decreased from 26.2% to 12.5%, p<.001, LDL decreased from 55.1% to 32%, p<.001, and high density lipoprotein improved in the proportion of patients with HDL below recommended values from 71.9% to 38.2% (p<.001), with the majority meeting recommendations. In addition, obesity and blood pressure, smoking status, and sedentary behaviors were also significantly reduced at follow-up. For diabetics with a baseline hemoglobin A1C (HbA1c) greater than 6.5%, nearly half of the participants reduced their HbA1c below targets (55.7% to 30.7%) (p <.001). Sedentary behaviors were also reduced from 46.5% to 11% (p <.001). Arthur et al., (2013) investigated women’s (n=203) levels of moderate to vigorous PA (MVPA) at CR program discharge, at 6 months and again at 12 months. The CR program sessions were 90 minutes in length and were held twice weekly over a six-month period. Levels of MVPA were calculated using the Godin Leisure-Time Exercise Questionnaire (GLTEQ) during CR (mean score of ≥ 24 units of PA/week), and found that women exercised a mean of 27 (units/week) at the end of CR, achieving health related benefits.

The physical health benefits provided during CR programs contribute to an overall reduction in CVD progression, mortality and morbidity rates, (Ginnuzzi et al., 2003; Taylor et al., 2004; Giannuzzi et al., 2008; Lawler et al., 2011). Along with reductions in cardiac risk
factors, increases in PA and MVPA were observed which resulted in enhanced exercise tolerance (METs) (Taylor et al., 2004; Gupta et al., 2007; Arthur et al., 2013). Therefore, the physical health benefits associated with CR Programs, not only reduce the risk of a second cardiac event, all-cause mortality and cardiac risk factors, they in turn reduce health care costs, disability rates and job absenteeism. In addition to these physical health benefits, there are also a number of psycho-social benefits.

2.5.2 Psycho-social Health Benefits

The psycho-social health benefits of CR Programs are well documented and include improved HRQOL, depressive symptoms, and anxiety Rosengren, Hawken, Ounpuu, Sliwa, Zubaid, Almhmeed, …& Yusuf’s (2004). Interheart study evaluated 52 countries regarding risks for the first myocardial infarction (MI) and of the nine modifiable risk factors experienced; psycho-social health factors (depressive symptoms and stress) had a three-fold increase risk of first MI. Furthermore, Williams, Ades, Hamm, Keteyian, LaFontaine, Roitman, & Squires’s (2006) review of clinical evidence for CR participants with various cardiac diagnoses (e.g. MI, CABG, heart failure, cardiac valve repair/replacement), found improvements in HRQOL regardless of diagnosis, which potentiates translation to reduced mortality rates through lifestyle modification, medical therapy and regular PA. Milani & Lavie (2009) retrospective review on CR participants (n=522) (12 weeks, 3 x week exercise and core education components) assessed psycho-social health factors including HRQOL utilizing the Kellner Symptom and Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) questionnaire and found the prevalence of psycho-social health factors were reduced from 10% to 4% (p<.0001) and HRQOL improved in those experiencing low and high psycho-social health factors (105.3±16.3 to 118.5 ±
14.2 vs 81.1 ± 15.2 to 103.9±19.5; p<.0001) at CR Program completion. A comparison was also made regarding mortality rates for those who experienced low to high psycho-social health factors and found those rated high, experienced a four-fold increase in mortality (22% vs 5%; p=.003). Milani & Lavie’s (2009) findings emphasize the importance of CR participation to improve participant’s psycho-social health status and mortality rates.

Moreover, McGrady, McGinnis, Badehop, Bentle, & Rajput’s (2009) retrospective chart review assessed participant’s psycho-social health status and CR program completion. The CR participants were assessed for depression, anxiety and HRQOL (n=380) regarding adherence and dropout rates to a CR Program (12 weeks, 3 x week exercise and core education components). The Beck Depression Inventory-II (BDI-II), Beck Anxiety Inventory (BAI) and SF-36 questionnaires were utilized. McGrady et al., (2009) observed approximately 50% of the participants completed the program. Statistically significant differences were observed between participants who completed or dropped out of the CR program regarding depression, anxiety and HRQOL. Those who dropped out experienced higher scores for depression, anxiety and experienced lower HRQOL. Overall, in comparing early drop outs vs completers, psychological variables were significant (p=.001) for those who dropped out. McGrady (2009) findings highlight the importance of addressing low HRQOL scores and depressive symptoms at entry of CR to enhance program completion. However, assessing HRQOL and depressive symptoms may not be feasible in smaller or rural settings as resources to address poor psycho-social health factors would require additional training and health care professionals to improve outcomes.

Unfortunately, if there is a lack of opportunity for persons with CVD to address diminished health related quality of life and modifiable CVD risk factors, consequently there are increased risks of disease progression, increased morbidity and mortality (Yusuf et al., 2004;
Williams et al., 2006; Leung et al., 2011). In a study by Janssen, De Gucht, van Exel & Maes (2012), the authors observed that illness perceptions of cardiac patients were related to HRQOL. They found that illness perception significantly improved (p<.001) during twelve weeks of CR (3 x week monitored exercise and core education components) specifically, patients perceived fewer consequences, symptoms, decreased emotional effect of the disease, and experienced an increased sense of understanding of CVD and HRQOL at program completion.

Additionally, research concerning CVD and psycho-social health has shown that improvements are not limited by age. Lavie & Milani (2006) examined HRQOL and risk profiles from 635 subjects both young (42-54 years) and old (70-85 years), utilizing the SF-36 and Kellner Symptom Questionnaire. The CR program included 12 weeks of exercise training (3 x week) and core education (CVD prevention, behavioral factors, stress, sexual function). Results included improvements in scores for depression (-58.5%), and HRQOL (15.8%) (p<.001). The prevalence of anxiety symptoms were similar in both young and old, with a statistically significant reduction observed in both groups (p<.001) following CR. Lavie & Milani’s (2006) research provides insight to the benefits observed for all ages regarding improvements in HRQOL and reduced anxiety.

Furthermore, psycho-social health improvements were observed among CR participants whether they participated in a brief (two months) or longer (six months) program. Yu et al., (2004) completed a prospective, RCT to assess improvements in HRQOL utilizing the SF-36 questionnaire. The participants (n=269) were randomized to two groups. Group one TM (2 x week exercise and education) and group two (control group) were excluded from supervised exercise and received a one-time two hour education class. At the end of the program, the control group showed no improvements in all eight dimensions of the SF-36 questionnaire and
experienced increased bodily pain. However, the CR group indicated significant improvements in HRQOL, anxiety, depression, relaxation and contentment (p<.05). Lueng et al., (2011) also compared HRQOL of patients who participated in three options; CR greater than six months (n=183), CR less than six months (n=148) and those who did not participate in CR (n=725). To assess HRQOL researchers utilized the Beck Depression Inventory-II (BDI-II). Lueng (2011) found no observable difference between duration < six months and ≥ six months regarding HRQOL. However, HRQOL improved significantly (p<.001) for those who participated in CR compared to those who did not participate, indicating enhancements in HRQOL for those who engage in CR (Yu et al., 2004; Lueng et al., 2011).

Depression has been identified as a risk factor for increased cardiovascular morbidity and mortality, however growing evidence suggests that CR programs, which include exercise, can significantly improve feelings of depression for those diagnosed with CVD (Blumenthal, 2007; Milani & Lavie, 2009; Rutledge, Redwine, Linke & Mills, 2013). Nearly, 25% of CVD patients beginning a CR program experience depressive symptoms (Grace, Abbey, Pinto, Shnek, Irvine & Stewart, 2005). Irvine & Rogler (2006) assessed the effectiveness of CR program (12 weeks exercise and education) on depressed patients (n=188) post cardiac event using the Beck Depression Inventory (BDI) scale. The baseline BDI score of 1.26 (95% CI 1.02 to 1.50) were observed and showed statistical improvements (p<.03) at completion of the CR program 1.01 (95% CI 0.77 to 1.24). Reddy, Rullo, Lee, Nicholson, & Cheslik-Candy (2010) reported similar findings regarding CR program participants (n=114) with varying levels of depression (low, moderate to severe). They found statistically significant improvements among all levels of depression (p<.005), specifically low, moderate and severe depression groups improved by 56%, 65.2% and 49.2% respectively. A meta-analysis on the effects of CR and depression by
Rutledge et al., (2013) found CR had a small to moderate effect size on depression severity ($d=0.23$, 95% CI$=0.10-0.35$, $I^2=32.3\%$), reduced CVD events and total mortality, whereas mental health treatments alone did not. This underscores the importance of comprehensive TM CR programs to enhance overall HRQOL, well-being and reduce depressive symptoms after a cardiac event, particularly for those patients experiencing poor HRQOL, depressive symptoms and depression after a cardiac event (Milani & Lavie, 2009).

### 2.6 Barriers to Cardiac Rehabilitation Participation

Despite the numerous benefits associated with participation in CR programs, there is a staggering low CR participation rate of only 30% (Suaya, Shepard, Normand, Ades, Prottas, & Stason, 2007: Pack, Mansour, Barboza, Hibner, Mahan, Ehrman, … Keteyian, 2013). These low participation rates have been attributed to a number of barriers associated with CR (Parkosewich, 2008). Most notable barriers to CR programs include; 1) Demographic factors, such as age, gender, ethnicity, income status and education; 2) Psycho-social factors, including lack of time or time conflicts, knowledge of programming, communication and social support; and 3) Environmental factors, particularly referral processes, transportation, and financial or funding concerns. (Harlan, Sandler, Lee, Lam, & Mark, 1995; Daly, Sindone, Thompson, Hancock, Chang & Davidson, 2002; Beswick, Griebisch, Taylor, Burke, West, Brown, … Ebrahim, 2004; Grace et al., 2006; Suaya et al., 2007; Parkosewich, 2008; Grace, Shanmugasegaram, Gravely-Witte, Brual, Suskin and Stewart, 2009; Dunlay, Witt, Allison, Hayes, Weston, Koepsell, & Roger, 2009; Valencia, Savage & Ades, 2011; Reges, Vilchinsky, Leibowitz, Khaskia, Mosseri, & Kark, 2014).
2.6.1 Demographic Factors

Age has been reported as one of the most common demographic barriers to CR participation. Grace et al., (2009) found that older adults (> 65 years old) had multiple barriers compared to younger adults (< 65 years old). For example, older adults perceived their own routine to be sufficient, and feared that exercise may exacerbate their condition as it may increase distress and discomfort. Older adults were also less likely to be referred to a CR program due to the complex health history of the patient (Suaya et al., 2007). Dunlay, Witt, Allison, Hayes, Weston, Koepsell, & Roger (2009) found among the 179 CVD patients referred to CR, those that participated were significantly younger than non-participants. The mean age of participation was 62.0 years compared to the mean age of 71.1 years who did not participate. Lawler, Fillion, & Eisenberg (2011) completed a systematic review on the effectiveness of exercise based CR (n = 6,111 post-MI patients) and found participants were generally younger (mean age 54.7). This was below average age at presentation for patients experiencing MI’s (Lawler et al., 2011). Parkosewich’s (2008) review on barriers to CR programs found physicians may assume the patient as frail, elderly and not interested in attending due to advanced age.

Gender has also been recognized as a barrier to CR participation. In a longitudinal study examining the uptake of CR programs, Grace, Abbey, Shnek, Irvine, Franche & Stewart (2002) found significant gender differences in referrals by physicians or cardiologists (p=.007). Also, men were 1.187 more likely to be referred to CR (95% C.I., 1.056-1.334) (Grace, 2002). Daly, Sindone, Thompson, Hancock, Chang & Davidson (2002) undertook a literature review on barriers to participation and adherence to CR, and found reduced program uptake, adherence and increased drop out among women. Women represented 20% of the participants in CR programming, which represents half of the women experiencing acute coronary syndrome (ACS)
(Daly et al., 2002). Harlan, Sandler, Lee, Lam, & Mark (1995) evaluated participants (n=393) with coronary by pass grafting (CABG) entering CR and found non-participants were more often women (26% vs 12%, p=.02). Women represent a very important demographic for CR participation in which commitment to improving attendance from this population is warranted (Lawler et al., 2011).

Ethnic origin has also been found to impact CR participation. In a prospective, longitudinal study, Allen, Scott, Stewart & Young (2004) found the rate of referral for CR was significantly lower (12%) for African American women (n=108) compared to (33%) Caucasian women (n=145)(p=.03). Allen et al., (2004) states being informed and receiving a referral to CR predetermined participation rates, in particular for women. Valencia, Savage & Ades (2011) review of population-based cohort studies found 19.6% whites as compared to 7.8% non-whites participated in CR post-MI or CABG. Furthermore, data collected from 242 CR programs in the United Kingdom included several demographics variables, one being ethnic background however, the numbers were too low to report formally for CR participation, indicating lack of referral and participation from these minority groups (Beswick, Griesbach, Taylor, Burke, West, Brown, … Ebrahim, 2004).

Lastly, low income level and educational attainment were found to be barriers to CR participation. Allen et al., (2004) found those with lower annual incomes were less likely to be referred and participate in CR (66%, p<.01). Specifically, Shanmugasegaram, Oh, Reid, McCumber & Grace (2013) reported those with a yearly income level of <$50,000 were less likely to participate in CR programs compared to those with a yearly income of >$50,000. In addition, Harlan et al., (1995) reported education level also impacted CR participation, indicating that those with less than high school education did not participate (p<.001). Dunlay et
al., (2009) reported similar findings as those whom participated in CR had post-high school education (p<.001).

The above research indicates age, gender, ethnic origin, income and education level as identified barriers to CR participation. Therefore, the implementation of alternative CR programming may increase uptake for those who may not have the resources, time or ability to commit to the TM. Further limitations are described below.

2.6.2 Psycho-social Factors

Time, or lack of time, has been reported as a common barrier to CR participation. Grace et al. (2009) indicated that those < 65 years old had employment, financial and family responsibilities which limited their participation in CR programs. However, they also found that evening CR programming may be one way to address some of these barriers. Shanmugasegaram et al.’s (2013) research also indicates residents living greater than 30 minutes away found time and family responsibilities to be a barrier to participation. Parkosewich (2008) also describe non-attendees as having minimal time in their day to participate, especially women, primary caregivers and those returning to work.

Lack of knowledge and poor communication concerning the importance of CR participation has also been identified as barriers to CR. Grace et al. (2006) assessed system-level barriers and facilitators of the continuity of care from hospital to CR and found key informants (e.g., CR staff, cardiologists, researchers, policy makers, and other doctors), communication and trust regarding CR programming, were imperative to CR program referral and attendance. Key informants and patients lack of awareness of the existence of CR programs resulted in low enrollment rates (Grace, 2006). Some physicians unfortunately experience a lack of knowledge of the benefits, costs, locations, and quality of CR programs in their community.
and may even experience disbelief regarding the benefits their patients may experience from participation in a CR program (Parkosewich, 2008). Formalizing official communication between the patients, health care providers and CR programs can foster improvements in participation (Grace et al., 2011).

Social support is an important indicator of CR participation as indicated by Daly, Sindone, Thompson, Hancock, Chang and Davidson (2002). They found that family member’s participation, health care practitioner’s enforcement and marital status were all predictors of CR participation and adherence. Specifically, those encouraged by spouses were more likely to attend CR programs. In addition, those who had family members participate in the rehabilitation process were also more likely to attend the CR program (Daly 2002; Parkosewich, 2008).

