HEALTH-RELATED QUALITY OF LIFE AMONG PATIENTS ATTENDING CARDIOVASCULAR REHABILITATION

Brandon Batey

Submitted in partial fulfillment of the requirements for the degree
Master of Science in Applied Health Sciences
(Health Sciences)

Supervisors: Deborah O'Leary, Ph.D.
Michael Plyley, Ph.D.

Faculty of Applied Health Sciences, Brock University
St. Catharines, Ontario

ABSTRACT

Purpose: First, an investigation of baseline differences in Health-Related Quality of Life (HRQOL) among adhere and non-adhere patients of Phase III cardiac rehabilitation (CR) was examined. Second, among patients who adhered to the program, effectiveness of treatment based on HRQOL was evaluated.

Methods: Data was collected by the Brock University Heart Institute. Participants completed a questionnaire battery at baseline and again at six months if they were still a client.

Results: The physical dimension of HRQOL differed at baseline between the adhere and non-adhere groups. For every one point increase in physical HRQOL scores there was an associated 1.06 times greater likelihood that an individual would adhere to the program. Second, in those who adhered to the program for six months, physical HRQOL scores improved 3.18 points.

Conclusions: Phase III CR significant improves HRQOL in patients suffering from cardiovascular disease.

ACKNOWLEDGEMENTS

I would like to dedicate this page to all who helped me make this project a reality. First, I would like to thank the members of my committee. All of their constructive criticisms throughout the process of completing this document are greatly appreciated. Dr. Deborah O'Leary offered me encouragement when times got tough; she always made it known that if and when I needed her that she would be there for me. I would also like to thank Dr. Terrance Wade in particular, who offered me guidance and exposed me to the reality of what a quality master's thesis is all about. Dr. Wade offered me encouragement and challenged me to challenge myself, providing me with a unique and interesting mentorship that cannot be described. Finally, I would like to thank Dr. Michael Plyley for all of his valuable contributions and support throughout this process. At this time I would like to extend thanks to the members at the Brock University Heart Institute for becoming my friends and always expressing interests in my well being. Without them this project would literally not be possible. I would also like to thank all of my friends, some of which I'll mention in particular. Thank you to my two fellow graduate students and great friends, Dan and Nicole, for always being there for me, if I ever needed anything they were the first to offer their humor and their new found expertise. Paul, always offering his time to assist me. Neil, "are you working on your paper?... I don't care...DO IT." And finally, Cristina my fiancée, always willing to drop everything to give me encouragement and lend me her intelligence, she brought out the best in me.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

GLOSSARY OF ABBREVIATED TERMS

Adherence:	Active membership at 6-months follow-up, despite attendance record and compliance to exercise regime
BP:	Blood Pressure
BUHI:	Brock University Heart Institute
CVD:	Cardiovascular Disease
GXT:	Graded Exercise Tolerance test
HR:	Heart Rate
HRQOL:	Health-Related Quality of Life
Ht:	Height
K-6:	Kessler-6
MC SF-12:	Mental Component of the SF-12
PC SF-12:	Physical Component of the SF-12
QOL:	Quality of Life
SDS:	Self-Rating Depression Scale
SF-12:	Medical Outcomes Short-Form 12 Health Status Survey
SF-36:	Medical Outcomes Short-Form 36 Health Status Survey
STAI:	State-Trait Anxiety Inventory Questionnaire
Wt:	Weight

HEALTH-RELATEED QUALITY OF LIFE AMONG PATIENTS ATTENDING CARDIOVASCULAR REHABILITAION

CHAPTER 1 – INTRODUCTION

In 2009, cardiovascular disease (CVD) was the leading cause of death in Canada[1] and the United States of America[2,3]. There are a number of risk factors that contribute to the development of CVD, and many of these are modifiable through lifestyle changes, including but not limited to hypertension, dislipidemia, diabetes, and overweight/ obesity[4,5]. Current research has demonstrated that cardiovascular mortality has decreased 30-40% in the past 30 years, which has been attributed to advances in primary and secondary prevention strategies[3], i.e., cardiovascular rehabilitation and prevention programs. However, CVD has many co-morbidities that can lead to high dropout rates in cardiovascular rehabilitation and prevention programs[6]. When CVD is left untreated, it is probable that it will further progress or worsen such that an individual may have a recurring event. A decreased Health-Related Quality of Life (HRQOL) likely results from the symptoms of CVD, and can be one of the most important predictors of adherence to treatment interventions and future mortality. Research has demonstrated that HRQOL is a stronger predictor of future mortality than many other risk factors, such as hypertension or even smoking[7]. Thus, it is important to investigate how current treatments and management strategies affect not only CVD, but a patient's HRQOL.

HRQOL is used to measure how a patient perceives the effects of disease and treatment in terms of their overall well-being. HRQOL has been best defined by Cella[8]

(1995): as referring "to the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment."[8] The ability of HRQOL measures to predict future mortality[7] and program adherence[9] can be used to help effectively guide policy and treatment strategies to improve overall health[10]. HRQOL is an important tool for evaluating therapeutic interventions[11], and has been increasingly used in clinical trials[12]. The use of HRQOL questionnaires in CVD studies specifically, has been important for tracking improvements in perceived psychological and physical well being over time[13].

Considerable research on primary and secondary prevention of CVD has been completed; however, only limited research has been conducted on the later stages of exercise rehabilitation programs. Specifically, with respect to HRQOL in Phase III/maintenance cardiovascular rehabilitation, only one study has been done to date[14]. However, this study was limited due to its small sample size (18 controls and 20 cases), and the fact that it only evaluated elderly males (mean age 70 years). Although these limitations existed, the results demonstrated that 6 months of enrolment resulted in an improvement in HRQOL. Finally, this study was carried out in Japan where there are many cultural differences from that of Canada, which may result in different outcomes. Thus, it is important to investigate if Phase III cardiovascular rehabilitation offers the same benefits to a person's HRQOL when enrolled in a Canadian Phase III program.

Purpose

The purpose of the present study was two-fold. First, it was to investigate baseline differences in HRQOL among dropouts and those patients who adhered to Phase III/maintenance cardiovascular rehabilitation for 6 months. Second, among those patients who adhere to the program, this study evaluated the effectiveness of treatment of a Phase III program on changes in HRQOL.

Hypotheses

Since a more positive HRQOL has been shown to have a strong association to adherence[9] in medical treatments, it was hypothesized that when compared to those who dropped out of the program, the group who adhered would have a higher baseline rating of HRQOL. Second, due to the fact that HRQOL has been shown to improve early in intervention strategies[15], it was hypothesized that with continued adherence the program, HRQOL would increase.

CHAPTER 2 – LITERATURE REVIEW

Quality of Life

In the 1960's, awareness of Quality of Life (QOL) and standards of living became popular among communities of social scientists, philosophers, and politicians[16]. Quality of life measures have been used to analyze the allotment of resources and well-being in society, as well as to measure quality of work, family life, and leisure[17]. In particular, various measures of QOL were utilized to evaluate the perceived inequalities within society, to help better understand perceived standards of living, and to provide insight on how inequity influences QOL. Quality of life measures take into consideration access to life's essentials: water, food, and shelter, and also to less tangible commodities, such as satisfaction with lifestyle, a sense of belonging in the community, and a feeling of self fulfillment[18].

Although QOL is often used as an outcome measure in research and clinical trials, it has been described as being ill defined by those who use it[19]. Gill and Feinstein (1994)[17] examined 75 randomly selected articles that described the use of QOL measurements and discovered that very few made an effort to define what was meant by QOL. Furthermore, Gill and Feinstein found that many of the articles did not justify their choice of measures used with regard to QOL. Without an accurate understanding of QOL, it is difficult to comprehend what exactly is being measured or why certain measures are included[19].

The medical field in particular has increasingly used QOL to evaluate the effects of interventions on patients. QOL in the health care field was employed when consumer dissatisfaction grew rapidly as care shifted exclusively to extending life overlooking basic human needs, such as well-being, autonomy, and a sense of belonging[16]. The importance of evaluating each patient's QOL became a desired outcome of treatment as it measures overall satisfaction with one's life. Because QOL in the medical field was used to evaluate the effect of various interventions on a patient's perceived health, the term Health-Related Quality of Life (HRQOL) became more appropriate.

Health-Related Quality of Life (HRQOL)

HRQOL has been defined by Cella (1995)[8] as the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or its treatment. In other words, HRQOL is used to measure the effects of disease on patients, and further, to assess how the condition, and any subsequent treatment, may interfere with a person's life and lifestyle. There are two health domains of HRQOL, and each has its own subcategories: physical and mental health. Physical health encompasses physical functioning, role-physical, bodily pain, and general health, while mental health encompasses vitality, social functioning, role-emotion, and mental health[20]. HRQOL has been utilized in different populations to identify and compare subgroups (i.e., hypertension vs. dislipidemia among CVD patients), and can help to guide the development of policies and interventions to improve overall health[21].

It has been demonstrated that HRQOL is something that can only be interpreted by the individual who is to be measured. Slevin et al. (1988) compared how doctors perceived cancer patients HRQOL vs. how the patients perceived their own HRQOL. Slevin found that doctors could not accurately predict how their patients' lives were affected by disease, enforcing that HRQOL measurements are individual and unique[22]. Although two individuals may be affected by the same disease and have the same symptoms, it is likely that there are differences in their satisfaction with life. As such, the importance of HRQOL measurements is that it offers insight concerning how a patient is dealing with his or her condition[23, 24], and provides health professionals with a subjective measurement of a patient's interpretation of his or her illness and health status beyond what a physician can ascertain[23]. Furthermore, using HRQOL as a tool to measure and compare two time points, whether it be an arbitrary unit of time or pre and post rehabilitation, has become common practice, and is widely accepted as a tool to evaluate the effectiveness of interventions and rehabilitation programs[25]. However, it must be noted that HRQOL can change favourably without changes in actual health or symptoms. Bury (1991) suggested that as an individual accepts the reality of long-term illness, hey/she may make psychological adaptations that preserve life satisfaction[26].

Implementation of HRQOL as a Measure

HRQOL has been made a tool for evaluating a patient's perceived satisfaction with life and also as an instrument to evaluate the care and treatment of a patient[13]. But perhaps the greatest contribution that HRQOL offers is its ability to predict future

mortality, and since several studies have investigated and reinforced this finding[7,27-33]. Kaplan and Camacho (1983) surveyed a random selection of 6928 adults in California longitudinally over a nine year period, and found that there was a significant relationship with perceived health and mortality[31]. They reported that perceived health independently predicted mortality when controlling for variables related to health practices, social networking, and psychological state. Notably, the findings of Kaplan and Camacho reinforce the use of HRQOL measures as an independent screening tool for future mortality. However, they reiterate the point that the variables they controlled for are not to be discounted, as they too possess predictive characteristics[31]. A more recent study by Tibblin et al. (1993) provides us with additional support and evidence that HRQOL can be a predictor of future mortality, possibly more so than disease or diagnosis[7]. Tibblin et al. measured the HRQOL of 1000 randomly selected fifty-year old Swedish men to identify the predictive capabilities of HRQOL on all-cause and CVD mortality. It was found that those men with an impaired health score were at a greater risk of death due to myocardial infarction, and that health scores were a greater predictor of this than hypertension. The most profound result discovered by Tibblin et al. was that smokers with the most positive health scores were at no greater risk for future all-cause mortality than those who did not smoke. The findings from Kaplan and Camacho and Tibblin et al. are impressive examples of how HRQOL measures possess the ability to predict future mortality and further stress the significant role that HRQOL

plays as an outcome measure in a clinical setting[7,31]. To date, many other studies have found similar results[27-33].

Although HRQOL can predict future mortality, it is not the only important use of this instrument. HRQOL has also been found to be a strong predictor of adherence to medical treatments and intervention strategies across all disciplines. A recent study measuring adherence to hepatitis C treatments by Bernstein et al. (2002) found a significant discontinuation in treatment among those with a reduced HRQOL[34]. Bernstein et al. found that patients receiving one particular treatment over another had better HRQOL scores. Furthermore, the higher HRQOL scores were linked to the improvement of symptoms from that particular treatment. This study demonstrates the importance of realizing that there is a positive feedback loop associated with treatment, adherence and HRQOL. Specifically, treatments that have favourable effects on disease symptoms will lead to improvements in HRQOL, which in turn leads to an increased adherence and subsequently more treatment (Figure 1). The findings of Bernstein et al. (2002) suggest that healthcare professionals need to ensure that their members are adhering to the program by choosing strategies that most positively affect HRQOL[34]. Support for this idea comes from Koertge et al. (2003) who, identified the predictive effects of HRQOL on adherence to a multi-component lifestyle program (Phase II cardiovascular rehabilitation) that focused on diet, exercise, stress management and social support over a one-year period[9]. Koertge et al. found that those with a lower initial health status were more likely to drop out from the program than those with

more favourable scores. Of the members who continued in the program, there were significant improvements in their blood pressure, cholesterol, weight, exercise capacity, stress management, diet, and HRQOL. Both the physical and mental health aspects of the patients' HRQOL improved. The positive feedback loop identified by Bernstein et al., was consistent with Koertge et al.'s findings in that treatment leads to improved symptoms, which then leads to improved HRQOL, and then to adherence, and back to treatment. Additional research measuring adherence to medical treatments and HRQOL exist and include, but are not limited to, physical activity[35], diabetes[36] and HIV[37].