2.6.3 Environmental Factors

The process of referring patients to a CR program has been one of the most cited barriers to CR participation. Grace, Scholey, Suskin, Arthur, Brooks, Jaglal, Abramson, & Stewart (2007) compared CR enrollment following automatic (hospital electronic record sent to CR center) vs usual referral (paper-based with on-site specialist or other health care provider recommendation) in a multi-centre trial. Participants (n=506) completed a mailed self-reported questionnaire assessing CR referral and participation nine months after CR commenced. Participants receiving care on cardiac wards with automatic referral were more likely to be referred (n=134, 52%) vs usual care (n=84, 32%) (p <.001) to CR programs. Additionally, the automatic referral improved rates of participation (p<.01) and timeliness of referrals received (p<.001). This finding is imperative as a systematic referral process is not standardized across all major centers nationally or internationally. Reges, Vilchinsky, Leibowitz, Khaskia, Mosseri, & Kark (2014) interviewed acute coronary syndrome (ACS) patients (n=420) during
hospitalization regarding barriers to participation to CR and found the presence of a written recommendation/discharge letter from the hospital to their family physician compared to those who did not have a recommendation letter increased participation rates by 71.9% vs 32.5%, respectively.

Distance to CR was also reported as a barrier to CR participation. Those living greater than 60 minutes away were less likely to participate (Brual, Gravely-Witte, Suskin, Stewart, Macpherson & Grace, 2010; Chan, Hart, Goodman, 2006) compared to those who lived near CR programs and who owned and drove a car (Daly et al., 2002). Shanmugasegaram et al.’s (2013) cross-sectional study on rural and urban CR participants reported distance as a barrier in both groups (p=.002). Dunlay et al. (2009) also found that those CR participants that were able to drive experienced an increase in participation (p=.001). Parkosewich’s (2008) review found a significant difference for participation rates for those patients who live near a CR program, as they were 2 to 4.5 times more likely to attend. Moreover, alternative CR program may address this barrier.

Although CR is cost effective for the health system (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009), there are often financial constraints associated with CR enrollment and participation for patients, such as user fees not covered by health insurance. In the US, where insurance reimbursement is limited, CR participation rates are low (Daly et al., 2002). In Canada, Grace et al. (2006) stated that health systems do not directly fund CR programs and therefore programs experience basic cost pressures, affecting participation and sustainability. Furthermore, this places CR programs in the position to collect user fees, limiting access to those experiencing financial barriers and therefore reducing accessibility and participation rates (Valencia et al., 2011). However, patients with lower socioeconomic status were also
underrepresented in Harlan et al. (1995) study (n=393) and despite active recruitment and waiving direct costs to patients who could not afford the program (Harlan et al., 1995), low participation rates still occurred (n=52).

In an attempt to address many of these barriers and increase awareness, accessibility and uptake of CR programs, CR health professionals across the globe have endeavoured to develop alternative CR program models (Yu et al., 2004; Reid, Morrin, Pipe, Dafoe, Higginson, Wielgosz, … Blanchard, 2006; Redfern, Briffa, Ellis, & Freedman, 2008; Korzeniowska-Kubacka, Bilińska, Dobraszkiewicz-Wasilewska, & Piotrowicz, 2014; Najafi & Nalini, 2015). These programs differ from the traditional CR program in an attempt to mitigate participation barriers by increasing program flexibility and diversity.

2.7 Alternative Cardiac Rehabilitation Models

Over time, CR programs have evolved to include targeted programs that meet the needs and preferences of cardiac patients. These alternative models have attempted to address some of the major barriers associated with low participation rates, such as lack of time and accessibility of programs (i.e., transportation, financial concerns). As a result, CR programs have started to offer programs with greater flexibility and diversity. Most common of these programs include home-based CR models (HM), in which participants are given some resources and a CR program plan to assist them with independently completing a program at home (Taylor, Dalal, Jolly, Moxham & Zawada, 2011), and hybrid CR models, which include baseline assessments, education classes, some monitored exercise sessions including safe progression, telephone or web-based follow up for cardiac risk reduction and self-management skills until the final assessment.
2.7.1 Home-based Cardiac Rehabilitation Program Model

HM were designed to provide flexibility for participants to achieve CV risk factor reduction and improvements in HrQOL by undertaking a tailored CR program in their own home. The HM monitors participants progress through follow up visits, telephone calls, tele-ECG, education manuals or self-monitoring log books (Jolly, Taylor, Lip & Stevens, 2006; Taylor et al., 2011). Ades, Pashkow, Fletcher, Pina, Zohman & Nestor (2000) completed a multi-center controlled trial, comparing a 12 week TM (n=50), which included CVD risk factor education and exercise, vs. a HM (n=83) consisting of exercise with tele-home monitoring ECG’s and informal conference calls. All patients were considered low to moderate-risk and primary outcomes included peak aerobic capacity and HRQOL. Aerobic capacity improved 23% in the TM compared to 18% in the HM (both groups p<.001 compared to baseline). Many HRQOL domains showed significant improvement for both CR models, including; physical and social functioning, physical and role limitations and energy (p<.05). There were slight differences in body weight (kg) between groups, in which the HM increased their body weight while the TM decreased in weight (p<.05). This difference in groups may be attributed to effective dietary education in the TM (Ades et al., 2000) and increased time spent with health care professionals whom provide direction on healthier lifestyle choices, components which are often limited with the HM.

Oliveria et al., (2008) randomized 30 low risk cardiac patients to either the HM or usual care (UC). The 12 week HM consisted of education and counseling on risk factors for CVD and PA guidance. Specifically, the first 6 weeks included educational information provided through two group classes, telephone contact, flyers, plus one home visit and the last 6 weeks included 2 telephone calls and 1 home visit on non-consecutive days. Those in the UC were only asked to
follow-up with their doctor as needed, no other treatment was given to this group. Results showed that the HM improved daily PA (278.2 to 525.5 counts per minute per day, p<.05) and time spent in moderate-intensity PA (from 16.8 to 63.7 minutes per day, p<.05). The UC group showed no significant differences in any of these measures. Unfortunately, Oliveria (2008) did not include a TM allowing for further investigation regarding the benefits of the TM compared to usual care or the HM.

Taylor et al.’s, (2010) systematic review on TM and HM (12 studies, n=1,938) for low risk acute MI and re-vascularized patients (PTCA, CABG) found similar benefits on maximal oxygen uptake, cardiac risk factors, HRQOL, and all-cause mortality in comparing the two models. Due to heterogeneity between the two groups data regarding maximal oxygen uptake (METs or ml/kg/min) were pooled on seven out of the 12 trials. No statistically significant differences were found in the short (3 to 6 months) or long (12-24 months) term (95% CI -0.35 to 0.13; p=0.36 vs 95% CI -0.44 to 0.77; p=0.59), for METs in the TM or HM, respectively. Seven out of the 12 trials found no between group differences for reductions in systolic blood pressure (95% CI -3.29 to 4.44; p=.002), however, there were small increases in pooled diastolic blood pressure for the HM (95% CI 0.74 to 2.94; p=.24). The pooled analysis on the participants lipid profile at 3 to 12 month follow up showed evidence for decreases in HDL cholesterol in the HM (95% CI -0.11 to -0.02; p=.16). As there is a linear relationship between HDL and PA, this may indicate reduced PA in the HM. There were no statistically significant differences for LDL and triglycerides; 95% CI -0.01 to 0.31; (p=.22); 95% CI -0.11 to 0.41; (p=.06), levels respectively. However, the effects of reductions in the cholesterol profile may be contributed to those taking statins not necessarily a program model. Taylor (2010) also reported no statistically significant differences in the proportion of smokers at follow up or all-cause mortality with either
models; 95% CI 0.71 to 1.41; (p=.34); 95% 0.65 to 2.66; (p=.80). Five out of the 12 trials reported on HRQOL. Due to different HRQOL measures there were challenges with the analysis, however, the authors report no evidence of a statistical difference in overall HRQOL at follow up between both models utilizing independent 2-group t-test (p > .05). Taylor et al., (2010) systematic review on TM vs HM shows promising evidence for the HM. However, upon further analysis the findings are only generalizable to those with a low to moderate risk stratification. Furthermore, the TM had greater evidence for improvements for DBP and HDL, indicating an advantage for the TM.

The Australian CHOICE HM (Choice of Health Options In prevention of Cardiovascular Events) program was a 12-week, single-blind, 3-arm RCT for low to moderate risk patients. The 3 arms included a usual care group (n=72), the CHOICE HM group (n=72) and a contemporary nonrandomized reference group starting a TM (n=65) (Redfern et al., 2008). Typically, a TM in Australia is 6 weeks in duration and includes two monitored exercise sessions and core education components two times per week. CHOICE HM participants included a one-hour face to face baseline assessment, including four 10 minute follow-up telephone calls, to review risk factor education (e.g., smoking cessation, increase PA, etc.), and a resource/education manual. They found that those who received the CHOICE HM program demonstrated statistically significant (p<.01) reduction of their cardiac risk factor profile compared to usual care, including: total cholesterol 158 vs 186 mg/dL, systolic blood pressure 133.5 vs 144.4 mmHg, BMI 28.9 vs 31.0 kg/m2, PA METs 1,187 vs 636 METS/kg/min, and smoking cessation 6% vs 23%, p<.01. This HM may improve CVD risk factors as compared to usual care. However, the TM results at 12 months for LDL, METs, total cholesterol were closest to the recommended targets. HRQOL scores in the CHOICE HM program were significantly better than controls for physical function
(SF-36) at 12 months (76.4 (2.7) vs 64.3 (2.8), p<.01). Yet, the TM had greater improvements in general health, social function, mental health and vitality compared to controls and CHOICE HM. At 3-months depressed moods, measured by the Cardiac Depression Scale, indicated increased depressive symptoms slightly over time between the CHOICE HM and usual care group, however there were no significant differences between groups (22% vs 16%). This underscores the importance of the TM for CR in reducing depressive symptoms. Although the HM has gained utilization globally, the uptake is limited to those participants risk stratified mainly as low risk (Jolly et al., 2006; Taylor et al., 2010).

### 2.7.2 Hybrid Cardiac Rehabilitation Program Model

To our knowledge there have been four published studies to date examining the outcomes of hybrid cardiac rehabilitation program model (HYM) on low to moderate risk patients (Korzeniowski-Kubacka, Dobraszkiewicz-Wasilewska, Bilinska, Rydzewska & Piotrowicz, 2011; Korzeniowska-Kubacka, Bilińska, Dobraszkiewicz-Wasilewska, & Piotrowicz, 2014; Szalewska, Tomaszewski, Kusiak-Kaczmarek, Niedzytko, Gierat-Haponiuk, Haponiuk, & Bakula, 2015; Najafi & Nalini, 2015). The HYM is described as a blend of on-site TM CR participation and off-site (HM), which includes multi-technology (telephone, email, web-based) contact with a health care professional for the duration of the program. Of these studies, all had a comparison or control group and have included diverse samples from geographic locations around the world.

Research by Najafi & Nalini (2015) compared coronary artery bypass grafting (CABG) patients enrolled in a comprehensive TM (n=585) vs a HYM (n=195) in West Iran. The program was set up in two comprehensive phases; preliminary and complementary. The preliminary phase of the program began with two to four weeks of monitored exercise (3 times per week) and
education classes (controlling risk factors, healthy diet, weight and stress management) for both groups. Those who successfully completed the preliminary phase (i.e., understood symptom management, low to moderate risk and able to safely progress their own exercise prescription) were allowed to proceed to the complementary phase. The complementary phase consisted of eight weeks of three times a week exercise for the TM or one time a week in the HYM. Outcomes assessed included METs, BP, heart rate, BMI, waist circumference (WC), lipid profile, depression and anxiety score (BII-II), smoking status, HRQOL (SF-36) and exercise frequency. Following the complementary phase, improvements in most outcomes were comparable for both models (Najafi & Nalini, 2015). However, only the TM showed significant improvements for WC (p<.002), total cholesterol (p<.01), triglycerides (p<.008), anxiety (p<.001) and physical HRQOL (p<.01). These results indicate support for the comprehensive TM. These differences however did not sustain adjustment for level of education, age, sex, heart function, exercise tolerance, anxiety score, and living area. Participants in the complementary phase had similar attendance rates to those in the TM and HYM (21.72 ±2.4 vs 7.21± 0.84, p<.001). Hospital records indicate a 38% less expenditure for the HYM compared to the TM and there were no reported incidences or cardiac events in either group.

Korzeniowska-Kubacka et al., (2011: 2014) examined the effectiveness of HYMs in two separate samples (male and female) of low risk MI patients with preserved heart failure in Poland. Firstly, Korzeniowski-Kubacka and colleagues (2011) compared males (n=62) in a TM (8 weeks, 3x week exercise) to a HYM (home based with tele-home monitoring and partly outpatient CR). The first four weeks of the CR programs were hospital-based. After participants completed 10 monitored exercise sessions (interval training on cycle-ergometers; six bouts of 80% heart rate reserve with 2 minute rest periods, 40 minutes in total) in the TM, the men were
divided into two groups (HYM; n=30 or TM; n=32). The HYM participants were provided with tele ECG monitoring and completed interval training three times per week (10 minute walks with two minute rest periods). Maximal workload and exercise duration increased significantly in both models from baseline to completion, METs; TM (7.3 ± 1.4 to 7.8 ± 1.2), (p < .05) and HYM (8.5 ± 1.8 to 9.9 ± 2.2), (p < .01) and exercise duration; TM (10.1 ± 2.0 to 13.5 ± 1.4), (p < .001) and HYM (10.9 ± 3.6 to 12.5 ± 4.1), (p < .05). Heart rate limit was significantly higher in the HYM than in the TM (26% vs 20%, p < .001). Although, PA outcomes were not researched in this study, the reduced HR in the TM may indicate increased PA compared to the HYM, as a lower HR rate is induced with regular PA. Though, prescribed cardio-protective medications would contribute to reduced heart rates. Secondly, Korzeniowska-Kubacka et al. (2014) examined HYM in a female only population, utilizing the same methods as above (n=53), with 33 females assigned to the TM condition and 20 females assigned to the HYM condition. All patients maintained standard cardio-protective medications. Similar benefits in maximal workload and test duration compared to baseline for both the TM and HYM were found, 9.5% and 9.1% (p<.05) and 12.8% and 17.5% (p<.01), respectively. Although promising results were observed, the study sample sizes were small and inclusive to low risk post MI patients under the age of 75 years of age. Furthermore, minimal outcome variables were researched.

In a recent Polish study, Szalewska et al., (2015) investigated the effects of a retrospective non-randomized trial with low risk patients diagnosed with CVD (n=125) referred to a HYM only and then were divided into two groups (type II diabetics or non-diabetics). Participants entered the HYM 12 weeks after hospital discharge to complete a five week HYM. The first phase of HYM (8-10 days) were completed at the outpatient rehabilitation centre and consisted of supervised exercise, education, relaxation sessions and risk factor reduction. The
second HYM phases (11-12 days) were completed in the home environment. The HYM used remote controlled equipment for tele-ECG, which transmitted data to the rehabilitation department. The physician provided voice communication discussing the patients’ health status and provided consent to the patient to exercise at home. Prior to HYM, maximal workloads were significantly lower in the diabetic group compared to the non-diabetic group (p=.02). An increase in maximal workloads were observed in both the diabetic and non-diabetic groups, before HYM 6.8±1.9 METs, after HYM 8.3 ± 2.0 METs; p<.001; before HYM 8.3 ± 2.7 METs, after HYM 9.1 ± 2.8 METs; p<.001, respectively. No statistically significant differences in changes in exercise stress tests, blood pressure and heart rates between groups were observed. Szalewska (2015) adds some evidence to the HYM for persons living with diabetes or not, however no TM comparison group is provided, leaving uncertainty of the benefits compared to the more comprehensive model.