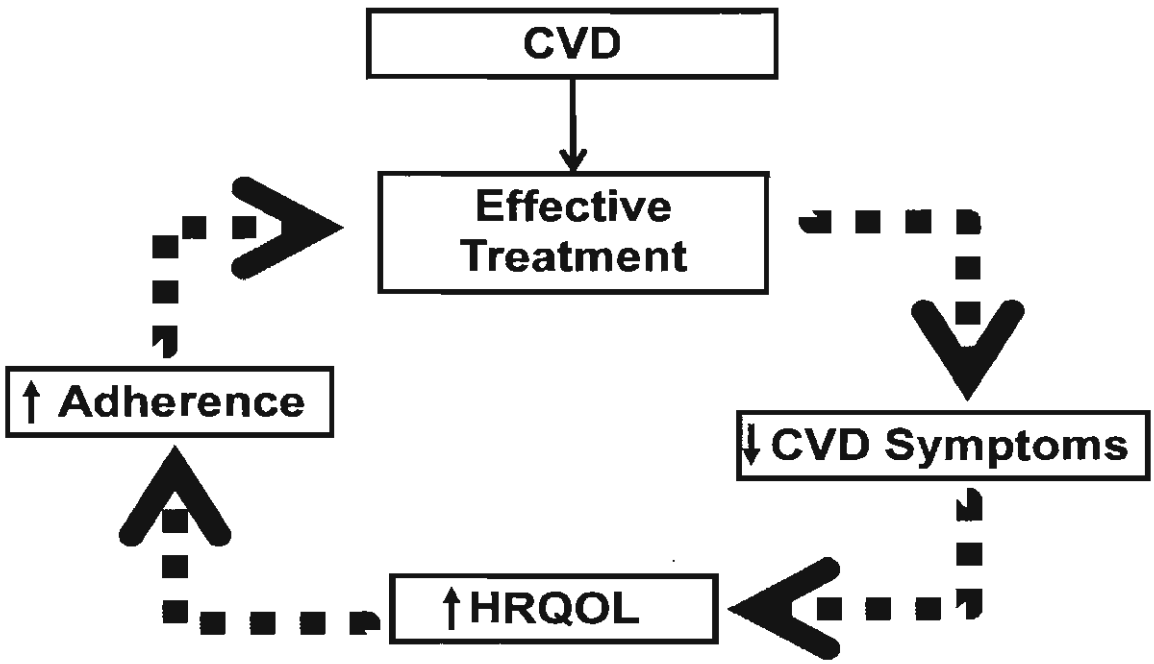


Figure 1: A positive feedback loop associated with treatment, symptoms, adherence, and HRQOL. Treatments that have favourable effects on disease symptoms will lead to improvements in HRQOL, in turn increased adherence which then leads back to more effective treatment.

As highlighted above, HRQOL measures are powerful predictors of mortality and adherence to treatment, while treatment itself has been shown to be an independent predictor of HRQOL. Nevertheless, it is essential to investigate any other factors that also predict HRQOL. The current literature clearly supports a strong relationship between depression, anxiety, and HRQOL. A two year longitudinal study by Hays et al. (1995) investigated how HRQOL differed in 428 patients with depression versus 1362 patients with chronic disease[39]. Hays et al. controlled for medical comorbidities, sociodemographics (age, ethnicity, gender, education, income, and marital status), healthcare system, and specialty of care. The results from this study indicated that negative HRQOL, specifically the psychological component, was affected more by depression than disease symptoms, and it was concluded that depression greatly influences one's perceived well-being. Furthermore, Dickens et al. (2006) inspected the relationship between depression, anxiety, and HRQOL in 260 myocardial infarct patients[38]. The patients' depression, anxiety, and HRQOL were assessed at baseline, at six months follow-up, and at twelve months follow-up. Anxiety and depression were found to be strong predictors of all aspects of HRQOL within a six month period, after which this prognostic characteristic diminished. Although depressive symptoms were unchanged from six to twelve months, overall HRQOL further improved in this time period. It was concluded that effective treatment strategies for depression and anxiety, as well as disease management strategies, were responsible for the enhanced overall HRQOL found at twelve months. The fact that depression scores did not further improve

from six to twelve months can be explained from research by Bury et al. (1991), who suggested that as an individual accepts the reality of long-term illness, they make psychological adaptations that preserve life satisfaction[26]. Therefore, Hays and Dickens' research makes it essential for clinicians examining the effects of therapy on HRQOL to control for depression and anxiety because of its over-riding influence on perceived HRQOL. The influence of depression on HRQOL has been well documented with similar results by other authors[40-43].

HRQOL is an important measurement tool for therapeutic intervention[11] and has been increasingly utilized in clinical trials[12]. The measurement of HRQOL in an intervention setting is of particular importance according to Shipper et al. (1983)[44] who state that if HRQOL measurements were non-existent, then the primary goal of intervention strategies would be only to increase life expectancy. Additionally, Shipper et al. indicate that implementation of HRQOL measures allows medicine to be more 'human' as we can evaluate not only the effectiveness of a treatment in terms of disease stage, but also how the treatment affects a person's overall life quality. In conclusion, Shipper et al. states that HRQOL is essential in providing the best care for each individual patient, further supporting the notion that HRQOL should be used to evaluate the effectiveness of care[44]. The use of HRQOL questionnaires, specifically in CVD studies, has been important in tracking improvements over time in CVD populations[13].

Measuring HRQOL is not only limited to measurements within a diseased population, but can also be used to assess the general health status of individuals without disease. For example, two different types of HRQOL instruments exist. This first is designed for generic use and may be applied across all populations, regardless of health status. Whereas, the second HRQOL instrument incorporates population specific designs, such as the form created to evaluate people with atrial fibrillation[45]. When comparing the two categories of HRQOL questionnaires, the application of each is different. In contrast to the disease specific questionnaires, a generic questionnaire was developed to have a broad spectrum of applicability, whereby the questionnaires can be used to evaluate both healthy and diseased populations. Based on the diverse nature of a generic questionnaire, it is possible to identify how health status compares between two different populations or within intervention strategies[45]. In contrast, disease specific questionnaires maintain a narrow scope of application due to the focus on concerns, symptoms, and effects of a specific disease and/or to the treatment[45]. One example of a disease specific measure is the MacNew Heart Disease HRQOL Instrument for coronary artery disease patients[46]. This HRQOL tool consists of five questions that specifically pertain to symptoms related to coronary artery disease.

In summary, the value of HRQOL instruments has been demonstrated throughout the literature. In particular, the implementation of these instruments has proven to be a better predictor of future mortality than disease symptoms or other established risk factors. HRQOL offers insight to clinicians regarding the effectiveness of

treatment, as well as the likelihood of continued adherence to management programs. Overall, the advantages of this tool make HRQOL measurements an important element to be used in designing and evaluating clinical trials/programs.

Cardiovascular Disease

Cardiovascular disease (CVD) is the leading cause of death in Canada[1]. In general, CVD encompasses all diseases of the circulatory system including the heart (cardio) and blood vessels (vascular) [1]. Cardiovascular disease is an umbrella term for any disease that interferes with normal heart function and includes cardiomyopathy, which is disease of the heart muscle; coronary artery disease, atherosclerosis of blood vessels supplying the heart; and valvular disease, in which a deterioration of the heart valves can lead to inadequate chamber filling and/or back flow (regurgitation) against the normal flow of blood[5]. Vascular disease refers to pathological abnormalities of blood vessels[47], including peripheral artery disease, obstructed flow common to the arms and legs, which can lead to emboli and claudication; coronary artery disease, which can be classified as either heart or vascular disease; and cerebrovascular accident, when blood flow to the brain is interrupted by either an embolus or vessel rupture[48].

Coronary artery disease, specifically atherosclerosis, is the most common CVD[49]. The process of atherosclerosis begins at birth and continues throughout life[49-51]. The advancement of plaque formation is dependent on age, genetics, and lifestyle choices (i.e., physical activity and dietary habits). When a coronary blood vessel becomes obstructed because of the progression of atherosclerosis, there is a greater likelihood

that the heart muscle will not receive enough oxygen during increased physical activity, or even at rest[52]. This obstruction of blood flow, known as ischemia, may present with typical symptoms, such as angina or radiating pain through the chest, neck, jaw, upper back, and arm[53]. When a coronary artery becomes severely occluded, there is a heightened risk of myocardial infarction. The lack of blood flow affects only the muscle area that the occluded blood vessel supplies[54]. This lack of blood supply can lead to dangerous arrhythmias, necrosis of heart muscle, or even death[54].

Risk Factors

There are many risk factors that can contribute to the development of CVD, each of which can be categorized as modifiable, non-modifiable, and emerging[55, 56]. Modifiable risk factors for CVD include factors such as elevated lipid levels, hypertension, cigarette smoking, diabetes, and obesity[55, 57]. Non-modifiable risk factors include factors such as age, male gender, and familial history of premature CVD[55, 58]. Finally, risk factors are considered "emerging" when it is scientifically uncertain if they are independent predictors of CVD; some examples of emerging risk factors are homocysteine and inflammatory markers[56, 57].

The American College of Sports Medicine[59] has published risk factor thresholds to measure overall CVD risk[59]. Individuals can be stratified into one of three categories depending on how many risk factors they have, their age and gender, and if they have known or suspected CVD. Those who have no more than one risk factor are considered at low risk of developing CVD; men older than 45, women over 55, or those with two or

more risk actors are labeled moderate risk; and finally those with signs and symptoms (i.e., angina, shortness of breath, etc.) and/or known CVD are considered high risk[59, 60]. Risk stratification is important because it assists in identifying those at high risk for CVD and whether further diagnostic testing is required[60].

Each individual case of CVD is unique, so it is important to treat the person and not just the disease. Because persons with CVD are all affected differently, they may also respond differently to medications, and present varying symptoms or even be asymptomatic. Common symptoms of CVD include chest discomfort, dyspnea, orthopenea, peripheral edema, palpitations, syncope, and cough[59]. When looking at some of the common symptoms, one may be able to imagine how this disease can negatively impact a person's QOL. The aforementioned symptoms of CVD and their relationship with HRQOL have been investigated on several occasions. It has been well documented that chest discomfort[61], dyspnea[62-64], peripheral edema[63], palpations[64], and syncope[65] in CVD disease patients all have a negative correlation with HRQOL. However, there is an abundance of research on exercise and its ability to attenuate the negative CVD symptoms in early intervention strategies, i.e., Phase I and II cardiovascular rehabilitation[59,66,35]. From the positive feedback loop that exists between treatment, enhanced HRQOL and adherence (Figure 1), it is clear that individuals with CVD should be encouraged to participate in regular exercise to help increase their HRQOL. Accordingly, it is warranted that this hypothesis be investigated in a Phase III/maintenance cardiovascular rehabilitation setting.

As discussed above, HRQOL has been identified as a reliable predictor of mortality[7], program adherence[9], and effectiveness of disease treatment[10]. Specific to CVD, a low HRQOL has also been explored as a risk factor. A three year prospective study followed a group of 416 middle aged blue collar workers to investigate the predictive ability of HRQOL as a risk factor for CVD[67]. It was concluded that those with a low HRQOL were at greater risk for early onset of myocardial infarction. In addition to substantiating HRQOL as a predictor of future mortality, this study established HRQOL as a predictor of CVD specific mortality as well.

Treatment

There are a variety of treatment options for persons with CVD, many of which depend on disease severity. Pharmacological, surgical, and exercise treatments have all been shown to decrease morbidity and mortality among CVD patients[68]. In terms of the management of most patients, it is common to prescribe a combination of exercise, surgery and/or pharmacological intervention. For most people with CVD, cardiovascular exercise is appropriate, and has been shown to be highly effective in reducing not only cardiovascular mortality and morbidity, but also all cause mortality and morbidity[69].

Cardiovascular Rehabilitation

Although CVD remains the number one cause of death in Canada, effective primary and secondary prevention approaches have reduced the prevalence of CVD related deaths[3]. Specifically, participation in regular exercise has been shown to be a very safe

and effective therapy for treating those with CVD[70]. An important long-term adaptation to exercise is a decreased myocardial oxygen demand during submaximal exercise[71]. Regular exercise training will help to increase parasympathetic and decrease sympathetic nervous stimulation, which will decrease submaximal heart rate (HR)[72]. Persistent exercise training will also attenuate endothelial dysfunction, increase capillary blood flow, and decrease blood viscosity, which will also decrease submaximal BP[73]. The attenuated increase in submaximal exercise HR and BP with training will directly decrease myocardial oxygen demand. Because of the enhanced efficiency of myocardial oxygen consumption, symptoms of angina, dyspnea, and edema are likely to diminish[74].