As outlined above, HYM shows some promise concerning health outcomes and CR completion rates (Korzeniowska-Kubacka et al., 2011; Korzeniowska-Kubacka, et al., 2014; Szalewska, et al., 2015; Najafi & Nalini, 2015). They provide flexibility and opportunity for greater access for those who may not be able to participate due to financial, geographic and transportation issues. However, research is still limited and little is known about the true effectiveness of the HYM compared to a TM. Only Najafi and Nalini (2015) provided insight into the many expected variables within the comprehensive TM of CR. As CVD related deaths increase, further research examining the most effective and feasible CR approaches is needed.

At COACH, the CR program models offered are similar to those presented in the literature. Participants have the option of choosing a TM or HYM, a decision often based on preference, cost and access. Anecdotally, COACH has witnessed some positive trends for both
models. However, no extensive evaluation has been performed, thus making it difficult to draw conclusions on which model provides the greatest outcome or is the most effective. The current study compares the TM and HYM models delivered at COACH, specifically examining the primary outcome of health related quality of life, and a number of secondary outcomes including PA, BP, lipids, blood sugars, METs, smoking status, dietary behaviors, depressive symptoms, and anthropometrics. The findings of this study will provide insight into which of the CR program models may or may not be most effective, which will help to inform program feasibility and future program delivery.
Chapter 3 Methodology

3.1 Design and Procedure

This study is a prospective, two-armed, non-randomized interventional study comparing the primary and secondary outcomes of the TM and HYM in the CR setting. The overarching purpose of this study was to complete a systematic evaluation of two existing, patient-selected, eight-week CR program models offered by COACH, a not-for-profit CR program, and determine which of these programs were significantly more effective for CR patients in terms of health related quality of life (primary outcome) and secondary cardiac outcome measures. Data collection began February 2015 and was continuous until July 2015 as individuals entered the programs at different times throughout those months. All data were collected at baseline (Time 1) and on completion of the eight week programs (Time 2), which varied based on participant start date of their respective program. Ethical approval was received from the Behavioral Research Ethics Board at the University British Columbia, Okanagan (#H15-00023).

Early outpatient CR should begin within 1 to 3 weeks after the diagnosis of CVD or related procedure (Thomas et al., 2007; Stone et al., 2009) as per clinical indications set by CR guidelines (Stone et al., 2009; Balady et al., 2007). This is the case at COACH, where the referral coordinator receives the referral by an electronic system from the local hospital and/or a general practitioner/specialist. He/she will then make initial telephone contact with the potential participant to provide information about the baseline assessment process, costs, and expectations for the CR program. If verbal consent to participate is provided, an appointment is made for the baseline assessment. There is a $45 fee for the assessment, which is applied to the total cost of the selected CR program if they choose to join.
After participants have arrived at their baseline assessment, they met with administrative personnel to read and sign the informed consent (Appendix A) (Balady et al., 2007; Stone et al., 2009). After the consent was obtained, the participant then completed a questionnaire assessing sociodemographic characteristics, health related quality of life, physical activity (PA), smoking status and depressive symptoms. Participants undergo a number of physical and objective assessments including: resting blood pressure, heart rate, resting ECG (if not provided from hospital discharge), review of cholesterol profile, treadmill or stationary bike exercise test (metabolic equivalents), and anthropometrics. CR program staff also review modifiable risk factors, exercise prescription and health history with participants.

Most baseline and final-program assessments are entered as de-identified data into the Canadian Cardiac Rehabilitation Registry (CCRR; Grace, Parsons, Duhamel, Somanader, & Suskin, 2014). Additional data, including referrals, questionnaires (e.g. Godin’s Leisure Time PA), completion dates, and reasons for declining or dropping out of the program are maintained in the COACH database. The data elements entered in the CCRR include participant’s time of referrals receipt, program selection, CV diagnosis and procedures, demographics, cardiac risk factors, psycho-social status, lipid profiles, exercise tests and medications.

3.2 Participants and Setting

Participants with cardiac indications were referred to COACH by an electronic referral from the local hospital and/or a general practitioner/specialist between January 2015 and May 2015. This referral was based on CR referral recommendations by the Canadian and American Association for Cardiovascular Prevention and Rehabilitation (CACPR and AACVPR) respectively (Balady et al., 2007; Stone et al., 2009). Those who were referred had a diagnosis or
procedure of: acute coronary syndrome, stable angina, heart failure, percutaneous coronary intervention, coronary artery bypass graft surgery, cardiac valve surgery, cardiac transplantation, left ventricular assist device, electronic implantation (pacemakers, defibrillators), or arrhythmia. Inclusion criteria for CR participation, requires individuals to have stable CVD, be greater than 19 years of age, referred by a specialist, surgeons, general or nurse practitioners, and sign an informed consent form. Exclusion criteria includes recent significant change in resting electrocardiogram, unstable angina, uncontrolled cardiac dysrhythmias with symptoms, symptomatic severe aortic stenosis, uncontrolled symptomatic heart failure, acute pulmonary embolus, acute myocarditis or pericarditis and acute systemic infection (ACSM, 2014).

The consecutive patients utilized in the study were residents from Central Okanagan, British Columbia (BC), which includes the jurisdictions of Peachland, West Kelowna, Kelowna, Lake Country and rural residents within the interior of BC. COACH is located within a community cardiology department in Kelowna, the largest of the jurisdictions. The CR program is under supervision of a Medical Director, and enforces standardized emergency response protocols (Balady et al., 2007; Stone et al., 2009; Grace et al., 2014).

3.3 Program Models

At COACH, participants have two program options: 1) TM, and 2) HYM. CR programs are not covered by BC healthcare, thus participants are responsible for covering the cost of the program. However, COACH does engage in fundraising activities to support those who are unable to pay the user fees. This fundraising helps to reduce the financial barrier by providing partial user fee subsidization. The fees associated with each of these programs are as follows:
$245 for the TM and $150 for the HYM. Each program has been described below and in further detail in Appendix A and B:

1) **Traditional CR Model (TM)**: consists of a baseline assessment which includes risk factor assessment, an exercise test, and blood work (e.g. lipid panel, glycated hemoglobin or fasting blood sugars). Two days per week, participants engage in a minimum 16 clinically supervised exercise sessions and a series of six weekly education classes at the COACH clinic. The clinically monitored exercise sessions are approximately 60 minutes, two times per week and patients are instructed to exercise independently on non-CR days (Stone et al., 2009). Exercise prescriptions for CR participants are described in detail (Appendix B) (ACSM, 2014). Each participant, regardless of program model, is provided with the same standards for exercise prescriptions development, which is dependent on individual capabilities and health status. The final assessment occurs at the end of CR for those who completed the program.

2) **Hybrid CR Model (HYM)**: consists of a baseline assessment, which includes the same elements as the TM. Over the next four weeks, participants engage in a minimum four monitored exercise sessions (once per week) and a series of six education classes, on alternate days, at the COACH clinic i.e. Tuesday exercise and Wednesday education. After the first four weeks are completed, the HYM participants are instructed to continue their exercise sessions independently. Exercise prescriptions for CR participants are described in detail, with similar exercise prescription development (Appendix B) (ACSM, 2014). Two 10 minute follow up phone calls are provided on alternate weeks for the purpose of reviewing goals and discussing cardiovascular risk factors, exercise prescription, barriers to exercise, and symptom or medication changes. A follow-up
assessment occurs at the end of CR for those who completed the program. To increase adherence to the HYM final assessment, which takes place at the COACH clinic, the participant is provided with a phone call reminder of their scheduled final assessment.

All program options are offered in the daytime, with no evening hours. Individualized diabetic support is offered off-site with community partners and small group smoking cessation meetings are offered quarterly to those who require these services. In addition, an onsite counselor is available to support participants experiencing depressive symptoms or other psychosocial distress.

At the baseline assessment (T1) each participant is provided with a COACH manual, which is a comprehensive resource tool of all education classes in plain language. The education classes are instructed in groups, and the topics covered include dietary/healthy eating behaviors, stress management, physical activity, cardiac risk factors (e.g. blood pressure, cholesterol, smoking cessation) and medication management. Education classes take place over a 6 week cycle on alternate exercise days and are approximately 1.5-2 hours in duration. To increase opportunities for patients to participate in the education classes, COACH offers a one day education class that condenses all 6 education classes into a single day. The one day education class is offered quarterly and is included in all programs or can be participated in separately for $100. Subsidization is provided for those in financial difficulty.

3.4 Measures

Demographic measures were collected at baseline (T1) and included: age, ethnic origin, family support, level of formal education, travel time to CR, employment and marital status (Appendix B). Participants also completed self-report measures concerning health related
quality of life, physical activity, smoking status, dietary behaviors, and depressive symptoms. In addition, anthropometrics, blood pressure, cholesterol, and metabolic equivalents were assessed by program personnel during each assessment period. The independent variables are the program models (TM vs HYM). The following provides a detailed outline of the outcome measures collected at the baseline (T1) and final assessments (T2).

3.4.1 Primary Outcome Measure

Health Related Quality of Life. Health related quality of life (HRQOL), the primary outcome, was measured by self-report using the Cantril’s Ladder of life-LOL (Cantril, 1965). Previous studies using a similar version of the LOL have found support for the construct validity of this test for patients diagnosed with CVD (Jenkins, Brodsky, Schron, Chung, Rocco, Lader, ... Shemanski, 2005; Jaarsma, Halfens, Abu-Saad, Dracup, Stappers, & van Ree, J. 1999; Jaarsma, Lesman-Leegte, Cleuren, & Lucas, 2005; Luttik, Lesman-Leegte, & Ja Arsma, 2009). Although, this measure is utilized by the CCRR to assess HRQOL (Grace et al., 2014), it is limited as it is not disease-specific or multi-dimensional. The concept of HRQOL is related to important aspects of physical and psychological health, such as coping and functional capabilities. The World Health Organization defines HRQOL as a person’s awareness of their place in life in the viewpoint of the beliefs and value systems in which they abide by relating to one’s aims, hopes, values and concerns (WHO, 1997). Cantril’s one-item LOL asks participants to rate their sense of health related quality of life on a 10 point Likert scale where 10 reflects the best possible life imaginable and 1 reflects the worst possible life imaginable (Cantril, 1965). A higher score indicates better health related quality of life.
3.4.2 Secondary Outcome Measures

*Physical Activity.* A modified version of the Godin Leisure-Time Exercise Questionnaire-GLTEQ (Godin & Shepard, 1985) was used to measure self-reported PA participation. Previous studies using GLTEQ have found support for construct validity of test scores across a number of populations (Amireault, Godin, Lacombe, & Sabiston, 2015; Arthur et al., 2014), including CR participants (Arthur et al., 2014; Kowal, Chessex, Lee & Grace, 2015). The total weekly leisure time PA score obtained from this questionnaire is expressed in 10 minute units (Amireault et al. 2015). The GLTEQ contains 3 questions that assess the frequency of mild, moderate and strenuous PA performed for at least 10 minutes during a typical week. The GLTEQ is utilized in a way that the self-reported weekly frequencies for strenuous, moderate and mild intensity levels are multiplied by 9, 5, and 3 METS (metabolic equivalents), respectively. These scores are multiplied and added, and the total scores greater than 24 are defined as ‘active’, whereas scores of 23 units or less are described as ‘inactive’ and of no health benefit (Godin & Shephard, 1985).

*Blood Pressure.* Blood pressures (BP) were measured using a mercury sphygmomanometer and reported in millimeters. BP was assessed after participants were seated for 5 minutes. Target BP goals include <140/90 mmHg and <130/80 mmHg for participants with diabetes or chronic kidney disease. BPs are taken repeatedly in two minute increments during the sub-maximal exercise test and before, during and after each supervised exercise session. If resting BP exceed 180/110 exercise tests were not performed (ACSM, 2014).

*Cholesterol and Blood Glucose.* A lipid profile was assessed for each participant and included total cholesterol, low density lipoprotein (LDL), and high density lipoprotein (HDL), along with either a fasting blood sugar or glycated hemoglobin (HbA1c). The baseline cholesterol profile was retrieved by COACH staff from hospital discharge reports, Valley
Medical lab reports or reports from general practitioner (GP) offices. If not available, participants were given a requisition to have a cholesterol profile completed at the baseline assessment. Following the standard protocol for repeat cholesterol profile (Anderson et al., 2012), blood work was completed at the final assessment.

_Metabolic Equivalents._ Exercise tests were performed on a motor driven treadmill or stationary bicycle adhering to submaximal incremental exercise protocol developed and recommended by the American College of Sports Medicine (2006; 2014) and supported by CACPR (Stone et al., 2009). Protocols with smaller increments, such as the modified-Naughton protocol, are preferred for older and deconditioned patients living with chronic diseases (ACSM, 2014). The modified-Naughton protocol provides a less aggressive increase of metabolic equivalent (MET) requirements, increasing by 1 MET per stage, and thus providing a more uniform response to exercise, better estimation of exercise capacity and reduces the reliance on hand rails to perform the required workload (ACSM, 2006; 2014). Patients exercised until limited by symptoms (volitional fatigue, dyspnea, and angina) or until they were stopped because of inappropriate physiological response (ACSM, 2006; 2014; Stone et al., 2009). For patients utilizing the cycle-ergometer, an incremental increase in workload was approximately 10 to 15 WATTS per stage. Tests were terminated at a predetermined HR level of 120 beats per minute or 70% of heart rate reserve (HRR) (ACSM, 2006, 2014; Stone et al., 2009) or to volitional fatigue (without symptoms). Pulse oximetry (heart rate and oxygen), blood pressure and heart rhythm were measured at rest, peak exercise and post-exercise.

_Smoking Status._ Smoking status was assessed via self-report with one of three response options: “I have never smoked”; “I currently smoke”; and “I quit smoking”. For the purpose of
data analysis, two of the three categories were collapsed; never smoked and quit smoking, allowing comparison of those who do not smoke and those that are current smokers.

*Dietary Behaviour.* Fruit and vegetable intake were assessed by a one item question; “how many fruits and vegetables do you consume in a day?” (e.g. ½ cup of fruits or vegetables are considered one serving). Participants circled 1 to 7, indicating the amount of fruits and vegetables they consume daily.

*Depressive Symptoms.* Depressive symptoms were assessed by the Patient Health Questionnaire PHQ-2 (Kroenke, Spitzer, & Williams, 2003). The PHQ-2 is a quick, reliable and valid screening tool (Beaudin & Burchuk, 2004). Previous studies using the PHQ-2 have found support for the construct validity of this test for patients diagnosed with CVD (Beaudin & Burchuk, 2004; Colquhoun, Bunker, Clarke, Glozier, Hare, Hickie, … Branagan, 2013; Ceccarini, Manzoni, & Castelnuovo, 2014; Cahill, Bilanovic, Kelly, Bacon & Grace, 2015). The PHQ-2 measures two fundamental symptoms of depression. Namely how often they had “little interest or pleasure in doing things” or were “feeling down, depressed or hopeless” in the past two weeks. There are four response options, based on a Likert scale, where 0 indicates ‘not at all’ to 3 ‘nearly every day’. Total scores range from 0 to 6, with higher scores indicating greater depressive symptomology (Kroenke et al., 2003). PHQ-2 provides guidance on whether subsequent diagnosis is required based on a score ≥ 3 (Beaudin & Burchuk, 2004), which would include on-site counseling and physician follow-up.

*Anthropometrics.* Weight (kg) and height (m²) were measured on the standardized health-o-meter professional scale and used to calculate body mass index (BMI) of each participant. BMI was calculated using the formula: weight (kg)/ height (m²), using the following cut-off for overweight: > 25 kg/m² (CSEP, 2010). Waist circumference was measured using an
anthropometric tape by positioning the tape mid-way between the iliac crest and rib cage, using the following cut-offs for increased health risk: males 102.0 cm and females 88.0 cm (CSEP, 2010).

3.4 Data Management

3.4.1 Data extraction from CCRR

Data extraction from Canadian Cardiac Rehabilitation Registry (CCRR) requires researchers to complete a data access application form (Appendix F). This includes a research plan, confirmation of privacy and confidentiality procedures and ethics approval (CCRR, 2012). Once the research sub-committee approves the request, data access is granted for a one year time period. In accessing the data, the research group must agree to the terms and conditions set out by the CCRR, such as ensuring confidentiality, securely maintaining de-identified data, and reporting of results to the CCRR sub-committee. For the current study, the relevant de-identified data were extracted by the CCRR data analyst, encrypted and sent to the researcher in Excel (csv files) file. These data were then imported into SPSS Statistic version 21.0 by the researcher.

3.4.2 Data extraction from COACH database

The COACH database provides additional de-identified data regarding participant’s outcomes that are not currently stored in the CCRR. This includes outcome data from the modified Godin Leisure Time Exercise Questionnaire (GLTEQ) and rate of program completion for each participant. This was extracted from the COACH database and was merged with the CCRR data (in SPSS) for analysis purposes.
3.5 Sample Size Justification

One hundred and two patients are required to detect a 0.5 unit change, from week one (T1) to week eight (T2), for the primary outcome variable of HRQOL. Comparing improvements between the TM and HYM, with a standard deviation obtained from the literature of 0.7 units (Luttik, Lesman-Leegte, & Jaarsma, 2009), was completed using a two-tailed test. A power calculation of 0.80 and an alpha level adjusted for multiple comparisons of \( \alpha = 0.008 \) were utilized. Taking into consideration that approximately 4 patients choose the traditional model for every three patients that choose the hybrid model, it was determined that 58 patients were needed in the TM compared to 48 in the HYM. Assuming a normal attrition in exercise rehabilitation studies of ~15% we aimed to recruit 71 patients and 55 patients into the TM and HYM, respectively.

3.6 Statistical Analysis

Two-way analysis of variance (ANOVA) was used to compare the CR program models. All six underlying assumptions for two-way ANOVA were tested (Tabachnick & Fidell, 2007). The first three assumptions: 1) dependent variables are measured at the continuous level, 2) two independent variables should require two or more categorical, independent groups, and 3) independence of observations (different participants in each group with no participant being in more than one group), were met pre-analysis. Assumptions four to six were met using SPSS Statistics, indicating that: 1) there were no significant outliers; 2) the dependent variable were approximately normally distributed for each combination of the groups for the two independent variables, 3) and homogeneity of variances for each combination of the groups of the two independent variables (Tabachnick & Fidell, 2007). Normal distribution was tested using the
Shapiro-Wilk test of normality, satisfying assumption five. Levene’s test was used in the analysis for homogeneity of variances, satisfying assumption six (Tabachnick & Fidell, 2007).

Pre-program baseline descriptive statistics, including means, standard deviations, and percentages were used to examine socio-demographic and clinical characteristics of participants. Differences in the socio-demographic and pre-CR clinical characteristics of participants who chose each of the 2 models were tested using independent t-tests for quantitative variables and Chi-square test for nominal variables were used to compare baseline characteristics between groups. Variables were reviewed for accuracy of data entry, missing/out of range values and plausible means and standard deviations. Furthermore, any data points that were three or more standard deviations (± 3 SD) away from the mean were considered an outlier and not used in the analyses, meaning 99% of the data fell within a normal distribution. The total number of outliers accounted for less than 5% of total values for each variable, except for sub-samples. Due to the insignificance of missing variables (<5%), a means substitution were not imputated (Tabachnick & Fidell, 2007).

The present study offered both between-subject factors (group) and within subject factors (time) for all outcome variables. To investigate the proposed hypotheses, the interaction effects between these factors were observed. Therefore, two-way ANOVA remained as the primary means for examining two different independent variables with a between groups design to analyze the dependent variables. For all analyses, Levene’s test for equality of variance and Boxer’s test of covariance were performed. All underlying assumptions of two-way ANOVA were satisfied (Tabachnick & Fidell, 2007). All statistical analyses were performed using SPSS Statistics version 21.0. A significance level of $p < .05$ was accepted as statistically significant.
Chapter 4 Results

4.1 Baseline Assessment Outcomes

4.1.1 Demographic and Clinical Characteristics

A total of 168 participants took part in the baseline CR assessment. Of those, 72 choose the TM and 53 choose the HYM (N=125). Participants who attended the baseline assessment but did not complete the final assessment were not included in the final analysis due to drop out (11 participants) or interim events (4 participants). Reasons for the 10 drop outs in the TM were as follows; one experienced transportation barriers; one participant experienced severe depression; three reported physical constraints and non-CVD concerns; one participant with heart failure prepared for left ventricular assisting device implantation; two were participants were limited by their occupation; two had unstable angina; an additional participant (high risk primary prevention) had an interim event, however the participant completed the CR program after recovering from CABG surgery. Reasons for the five drop outs in the HYM were as follows; two participants were unable to reached; one participant was limited by their occupation; and finally, two reported physical constraints and non-CVD concerns.

Participants were predominantly male (70.4%), Caucasians (97.6%), married (77.6%), educated (49.6% certified trade or university), retired (68.8%), experienced family support (89.6%) and lived within 30 minutes of CR (88%). Participants mean age was 67.1 years (±10.4) in both groups. There were no significant differences between the TM and HYM for baseline demographics in terms of age, gender, ethnic origin, marital status, education level, work status, family support, and travel to CR time (Table 1).
<table>
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<tr>
<th>Characteristic</th>
<th>Traditional Model</th>
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<td>(n=72), n (%)</td>
<td>(n=53), n (%)</td>
<td>(N=125), n (%)</td>
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| Age, years                    | 68.1 ±10.9        | 65.7 ±10.4   | 67.1 ±10.6| 0.196<sub>a</sub>  
| Sex                           |                   |              |          |  
| Male                          | 48 (66.7)         | 40 (75.5)    | 88 (70.4)| 0.287<sub>b</sub>  
| Female                        | 24 (33.3)         | 13 (24.5)    | 37 (29.6)|            |  
| Ethnic Origin                 |                   |              |          |  
| Caucasian                     | 70 (97.2)         | 52 (98.1)    | 122 (97.6)| 0.748<sub>b</sub>  
| Aboriginal                    | 2 (2.8)           | 1 (1.9)      | 3 (2.4)  |            |  
| Marital Status                |                   |              |          |  
| Single                        | 4 (5.6)           | 3 (5.7)      | 7 (5.6)  | 0.319<sub>b</sub>  
| Married                       | 53 (73.6)         | 44 (83)      | 97 (77.6)|            |  
| Divorced or widowed           | 12 (16.6)         | 4 (7.6)      | 16 (11.2)|            |  
| Education                     |                   |              |          |  
| Less than high school         | 2 (2.8)           | 1 (2.8)      | 3 (2.4)  | 0.825<sub>b</sub>  
| High school                   | 32 (44.4)         | 27 (50.9)    | 59 (47.2)|            |  
| College or Trade              | 21 (29.1)         | 13 (24.5)    | 33 (27.2)|            |  
| University                    | 17 (23.6)         | 11 (20.8)    | 28 (22.4)|            |  
| Unknown                       | -                 | 1 (2.8)      | 1 (2.8)  |            |  
| Work Status                   |                   |              |          |  
| Employed full time            | 9 (12.5)          | 14 (26.4)    | 23 (18.0)| 0.103<sub>b</sub>  
| Employed part time            | 4 (5.6)           | 3 (5.7)      | 7 (5.6)  |            |  
| Retired                       | 55 (76.3)         | 32 (60.4)    | 87 (68.8)|            |  
| Disability                    | 4 (5.6)           | 1 (1.9)      | 5 (4.8)  |            |  
| Unemployed                    | -                 | 3 (5.7)      | 3 (2.8)  |            |  
| Family Support                |                   |              |          |  
| Lives alone                   | 8 (11.1)          | 5 (9.4)      | 12 (10.4)| 0.382<sub>b</sub>  
| Lives with spouse/partner     | 58 (80.6)         | 47 (88.7)    | 105 (84.0)|            |  
| Lives with friends/family     | 6 (8.3)           | 1 (1.9)      | 7 (5.6)  |            |  
| Travel time to CR             |                   |              |          |  
| 0-30 min                      | 66 (91.7)         | 44 (83.0)    | 110 (88.0)| 0.213<sub>b</sub>  
| 31-45 min                     | 3 (4.2)           | 6 (11.3)     | 9 (7.2)  |            |  
| > 60 min                      | -                 | 2 (3.8)      | 2 (1.6)  |            |  
| Unknown                       | 3 (4.2)           | 1 (1.9)      | 1 (3.2)  |            |  
| HRQOL score                   | 6.8±2.1           | 6.9±2.1      | 6.8±2.1  | 0.796<sub>c</sub>  
| PA (units)                    | 21.1±19.2         | 25.4±19.9    | 22.9±19.5| 0.227<sub>c</sub>  
| RSBP (mmHg)                   | 126.0±20.0        | 119.0±22.0   | 123.0±21.0| 0.072<sub>c</sub>  
| RDBP (mmHg)                   | 72.0±16.0         | 70.0±11.0    | 70.0±14.0| 0.423<sub>c</sub>  
| Chol (mmol/L)                 |                   |              |          |  
| Tc                            | 4.58±1.21         | 4.19±1.25    | 4.41±1.24| 0.088<sub>c</sub>  
| LDL                           | 2.61±1.02         | 2.30±0.82    | 2.48±0.95| 0.081<sub>c</sub>  

<sup>a</sup> p value for comparison between Traditional and Hybrid models.

<sup>b</sup> p value for comparison between Hybrid and Combined models.

<sup>c</sup> p value for comparison between Combined models.

Table 1 • Demographic and Clinical Characteristics of Participants
4.1.2 Cardiac Risk Factor History and Medications

There were no significant differences between baseline cardiac risk factor history and prescribed medications when comparing both models. Therefore, comparing baseline measures for both models was appropriate. Concerning baseline cardiac risk factors, 85.6% were considered overweight, nearly 15% smoked, three quarters reported a diagnosis of high blood pressure, close to 30% had diabetes, approximately one third of the participants reported physical inactivity, and 59.2% had a family history of CVD (Table 2).
Table 2 • Cardiac Risk Factor History and Medication

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Traditional Model (n=72), n (%)</th>
<th>Hybrid Model (n=53), n (%)</th>
<th>Combined (N=125), n (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overweight</td>
<td>60 (83.3)</td>
<td>47 (89.0)</td>
<td>107 (85.6)</td>
<td>0.400b</td>
</tr>
<tr>
<td>&gt;24.9 BMI (kg/m²)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently smoking</td>
<td>10 (13.9)</td>
<td>8 (15.1)</td>
<td>18 (14.4)</td>
<td>0.850b</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>52 (72.2)</td>
<td>39 (73.6)</td>
<td>91 (72.8)</td>
<td>0.866b</td>
</tr>
<tr>
<td>Diabetes</td>
<td>21 (29.2)</td>
<td>13 (24.5)</td>
<td>34 (27.2)</td>
<td>0.565b</td>
</tr>
<tr>
<td>Physically inactive</td>
<td>28 (38.9)</td>
<td>22 (41.5)</td>
<td>50 (40.0)</td>
<td>0.768b</td>
</tr>
<tr>
<td>Family History</td>
<td>44 (61.1)</td>
<td>30 (56.6)</td>
<td>74 (59.2)</td>
<td>0.612b</td>
</tr>
<tr>
<td>CVD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B-Blockers</td>
<td>55 (76.4)</td>
<td>42 (79.2)</td>
<td>97 (78.4)</td>
<td>0.705b</td>
</tr>
<tr>
<td>ACE-Inhibitors</td>
<td>41 (56.9)</td>
<td>31 (58.5)</td>
<td>72 (57.6)</td>
<td>0.863b</td>
</tr>
<tr>
<td>Statins</td>
<td>57 (79.2)</td>
<td>43 (81.1)</td>
<td>100 (80.8)</td>
<td>0.786b</td>
</tr>
<tr>
<td>Anti-coagulants</td>
<td>20 (32.2)</td>
<td>11 (20.8)</td>
<td>31 (25.6)</td>
<td>0.128b</td>
</tr>
<tr>
<td>Anti-platelets</td>
<td>55 (76.4)</td>
<td>46 (86.8)</td>
<td>100 (81.6)</td>
<td>0.144b</td>
</tr>
<tr>
<td>Calcium Channel Blockers</td>
<td>20 (27.8)</td>
<td>15 (28.3)</td>
<td>35 (28.8)</td>
<td>0.949b</td>
</tr>
</tbody>
</table>

\[p < .05.\]
\[b\] Chi-square test.

4.1.3 Reason for Referral Diagnosis

The majority of participants referred, had a diagnosis of myocardial infarction (STEMI, 18.4%; NSTEMI, 24% and unspecified, 6.4%), heart failure (moderate LV function, 9.6%; severe LV function 6.4%), arrhythmia (12%), and angina (stable, 8%; unstable, 4%) at hospital discharge. There were significant differences between the TM and HYM concerning diagnosis. Those in the HYM had more angina diagnosis and those in the TM had more peripheral vascular disease and trans-ischemic attack diagnosis (Table 3).
### Table 3 • Referral Diagnosis

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Traditional Model (n=72), n (%)</th>
<th>Hybrid Model (n=53), n (%)</th>
<th>Combined (N=125), n (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angina</td>
<td></td>
<td></td>
<td></td>
<td>.043b*</td>
</tr>
<tr>
<td>Stable</td>
<td>3 (4.2)</td>
<td>7 (13.2)</td>
<td>10 (8.0)</td>
<td></td>
</tr>
<tr>
<td>Unstable</td>
<td>2 (2.8)</td>
<td>3 (5.7)</td>
<td>5 (4.0)</td>
<td></td>
</tr>
<tr>
<td>MI</td>
<td></td>
<td></td>
<td></td>
<td>.439b</td>
</tr>
<tr>
<td>Unspecified</td>
<td>3 (4.2)</td>
<td>5 (9.4)</td>
<td>8 (6.4)</td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>14 (19.4)</td>
<td>9 (17.0)</td>
<td>23 (18.4)</td>
<td></td>
</tr>
<tr>
<td>NSTEMI</td>
<td>16 (22.2)</td>
<td>14 (26.4)</td>
<td>30 (24.0)</td>
<td></td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>9 (12.5)</td>
<td>6 (11.4)</td>
<td>15 (12.0)</td>
<td>.084b</td>
</tr>
<tr>
<td>HF</td>
<td>14 (19.4)</td>
<td>6 (11.3)</td>
<td>20 (16.0)</td>
<td>.221b</td>
</tr>
<tr>
<td>LV function</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate (30-39%)</td>
<td>6 (8.3)</td>
<td>6 (11.3)</td>
<td>12 (9.6)</td>
<td></td>
</tr>
<tr>
<td>Severe (&lt;30%)</td>
<td>5 (6.9)</td>
<td>3 (5.7)</td>
<td>8 (6.4)</td>
<td></td>
</tr>
<tr>
<td>HR Primary</td>
<td>4 (5.6)</td>
<td>3 (5.7)</td>
<td>7 (5.6)</td>
<td>.980b</td>
</tr>
<tr>
<td>Prevention</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>7 (9.7)</td>
<td>-</td>
<td>7 (5.6)</td>
<td>.019b*</td>
</tr>
</tbody>
</table>

Abbreviations: MI, myocardial infarction; STEMI, ST elevation myocardial infarction; NSTEMI, non-ST elevation myocardial infarction; HF, heart failure; LV, left ventricle; HR, high risk; Other, trans-ischemic attack and peripheral vascular disease.

a p < .05.
b Chi-square test.