Phases of Cardiovascular Rehabilitation

There are three Phases of cardiovascular rehabilitation (Figure 2), each aimed at building on the cardiovascular improvements developed during the previous Phase[75]. Phase I cardiovascular rehabilitation is a secondary prevention program that is usually initiated while the patient is still in the hospital. Phase I incorporates low level supervised exercise, as well as lifestyle education. Phase II cardiovascular rehabilitation is an outpatient exercise and education program in which participants are monitored by exercise specialists and/or telemetry systems to assess hemodynamic responses during the activity. Phase II cardiovascular rehabilitation usually lasts from 3-6 months, at which time, a patient graduates to Phase III/maintenance. Phase III/maintenance cardiovascular rehabilitation incorporates a low level of supervision, and is

characterized as lifetime maintenance of physical activity and other positive lifestyle habits obtained through previous cardiovascular rehabilitation Phases[75]. Further risk factor reduction and continuing education is emphasized in Phase III/maintenance. It is not uncommon for primary prevention patients, patients with risk factors but without known CVD, to be involved in a Phase III/maintenance program[75].

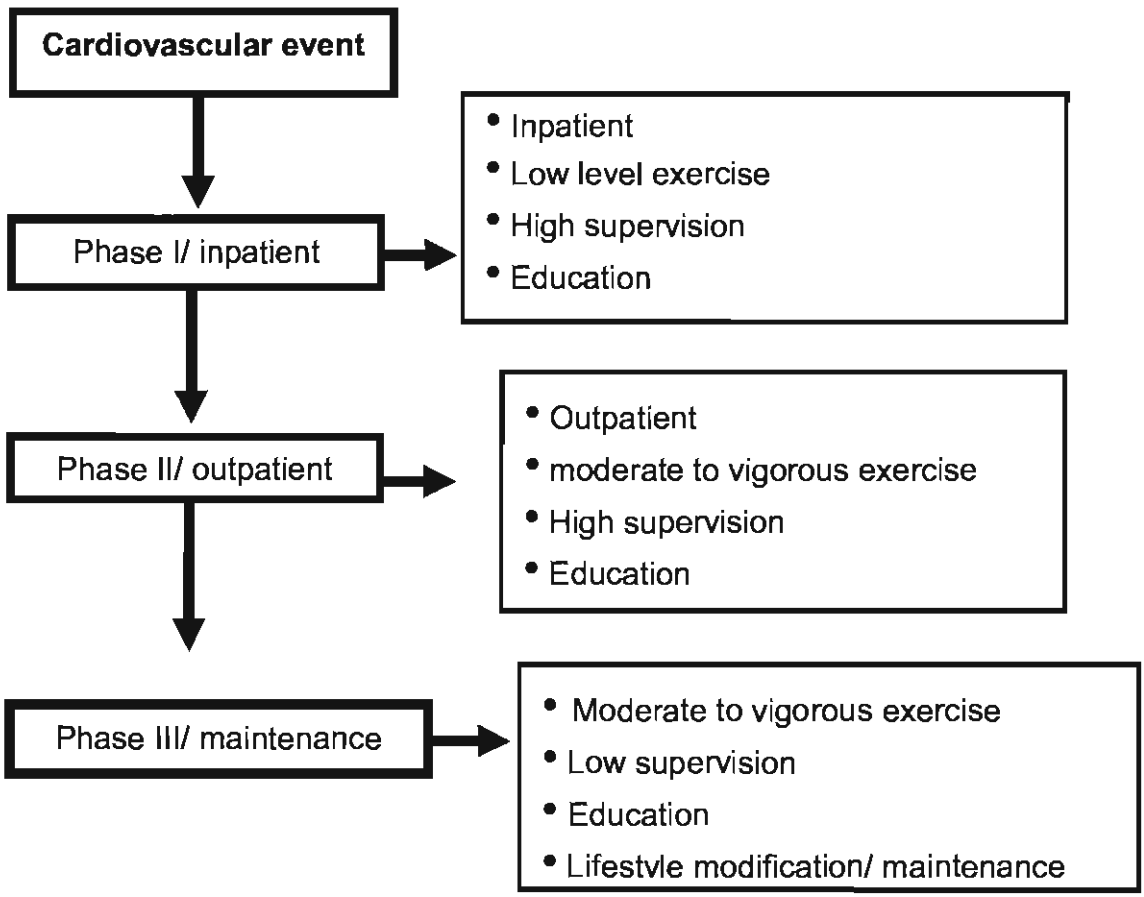


Figure 2: A Flow Table of the Phases of Cardiovascular Rehabilitation

HRQOL of a Cardiovascular Disease Patient

Although it has been demonstrated that early treatment, as seen in Phase I and II cardiovascular rehabilitation, improves the HRQOL[76] of CVD patients, there is still very limited research with respect to Phase III/maintenance cardiovascular rehabilitation. Persons with CVD share many common detriments in terms of their HRQOL. Many of their symptoms are associated with a decreased QOL either because of pain or physical limitations[77, 78]. It is also typical for patients with CVD to express symptoms of depression or anxiety, both of which play an important role in HRQOL[79].

A recent meta-analysis by Salmon (2001) on the effects of exercise on depression and anxiety found promising evidence to support the notion of exercise as a 'stress reliever'[80]. Through this investigation, Salmon found that participation in regular exercise decreased both depressive symptoms and anxiety; however, he concluded that there is limited evidence and research on exercise and clinical depression. Although there is limited research on clinical depression and exercise, the effect of exercise on depressive symptoms and anxiety is of particular interest as both have been linked to an increased risk of myocardial infarction and cerebrovascular accidents[81]. It can be further suggested that regular exercise increases HRQOL by reducing depression and anxiety, further supporting the notion of cardiovascular rehabilitation improving HRQOL[9].

Phase III/Maintenance Cardiovascular Rehabilitation and HRQL: Research

Although considerable research on Phase I and Phase II cardiovascular rehabilitation has been completed, only a limited amount of research has been

conducted on the later stages of exercise rehabilitation programs, specifically Phase III/maintenance cardiovascular rehabilitation. In fact, only one study could be found that has investigated HRQOL during Phase III/maintenance cardiovascular rehabilitation[14]. In this study, 38 elderly males (mean age 70 years) with coronary artery disease participated, with 20 making up the intervention group and 18 the control group. The intervention group participated in Phase III cardiovascular rehabilitation for six months; the control group received standard care (physician scheduled visits with no cardio-vascular rehabilitation) as outpatients. Health-Related Quality of Life, anxiety, and depression were measured using the Medical Outcome Study Short-Form 36 Health Status Survey (SF-36), State-trait Anxiety Inventory questionnaire (STAI), and Self-rating Depression Scale (SDS). Baseline and six months follow-up data were collected. At baseline, all scores except for general health of the SF-36 were the same in both groups. After six months, the intervention group's scores of bodily pain, general health, vitality and mental health of the SF-36, as well as anxiety scores, improved significantly, but depression did not improve. In the control group, none of the measurements changed significantly. These results indicate that patients with coronary artery disease should be encouraged to attend Phase III/maintenance cardiovascular rehabilitation. Although the rating of depression did not improve, this is consistent with the finding from Dickens et al., who found that depression improved during the first six months of disease treatment, but not thereafter. While this study is informative, it does have some limitations, including a small heterogeneous sample size, consisting of only elderly males

(mean age 70 years). Notwithstanding these limitations, the results demonstrate that six months of Phase III enrolment contributed to improving HRQOL. However, this study was carried out in Japan, highlighting the fact that cultural differences may also exist compared to Canada. Thus, it is important to investigate if Phase III/maintenance cardiovascular rehabilitation translates into similar improvements in HRQOL among participants in Phase III/maintenance programs in Canada.

Choosing a HRQOL Measurement Tool

If one were to search for a HRQOL measurement tool through any search engine, the results would be overwhelming. A recent review found that there was 144 to 650 HRQOL measures used or developed between 1990 and 1999[82]. Some of these are general measures and some focus on specific clinical populations. As such, it is important to recognize that there is no single instrument that is ideal for every situation or population; this makes the choice of HRQOL very difficult [45].

Before choosing a measurement, it is important to identify the characteristics of the group being measured. The group that was measured in the present study was diverse, containing both primary (patients at risk for CVD) and secondary prevention patients (patients with known CVD). Because it was desired to evaluate not one specific diseased group, a generic HRQOL instrument would more likely be useful. Moreover, a well constructed generic HRQOL instrument has many advantages over a disease-specific measure, including: applicability across various populations, the provision of benchmark measures, comparisons between cross-disease and cross-intervention

groups, provision of a valid indicator of overall health status, and its sensitivity to comorbid conditions[45]. Because of the diverse nature of the population engaged in this study at the BUHI, a generic HRQOL tool was utilized.

SF-12: A Measure of HRQOL

One of the most established and widely used measurement tools of general health is the Medical Outcomes Study 36-Item Short-Form Health Survey[45,83]. Since this survey is relatively long, a shorter version of the SF-36, known as the SF-12, has gained in popularity and is becoming the instrument of choice. The SF-12 measures the same two specific dimensions of health as the SF-36, perceived physical health and perceived mental health, both of which are important aspects of HRQOL. Each dimension is comprised of four categories. Physical health is comprised of physical functioning (the perceived effect on physical activities), role-physical (problems with work or other daily activities as a result of physical health), bodily pain (very severe and extremely limiting pain), and general health (an evaluation of personal health). The dimension of mental health is comprised of vitality (feeling tired and worn out all of the time), social functioning (extreme and frequent interference with normal social activities), role-emotion (problems with work or other daily activities as a result of emotional problems), and mental health (feelings of nervousness and depression all of the time). The SF-12 is a self-administered questionnaire and has been demonstrated to be as effective as the SF-36 in measuring the same outcomes[40,84]. Work by Jenkins et al. (1997) confirms the SF-12's ability to reproduce the results of the SF-36[84]. Jenkins et al.

measured the HRQOL of various diseased populations using the SF-36 and the SF-12 and found the results to be very similar, both indicative of assessing the level of health/ill-health and degree of change overtime. Jenkins' concluded that because the SF-12 has the same ability to measure HRQOL as the SF-36, it may be the instrument of choice[84]. The SF-12 also possesses high test-retest reliability in a cardiovascular setting[84,87]. From the evidence presented, it becomes clear that implementation of the SF-12 questionnaire in the present study is very appropriate as many authors have reported its use when evaluating changes in HRQOL, specifically in a cardiovascular rehabilitation setting[86, 88-92].

However, some limitations of the SF-36 have been reported in recent literature, specifically on the sensitivity of using the tool in cardiac disease patients[93,94]. Smith et al. (2000)[93]compared four QOL instruments on a group of cardiac patients and found that the SF-36 demonstrated the most sensitivity to change among the four surveys tested. However, they concluded that none of the tools were sensitive enough at evaluating changes in QOL, and that more sensitive QOL surveys need to be developed. Although the sensitivity of the SF-36 to evaluate changes in cardiac patients has been question, it seems to be the best option until more cardiac disease sensitive and specific measurement tools are developed.

Purpose

The purpose of the present study was to investigate the relationship between HRQOL and the effects of a Phase III/maintenance cardiovascular rehabilitation program

while accounting for psychological distress, age, sex, and if the patient was enrolled for primary or secondary prevention. Using the SF-12, baseline differences in HRQOL were examined between dropouts and those patients who adhered to the phase III cardiovascular rehabilitation program for six months. In addition, the effectiveness of the treatment/program was determined following six months of participation.

Hypotheses

Since a more positive HRQOL has been shown to have a strong association with adherence[9] in medical treatments, it was hypothesized that compared to those who dropped out of the program, the group who adhered to the program would have a higher rating of HRQOL (as measured by the SF-12). Moreover, since HRQOL has been shown previously to exhibit improvement in early intervention strategies[15], it was hypothesized that with continued adherence to a Phase III/maintenance cardiovascular rehabilitation program, HRQOL, as measured by the SF-12, would increase.

CHAPTER 3 – METHODS

Participants

Data for this prospective study was collected from the participants of the Brock University Heart Institute (BUHI) Phase III/maintenance rehabilitation program (n=59). The BUHI has been in operation since January 2008, and has been collecting baseline and six month follow-up data from members as they join. It was required that all participants submit a physician referral consenting to a graded exercise tolerance test (GXT) and to participate in regular exercise within the Brock Phase III/maintenance program (see Appendix A-1). Prior to commencing the exercise program, it was required that all members complete a GXT, the BUHI consent, and a questionnaire battery (see Appendix A-2), which are administered again at six months. The BUHI questionnaire battery is a comprehensive survey, collecting information on demographics, medical conditions, physiological measures, body satisfaction, depression, fat intake, leisure time exercise, psychological distress, multi-dimensional body-self relations, HRQOL, smoking and alcohol consumption, stress, mastery, self-esteem, and social support. Potential members of the BUHI become aware of the Institute through communication with their physicians or advertisements displayed throughout the community. Participants are primarily located in the Niagara Region due to the location of the Institute; however, the BUHI is open to all individuals with CVD or those at risk.