### 4.1.4 Referral Event and Intervention in Hospital

Most participants received PCI as the primary intervention (36%), followed by medical management (20%), and CABG surgery (11.2%). There were significant differences in terms of referral event and intervention in hospital, for example 5.6% experienced valve surgery in the TM (p < .05) compared to none in the HYM. The TM and HYM experienced similar amounts of comorbidities (89.6%).
Table 4 • Referral Event and Intervention in Hospital

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Traditional Model (n=72), n (%)</th>
<th>Hybrid Model (n=53), n (%)</th>
<th>Combined (N=125), n (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCI</td>
<td>23 (31.9)</td>
<td>22 (41.5)</td>
<td>45 (36.0)</td>
<td>.271b</td>
</tr>
<tr>
<td>CABG</td>
<td>8 (11.1)</td>
<td>6 (11.3)</td>
<td>14 (11.2)</td>
<td>.970b</td>
</tr>
<tr>
<td>VS</td>
<td>7 (9.7)</td>
<td>-</td>
<td>7 (5.6)</td>
<td>.019*</td>
</tr>
<tr>
<td>CABG &amp; VS</td>
<td>2 (2.8)</td>
<td>2 (3.8)</td>
<td>4 (3.2)</td>
<td>.729b</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>3 (4.2)</td>
<td>1 (1.9)</td>
<td>4 (3.2)</td>
<td>.474b</td>
</tr>
<tr>
<td>Device Insertion</td>
<td>2 (2.8)</td>
<td>4 (7.5)</td>
<td>6 (4.8)</td>
<td>.218b</td>
</tr>
<tr>
<td>Medically Managed</td>
<td>15 (20.8)</td>
<td>10 (18.9)</td>
<td>25 (20.0)</td>
<td>.786b</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>4 (5.6)</td>
<td>4 (7.5)</td>
<td>8 (6.4)</td>
<td>.653b</td>
</tr>
<tr>
<td>HR Primary Prevention</td>
<td>4 (5.6)</td>
<td>3 (5.7)</td>
<td>7 (5.6)</td>
<td>.980b</td>
</tr>
<tr>
<td>Other</td>
<td>4 (5.6)</td>
<td>1 (1.9)</td>
<td>5 (4.0)</td>
<td>.180b</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>65 (90.3)</td>
<td>47 (88.7)</td>
<td>112 (89.6)</td>
<td>.772b</td>
</tr>
</tbody>
</table>

Abbreviations: PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; VS, valve surgery; HR, high risk; other; Other, transient ischemic attack, ablation; Comorbidities, arthritis, hip and knee replacement, renal failure, kidney failure, respiratory condition, anemia, chronic musculoskeletal pain.

a p < .05.
b Chi-square test.

4.2. Primary and Secondary Outcomes

At eight weeks, 62 TM and 48 HYM participants completed the final assessment, representing 86% and 91% retention. There were no significant differences between baseline measures of the TM and HYM. Upon CR program completion, a two-way ANOVA for participants between subject’s effects, within subject’s effects and over time for program modes were performed. Choosing the two-way ANOVA as the primary means of analysis protected against inflation of type 1 errors as all two levels of the dependant variables were considered concurrently (Tabachnick & Fidell, 2007).

Results concerning the primary and secondary outcomes measures are presented below in Sections 4.3 and 4.4 and displayed in Table 5 and Table 6. Table 5 provides an overview of the within subject effects interaction for time and model with no significant interactions observed,
based on an alpha level of .05. Table 6 displays the analysis of variance, means, and standard deviations for repeated measures across both models over time. Preliminary analyses showed that the distributions of scores for PA, dietary behavior, depression score and BMI were skewed. Therefore, a minimum of two to a maximum of four outliers were excluded and not used in the analyses. As these data points were outside of the 99% normal distribution.

4.2.1 Primary Outcome

Health Related Quality of Life. Multivariate analysis results indicated that there were no significant interactions between program models and HRQOL, \( F(1, 108) = .516, p = .47 \). Furthermore, no main effects were found between program models, \( F(1, 108) = .261, p = .61 \). Therefore, the mean differences between program models were not significant. However, there were significant positive effects over time on HRQOL, \( F(1, 108) = 13.95, p < .001 \). This indicates that the majority of participants improved significantly in HRQOL from the baseline (T1) to final assessments (T2). Therefore, the first hypothesis was not supported; the TM did not have greater positive changes on HRQOL compared to the HYM.

4.2.2 Secondary Outcomes

Physical Activity. PA were recorded and assessed at baseline (T1) and at final assessment (T2). Results showed that there were no significant interaction between program models and PA, \( F(1, 104) = .232, p = .63 \), nor were there no main effects found between program models, \( F(1, 104) = .1856, p = .18 \). Multivariate analysis of overall PA, regardless of model, indicated a significant increase in PA over time, \( F(1, 104) = 60.99, p < .001 \).

Blood Pressure. Resting systolic blood pressures (RSBP) and diastolic blood pressures (RDBP) were recorded at baseline (T1) and at the final assessment period (T2). Results indicated that there were no significant interactions between program models and overall RSBP,
There were significant main effects between program models, $F(1, 108) = 3.894$, $p < .051$. There were significant main effects between program models, $F(1, 108) = 4.85$, $p = .030$, indicating significant mean differences between the program models from the baseline and final assessments (128.0 to 117.0 vs 118.0 to 113.0) in support of the TM. However, these results are less powerful due to the nonsignificant model by time interaction and perhaps less meaningful as individual differences are not accounted for (Tabachnick & Fidell, 2007).

RDBP results did not indicate a significant interaction between models, $F(1, 108) = 1.37$, $p = .24$ or a main effect between models, $F(1, 108) = 1.30$, $p = .256$. Overall and regardless of model, there were no significant reductions in RDBP over time, $F(1, 108) = 1.37$, $p = .244$.

**Cholesterol and Blood Glucose.** Cholesterol values were available for the majority of participants (81.4%). However, the fasting blood sugars (FBS) and hemoglobin A1c (HbA1c) were available only on a subsample of the participants and are indicated on Table 5. Total cholesterol (Tc) results showed that there were no significant differences between models on overall reduction in Tc, $F(1,88) = .064$, $p = .800$. There were significant main effects between program models observed, $F(1, 88) = 5.33$, $p = .023$, however, this result is less important as the mean difference between program models were not significant ($p=.800$). Multivariate analysis of overall reduction in Tc indicated a significant change in Tc within all participants over time $F(1, 88) = 19.55$, $p < .001$, indicating an overall reduction in Tc were observed among the majority of participant’s from baseline (T1) to final assessments (T2).

Low density lipoprotein (LDL) indicated no significant interaction between models and overall reduction in LDL, $F(1,79) = .185$, $p = .67$. There were significant main effects between program models, $F(1, 79) = 5.99$, $p = .017$, however, these results were superseded by a nonsignificant model by time interaction and therefore less meaningful. LDL analysis indicated a
significant change for LDL within all participants over time, \( F(1,79) = 12.13, p < .001 \). Therefore, significant reductions in LDL were observed over time.

Multivariate analysis of overall high density lipoprotein (HDL) indicated that there were no significant interactions between models \( F(1, 88) = 3.26, p = .07 \). There were no significant main effects between program models, \( F(1, 88) = 1.67, p = .20 \). Further analysis regarding HDL indicated no significant change within all participants over time, \( F(1, 88) = .448, p = .51 \).

Fasting blood sugars (FBS) were available in a subsample of participants (n=71, TM=38; HYM=33) at the baseline (T1) and the final assessment (T2). HbA1c were also available in a subsample of participants (n=18, TM=12; HYM=33) at baseline (T1) and at the final assessment (T2). There were no significant interactions between models for FBS and HbA1c, \( F(1, 69) = 1.22, p = .27 \); \( F(1,16) = 1.07, p = .32 \), respectively. There were also no significant main effects between program models for FBS and HbA1c, \( F(1, 69) = .05, p = .83 \); \( F(1, 16) = .25, p = .62 \). There were no significant reductions in FBS or HbA1c within all participants over time \( F(1, 69) = .54, p = .47 \); \( F(1, 16) = .119, p = .74 \), respectively.

**Metabolic Equivalents.** Exercise capacity (METs) were measured using a sub-maximal protocol at baseline (T1) and at the final assessment (T2). METs results showed that there were no significant interactions between models, \( F(1, 108) = .318, p = .57 \), and no main effects between program models were observed, \( F(1, 108) = 3.72, p = .06 \). A significant increase in METs within all participants over time were observed, \( F(1,108) = 92.20, p < .001 \), indicating an increase in exercise tolerance over time for all participants.

**Smoking Status.** At baseline, 10 participants in the TM reported that they were current smokers (13.9%) compared to the eight participants in the HYM (15.1%). Results showed no significant interactions between models on changes in smoking status, \( F(1, 110) = .096, p = .76 \).
At program completion, there were eight participants that continued to smoke in the TM (11.1%) and six participants (11.3%) in the HYM. No main effects between program models were observed, \( F(1, 110) = .015, p = .90 \), however there were significant reductions over time within all participants for smoking status, \( F(1, 110) = 4.17, p = .043 \), which equated to four participants quitting smoking during the CR program.

**Dietary Behaviour.** Dietary behaviour changes were identified by an increase in fruit and vegetable intake. Multivariate analysis results indicated no significant interactions between models on overall behavioral changes in fruit and vegetable intake, \( F(1, 106) = 1.56, p = .22 \). No main effects for program models were observed, \( F(1, 106) = .009, p = .93 \), however, there were significant changes in dietary behavior (fruit and vegetable intake) over time, \( F(1, 106) = 28.33, p < .001 \), indicating the majority of participants, regardless of group, were consuming more fruit and vegetables at program completion (T2).

**Depressive Symptoms.** Concerning depressive symptoms, results showed no significant interactions between models on overall reduction in symptoms, \( F(1, 106) = 1.48, p = .23 \). No main effects for program models were observed, \( F(1, 106) = 1.50, p = .22 \). Multivariate analysis of overall reductions in depressive symptoms within all participants over time indicated a significant decrease in symptomology, \( F(1, 106) = 23.53, p < .001 \), suggesting that the majority of participants experienced a reduction in depressive symptoms at program completion (T2).

**Anthropometrics.** Results indicated no significant interactions between models on overall body mass index (BMI) and waist circumference (WC) changes, \( F(1, 106) = .000, p = .99 \) and \( F(1, 108) = 2.25, p = .14 \), respectively. No main effects were found for program models regarding BMI or WC, \( F(1, 106) = 1.72, p = .19; F(1, 108) = 1.30, p = .26 \), respectively. There were no significant differences within all participants over time for BMI, \( F(1, 106) = 1.07, p = \)
.30, however, there were significant reductions within all participants over time for WC, $F(1, 108) = 29.50, p < .001.$

### Table 5 • Analysis of Variance for Within Subject Effects Interaction for Time and Model

<table>
<thead>
<tr>
<th></th>
<th>Traditional Model (n=62)</th>
<th>Hybrid Model (n=48)</th>
<th>$p$ a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1</td>
<td>Time 2</td>
<td>Time 1</td>
</tr>
<tr>
<td>HRQOL score</td>
<td>7.1±1.9</td>
<td>7.5±1.5</td>
<td>7.1±2.0</td>
</tr>
<tr>
<td>PA, units</td>
<td>22.0±20.0</td>
<td>36.2±19.0</td>
<td>25.9±20.0</td>
</tr>
<tr>
<td>RSBP, mmHg</td>
<td>127.0±20.0</td>
<td>117.0±15.0</td>
<td>118.0±21.0</td>
</tr>
<tr>
<td>RDBP, mmHg</td>
<td>73.0±16.0</td>
<td>69.0±10.0</td>
<td>69.0±10.0</td>
</tr>
<tr>
<td>Cholesterol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tc (mmol/L)</td>
<td>4.68±1.19</td>
<td>4.14±1.26</td>
<td>4.15±1.11</td>
</tr>
<tr>
<td>(n=52)</td>
<td>(n=52)</td>
<td>(n=38)</td>
<td>(n=38)</td>
</tr>
<tr>
<td>LDL (mmol/L)</td>
<td>2.71±1.01</td>
<td>2.30±1.02</td>
<td>2.24±.76</td>
</tr>
<tr>
<td>(n=48)</td>
<td>(n=48)</td>
<td>(n=33)</td>
<td>(n=33)</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>1.17±.41</td>
<td>1.14±.36</td>
<td>1.04±.28</td>
</tr>
<tr>
<td>(n=52)</td>
<td>(n=52)</td>
<td>(n=38)</td>
<td>(n=38)</td>
</tr>
<tr>
<td>FBS, (mmol/L)</td>
<td>5.78±1.16</td>
<td>5.82±1.02</td>
<td>5.95±1.20</td>
</tr>
<tr>
<td>(n=38)</td>
<td>(n=38)</td>
<td>(n=33)</td>
<td>(n=33)</td>
</tr>
<tr>
<td>HbA1c, %</td>
<td>6.9±0.6</td>
<td>7.3±0.9</td>
<td>6.5±0.8</td>
</tr>
<tr>
<td>(n=12)</td>
<td>(n=12)</td>
<td>(n=6)</td>
<td>(n=6)</td>
</tr>
<tr>
<td>METs</td>
<td>4.9±1.7</td>
<td>6.3±2.1</td>
<td>5.7±2.1</td>
</tr>
<tr>
<td>Smoking Status</td>
<td>10 (13.9%)</td>
<td>8 (11.1%)</td>
<td>8 (11.1%)</td>
</tr>
<tr>
<td>Dietary Behavior</td>
<td>3.7±1.5</td>
<td>4.3±1.5</td>
<td>3.5±1.4</td>
</tr>
<tr>
<td>Depression score</td>
<td>.95±1.2</td>
<td>.61±.93</td>
<td>.85±1.2</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td>30.0±5.0</td>
<td>30.0±5.0</td>
<td>29.0±4.0</td>
</tr>
<tr>
<td>WC, cm</td>
<td>106.1±13.4</td>
<td>103.8±12.6</td>
<td>103.0±11.0</td>
</tr>
</tbody>
</table>

Abbreviations; HRQOL, health related quality of life; PA, physical activity; RSBP, resting systolic blood pressure; RDBP, resting diastolic blood pressure; Chol, cholesterol; Tc, total cholesterol; LDL, low density lipoprotein; HDL, high density lipoprotein; FBS, fasting blood sugar; HbA1c; hemoglobin A1c; METs, metabolic equivalents; BMI, body mass index; WC, waist circumference.

a Analysis of change in program model within pre- and post-program.

b $p < .05$. 

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Summary of Main Findings

In summary, the first hypothesis, that there would be greater positive changes in the primary outcome (HRQOL) in the TM compared to the HYM, was not supported (Table 5). The second hypothesis, that there would be greater positive changes in the secondary outcomes in the TM compared to the HYM, was also not supported. However, the results did indicate significant changes over time within all participants, regardless of group. Overall, both programs (TM and

Table 6 • Analysis of Variance, Means and Standard Deviations for Repeated Measures Over Time

|                               | n  | Time 1         | Time 2         | \( p \)  \\n|-------------------------------|----|----------------|----------------|--------
| HRQOL score                  | 110| 7.1±1.9        | 7.6±1.4        | <.001* \\n| PA, units                    | 106| 23.7±20.0      | 38.7±21.0      | <.001* \\n| RSBP, mmHg                   | 110| 123.0±21.0     | 115.0±16.0     | <.001* \\n| RDBP, mmHg                   | 110| 71.0±14.0      | 69.0±14.0      | .244  \\n| Cholesterol                  |    |                |                |        \\n| Tc (mmol/L)                  | 90 | 4.45±1.18      | 3.94±1.16      | <.001* \\n| LDL (mmol/L)                 | 81 | 2.52±.94       | 2.14±.90       | <.001* \\n| HDL (mmol/L)                 | 90 | 1.12±.36       | 1.04±.28       | .505  \\n| FBS, (mmol/L)                | 71 | 5.86±1.17      | 5.79±1.06      | .465  \\n| HbA1c, %                     | 18 | 6.8±.7         | 7.1±.1         | .078  \\n| METs                         | 110| 5.2±1.9        | 6.5±2.2        | <.001* \\n| Smoking Status               | 110| 10 (13.9%)     | 8 (11.1%)      | .043* \\n| Dietary Behavior             | 108| 3.6±1.5        | 4.3±1.5        | <.001* \\n| Depression score             | 108| .91±1.2        | .47±.83        | <.001* \\n| BMI, kg/m²                   | 108| 29.6±4.8       | 29.5±4.8       | .304  \\n| WC, cm                       | 110| 104.7±12.5     | 102.9±12.0     | <.001* \\n
Abbreviations; HRQOL, health related quality of life; PA, physical activity; RSBP, resting systolic blood pressure; RDBP, resting diastolic blood pressure; Chol, cholesterol; Tc, total cholesterol; LDL, low density lipoprotein; HDL, high density lipoprotein; FBS, fasting blood sugar; HbA1c, hemoglobin A1c; METs, metabolic equivalents; BMI, body mass index; WC, waist circumference.

a Analysis of the change over time within pre- and post-program.

b \( p < .05 \).

4.3 Summary of Main Findings

In summary, the first hypothesis, that there would be greater positive changes in the primary outcome (HRQOL) in the TM compared to the HYM, was not supported (Table 5). The second hypothesis, that there would be greater positive changes in the secondary outcomes in the TM compared to the HYM, was also not supported. However, the results did indicate significant changes over time within all participants, regardless of group. Overall, both programs (TM and
HYM) indicated significant improvements over time within all participants for HRQOL (primary outcome) and a number of secondary outcomes measures, including physical activity, systolic blood pressure, total cholesterol, low density lipoprotein, metabolic equivalents, smoking status, dietary behaviors, depressive symptoms, and waist circumference. However, there were no significant improvements over time for diastolic blood pressure, high density lipoprotein, fasting blood sugars, hemoglobin A1c or body mass index.
Chapter 5 Discussion

Based on the research question and hypotheses of this study, the discussion has been organized into three sections. Firstly, a review of the demographic variables of this study and how they pertained to CR participation barriers will be discussed. Secondly, focus will be placed on the primary outcome (health related quality of life) and the effectiveness of the models in eliciting differences over the duration of the CR programs. Finally, secondary outcomes will be discussed and the significant changes observed over time. The discussion also includes probable explanations and suggestions concerning the findings.

5.1 Demographics

In reviewing the demographic characteristics of the study’s sample, there were two particular characteristics which warrant further discussion, specifically gender and ethnic origins. The gender and ethnic breakdown in this study resembles that of other CR studies, in that the majority of participants were male (70.4%) and Caucasian (97.6%) (Grace et al., 2002; Heran et al., 2011; Valencia et al., 2011). Research has indicated that this may be a consequence of certain barriers faced by women, in particular researchers have reported that women are less likely to be referred to CR, and for those that are referred, are less likely to participate due to increased family responsibility (e.g., domestic duties) compared to their male counterpart (Grace et al., 2002; Allen et al., 2004; Grace et al., 2004; Parkosewich, 2008). Furthermore, research has indicated that more men participate in CR programs due to enhanced self-efficacy (Grace et al., 2002; Woodgate & Brawley, 2008) and greater psychosocial health status, as men tend to experience less anxiety with a cardiac event (Grace et al., 2002). Alternatively, a vast amount of literature indicates that men are an extremely “hard to reach” population who are less likely to
participate in health promotion services or engage in health promotion practices (Morgan, Collins, Plotnikoff, Cook, Berthon, Mitchell, & Callister, 2011; Hunt, Wyke, Gray, Anderson, Brady, Bunn, … Treweek, 2014; Caperchione, Sharp, Bottorff, Stolp, Oliffe, Johnson, … Lamont, 2015). The fact that they are so highly represented in CR programs is positive, and may provide further insight concerning recruitment and participation of men for other health promotion programs. Further supporting women to participate and adhere to CR programs is essential, given that they are commonly underrepresented (Daly et al., 2002; Grace et al., 2002; Lawler et al., 2011) and experience CVD as the second leading cause of death (Statistics Canada, 2014).

The low proportion of other ethnic origins is of concern given that many of these groups are in the greatest need of CR programs. For instance, research has indicated that those from South Asian and Aboriginal origin have some of the highest incidence of CVD and are less likely to engage in health promoting behaviours (Beswick et al., 2004; Caperchione, Kolt & Mummery, 2009; Valencia et al., 2011). Furthermore, improving access for these ethnic origins is a challenge for CR in particular due lack of automatic referrals or knowledge of CR (Allen et al., 2004; Grace et al., 2011). In the Kelowna area, there are 7.6 % visible minorities, described as South Asians and Chinese, along with 4.5% of the population who identify as Aboriginal origin (Statistics Canada, 2011). Therefore, further efforts should be made to enhance this population’s access to CR as they are a high risk population for CVD (Allen et al., 2004; Parkosewich, 2008; Valencia et al., 2011).
5.2 Primary Outcome

Health Related Quality of life (HRQOL) has been recognised as a crucial element impacting the overall health of CVD patients and has been shown to increase for participants of CR programs (Yusuf et al., 2004; Lavie & Milani, 2006; McGrady et al., 2009; Milani & Lavie, 2009; Leung et al., 2011; Janssen et al., 2012). In this study, it was hypothesized that this would be more evident in those who were in the TM group due to the increased face to face contact, group interaction, increased monitored exercise sessions etc. however, this hypothesis was not supported as there was no significant differences between groups concerning HRQOL. HRQOL improvements have been observed in other CR alternative models (Jolly et al., 2009; Taylor et al., 2010) where face to face time is limited, thus it is not surprising that both models did show significant improvements. This improvement could be due to the core education components, social interaction and supportive counseling sessions which were consistently delivered in both the TM and HYM. There was also substantial family and friend support reported in the TM (88.9%) and HYM (90.6%); this alone may have enhanced psycho-social well-being (Lavie et al., 2006; Najafi & Nalini 2015). Yusuf et al., (2004) and Leung et al., (2011) research underscore the importance of CR programs that offer some psycho-social support to assist in improving HRQOL, further indicating that lack of support is associated with diminished HRQOL, which in turn contributes to disease progression, increased morbidity and mortality. Notably, additional research has also indicated that diminished psychosocial factors, such as HRQOL, are an independent risk factor contributing to a third of the population’s attributable risk for MI (Rosengren et al., 2004). This further postulates the need for CR participation as control groups in previous research that did not complete CR had worse outcomes for psycho-social health (McGrady et al., 2009; Lueng et al., 2011). Therefore, the impact of both of the
eight week CR models outlined in this study would have significant implications for those
diagnosed with CVD; however the lack of a control group reduces the ability to draw
conclusions of whether the changes in HRQOL were influenced by CR participation, or merely
the effects of recovering over time from a cardiac event.

One would be remiss to not consider the benefits of positive health behaviours (such as
increased PA and healthy eating) as contributing factors to enhanced HRQOL. In a previous
RCT, PA was found to be as effective as antidepressant medication in patients diagnosed with
depression (Babyak, Blumenthal, Herman, Khatri, Doraiswamy, Moore,… Krishnan, 2000).
Also, CR participants compared to non-CR participants experienced significant increases in both
METs and HRQOL at program completion (Belardinelli, Paolini, Cianci, Piva, Georgiou, &
Purcaro, 2001). Research has also outlined correlations between healthy eating and improved
HRQOL. In particular, Mohammadi, Sulaiman, Koon, Amani & Mohammad-Hosseini (2013),
found that improved healthy eating practices, such as increased fruit and vegetable intake,
resulted in better HRQOL. Concurrently, the multifactorial benefits achieved in CR, particularly
increased PA, healthy eating and social interaction have been linked to improved emotional well-
being (Lavie et al., 2006; Mohammadie et al., 2013). Lavie and colleague’s (2006) study on
depression, anxiety, hostility and HRQOL for both young and old CR participants (n=364) found
a marked improvement in HRQOL, coping, social and emotional recovery post program. This
indicates that improvements were observed when persons engaged in their own healthcare after a
cardiac event, including increases in health promoting behaviours such as PA, healthy eating and
social interaction. Furthermore, Najafi & Nalini (2015) research on the TM vs HYM observed
similar benefits of participants becoming active in their own healthcare through the socialization
process. Therefore, increases in HRQOL may be due to the social support, PA increases, healthy
eating, group interaction and education classes which influenced participant’s engagement in healthy lifestyle behaviours, thus resulting in improved overall health (Babyak et al., 2000; Lavie et al., 2006; Mohammadi et al., 2013).

5.3 Secondary Outcomes

Similar to the outcomes witnessed for HRQOL, results concerning the secondary outcomes of this study demonstrated positive clinical and behavioral health changes in both CR models. Therefore, the second hypothesis regarding greater positive changes of secondary outcomes in the TM were not supported; however, both program models indicated improvements over time in most of these measures, except for BMI, HDL, FBS and HbA1c. Specifically, statistically significant improvements were observed for PA, systolic blood pressure, total cholesterol, low density lipoprotein, METs, reductions in smoking status, dietary behaviors, depressive symptoms, and waist circumference (WC).

Reductions in cardiac risk factors, similar to the outcome variables in this study, have been observed in other comprehensive TM and HYM CR programs over time (Taylor et al., 2004; Gupta et al., 2007; Lawler et al., 2011; Magelhaes et al., 2013; Arthur et al., 2013; Najafi & Nalini, 2015). Najafi & Nalini (2015) found comparable improvements when evaluating outcome variables between TM and HYM at completion of CR (10 to 12 weeks) for WC (p=.002), Tc (p=.01), anxiety (p<.001), HRQOL (p=.01 and p=.08). Similarly, Korzeniowska-Kubacka et al., (2011) found improvements in METs for both the TM and HYM at the final assessment period. The following discusses results from each of the secondary outcomes in further detail.
Physical Activity. PA has been the cornerstone of CR. The benefits of PA are numerous and particularly relevant to CVD regression. In this study, there were no statistically significant differences in the baseline measures between both models, however, final outcomes indicated all participants were significantly engaging in more PA at program completion. The improvements observed in both program models may be due to a focused intention to increase PA by including core education classes regarding the importance of PA for reductions in subsequent cardiac events, risk factors, addressing individual PA barriers (e.g. time, accessibility, walking aids, safe places to exercise), learning how to set PA goals, modifying PA to suit individual needs, and engaging in self-monitoring by maintaining a weekly PA log. Anecdotally, modeling other participant’s physical abilities within the CR setting may also encourage participants to challenge themselves further. Previous research has highlighted the importance of increasing PA in this particular population to incur greater exercise tolerance and health benefits. For instance, Milani & Lavie (2009) observed a 60% lower mortality rate for CR participants who had higher exercise tolerance achieved through increased PA during CR participation. Similarly, Belardinelli et al., (2001) concedes that improvements in METs via PA adaptation, may improve perception of overall well-being. Furthermore, research has also indicated that CR participants who choose not to participate in a CR program after a cardiac event, regardless of the type of model, often report lower levels of PA, thus resulting in fewer opportunities to gain the positive health benefits often associated with increased PA (Oliveiria, 2008; Redfern et al., 2008).

Blood Pressure. Although, there were no statistically significant differences between both models, final outcomes indicated all participants experienced statistically significant reductions in RSBP for both the TM and HYM over time. Many covariates would interact with the reductions observed and offer insight as to why no significant differences existed between
models. Firstly, 73% of participants had a history of high blood pressure, indicating that many may have been on anti-hypertensive medications prior to their cardiac event. Participants were treated aggressively by various agents that reduce RSBP, including; beta-blockers (78.4%), ace inhibitors (57.6%) and calcium channel blockers (28.8%). Secondly, both models offered core education classes which focused on healthy eating, cardiac risk factor and medication management, all of which provides further information and instruction about how to reduce RSBP (e.g. reduced sodium intake, avoiding process and packaged foods, benefits of regular PA, taking prescribed medications). Other research has observed similar reductions in RSBP for those who participate in CR programs (Taylor et al., 2004; Lawler et al., 2011). Furthermore, if participants BP were above cut-offs, a 24-hour BP monitoring system was utilized to provide physicians with additional information for adjusting medications to treat and reach targets prior to program discharge. This underscores the importance of CR programs compared to usual care, as elevated BP may not be recognized and can be difficult to control, particularly for the aging population. There were no statistically significant differences observed for resting diastolic BP (p=.244), as found in similar research which indicates minimal physiologic changes for DBP (i.e. similar blood flow within the arteries during diastole) (Lavie & Milani, 2006).

**Depressive symptoms.** The current study also observed statistically significant reductions in depressive symptoms over time, regardless of the program model. However, one needs to interpret these results with caution as other research has indicated a natural reduction in depressive symptomology after one year in both CR participants and non-participants (Grace et al., 2005). Furthermore, the brief duration and single site of this study warrants careful consideration in these interpretations as over time participants may experience a reduction in the acuity of the cardiac event by learning how to live with their cardiac condition, perhaps relieving
depressive symptoms (Grace et al., 2005; Lavie and Milani, 2006; McGrady et al., 2009). Furthermore, CR programs that observed reductions in depressive symptoms also observed enhanced HRQOL (Yu et al., 2004; Milani & Lavie, 2009), possibly due to the increases in other health behaviours such as PA. Both program models achieved increases in PA and it has been observed that there is a direct positive relationship between PA and depressive symptoms (Blumenthal, 2007; Milani & Lavie, 2009; Reddy et al., 2010; Rutledge et al., 2013). Specific to CR, Milani & Lavie (2009) found that exercise training during CR can reduce depressive symptoms and increase CVD survival rates. Similarly, Rutledge et al., (2013) suggested that exercise based CR has a small to moderate effect on depressive symptom severity in participants with CVD. Furthermore, as indicated earlier, both models at the COACH program offer core components to support the management of psycho-social health status (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009). A registered Social Worker/Counsellor provides one to one counseling sessions for those who rate their depressive symptoms high (≥3; PHQ2) and also offers a psycho-social/stress management class which engages participants in emotions, relationships, behavior change strategies, relaxation techniques, and self-management (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009). Exposure to these core components, and the social interaction associated with their delivery, may play a vital role in managing depressive symptoms as well as overall wellbeing of CVD patients.