Procedures and Measurements

Figure 3 summarizes the BUHI data collection battery. Data collection Includes the results of the GXT and data from the various BUHI questionnaires collected at intake (baseline) and at six months follow-up. The total assessment time required was approximately two hours and fifteen minutes per person. Factors significant to this study are described in detail below.

Physician Referral

The BUHI program requires physician referral prior to commencing the program. The referral form is generic, ensuring that the referring physician's is in agreement that the patient can perform both a GXT and safely participate in regular exercise. The referral form also discloses the patients' past medical history, including any CVD risk factors (Appendix A-1).

Graded exercise tolerance test

A Bruce protocol GXT was administered by an exercise technician and interpreted by a cardiologist. The American College of Cardiology and the American Heart Association are both advocates of the Bruce protocol in patients with cardio-vascular disease[2]. The GXT serves three purposes for the BUHI and the patient. First and most importantly, the GXT is used to screen for any underlying CVD. If there is an abnormality discovered that is not documented on the referral form, the referring physician is notified for a decision if the program is still suitable for the patient. Second,

the test is used to determine a target exercise HR, using the Karvonen formula [HRR = (HR_{max} – HR_{rest})*desired % intensity + HR_{rest}]. Finally, the GXT is used as a baseline measurement of exercise capacity in order to compare the progress of a patient over a six month period.

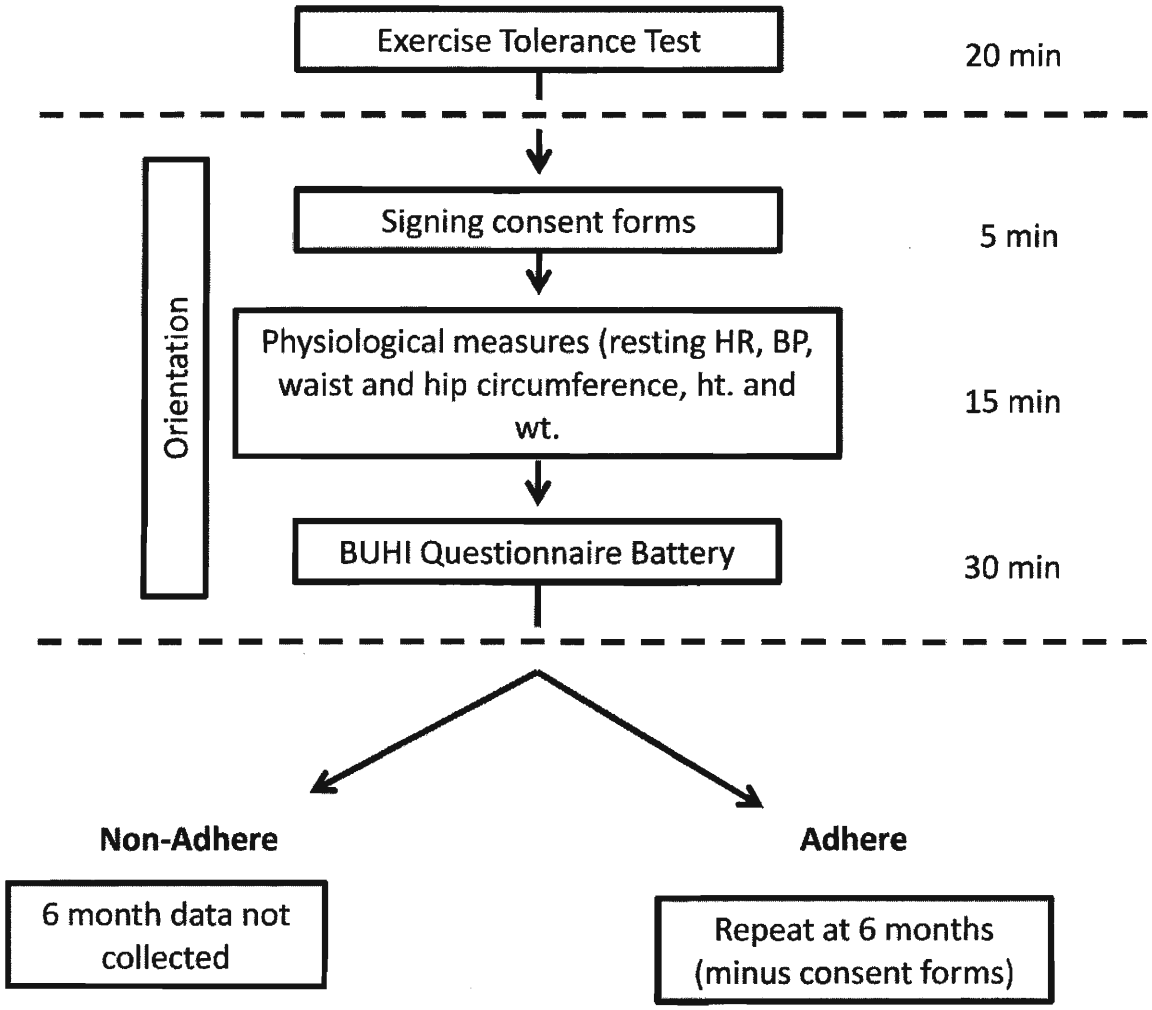


Figure 3: Summary of Data Collection Process from the BUHI: Heart Rate (HR), Blood Pressure (BP), Height (ht), Weight (wt). Refer to Figure 4 for discrepancy of adhere versus non-adhere group.

Intake

The intake is best described as an orientation for new patients and was scheduled as soon as the patient completed the GXT. The orientation consisted of three segments. First, the participant was required to sign consent forms for participating in regular exercise and for the use of the BUHI questionnaire battery as a research tool (approved by Brock University Research Ethics Board, see Appendix A-3). Once the consent forms were completed, the patient filled out the BUHI questionnaire battery, and various physiological and anthropometric measures were obtained, including resting HR, resting BP, height, weight, and waist and hip circumference. Resting HR and BP were taken using an Omron HEM-705CPCAN automatic BP monitor following the recommendations for accurate measurements set forth by the American Heart Assocation[95]. Weight was measured with a Heath-o-meter Professional Scale, without shoes and in exercise attire to the nearest half pound. Height was measured to the closest 10th of a centimeter using a SECA Stadiometer with shoes removed. Waist circumference was measured were taken from the narrowest point on the torso, and measurement of hip circumferance was taken from the widest part of the hips to the nearest 10th of a centimeter[59].

The SF-12 HRQOL questionnaire, a component of the BUHI questionnaire battery, was self-administered. Considered worldwide to be the most valid tool for measuring generic HRQOL, the SF-12 also possesses high test-retest reliability (α= 0.72–0.94)[14, 85]. The SF-12 has been used in many cardiac rehabilitation settings[14, 88-90], has

demonstrated appropriateness for measuring general HRQOL in cardiovascular rehabilitation settings[14, 85], and therefore, is a good fit for the BUHI population. Norm-based scores (Mean = 50, SD = 10) are utilized by the SF-12. Norm-based scoring is especially beneficial to the tester as the general population norm is built into the scoring algorithm, eliminating the need to memorize population norm scores. Furthermore, it is easy to identify how above or below a person is in relation to the population because of the equalized standard deviations of ten[96]. As well, measurements of psychological distress were obtained by the K-6 (Kessler -6) questionnaire that has been utilized by the Canadian National Health Survey[97]. Based on previous research from Seki et al. (2003) and Dickens et al. (2006), psychological distress was measured instead of depression and anxiety[14, 38]. Both Dickens et al. and Seki et al. found that depression scores improved up to six months post cardiovascular event or procedure, but did not change thereafter. Since the program being analyzed is implemented after the patient has experienced both Phase I and II programs, depression was removed from the analysis.

After the BUHI questionnaire battery was completed, the patient was introduced to the exercise program. Exercise was prescribed using a target HR range that was determined by using the Karvonen formula (see above). All exercise prescriptions were based on guidelines established by the American College of Sports Medicine [59].

Exercise Protocol

Participants were required to exercise at the BUHI two to three times a week, and were encouraged to exercise at home most other days. The participants completed,

on average, 45 minutes of cardiovascular endurance training each visit, and were introduced to four different modes of endurance exercise, including the treadmill, recumbent leg cycle ergometer, upright leg cycle ergometer, and arm cycle ergometer. Patients were educated and encouraged about the benefits of regular exercise. Information and education about maintaining exercise target HR, HR palpation, and safe exercise were given to the patients. Two to four weeks after regular endurance exercise commenced, the members were educated about the benefits and proper techniques of resistance training and were introduced to the equipment. Again, all techniques and precautions are based on the guidelines established by the American College of Sports Medicine [59]. All exercise information was recorded by the patients into individual log books. During every session, the patients recorded their cardiovascular training mode, duration, intensity, rating of perceived exertion, and exercise HR, along with their repetitions, sets, and weight used for each resistance training exercise. Lastly, they also recorded their resting HR and BP pre- and post-workout.

Participants were considered to "adhere" to the program if they were still an active member at 6-months follow-up. Attendance and compliance to the program did not affect the classification of an individual's adherence. This method allowed for the present study to have more 'real world' applicability because the nature of the rehabilitation programs was not an artificial experimental situation, and adds external validity to the results obtained.

6 month follow-up

The most uncomplicated and sometimes valid explanation to why six months is used as a cutoff, is that a lot of studies use it. A simple search using "six month" as the criterion in any scientific search engine yields thousands of studies from all disciplines using this cutoff. However, this time point can be found to be anything but arbitrary, and perhaps the most pertinent evidence based reason for choosing six months in the present study concerns the time course of the physiological response to exercise. Denis et al. (1982)[97] measured improvements in aerobic capacity among apparently healthy individuals every ten weeks over a forty week period, and observed a threshold for improvement after 20 weeks (roughly six months) of training in which improvements in aerobic threshold began to plateau. Since the cardiovascular rehabilitation program at the BUHI is primarily aerobic exercise oriented, we can utilize Denis' results to implement a six-month cutoff.

When six months of participation in the BUHI rehabilitation program elapsed, the BUHI questionnaire battery was re-administered and a follow-up stress test was performed. The BUHI questionnaire battery remained unchanged from that administered at baseline. The physiological measures: resting BP and HR, waist and hip circumference, and height and weight were re-assessed using the same protocols and by the same examiner. Both the baseline and follow-up GXT were carried out and observed by the same exercise technician and cardiologist. Since the beginning of the program in 2008, the BUHI has had a total of 87 members. As of March 2010, of these

87, 32 dropped out, 27 exceeded 6 months, and 28 have been members for less than six months and were not included in the study. The total population analyzed for the present study was 59, in which 32 did not adhere to the program and 27 did adhere to the program, refer to figure 4 below.

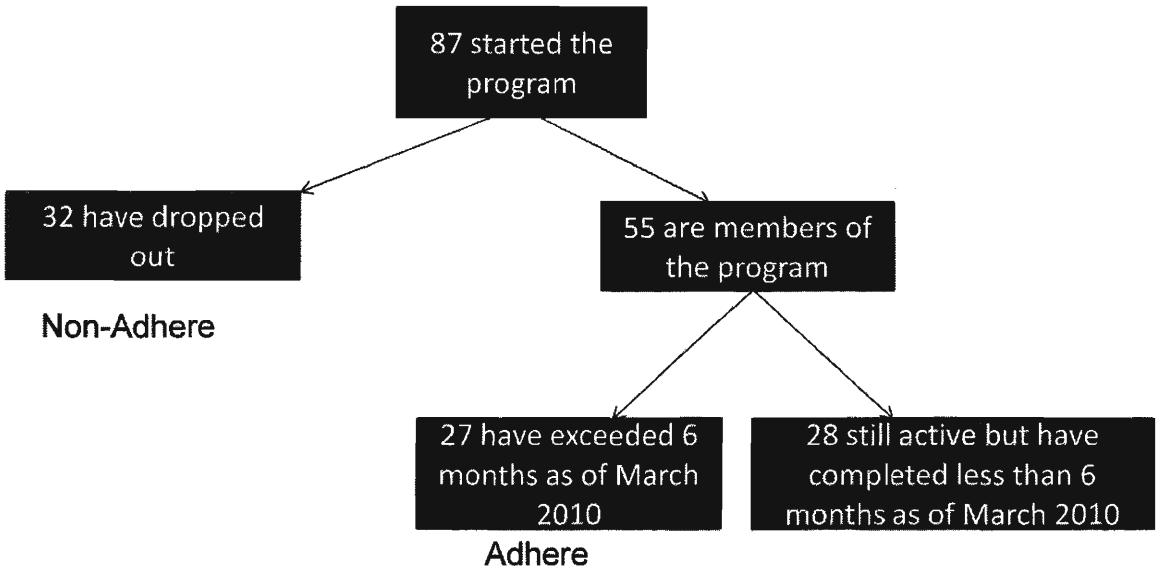


Figure 4. Selection Process for the Adhere and Non-adhere Groups

Statistical Analysis

Dichotomous and continuous sample characteristics were analyzed appropriately by Chi Squared and t-test methods respectively. Both the Chi squared and t-test were used to analyze any statistically significant discrepancies between the groups to be measured with respects to age, sex, if the patient was enrolled for primary or secondary prevention, psychological distress, and scores of physical and mental health as measured by the SF-12.