*Cholesterol Profile and Blood Sugars.* Caution should be taken when interpreting the results of the lipid profile, in particular the significant reductions in total cholesterol and low density lipoprotein. Reductions in the short term of the CR program could be attributed to the effects of statin therapy. Although dietary changes, similar to what this current study observed, may impact reductions in these two variables, the findings cannot be isolated to changes in
dietary behavior alone as 80% of the participants were taking prescribed statin medications. However, a brief RCT (three treatment arms; a statin, dietary and control group) on relatively healthy adults with diagnosed high cholesterol (n=46) (Jenkins, Kendall, Marchie, Faulkner, Wong, de Souza, … Connelly, 2003) found that within four weeks the statin group and dietary group had reduced LDL by 30.9% (3.6%) (p<.001) and 28.6% (3.2%) (p<.001), yet the control group only reduced LDL by 8.0% (2.1) (p = .002). The reductions in blood lipids in both the statin and dietary groups were significantly greater (p<.005) than the corresponding changes in the control group for total cholesterol and LDL. It should be noted that all three arms of the study were told to follow a low fat diet prior to the commencement of the randomization. However, the impact of healthy nutrition and statin therapy offered superior reduction in Tc and LDL in four weeks. Therefore, the reductions seen in the current study may be a combination of both statins and dietary behavior changes. The healthy eating classes that are offered at the COACH program emphasize reductions in animal fat intake while increasing fibre in their diets (e.g. whole grains), which may have led to the significant increases in fruit and vegetable intake.

Unfortunately, there were no statistically significant improvements in high density lipoprotein (HDL) across time in either model. These findings are similar to systematic reviews undertaken by Jolliffe, Rees, Taylor, Thompson, Oldridge, & Ebrahim (2001) and Taylor et al., (2004), however; many of the studies reviewed were exercise only and did not provide the core components of CR. Contrarily, in a more recent study which found increases in HDL within a TM of CR, the authors attributed this positive change to nutritional support, educational sessions, reductions in BMI and program duration (3 to 12 months) (Belardinelli et al., 2001; Lavie & Milani, 2006; Magalheas et al., 2013). Therefore, baseline improvements in HDL were observed and may be a result of program duration.
Data regarding FBS and HbA1c were collected on a sub-sample of participants, n=71 and n=18, respectively. There were no statistically significant reductions in FBS or HbA1c, which may be due to the small sample size and brevity of program length, as many CR programs elicit a reduction in these variables of greater duration (Lavie & Milani, 2006; Magalhaes et al., 2013). However, given the direct relationship between diabetes and CVD, extended support is needed to detect improvements for this vulnerable population living with diabetes or a history of diabetes. Currently, Kelowna’s CR program collaborates with the Central Okanagan Diabetes Program in order to provide support, however given the results of the current study; this collaboration may require further intensive interactions for these particular participants. More specifically, additional tailored components may be required to meet the specific needs of those living with diabetes as their risk of a second event and increased comorbidities are higher than those not living with diabetes (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009).

Metabolic Equivalents. There were no significant differences between program models regarding METs. However, there were statistically significant improvements in METs over time for both CR models. This may be due to increased PA within both models over time and tailored exercise prescriptions throughout the program duration. More importantly, each model in the current study increased their exercise tolerance significantly, an outcome that is associated with reduced mortality rates (Kavanaugh, Martens, Hamm, Beyene, Kennedy, Corey & Shephard (2003). Research by Kavanaugh et al., (2003) indicates an enhanced oxygen uptake as determined by METs reduces cardiac mortality rates by 10% for every 1 ml/kg/min increase. Those achieving a MET level of eight are at the lowest risk of cardiac death and those achieving five to eight METs are at an intermediate risk of cardiac death (Kavanagh, Mertens, Hamm, Beyenne, Kennedy, Corey, & Shephard, 2002). The final assessment, using sub-maximal
Naughton protocol, mean average for METs in the TM and HYM improved from high risk to low-moderate risk of a cardiac death, 4.9(±1.7) to 6.3(±2.1) and 5.7(±2.1) to 6.9 (±2.2), respectively. Therefore, the statistically significant improvements in METs (p<.001) observed in both groups could influence a translation into enhanced longevity and reduced cardiac deaths, which is an important indicator for psycho-social improvements (i.e. HRQOL and depressive symptoms) (Milani & Lavie, 2009).

Dietary Behaviors. Dietary behaviors within this study indicated a statistically significant change in overall fruit and vegetable intake (p<.001). The enhanced dietary behaviors may have also contributed to the reduced Tc and LDL due to increased plant sterols, as observed in Jenkins et al., (2003). There are relatively few studies within CR literature indicating the impact of dietary changes such as fruit and vegetable intake (F&V). However, in a systematic review by Pomerleau, Lock, Knai & McKee (2005) regarding increased F&V intake in adults both healthy and living with a chronic condition provided some insight. The researchers observed greater intervention responses of increased consumption of F&V for those living with a chronic condition and attribute this to having enhanced motivation in improving their health (3.9 to 4.9 servings per day). The achieved results are similar to those observed in this study 4.3±1.5 and 4.4±1.4 in the TM and HYM, respectively. Kelowna’s CR Programs (including the TM and HYM) offers two education classes and a shop smart tour at a local grocer with a registered dietitian to enhance behavior change. In addition, the CR program environment provides visual aids of healthy eating such as poster boards, cookbook, handouts and the COACH education manual. During, the in-depth education sessions, exposure to direct and simple messaging concerning healthy eating, and the ‘hands on’ teaching approaches seem to have positively impacted the eating behaviours of participants. However, the dietary behaviors were self-
reported and one must use caution when making inferences regarding changes in outcome variables due to over-reporting, a common limitation of self-report measures (Donaldson & Grant-Vallone, 2002).

**Smoking status.** Smoking cessation alone has been reported to decrease the relative risk of death by 50% during the first year of cessation, and eliminates the absolute risk of death in 15 years compared with lifelong non-smokers (Edwards, 2004). The current study experienced statistically significant reductions in smoking status over time; 18 participants reported smoking at baseline, which reduced to 14 participants at the final assessment. Tzou, Vitcenda & McBride (2004) reviewed patient records after a cardiac event (n=624) and found those who did not participate in CR continued to smoke (30.5%) compared to those who participated in CR (13.6%) (p<.0002). The COACH program offers three opportunities for enhanced smoking cessation; a small group session, specialized trained staff and BC Quit Now services. These targeted and specialized sessions may have had a positive impact on smokers in the CR programs, although this study did not have a control group to compare these individuals. Furthermore, not all participants discontinued smoking and for those that did, little is known if they will continue to be smoke free over the long term. A population-based longitudinally cohort study (n=768 post MI patients) by Gerber, Koren-Morag, Myers, Benyamini, Goldbourt & Drory (2011) found 41% of post MI patients continue to smoke at 1-2 years and 56% at 5 years, which means many are not benefitting from the 50% reduction in mortality after smoking cessation (Greenwood, Muir, Packham, Madeley, 1995: Wilson, Gibson, Willan, & Cook, 2000: Gerber, Rosen, Goldbourt, Benyamini, & Drory, 2009). However, for those who did participate in CR, research indicates that the social support of the CR program enhances the recovery process and behavior change (Lavie et al., 2006; Najafi & Nalini, 2015). Furthermore, those that continue to
smoke within CR have lower cardiac self-confidence scores (p=.003) compared to former or non-smokers (Tzou et al., 2004), which underscores the importance of enhanced resources within the CR setting.

**Waist circumference and Body Mass Index.** There were no statistically significant differences regarding WC between models, however there were statistically significant reductions in WC (p<.001) over time. WC may be a better predictor of weight loss over time due to physiological changes with increased PA and dietary behaviors. Magelhaes (2013) assessed WC at three different time points (12, 28 and 52 weeks) and found statistically significant improvements at all assessment periods (<.001). Moreover, Najafi & Nalini (2015) TM and HYM provided similar statistically significant results for reductions in WC (p=.002) however, had no significant improvements in BMI (p=.40).

Similarly, there were no statistically significant differences between models over time for BMI in this study. Lawler et al., (2011) reviewed 34 RCTs for CR programs of either a shorter (two weeks) or longer (52 weeks) duration to examine the effects of CVD risk factors (i.e. BMI). Lawler (2011) found that changes in BMI were minimal in both program durations, which could potentially be explained by the use of the intention to treat approach. Alternatively, some researchers found statistically significant reductions for BMI in the comprehensive CR programs (12 weeks, 2-3 x week exercise) (Gupta et al., 2007; Magelhaes et al., 2013). In another study regarding BMI, Lavie and Milani (2006) found reductions in the younger participants (<55 years) however, not in the older participants (>70 years) (12 weeks, 3x week exercise). Therefore, age may contribute to the lack of BMI changes, as this prospective study sample was mostly older adults 68.1 ±10.9 and 65.7±10.4, in the TM and HYM, respectively.
At COACH, both CR program models (TM and HYM) follow the North American recommended guideline components for standardized CR Programs (Balady et al., 2007; Thomas et al., 2007; Stone et al., 2009), thus one would expect that CV risk reduction for CVD participants in a comprehensive eight week TM or HYM would have positive health implications. However, it may not be about the actual delivery but rather offering a variety of programs that address the barriers, challenges and preferences of the participants. The HYMs blend of both off and on-site may also be more feasible with the high risk populations as more face time and supervision are offered.
Chapter 6 Conclusion

Engaging those suffering from heart disease, and/or recovering from associated trauma or surgery, in CR programs remains difficult. Specific barriers concerning program accessibility cost and preference has resulted in low CR participation rates (Dafoe et al., 2006; Candido et al., 2011). In an attempt to increase participation, many CR programs across Canada have developed alternative CR programs that offer flexibility, reduced costs and can be tailored to the participants preferences. However, little research has evaluated these alternative programs or compared them to more traditional programs, thus making it difficult to realize the true value of offering alternative programs. The present study endeavored to address this concern by comparing specific outcomes variables related to both a TM & HYM program. Based on the research literature supporting a TM, it was hypothesized that the TM would show greater benefits in terms of health related quality of life and secondary outcome measures (e.g., PA, resting blood pressure, cholesterol profile, blood sugars, METs, smoking status, fruit and vegetable intake, depressive symptoms, and anthropometrics). The results of this study did not support the first or second hypothesis as there were no statistically significant differences between the TM & HYM on the primary or secondary outcome variables. However, regardless of group, the results did indicate a positive change over time for many of the outcome variables, providing some support that both models are effective in engaging cardiac patients and assisting them with making health promoting behavior changes. Offering alternative program models may provide an opportune way to engage more participants in CR programs as they offer greater flexibility in terms of costs and accessibility, and they can be tailored to the preferences and needs of the participant.
6.1 Strengths

This study has a number of strengths which will be valuable to future CR programming across Canada and particularly at COACH. Firstly, the study was sufficiently powered based on the required sample size to detect an effect between the two models, in addition to accounting for 15% attrition. As such, little attrition (12%) was experienced; this may be due to the collaborative support regarding the referral process. For instance, the local hospital and local doctors were proactive in advocating for the benefits of CR and the COACH program. Moreover, staff accountability to the participants in supporting their goals of improved CV health after a cardiac event also assisted with keeping attrition rates low. Secondly, this study did permit the collection of many outcome variables including a number of physiological variables and clinical risk factors. The large amount and depth of the data collected provides detailed insight into the effectiveness of these programs concerning specific physiological and clinical risk factor variables. Furthermore, the highly trained multi-disciplinary team at COACH was also a strength, as they were able to provide consistency of content for both interventions. Although the models differed in delivery and contact, the core components necessary for health behaviour change were consistent throughout, signaling that alternative programs such as HYM may be as effective as TM when the core messages of CR are consistent and delivered (by trained staff) as they were intended to be delivered. Lastly, another strength of this study was the utilization of the Canadian Cardiac Rehabilitation Registry (CCRR) which allowed for high quality data storage, accountability, and monitoring of records, thus further assisting in the management of quality of care and patient clinical outcomes to enhance care delivery (Lewancsuk, Suskin & Arthur, 2009). Quality indicators as observed in the CCRR are an important aspect in
improving and maintaining best practices of health care, particularly concerning program development.

6.2 Limitations

Although this study included a number of strengths to support the use of both models, this study is not without its limitations. Firstly, this study did not include a control group, thus the true causal effect of the TM or HYM cannot be determined. Additionally, selection bias existed in that the data originated from a single CR community setting, where participants were given the opportunity to choose which program they would like to participate in. Thus, results may not be representative of all participants who complete CR programs in other settings or jurisdictions and do not have a choice of program models. Similarly, lack of randomization may have resulted in selection bias (Cawley & Price, 2012). Participants were not randomly assigned to either the TM or HYM, therefore other external variables not measured in this study, may have impacted the results observed. Also, the lack of adherence to the intervention is unknown beyond the CR clinic. Therefore, the true effectiveness of this intervention cannot be completely understood without randomization.

Additionally, some of the outcome variables are self-reported, and the participants may not reveal information accurately, as self-reported data may be over or under reported and may also suffer from recall bias (Donaldson & Grant-Vallone, 2002; Prince, Adamo, Hamel, Hardt, Gorber & Tremblay, 2008). Furthermore, the primary outcome HRQOL scale (Cantril’s Ladder of Life) has construct validity for CVD populations, however it is not multi-dimensional as it only evaluates HRQOL as a single component. HRQOL has been described as multi-faceted, thus employing a questionnaire that considers the many facets of HRQOL would be beneficial.
(Jaarsma et al., 1999; Jenkins et al., 2005; Jaarsma et al., 2005; Luttik et al., 2009). For example, using the SF-36 questionnaire to assess HRQOL would provide an assessment of eight dimensions inclusive of overall health, including physical, mental, and emotional health (Jaarsma et al., 2005).

The above research was short in duration and measures were only evaluated over two time periods (baseline-T1 and 8 weeks-T2), making it difficult to comment on long term maintenance or sustainability. Assessing the outcome variables again at 12 months and two years post intervention may provide information on long-term effects, as well as potential differences between groups (Reid et al., 2006). Lastly, fee for services may have also impacted this study’s results, as participants invested in improving their own health care and may have experienced a greater desire to complete the program due to their personal health investment (Artinian et al., 2010). Furthermore, the sample over-represents educated and Caucasian participants, as nearly 50% had greater than high school education and 97.6% were Caucasian, further limiting the generalizability of these findings.