Logistic regression, accounting for the effects of psychological distress, age, sex, and if the patient was enrolled for primary or secondary prevention, was used to compare baseline HRQOL among those who dropped out compared to the HRQOL of those patients who adhered to cardiovascular rehabilitation program for six months. Table 1 (below), provides the order of the logistic regression analyses that were preformed in this study. Model 1 was used to regress adherence on the physical component (PC) SF-12/mental component (MC) SF-12. In models two to five, PC SF-12/MC SF-12 and each of the independent variables were regressed on adherence. This was done to examine whether the effects were explained by other factors, and to identify if the effects were conditional based on the level of other factors. It is important to note that each covariate was examined separately and not simultaneously because of sample size limitations.

A generalized linear model, with psychological distress, age, sex, and if the patient was enrolled for primary or secondary prevention as covariates, was used to determine whether six months of a Phase III/maintenance cardiac rehabilitation program improved overall HRQL. The numbers are reported in odds ratios and confidence intervals; the significance was set at $p<0.05$. Table 2 (below), provides the models of the generalized linear model analyses preformed in this study. Model 1 was used to examine PC SF-12/MC SF-12 changes over six months (time point). In models two through nine, each of the independent variables were adjusted for, and any

interactions were investigated. The numbers are reported as beta values and standard deviations; the significance was set at $p<0.05$.

Table 1
Logistic Regression Analysis of Adherence

Model 1	**Model 2**	**Model 3**	**Model 4**	**Model 5**
PC SF-12 or MC SF-12	PC SF-12 or MC SF-12	PC SF-12 or MC SF-12	PC SF-12 or MC SF-12	PC SF-12 or MC SF-12
	Sex			
		Prevention		
			Age	
				K6

PC SF-12 = Physical Component of the SF-12, MC SF-12 = Mental Component of the SF-12

Table 2
Generalized Linear Model for Changes in HRQOL

Model 1	Model 2	Model 3	Model 4	Model 5	Model6	Model 7	Model 8	Model 9
Time Point	Time Point	Time Point	Time Point	Time Point	Time Point	Time Point	Time Point	Time Point
	Sex	Sex						
		Sex * Time Point						
			Age	Age				
				Age * Time Point				
					Prevention	Prevention		
						Prevention * Time Point		
							K6	K6
								K6 * Prevention

K6 = Psychological Distress, Time Point= Baseline to six month follow up HRQOL scores

CHAPTER 4 – RESULTS

Introduction

Chapter 4 summarizes the results of the study. This chapter is comprised of two sections, the first section entitled Adherence contains the results pertinent to the first hypothesis that those who have a higher rating of HRQOL will adhere to a Phase III/maintenance cardiovascular rehabilitation program, while the second section entitled Changes with Cardiac Rehabilitation contains the results pertinent to the second hypothesis that HRQOL will improve after six months of adherence to a Phase III/ maintenance cardiovascular rehabilitation program.

Adherence

A comparison of the sample characteristics of those who adhered versus those who did not adhere can be found in Tables 3, 4, and 5. Table 3 compares the population characteristics of those who adhered (n=27) versus those who did not adhere (n=32) to the program. Table 3 also contains the appropriate Chi-square analyses for sex and primary versus secondary prevention and the appropriate t-tests for the variables of age, K-6, PC SF-12, and MC SF-12. The Chi-square analysis showed no significant results; however, the t-test analyses demonstrated a significant effect for PC SF-12 on adherence, where those who adhered to the program had a higher SF-12 score compared to those that did not adhere.

Table 3
Pre-training Scores of Those who Adhered and Those who did not to the Phase III Cardiovascular Rehabilitation/Maintenance Program

	Adhere	**Non-Adhere**	
N (%)	27 (45.8%)	32 (54.2%)	
Age (mean, sd)	63.3 (9.5)	64.5 (11.7)	t=0.42 (p=0.68)
Sex (males) (%)	70.0%	50.0%	χ^2=2.518 (0.183)
Secondary Prevention (%)	70.0%	53.1%	χ^2= 1.83 (0.19)
K6 (mean, sd)	9.2 (2.8)	9.2 (3.3)	t=0.09 (p=0.93)
PC SF-12 (mean, sd)	47.6 (8.4)	**41.8 (11.2)***	t=-2.20 (p=0.032)
MC SF-12 (mean, sd)	44.0 (5.9)	46.8 (6.5)	t=1.75 (p=0.086)

* p<0.05 (Two-tailed), t= t-test, χ^2=Chi squared, K6 = Psychological Distress, PC SF-12 = Physical Component of the SF-12, MC SF-12 = Mental Component of the SF-12

The same regression models were used for both PC SF-12 and MC SF-12 on adherence (refer to Table 1 in the Methods section). Tables 4 and 5 provide the results for the logistic regression models displayed in Table 3. Table 4 provides the odds ratio of adhering to the program based on the score of the PC SF-12. Table 5 provides the odds ratio of adhering to the program based on the score of the MC SF-12. The odds ratios for each of the dichotomous variables were obtained by comparison to the reference group indicated in the Table. The odds ratios for the continuous variables are indicative of the likelihood of adherence for every one-unit increase in the independent variable of interest.

Table 4 offers evidence that the PC SF-12 scores predict whether or not someone will adhere to the program independent of all covariates measured. In other words, for every one point improvement in the PC SF-12 score, there is an associated 1.06 times greater likelihood that an individual will adhere to the program. As for Table 5, MC SF-12 scores did not predict adherence.

Table 4
Logistic Regression of the Likelihood of Adherence by PC SF-12 Score and Covariates (N=59)

	Model 1 O.R. (95%CI)	**Model 2 O.R. (95%CI)**	**Model 3 O.R. (95%CI)**	**Model 4 O.R. (95%CI)**	**Model 5 O.R. (95%CI)**
PC SF-12	**1.1* (1.0, 1.1)**	**1.1* (1.0, 1.1)**	**1.1* (1.0, 1.1)**	**1.1* (1.0, 1.1)**	**1.0* (1.0, 1.1)**
Sex (males)		1.0 (0.9, 1.1)			
Prevention (Primary)			1.1 (1.0, 1.1)		
Age				1.1 (0.7, 1.6)	
K6					1.1 (0.9, 1.2)

* $p<0.05$ (two-tailed), PC SF-12 = Physical Component of the SF-12, K6 = Psychological Distress

Table 5
Logistic Regression of the Likelihood of Adherence by MC SF-12 Score and Covariates (N=59)

	Model 1 O.R. (95%CI)	**Model 2 O.R. (95%CI)**	**Model 3 O.R. (95%CI)**	**Model 4 O.R. (95%CI)**	**Model 5 O.R. (95%CI)**
MC SF-12	0.9 (0.9, 1.01)	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	0.9 (0.9, 1.0)
Sex (males)		1.0 (0.9, 1.1)			
Prevention (Primary)			0.9 (0.9, 1.1)		
Age				0.6 (0.3, 1.1)	
K6					0.9 (0.7, 1.2)

* p<0.05(two-tailed), MC SF-12 = Mental Component of the SF-12, K6 = Psychological Distress

Changes with Cardiac Rehabilitation

An examination of the change in the characteristics of those who adhered after six months (time point two) of cardiac rehabilitation is presented in Table 6; however characteristics of age, sex, and type of prevention were not included at time point two (post program) due to redundancy. The results of the generalized linear regression exploring the effect of six months adherence to the program on changes in PC and MC of the SF-12 are presented separately in Tables 7 and 8. The effects of sex, primary vs. secondary prevention, age, and psychological distress (measured by the K-6) have been adjusted for, and any interactions of these factors with time are also presented.

The results from this analysis are presented in Tables 6, 7, and 8. Table 6 compares the characteristics at baseline (n=27) of all those who adhere to the results obtained at six months follow-up (n=26). One subject was lost because of missing SF-12 follow-up data. Table 6 also contains the appropriate t-tests results to assess change over time on the variables K-6, PC SF-12, and MC SF-12. Table 6 shows that only PC SF-12 differed significantly between the intake period and following six months of rehabilitation.

As for PCSF-12, the regression analysis shown in Table 7 offers evidence that the PC SF-12 scores improved independently of all other variables, with the exception of psychological distress. That is, the changes in physical HRQOL occurred independently of sex, prevention, and age. It can further be deduced that at time point two, PC SF-12 scores improved 3.18 points on average from baseline. As well, an interaction between time and psychological distress scores was observed. This interaction is demonstrated in

Figure 6, where it can be seen that those with higher levels of psychological distress at baseline were more likely to have lower baseline ratings of perceived physical HRQOL. However, after six months of adherence to the exercise program, those with higher initial psychological distress had physical HRQOL scores equivalent to the other participants.

The MC SF-12 regression results are displayed in Table 8. The results show that the MC SF-12 scores at time point two do not differ significantly from baseline scores. However, there was a suppressor effect evident in Models 2 and 3 when adjusting for sex. That is, when sex was controlled for statistically, there was a significant loss in perceived mental HRQOL over time from baseline to six month follow-up.

Table 6
Characteristics of Those who Adhere to the Phase III Cardiovascular Rehabilitation/Maintenance Program at Baseline and Six Month Follow-Up

	Time Point1	Time Point2	
N	26[1]	26[1]	
Age (mean, sd)	62.3 (9.4)		
Sex (males) (%)	66.6%		
Secondary Prevention (%)	66.6%		
K6 (mean, sd)	9.2 (2.3)	9.3 (3.4)	t=0.32 (p=0.76)
PC SF-12 (mean, sd)	47.6 (8.4)	50.8 (7.7)*	t=2.08 (p=0.048)
MC SF-12 (mean, sd)	44.0 (5.9)	42.0 (7.4)	t=-1.79 (p=0.09)

* $p<0.05$ (Two Tailed), t= t-test, χ^2=Chi squared, PC SF-12 = Physical Component of the SF-12, MC SF-12 = Mental Component of the SF-12, K6 = Psychological Distress, Time Point1 = Baseline, Time Point2 = Six month follow-up

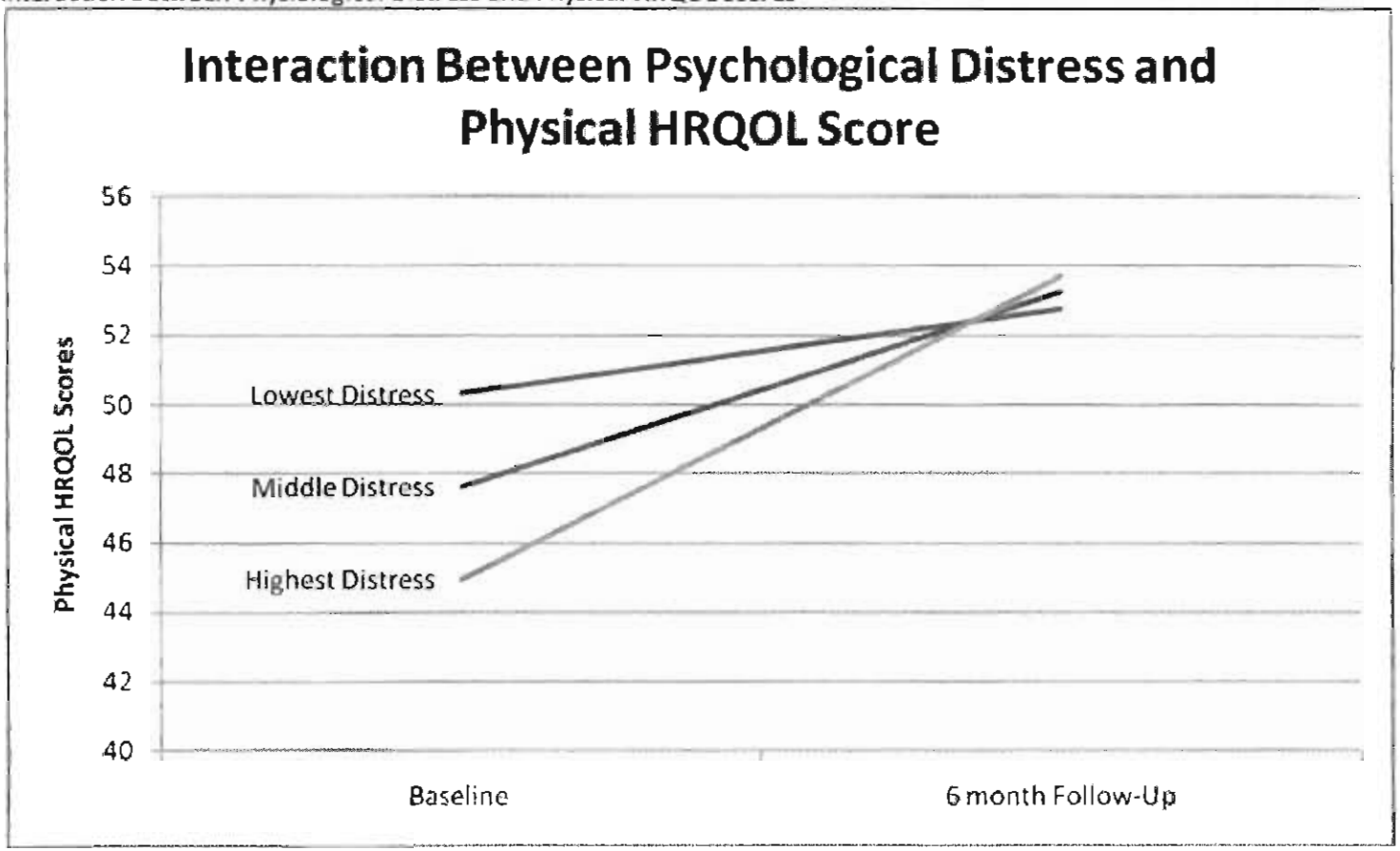
[1] Subject was missing SF-12 (HRQOL) data at Time Point 2 and was eliminated from the analysis