6.3 Future Recommendations

This study looked at only two programs offered at COACH, however there are many other alternative programs currently being delivered nationally (e.g. web-based, tele-health etc.) and locally (i.e., COACH home program model). Future research should extend the current study and examine the effectiveness of the COACH home program model. This is important for future allocation of resources, staff and recruitment. In addition, the brief duration of the program (eight weeks) and the assessment periods provide only short term outcome effects. Research has supported short term interventions, showing promising results; however this is
often lost in the long term (Reid et al., 2006). For those suffering from CVD it is important that lifelong changes are made in order to prevent future episodes, thus it is key to understand if what was adopted from the intervention was maintained. Therefore, examining CR participants long term post intervention (e.g. six to 12 months) would provide an indication of behavior change maintenance. Also, future research should consider an economic assessment of the program models to quantify the resources allocated between models and the return of investment within the program (e.g. staff resources, enhanced participation rates and transferability to smaller CR programs). Lastly, as the Central Okanagan continues to grow and become more diverse of ethnic origins, CR programs must adapt to meet the needs of this changing population. It is well known that those from diverse ethnic origins (e.g., South Asians and Aboriginals origins) are not only more likely to experience CVD (Caperchione et al., 2009) but they are also less likely to participate in health promotion programs such as CR (Parkosewich, 2008; Valencia et al., 2011), thus further research addressing these disparities is needed.
References


Appendices

Appendix A: Description of CR Programs at COACH

<table>
<thead>
<tr>
<th>Week 1 - Baseline Assessment</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Consent form</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>CVD Health History</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Quality of life score</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>PA</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Resting BP and heart rate</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Lipids, FBS or HbA1c</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Exercise Test (METs)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Smoking status</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Depression score</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

2 x week exercise and education (exercise progression and cardiac risk factors) 1 x week exercise and education (exercise progression and cardiac risk factors)

<table>
<thead>
<tr>
<th>Week 2</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x week exercise and education (medications)</td>
<td>1 x week exercise and education (medications)</td>
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</table>

<table>
<thead>
<tr>
<th>Week 3</th>
<th>Traditional Program</th>
<th>Custom Program</th>
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</thead>
<tbody>
<tr>
<td>2 x week exercise and education (stress management)</td>
<td>1 x week exercise and education (stress management)</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 4</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x week exercise and education; healthy eating I</td>
<td>1 x week exercise and education; healthy eating I</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 5</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x week exercise and education; healthy eating II</td>
<td>home exercise and education; healthy eating II</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 6</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x week exercise and education (heart anatomy)</td>
<td>home exercise and education (heart anatomy)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 7</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 x week exercise</td>
<td>home exercise and phone call follow up</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 8 - Follow-up Assessment</th>
<th>Traditional Program</th>
<th>Custom Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of life score</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>PA</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Resting BP and heart rate</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Lipids, FBS or HbA1c</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Exercise Test (METs)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Smoking status</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Depressive symptoms score</td>
<td>x</td>
<td>x</td>
</tr>
</tbody>
</table>

Note: BP=blood pressure, CVD=cardiovascular disease, HbA1c=hemoglobin A1c, METs=metabolic equivalents, PA=Physical activity
Appendix B: Exercise prescriptions for the TM and HYM*

<table>
<thead>
<tr>
<th>Frequency:</th>
<th>Minimum 3 days to most days of the week (depends on baseline exercise tolerance, limited exercise capacities, fitness and other health goals) or several brief bouts (1-10 min) daily or on alternate days may be required. The goal is a minimum of 150 minutes per week.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensity:</td>
<td>Based on the results of the exercise test; 70% of heart rate reserve and 10 beats below the ischemic threshold assists participants to develop the skills for utilizing the rate of perceived exertion (RPE). An RPE of 3-6 on a scale of 1-10 (3= moderate to 6=heavy, but comfortable), indicates a safe exercise zone to be completed on-site and off-site. Signs and symptoms should be monitored, such as dizziness, light-headedness and pain. If symptoms occur, instruction to slow down or stop is provided until symptoms subside.</td>
</tr>
<tr>
<td>Time:</td>
<td>Warm up and cool down should proceed and follow each exercise session. The duration will vary from 5 to 10 minutes, which is dependent on medications, level of disease, symptoms, deconditioning and familiarity to exercise. The goal of the conditioning phase of the exercise should be 20-60 minutes. However after a cardiac event, 5-10 minutes of aerobic conditioning as a baseline, with increases of 1-5 minute increments per exercise session maybe appropriate.</td>
</tr>
<tr>
<td>Type:</td>
<td>Rhythmic, large muscle group activities, which includes upper and lower extremities with multiple forms of on-site exercise equipment; arm ergometer, upright and recumbent cycle ergometer, treadmill for walking or interval jogging. Off-site exercise is dependent on accessibility to equipment i.e. community facilities (recreational or home based). However, participants are encouraged to walk in safe outdoor areas e.g. marked pathways, malls or within their home environment.</td>
</tr>
<tr>
<td>Resistance Training Guidelines;</td>
<td>The goal for muscle strength and endurance training varies from return to work or normal activities of daily living. Depending on CVD diagnosis, resistance training may begin 2 to 4 weeks following a cardiac event and may not include upper body exercise until 8 weeks post CABG. Equipment; elastic bands, hand weights. Initial load; 1 set of 10-15 repetitions (week one), then adding a second set to week two as long as recovery period of muscle soreness is normal. Targeting three sets by week three, as tolerated. Progress resistance 2-5 lbs•wk for upper body and 5-10 lbs•wk for lower body, as tolerated. Perform eight to 10 major muscle groups. Frequency varies from two to three times per week, with 48h rest between resistance training days.</td>
</tr>
</tbody>
</table>

*Note: Each participant, regardless of program model, is provided with the same standard of exercise prescription development, which is dependent on individual capabilities and health status.
Appendix C: Baseline Questionnaire

Name: ___________________________ Date: ______________________

Date of Birth: ____________________ Occupation: ______________________

Mailing Address: ___________________ City: __________ Postal Code: ______

Home phone: ______________ cell: ______________ Email: ______________

Doctor(s): __________ Allergies: ________ Do you have extended health coverage?

Do you experience any of the following:

_____ Chest discomfort  _____ Extra, skipped, rapid beats or palpitations

_____ Ankle swelling  _____ Unusual shortness of breath

Do you have any other physical condition that may limit your exercise?

Emergency Contact:  Telephone:  Relationship to you:

1. Your Marital Status:
   ☐ Single  ☐ Married  ☐ Widowed
   ☐ Common-Law  ☐ Separated  ☐ Divorced

2. Please check the level of formal education that you have completed:
   ☐ No High School  ☐ Post Graduate Degree
   ☐ High School  ☐ Other ______________________

   ☐ Bachelor Degree

3. Family support:
   ☐ Live alone.
   ☐ Live with spouse / partner.
   ☐ Live with friends / family.

4. Travel time to COACH Cardiac Rehab:
   ☐ 0 – 30 minutes
   ☐ 31 – 45 minutes
   ☐ 46 – 59 minutes
   ☐ > 60 minutes
5. Please share your ethnic background:
   - □ Aboriginal
   - □ Japanese
   - □ White/Caucasian
   - □ Arab/West Asian
   - □ Korean
   - □ Other___________
   - □ Black
   - □ Latin American
   - □ Unknown
   - □ Chinese
   - □ South Asian
   - □ Filipino
   - □ South East Asian

6a. Have you used tobacco in the last month?  □ No – Congratulations! (go to 7)
   □ Yes (go to 6b)

6b. Please check the correct statement…
   □ I am not thinking about stopping
   □ I am thinking about stopping in the next 6 months
   □ I am thinking about stopping in the next 30 days

7. What percentage on average do you feel you eat well? (quality & quantity of food)

8. How many servings of fruits and vegetables do you eat a day? (e.g. 1C spinach, 1 fruit, ½ cup fresh or frozen fruit and vegetable, ½ cup juice). Please circle one answer below.

9. Over the past 2 weeks, how often have you been bothered by any of the following problems?

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Several Days</th>
<th>More Than Half the days</th>
<th>Nearly Everyday</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
10. Assume this ladder below is a way of picturing your life. The top of the ladder represents the best possible life for you. The bottom rung of the ladder represents the worst possible life for you. Indicate where on the ladder you feel you personally stand right now by circling a number.

<table>
<thead>
<tr>
<th>10</th>
<th>Best Possible Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

11. Leisure-Time Exercise Questionnaire
During a typical 7 day period (a week), how many times on average do you do the following kinds of exercise for more than 10 minutes during your free time (write on each line the appropriate number).

a) Strenuous exercise
   (heart beats rapidly)
   e.g. jogging, hockey, soccer, squash, cross country skiing, vigorous swimming, vigorous bicycling
   _________________ times per week

b) Moderate exercise
   (not exhausting)
   e.g. fast walking, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing
   _________________ times per week

c) Mild exercise
   (minimal effort)
   e.g. easy walking, yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling
   _________________ times per week

During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)? Please check one.

<table>
<thead>
<tr>
<th>OFTEN</th>
<th>SOMETIMES</th>
<th>NEVER/RARELY</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Thank you!
Appendix D: Written Informed Consent

The Central Okanagan Association for Cardiac Health (C.O.A.C.H.) is an education and exercise program to manage cardiovascular risk factors for heart disease. The C.O.A.C.H. Program endeavours to assist individuals to make positive changes in their lifestyle, to control cardiovascular risk factors, and to improve physical capacity while reducing the risk of premature death due to cardiovascular disease.

I, ______________________________________ do hereby make application to participate in the C.O.A.C.H. Program and in doing so acknowledge and understand that:

- It is essential to carefully follow instructions given by program personnel during the course of the program.
- The following information will be collected and reviewed by C.O.A.C.H. personnel:
  - Personal information: Name, address, phone number, personal health number, age.
  - Health information from my family doctor, Cardiologists and Interior Health facilities
- My information will be shared with and used by:
  - C.O.A.C.H. personnel
  - family doctors or specialist
  - other health care professionals involved in your care
  - Canadian Cardiac Rehab Registry (CCRR) only de-identified data is shared
  - C.O.A.C.H. personnel as a dual role who is undertaking research with U.B.C.O.
- My information will be used for the following purposes:
  - treatment and care
  - administrative purposes according to approved policies and practices
  - for CCRR to monitor and evaluate the progress made by attending Cardiac Rehabilitation
- Information will be stored in accordance with security standards followed by my doctor, Interior Health, C.O.A.C.H., and the CCRR.

By signing this form I consent to the collection, use and disclosure of my information as described above. I expressly release and discharge liability from the C.O.A.C.H. organization and all or any of their agents participating in the said program from any claims or demands which I may have now or at any other time in the future resulting from any illness, injury or occurrence as a result of participation in the said program, and I assume any risks in connection therewith. Furthermore, I agree to look to a private physician for medical care and agree to have an evaluation by him or her from time to time as required.

___________________________   _______________________________  _________________
Client Name (Please Print)                      Client Signature             Date

___________________________  _________________  _____________
Witness Name (Please Print)                   Witness Signature           Date
Appendix E: Discharge Evaluation Form

This questionnaire is to help us find out what you thought of the program. Your responses will be strictly confidential, and will help us improve the program. Thank you for your honest answers!

You chose the following program; □ Full (go to question 1) □ Custom □ Home
Please select your reason why?
□ Limited transportation □ live far from rehabilitation
□ Return to work □ felt confident in your knowledge of heart disease and exercise
□ Cost of the full program □ other, please explain________________________

1. Since you began this program, have your smoking habits changed at all?
   □ NOT APPLICABLE since I used to smoke or have never smoked.
   □ NO
   □ YES…..Please describe.

2. Please place an "X" on the line below to show how you rate your eating patterns at this time. 0 represents poor eating habits and 100 represents excellent eating habits.

   □ □ □ □ □ □ □ □ □ □ □ □
   0 10 20 30 40 50 60 70 80 90 100

3. Would you recommend this program to others?
   □ YES!
   □ NO.....Please explain.

   □ I would like to volunteer for COACH fundraising events.
   □ I would like to volunteer for the hospital visitation group.
   □ Please contact me about COACH events via email.

4. How many servings of fruits and vegetables do you eat a day?
   (e.g. 1C spinach, 1 fruit, ½ C fresh or frozen fruit and veg, ½ C juice). Please circle below.

   1 2 3 4 5 6 7
5. **Over the past 2 weeks, how often have you been bothered by any of the following problems?**

<table>
<thead>
<tr>
<th></th>
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<th>More Than Half the days</th>
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</tr>
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6. **Assume this ladder below is a way of picturing your life. The top of the ladder represents the best possible life for you. The bottom rung of the ladder represents the worst possible life for you.**

Indicate where on the ladder you feel you personally stand right now by circling a number.

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<td>6</td>
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<tr>
<td>5</td>
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<tr>
<td>4</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>
8. Leisure-Time Exercise Questionnaire

During a typical 7 day period (a week), how many times on average do you do the following kinds of exercise for more than 10 minutes during your free time (write on each line the appropriate number).

d) Strenuous exercise  _____________ times per week  (heart beats rapidly)
   e.g. jogging, hockey, soccer, squash, cross country skiing, vigorous swimming, vigorous bicycling

e) Moderate exercise  _____________ times per week  (not exhausting)
   e.g. fast walking, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular folk dancing

f) Mild exercise  _____________ times per week  (minimal effort)
   e.g. easy walking, yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling

During a typical 7-Day period (a week), in your leisure time, how often do you engage in any regular activity long enough to work up a sweat (heart beats rapidly)? Please check one.

   OFTEN   SOMETIMES   NEVER/RARELY
   □       □             □

Thank you!
Appendix F: UBCO Ethics Approval

The University of British Columbia Okanagan
Research Services
Behavioural Research Ethics Board
3333 University Way, Kelowna, BC V1V 1V7
Phone: 250-807-8832250-807-8832, Fax: 250-807-8438

CERTIFICATE OF APPROVAL - MINIMAL RISK

PRINCIPAL INVESTIGATOR: INSTITUTION / DEPARTMENT: UBC BREB
NUMBER:
Cristina Caperchione
UBC/UBCO Health & Social Development/UBCO Health and Exercise Sciences
H15-00023

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

Institution Site
CO-INVESTIGATOR(S):
Jacqueline B Gabelhouse
Neil Eves

SPONSORING AGENCIES:
N/A

PROJECT TITLE:
Examining the effectiveness of hybrid cardiac rehabilitation programs in achieving cardiovascular improvements

CERTIFICATE EXPIRY DATE: March 9, 2016

DOCUMENTS INCLUDED IN THIS APPROVAL: DATE APPROVED:
March 9, 2015
Document Name Version Date
Consent Forms:
Consent Form 2 March 3, 2015
Other Documents:

COACH BOD letter to access CCRR N/A January 26, 2015
The application for ethical review and the document(s) listed above have been reviewed and the procedures were found to be acceptable on ethical grounds for research involving human subjects.

This study has been approved either by the full Behavioural REB of the UBC Okanagan or by an authorized delegated
Appendix G: Letter of Approval for Data Extraction CCRR

September 17, 2015

Jacqueline Gabelhouse
Program Coordinator Kelowna Cardiac Rehab Program, COACH
University of British Columbia (Okanagan)
201-2622 Pandosy Street
Kelowna, BC V1Y 1V6

RE: CCRR DATA ACCESS APPLICATION

Dear Ms Jacqueline Gabelhouse,

This letter confirms that you have been granted approval for use of Canadian Cardiac Rehab Registry (CCRR) data for your study entitled, “Comparison of an alternative outpatient cardiac rehabilitation program”. Your application has been reviewed and was approved by the CCRR Research Sub-Committee on July 6, 2015. The CCRR data will be provided by July 31, 2015.

Please refer to your completed CCRR Data Access Application form for agreed-upon details regarding your obligations in using CCRR data for your research. Should you have questions, please feel free to contact me at kgresty@cacpr.ca or 514-513-6888

On behalf of the CCRR Committee and its Sub-Committees, I wish you great success with your research. It is through projects such as this that the value of the CCRR is truly realized.

Sincerely,

Katelin Gresty
CACPR Special Projects Coordinator
On behalf of Todd Duhamel – Chair of CCRR Research sub-committee