Table 7
Generalized Linear Model Time Point by Improvement of PC SF-12 Score and Covariates (N=26)

	Model 1 β (SD)	Model 2 β (SD)	Model 3 β (SD)	Model 4 β (SD)	Model 5 β (SD)	Model 6 β (SD)	Model 7 β (SD)	Model 8 β (SD)	Model 9 β (SD)
Time Point2	**3.1* (6.4)**	**3.3* (6.4)**	**3.7* (6.8)**	**3.0* (6.4)**	**6.0 (14.5)**	**3.1* (6.4)**	**3.2* (6.5)**	**3.0* (6.4)**	-6.4 (6.3)
Sex (males)		**6.0* (7.8)**	5.3 (7.7)						
Sex * Time Point2 (males)			1.3 (7.7)						
Age				0.2 (5.2)	0.2 (5.2)				
Age * Time Point2					0.1 (5.1)				
Prevention (Primary)						2.1 (8.5)	2.0 (9.0)		
Prevention * Time Point2 (Primary)							0.3 (8.2)		
K6								**0.5* (5.5)**	0.1 (5.4)
K6 * Time Point2									**1.0* (5.4)**

* p<0.05 (two-tailed) K6 = Psychological Distress, Time Point2= Six month follow-up Physical Component of SF-12(PC SF-12)

Figure 5
Interaction Between Physiological Distress and Physical HRQOL Scores



Lowest Distress = +1 SD from the mean Psychological Distress score, Middle Distress = mean Psychological Distress score, Highest Distress = -1 SD from the mean Psychological Distress score
Psychological Distress and Physical Health-Related Quality of Life (HRQOL) were measured by the K6 and the physical component of the SF-12, respectively

Table 8
Generalized Linear Model Time Point by Improvement of MC SF-12 Score and Covariates (N=26)

	Model 1 β (SD)	**Model 2 β (SD)**	**Model 3 β (SD)**	**Model 4 β (SD)**	**Model 5 β (SD)**	**Model 6 β (SD)**	**Model 7 β (SD)**	**Model 8 β (SD)**	**Model 9 β (SD)**
Time Point2	-2.0 (5.0)	**-2.0* (5.0)**	**-2.8* (6.4)**	-1.9 (6.0)	6.6 (13.6)	-1.9 (6.0)	-2.4 (6.3)	-1.9 (6.1)	0.3 (8.9)
Sex (males)		3.0 (7.4)	1.5 (8.1)						
Sex * Time Point2 (males)			2.8 (7.6)						
Age				0.1 (5.1)	0.1 (5.1)				
Age * Time Point2					-0.1 (5.1)				
Prevention (Primary)						3.0 (8.0)	2.2 (8.5)		
Prevention * Time Point2 (Primary)							1.7 (6.9)		
K6								0.7 (5.3)	**0.8* (5.3)**
K6 * Time Point2									0.2 (5.4)

* p<0.05 (two-tailed), K6 = Psychological Distress, Time Point2= Six month follow-up Mental Component of SF-12 (MC SF-12)

In summary, individuals who had higher PC SF-12 HRQOL scores at baseline were more likely to adhere to the program than those with lower scores. This significant effect remained after adjusting for sex, age, psychological distress, and primary versus secondary prevention. Furthermore, this study demonstrated that PC SF-12 HRQOL improved over time among those who adhered to the program. In fact, those with greater distress levels at baseline appeared to derive the greatest benefit, of perceived physical health, from six months of Phase III cardiovascular rehabilitation/maintenance.

CHAPTER 5 – DISCUSSION

The following chapter will discuss the results within the framework of the research objectives. Firstly, a review of the research objectives, hypotheses, and theory guiding this study will be presented. Second, all results from the descriptive and logistic regressions between those who did and those who did not adhere will be discussed. Third, the longitudinal results from the descriptive and generalized linear models following those who adhered to six months of cardiac rehabilitation will be discussed. Fourth, the limitations of the current study are identified and discussed in relation to the findings. Finally, the implications of this study as well as future research directions are discussed.

Review of Research Objectives

While considerable research on Phase I and Phase II cardiovascular rehabilitation has been completed to date, limited research has been carried out on the later stages of these rehabilitation programs, specifically Phase III/maintenance cardiovascular rehabilitation. In fact, only one study was found that has investigated HRQOL during Phase III/maintenance cardiovascular rehabilitation[14]. This study was a randomized control trial that found six months of rehabilitation significantly improved psychological distress and HRQOL scores, with no change in the ratings of depression from baseline in the intervention group. In contrast, none of the measurements significantly changed in the control group. However, limitations of this study included a small, heterogeneous

sample (18 controls and 20 cases), consisting of only elderly Japanese males; many cultural differences from that of Canada bring into question the external validity of the study. These limitations notwithstanding, the results of the Seki et al. study demonstrate that six months of Phase III enrolment contributed to improving HRQOL among participants. Therefore, it was important to investigate whether a Canadian Phase III cardiovascular rehabilitation/maintenance program would offer the same benefits to an individual's HRQOL when enrolled for six months.

HRQOL in cardiovascular rehabilitation is an important marker for health and adherence to medical regimens and treatments, as this has been consistently shown in previous work. For example, Koertge et al. (2009)[9] recently identified the predictive effects of HRQOL on adherence to a multi-component lifestyle program (Phase II cardiovascular rehabilitation) focusing on diet, exercise, stress management, and social support over a one year period. They found that those with a lower initial health status were more likely to drop out from the program compared to those with more favourable scores. Of the members who continued in the program, there were significant improvements to both the physical and mental health aspects of the patients' HRQOL. Additional research measuring adherence to medical treatments and HRQOL includes, but is not limited to, physical activity[35], diabetes[36], and HIV[37].

The literature explored in the development of the present study has clearly shown that a more positive HRQOL has a strong association with adherence[9] in medical treatments, which provided the basis for the first hypothesis that, when compared to

those who dropped out of a Phase III cardiovascular rehabilitation/maintenance program, those who adhered would have a higher rating of HRQOL (as measured by the SF-12). Moreover, due to the fact that HRQOL has been shown to improve in early intervention strategies[15], it was hypothesized that with continued adherence to these programs through Phase III/maintenance cardiovascular rehabilitation, HRQOL will further improve as measured by the SF-12 (hypothesis 2).

Patients who Adhered versus Non-Adhered

In the population characteristics, the only discrepancy between the adhered and the non-adhered groups was in their PC SF-12 HRQOL scores. This finding is different from the first hypothesis of this thesis, as well as previous research findings that found adherence to be predicted by both dimensions (PC and MC) of the HRQOL. For example, Hanestad et al. (1991)[36] and Bernstein et al. (2002)[34] found that both the physical and mental dimensions of HRQOL predicted future program adherence. Specifically, Hanestad and colleagues found that those with higher levels of HRQOL perceived adherence to a diabetic regimen to be less difficult than those who had lower levels of HRQOL. Similarly, Bernstein et al. explored the relationship between HRQOL scores and adherence to hepatitis C treatment[34]. Bernstein et al. discovered that both dimensions of HRQOL were predictors of adherence to treatment. Although the findings of this thesis do not agree with the reports of Hanestad et al. and Bernstein et al., it is important to note that these studies examined the adherence and HRQOL relationship

in populations outside of Canada, and in programs other than Phase III cardiovascular rehabilitation/maintenance.

It is essential to discuss why the physical dimension of HRQOL differed significantly between the two groups in this thesis. In exploring the questions included in the HRQOL questionnaire, we find that they reflect the patient's perceived limitations when performing physical tasks, and therefore higher scores indicate a greater perceived ability. A patient who scores higher in the physical dimension of HRQOL is likely to have greater confidence in his or her ability to be involved in physical activity, abilities, which in turn may help facilitate continued participation in the program. Conversely, those individuals who score lower on the physical dimension of HRQOL are likely to perceive their physical functioning as a limitation to perform physical activity, and thus, are less able to continue to participate. Several popular theories pertaining to exercise behaviour (such as the Theory of Planned Behaviour or Self-Efficacy Theory) help to support this reasoning. Stemming from the Theory of Planned Behaviour (TPB), it can be proposed that those individuals who feel that they are good at physical activity, or have high self efficacy, are more likely to participate in physical activity than those with lower competence[99]. It can be further postulated that the reason why there was only a difference in the physical HRQOL sores of those who adhered versus those who did not adhere, was because the program was primarily exercise oriented, addressing only the physical health of the patient. It may be proposed that if the Phase III cardiovascular rehabilitation/maintenance program targeted mental health as well, then

those with higher mental HRQOL scores may be more likely to adhere. When looking at the work by Koertge et al. (2009)[9], this becomes more clear. Koertge et al. examined a comprehensive Phase II cardiovascular rehabilitation program that included mental health care in addition to an exercise program. They found that both the physical and mental dimensions of HRQOL predicted adherence separately. From the research of Koertge et al., it can be speculated that with the addition of a mental health component, mental HRQOL may surface as a predictor of future program adherence. This theory would need to be addressed in future research.

Another point of interest to examine is the possibility that the individuals who enrolled in the program for primary prevention influenced the predictive power of physical HRQOL on adherence compared to those who enrolled for secondary prevention. Intuitively, it is logical to explore the possibility that those who joined the program for primary prevention would have influenced the results, as they are more likely to have actively sought out the program independently without diagnosed CVD. However, it is likely that the primary and secondary prevention groups contained a similar mixture of those who were referred directly by a physician or sought the program out on their own. Therefore, it is likely that the group who enrolled for primary prevention possessed the same initiative to exercise as those who enrolled for secondary prevention. In the future, it would be beneficial to examine the difference in adherence between those who actively seek out rehabilitation compared to those who are referred by their physician.

Unlike Koertge et al. (2003)[9], sex did not appeared to have a significant effect on program adherence in this study. Koertge et al. found that women scored lower than men on overall HRQOL at baseline and were found to have a higher program dropout rate. However, differences exist between the patients of the present study and those of Koertge et al. First, the study of Koertge et al. involved only secondary prevention patients, provided for less spousal involvement, and included women in the study who had higher depression scores than the males. However, it is possible that if our subject population was larger, a comparable result to that of Koertge et al. may have been discovered. Additionally, McAuley et al. (1991)[100] discovered that women who joined an exercise program were less likely to adhere than men because of lowered self efficacy, which remains consistent with the findings of Koetrge et al.[9]. Although sex appeared to have no effect on program adherence in the present study, it is probable that with a greater sample of women and overall sample size, the present study would yield results confirming that women, on average, would have a lower perceived HRQOL than men, and thus would be less likely to adhere to a cardiovascular rehabilitation program.

Finally, in comparing the results to the work done by Glazer et al. (2002)[99] on psychological predictors of adherence to cardiovascular rehabilitation, it can be explained why psychological distress did not predict program adherence in the present study. Glazer et al. reported that program dropouts were more psychologically distressed at baseline than those participants who completed the program. However, this group of researchers included participants who attended less than two thirds of the

exercise sessions as dropouts from the program. This classification of adherence does not seem realistic in real life situations, and leads to poor external validity, especially since 70% of those who were labeled as dropouts because of poor attendance had full-time occupations[99]. The program described in the present study defined non-adherence as someone who completely stopped participating in the program prior to the six month follow-up, and was not based on a fixed level of attendance. Furthermore, the current results are very applicable to the population of interest, as members of the program who did not participate regularly because of external factors (i.e., work constraints and other commitments) were still included in the analysis.

Overall, the present study demonstrated that adherence to a Phase III cardio-vascular rehabilitation/maintenance program can be predicted by physical HRQOL scores regardless of whether a patient enrolls for primary or secondary rehabilitation. In addition, the present study differs from past adherence studies in that it was found that only the physical dimension of the HRQOL predicted adherence. However, based on the literature, if mental health was also addressed in the treatment strategy, it is more likely that an association would become apparent. As well, sex did not influence program adherence, but a review of the literature suggests that a significant finding may have been found if a larger total sample, particularly of women, was included in the present study. Furthermore, the ability of the physical HRQOL to predict adherence is not conditional on psychological distress. In summary, it is recommended that HRQOL measurements be implemented in Phase III cardiovascular rehabilitation/maintenance

programs to identify those individuals at risk of dropping out. Strategies can be developed early upon identification of high risk individuals, so that resources may be allocated to aid in their adherence.

Effects of Cardiac Rehabilitation

The second research hypothesis that "HRQOL will improve after six months of adherence to a Phase III/maintenance cardiovascular rehabilitation program," was examined. The descriptive statistics showed only a significant improvement in PC SF-12 scores between the two time points. This finding is inconsistent with the findings of Seki et al. (2003)[14], who found that those enrolled in a Phase III cardiovascular rehabilitation program experienced improvements in both their physical and mental dimension of the HRQOL. The major differences between the research of Seki et al. and that of the present study was in program design, in that a team of physicians, nurses, and exercise physiologists were responsible for the rehabilitation of the patients in Japan, where as the population at the Brock University Heart Institute was supervised only by exercise physiologists. This discrepancy in care is likely to be the reason why no improvement in mental HRQOL was discovered, i.e., the patients in Japan were likely to be provided with comprehensive care that not only addressed their need for exercise, but also included a facet of the program aimed at mental health care.

Many studies have examined HRQOL improvement with intervention in populations outside of Canada and in programs other than Phase III cardiovascular rehabilitation/maintenance. These studies found similar results to Seki et al. with regard

to exercise training[14,34,35,102] in that both the physical and mental dimensions of HRQOL improve with intervention. In contrast, the only significant difference found in the present study was in the physical dimension of the HRQOL following an exercise-based intervention. However, there are several differences between the program used by previous researchers and the one used in the current study. First, in the study by Koertge and colleagues (2003)[9], the sample consisted completely of secondary prevention patients that underwent a comprehensive treatment strategy that included exercise, diet, stress management, and social support. The comprehensive program described by Koertge et al. addressed the physical and mental needs of its participants. Koertge et al. found positive changes in both the physical and mental components of HRQOL. In contrast, the BUHI program is solely exercise oriented. Therefore, it is reasonable to assume that when focusing treatment towards exercise only, it is probable that the physical dimension of HRQOL would improve alone. However, it is not enough to say that the absence of a mental health component in the BUHI program is the reason why no improvement in mental HRQOL was observed. Additionally the negative trend seen in MC SF-12 contradicts previous research findings and warrants further investigation.

In the present study, physical HRQOL scores improved independent of the other variables accounted for, except psychological distress scores. An interaction between PC SF-12 and psychological distress scores was observed, which indicated that those who had greater levels of distress at baseline were likely to have a lower initial rating of

perceived physical HRQOL. However, after six months of adherence to the exercise program, those with worse symptoms of psychological distress at baseline saw improvements in their PC SF-12 scores to levels similar to those seen in the rest of the group. In fact, more modest improvements in physical HRQOL scores were observed in those who had the lowest psychological distress scores at baseline. This finding demonstrates that those with high distress have the most to gain with respect to their physical HRQOL and should be targeted for future enrollment in exercise oriented intervention programs.

In summary, with this research, it was demonstrated that continued adherence to a Phase III cardiovascular rehabilitation/maintenance program will further improve the physical dimension of the HRQOL of those involved. More specifically to this research, it can be deduced that the rehabilitation program at Brock University is effective in improving the physical HRQOL of its members.

Limitations

One of the limitations that influences the present study is the small number of individuals that participated in this study. The effect of a small sample size is based on the statistical power to identify bonafide significant effects. As such, smaller samples are prone to type II errors, which indicate the potential for false negative results. The results from this study indicated that the physical dimension of HRQOL significantly predicted adherence, and also showed a significant improvement after six months of rehabilitation. However, with the small sample, it is possible that a type II error occurred

in terms of observing a difference in mental health scores over time. The small sample size may have influenced the ability to predict adherence. It is also important to note that MC SF-12 scores, although not significant, decreased with six months enrolment in the program. Furthermore, despite the small sample, PC SF-12 scores were significantly improved, suggesting that a very strong relationship exists. However, it must be reiterated that potential effects of MC SF-12 scores and other variables may exist.

A second limitation to this study is that six month follow-up data for those who did not adhere to the program was not collected. Past studies have shown that the greatest adaptations after a CVD event occur over the first six months[39]. A Phase III cardiovascular rehabilitation/maintenance program is implemented at least six months post event, and therefore, limited improvements without intervention would be expected to occur. However, it would have been beneficial to obtain follow-up data from those who did not adhere to eliminate this possibility.

Implications

Although many studies measuring adherence and improvements in HRQOL currently exist, this project is the first of its kind to demonstrate the benefits of a Phase III cardiovascular rehabilitation/maintenance program on HRQOL in Canada. Cardiovascular disease remains the number one cause of mortality and morbidity in Canada, emphasizing the need for primary and secondary cardiovascular prevention. This study contributes to the understanding of the need for more cardiovascular

intervention programs by demonstrating the positive effects of this type of intervention on HRQOL.

As Identified in previous work, HRQOL has been shown to be a major predictor of future morbidity and mortality. As such, any significant improvements in HRQOL, like the ones seen in this study, can be seen as potentially having an improvement on the overall quality and quantity of people's lives.

This study contributes further evidence on the predictive power of HRQOL on adherence, but more specifically, to a rehabilitation setting. It was seen that the physical component of HRQOL can be used to predict future adherence to an exercise intervention program. Based on the findings of this research, implementing a HRQOL assessment may be important as a screening tool to identify those with a lower initial HRQOL score as more likely to drop out of the program. By identifying these patients, it will allow therapists to focus on the needs of these individuals to help them adhere to the program and improve their HRQOL. The retention of those at risk for drop out will continue to help in combating CVD in Canada.

This study used a rehabilitation program that was loosely regimented. Clients were allowed to exercise up to three times a week and were encouraged to exercise at home on most other days. Additionally, members were welcome to exercise when it best fit their schedules, which resulted in inconstant exercise frequencies throughout the group; this was not monitored or accounted for in the study. However, because the

rehabilitation setting was not an artificial experimental situation these circumstances add external validity to the results as they are "real world" in nature.

Future Research Considerations

Due to the small sample size in the current study, it would be beneficial to conduct the study again with a larger group to ensure sufficient statistical power to identify any significant effects and avoid the potential of false negative results. Additionally, a larger sample size would allow for the examination of additional covariates to be included in the analyses.

A second consideration would be to conduct a follow-up with those who failed to adhere to the program. This would provide further evidence that any observed improvement in HRQOL was attributable to the rehabilitation program. Complimentary to this suggestion would be to more tightly control and monitor the weekly amount of exercise that individuals participated in to investigate any dose-response relationship. Investigating a potential dose-response relationship would assist therapists in adequately prescribing the safest and most effective amount of treatment for maximal gains.

A third and final suggestion for future research would be to include mental health care for those with lower initial mental health scores. The fact that the current study identified no significant differences in mental health scores in those that adhered could be due to the fact that the program primarily consisted of exercise.

Concluding Remarks

As CVD remains a major cause of mortality and morbidity for Canadians, it is important to continuously investigate all avenues for improvement of this condition. Many research studies exist on surgeries, medications, and early intervention strategies to help reduce CVD. However, there is limited research on the later stages of intervention and prevention specifically with regards to Phase III cardiovascular rehabilitation/maintenance program. In this context, the current study has added to the research on the later stages of cardiac rehabilitation, and the importance that HRQOL has on predicting adherence to Phase III rehabilitation.

In conclusion, the BUHI has been effective at improving the HRQOL of its members. In the future, it is suggested that the BUHI, along with other similar rehabilitation programs, make use of the HRQOL scores as a screening tool to help identify those at risk of dropping out of the program, shifting more attention to keeping those at risk in the program.

References

1. Cardiovascular Disease [Internet]: Public Health Agency of Canada; c2008 [cited 2009 07/24]. Available from: http://www.phac-aspc.gc.ca/cd-mc/cvd-mcv/index-eng.php.

2. AHA, ACC, National Heart, Lung, and Blood Institute, Smith SC,Jr, Allen J, Blair SN, Bonow RO, Brass LM, Fonarow GC, Grundy SM, Hiratzka L, Jones D, Krumholz HM, Mosca L, Pearson T, Pfeffer MA, Taubert KA. AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update endorsed by the national heart, lung, and blood institute. J Am Coll Cardiol 2006 May 16;47(10):2130-9.

3. Miller M VR. The practice of coronary artery prevention. 1st ed. Baltimore: Williams & Wilkins; 1996. .

4. Ridker PM. Evaluating novel cardiovascular risk factors: Can we better predict heart attacks? Ann Intern Med 1999 Jun 1;130(11):933-7.

5. What is HEart Disease [Internet] 2. : Genetic Health; c2000 [cited 2009 10/05]. Available from: http://www.geneticheath.com/HD_What_Is_Heart_Disease.shtml.

6. Daly J, Sindone AP, Thompson DR, Hancock K, Chang E, Davidson P. Barriers to participation in and adherence to cardiac rehabilitation programs: A critical literature review. Prog Cardiovasc Nurs 2002 Winter;17(1):8-17.

7. Tibblin G, Svardsudd K, Welin L, Erikson H, Larsson B. Quality of life as an outcome variable and a risk factor for total mortality and cardiovascular disease: A study of men born in 1913. J Hypertens Suppl 1993 Jun;11(4):S81-6.

8. Cella DF. Measuring quality of life in palliative care. Semin Oncol 1995 Apr;22(2 Suppl 3):73-81.

9. Koertge J, Weidner G, Elliott-Eller M, Scherwitz L, Merritt-Worden TA, Marlin R, Lipsenthal L, Guarneri M, Finkel R, Saunders Jr DE, McCormac P, Scheer JM, Collins RE, Ornish D. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the multicenter lifestyle demonstration project. Am J Cardiol 2003 Jun 1;91(11):1316-22.

10. Fast YJ, Steinke EE, Wright DW. Effects of attending phase II cardiac rehabilitation on patient versus spouse (proxy) quality-of-life perceptions. J Cardiopulm Rehabil Prev 2009 Mar-Apr;29(2):115-20.

11. Treasure T. The measurement of Health-Related quality of life. Heart 1999 Apr;81(4):331-2.

12. Doba N, Tomiyama H, Nakayama T. Drugs, heart failure and quality of life: What are we achieving? what should we be trying to achieve? Drugs Aging 1999 Mar;14(3):153-63.

13. McGee HM. Can the measurement of quality of life contribute to evaluation in cardiac rehabilitation services? J Cardiovasc Risk 1996 Apr;3(2):148-53.

14. Seki E, Watanabe Y, Sunayama S, Iwama Y, Shimada K, Kawakami K, Sato M, Sato H, Mokuno H, Daida H. Effects of phase III cardiac rehabilitation programs on health-related quality of life in elderly patients with coronary artery disease: Juntendo cardiac rehabilitation program (J-CARP). Circ J 2003 Jan;67(1):73-7.

15. Austin J, Williams R, Ross L, Moseley L, Hutchison S. Randomised controlled trial of cardiac rehabilitation in elderly patients with heart failure. Eur J Heart Fail 2005 Mar 16;7(3):411-7.

16. Katschnig H. How useful is the concept of quality of life in psychiatry? Curr Opin Psychiatry 1997;10(5):337-45.

17. Albrecht GL, Fitzpatrick R. A sociological perspective on health-related quality of life research. Adv Med Sociol 1994;5:1-21.

18. Campbell A, Converse PE, Rodgers WL. The quality of american life: Perceptions, evaluations, and satisfactions. New York, N.Y.: Russell Sage Foundation; 1976. .

19. Hunt SM. The problem of quality of life. Qual Life Res 1997;6:205-12.

20. Ware JE,Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. conceptual framework and item selection. Med Care 1992 Jun;30(6):473-83.

21. Centers for Disease Control and Prevention [Internet]Atlanta, GA: Centers for Disease Control and Prevention; c2009 [cited 2009 10/22]. Available from: http://www.cdc.gov.

22. Slevin ML, Plant H, Lynch D, Drinkwater J, Gregory WM. Who should measure quality of life, the doctor or the patient? Br J Cancer 1988 Jan;57(1):109-12.

23. Testa MA, Simonson DC. Assesment of quality-of-life outcomes. N Engl J Med 1996 Mar 28;334(13):835-40.

24. Cohen SR, Mount BM, MacDonald N. Defining quality of life. Eur J Cancer 1996 May;32A(5):753-4.

25. Gulanick M, Gavic AM, Kramer V, Rey J. Outcomes in cardiac rehabilitation programs across illinois. J Cardiopulm Rehabil 2002 Sep-Oct;22(5):329-33.

26. Bury M. The sociology of chronic illness: A review of research and prospects. Sociol Health Illn 1991;13:451-68.

27. Mossey JM, Shapiro E. Self-rated health: A predictor of mortality among the elderly. Am J Public Health 1982 Aug;72(8):800-8.

28. Wolinsky FD, Johnson RJ. Perceived health status and mortality among older men and women. J Gerontol 1992 Nov;47(6):S304-12.

29. Idler EL, Kasl SV, Lemke JH. Self-evaluated health and mortality among the elderly in new haven, connecticut, and iowa and washington counties, iowa, 1982-1986. Am J Epidemiol 1990 Jan;131(1):91-103.

30. Wannamethee G, Shaper AG. Self-assessment of health status and mortality in middle-aged british men. Int J Epidemiol 1991 Mar;20(1):239-45.

31. Kaplan GA, Camacho T. Perceived health and mortality: A nine-year follow-up of the human population laboratory cohort. Am J Epidemiol 1983 Mar;117(3):292-304.

32. Stull DE, Clough LA, Van Dussen D. Self-report quality of life as a predictor of hospitalization for patients with LV dysfunction: A life course approach. Res Nurs Health 2001 Dec;24(6):460-9.

33. Rumsfeld JS, MaWhinney S, McCarthy M,Jr, Shroyer AL, VillaNueva CB, O'Brien M, Moritz TE, Henderson WG, Grover FL, Sethi GK, Hammermeister KE. Health-related quality of life as a predictor of mortality following coronary artery bypass graft surgery. participants of the department of veterans affairs cooperative study group on processes, structures, and outcomes of care in cardiac surgery. JAMA 1999 Apr 14;281(14):1298-303.

34. Bernstein D, Kleinman L, Barker CM, Revicki DA, Green J. Relationship of health-related quality of life to treatment adherence and sustained response in chronic hepatitis C patients. Hepatology 2002 Mar;35(3):704-8.

35. Fletcher GF, Balady G, Blair SN, Blumenthal J, Caspersen C, Chaitman B, Epstein S, Sivarajan Froelicher ES, Froelicher VF, Pina IL, Pollock ML. Statement on exercise: Benefits and recommendations for physical activity programs for all americans. A statement for health professionals by the committee on exercise and cardiac rehabilitation of the council on clinical cardiology, american heart association. Circulation 1996 Aug 15;94(4):857-62.

36. Hanestad BR, Albrektsen G. Quality of life, perceived difficulties in adherence to a diabetes regimen, and blood glucose control. Diabet Med 1991 Oct;8(8):759-64.

37. Fumaz CR, Tuldra A, Ferrer MJ, Paredes R, Bonjoch A, Jou T, Negredo E, Romeu J, Sirera G, Tural C, Clotet B. Quality of life, emotional status, and adherence of HIV-1-infected patients treated with efavirenz versus protease inhibitor-containing regimens. J Acquir Immune Defic Syndr 2002 Mar 1;29(3):244-53.

38. Hays RD, Wells KB, Sherbourne CD, Rogers W, Spritzer K. Functioning and well-being outcomes of patients with depression compared with chronic general medical illnesses. Arch Gen Psychiatry 1995 Jan;52(1):11-9.

39. Dickens CM, McGowan L, Percival C, Tomenson B, Cotter L, Heagerty A, Creed FH. Contribution of depression and anxiety to impaired health-related quality of life following first myocardial infarction. Br J Psychiatry 2006 Oct;189:367-72.

40. Rosen RC, Contrada RJ, Gorkin L, Kostis JB. Determinants of perceived health in patients with left ventricular dysfunction: A structural modeling analysis. Psychosom Med 1997 Mar-Apr;59(2):193-200.

41. Gaynes BN, Burns BJ, Tweed DL, Erickson P. Depression and health-related quality of life. J Nerv Ment Dis 2002 Dec;190(12):799-806.

42. Spitzer RL, Kroenke K, Linzer M, Hahn SR, Williams JB, deGruy FV,3rd, Brody D, Davies M. Health-related quality of life in primary care patients with mental disorders. results from the PRIME-MD 1000 study. JAMA 1995 Nov 15;274(19):1511-7.

43. Stafford L, Berk M, Reddy P, Jackson HJ. Comorbid depression and health-related quality of life in patients with coronary artery disease. J Psychosom Res 2007 Apr;62(4):401-10.

44. Schipper H. Why measure quality of life? Can Med Assoc J 1983 Jun 15;128(12):1367-70.

45. Cella D, Nowinski CJ. Measuring quality of life in chronic illness: The functional assessment of chronic illness therapy measurement system. Arch Phys Med Rehabil 2002 Dec;83(12 Suppl 2):S10-7.

46. Valenti L, Lim L, Heller RF, Knapp J. An improved questionnaire for assessing quality of life after acute myocardial infarction. Qual Life Res 1996 Feb;5(1):151-61.

47. Gibbons RJ, Balady GJ, Beasley JW, Bricker JT, Duvernoy WF, Froelicher VF, Mark DB, Marwick TH, McCallister BD, Thompson PD, Winters WL,Jr, Yanowitz FG, Ritchie JL, Cheitlin MD, Eagle KA, Gardner TJ, Garson A,Jr, Lewis RP, O'Rourke RA, Ryan TJ. ACC/AHA guidelines for exercise testing: Executive summary. A report of the american college of Cardiology/American heart association task force on practice guidelines (committee on exercise testing). Circulation 1997 Jul 1;96(1):345-54.

48. Gibbons RJ, Balady GJ, Beasley JW, Bricker JT, Duvernoy WF, Froelicher VF, Mark DB, Marwick TH, McCallister BD, Thompson PD, Winters WL,Jr, Yanowitz FG, Ritchie JL, Cheitlin MD, Eagle KA, Gardner TJ, Garson A,Jr, Lewis RP, O'Rourke RA, Ryan TJ. ACC/AHA guidelines for exercise testing: Executive summary. A report of the american college of Cardiology/American heart association task force on practice guidelines (committee on exercise testing). Circulation 1997 Jul 1;96(1):345-54.

49. Ford E, Cooper R, Castaner A, Simmons B, Mar M. Coronary arteriography and coronary bypass survey among whites and other racial groups relative to hospital-based incidence rates for coronary artery disease: Findings from NHDS. Am J Public Health 1989 Apr;79(4):437-40.

50. Surgeon General. Physical activity and health: A report of the surgeon general. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion; 1996.

51. Ford E, Cooper R, Castaner A, Simmons B, Mar M. Coronary arteriography and coronary bypass survey among whites and other racial groups relative to hospital-based incidence rates for coronary artery disease: Findings from NHDS. Am J Public Health 1989 April 1;79(4):437-40.

52. Corti R, Fuster V, Badimon JJ. Pathogenetic concepts of acute coronary syndromes. J Am Coll Cardiol 2003 Feb 19;41(4 Suppl S):7S-14S.

53. Nesto RW, Kowalchuk GJ. The ischemic cascade: Temporal sequence of hemodynamic, electrocardiographic and symptomatic expressions of ischemia. Am J Cardiol 1987 Mar 9;59(7):23C-30C.

54. Pasternack RC, Braunwald E, Sobel BE. Acute myocardial infarction. In: Textbook of cardiovascular medicine. 3rd ed. Philadelphia: WB Saunders; 1988. .

55. Gordon T, Kannel WB. Multiple risk functions for predicting coronary heart disease: The concept, accuracy, and application. Am Heart J 1982 Jun;103(6):1031-9.

56. Wilson PW, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of coronary heart disease using risk factor categories. Circulation 1998 May 12;97(18):1837-47.

57. Adult Treatment Panel. Third report of the expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (adult treatment panel III) . Bethesda, MD: NIH publication; 2002. Report nr 3.

58. Kannel WB, McGee DL. Diabetes and glucose tolerance as risk factors for cardiovascular disease: The framingham study. Diabetes Care 1979 Mar-Apr;2(2):120-6.

59. American College of Sports Medicine. ACSM's resource manual for guidelines for exercise testing and prescription 7th edition. 5th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2006. .

60. Vasan RS, Sullivan LM, Wilson PW, Sempos CT, Sundstrom J, Kannel WB, Levy D, D'Agostino RB. Relative importance of borderline and elevated levels of coronary heart disease risk factors. Ann Intern Med 2005 Mar 15;142(6):393-402.

61. Rumsfeld JS, Magid DJ, Plomondon ME, Sales AE, Grunwald GK, Every NR, Spertus JA. History of depression, angina, and quality of life after acute coronary syndromes. Am Heart J 2003 Mar;145(3):493-9.

62. Feinstein AR, Fisher MB, Pigeon JG. Changes in dyspnea-fatigue ratings as indicators of quality of life in the treatment of congestive heart failure. Am J Cardiol 1989 Jul 1;64(1):50-5.

63. Rector TS, Anand IS, Cohn JN. Relationships between clinical assessments and patients' perceptions of the effects of heart failure on their quality of life. J Card Fail 2006 Mar;12(2):87-92.

64. Hagens VE, Ranchor AV, Van Sonderen E, Bosker HA, Kamp O, Tijssen JG, Kingma JH, Crijns HJ, Van Gelder IC, RACE Study Group. Effect of rate or rhythm control on quality of life in persistent atrial fibrillation. results from the rate control versus electrical cardioversion (RACE) study. J Am Coll Cardiol 2004 Jan 21;43(2):241-7.

65. Rose MS, Koshman ML, Spreng S, Sheldon R. The relationship between health-related quality of life and frequency of spells in patients with syncope. J Clin Epidemiol 2000 Dec;53(12):1209-16.

66. Hoekstra J, Cohen M. Management of patients with unsTable angina / non-ST-elevation myocardial infarction: A critical review of the 2007 ACC /AHA guidelines. Int J Clin Pract 2009 Apr;63(4):642-55.

67. Siegrist J. Impaired quality of life as a risk factor in cardiovascular disease. J Chronic Dis 1987;40(6):571-8.

68. Whaley MH. ACSM's resource manual for guidelines for exercise testing and prescription. 5th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2006. .

69. Massie BM, Shah NB. Evolving trends in the epidemiologic factors of heart failure: Rationale for preventive strategies and comprehensive disease management. Am Heart J 1997 Jun;133(6):703-12.

70. Jolliffe JA, Rees K, Taylor RS, Thompson D, Oldridge N, Ebrahim S. Exercise-based rehabilitation for coronary heart disease. Cochrane Database Syst Rev 2001;(1)(1):CD001800.

71. Dressendorfer RH, Smith JL, Amsterdam EA, Mason DT. Reduction of submaximal exercise myocardial oxygen demand post-walk training program in coronary patients due to improved physical work efficiency. Am Heart J 1982 Mar;103(3):358-62.

72. Coats AJ, Adamopoulos S, Radaelli A, McCance A, Meyer TE, Bernardi L, Solda PL, Davey P, Ormerod O, Forfar C. Controlled trial of physical training in chronic heart failure. exercise performance, hemodynamics, ventilation, and autonomic function. Circulation 1992 Jun;85(6):2119-31.

73. Whelton SP, Chin A, Xin X, He J. Effect of aerobic exercise on blood pressure: A meta-analysis of randomized, controlled trials. Ann Intern Med 2002 Apr 2;136(7):493-503.

74. Gibbons RJ, Abrams J, Chatterjee K, Daley J, Deedwania PC, Douglas JS, Ferguson TB,Jr, Fihn SD, Fraker TD,Jr, Gardin JM, O'Rourke RA, Pasternak RC, Williams SV, American College of Cardiology, American Heart Association Task Force on practice guidelines (Committee on the Management of Patients With Chronic STable Angina). ACC/AHA 2002 guideline update for the management of patients with chronic sTable angina--summary article: A report of the american college of Cardiology/American heart association task force on practice guidelines (committee on the management of patients with chronic sTable angina). J Am Coll Cardiol 2003 Jan 1;41(1):159-68.

75. Thomas RJ, King M, Lui K, Oldridge N, Pina IL, Spertus J, Bonow RO, Estes NA,3rd, Goff DC, Grady KL, Hiniker AR, Masoudi FA, Radford MJ, Rumsfeld JS, Whitman GR, AACVPR, ACC, AHA, American College of Chest Physicians, American College of Sports Medicine, American Physical Therapy Association, Canadian Association of Cardiac Rehabilitation, European Association for Cardiovascular Prevention and Rehabilitation, Inter-American Heart Foundation, National Association of Clinical Nurse Specialists, Preventive Cardiovascular Nurses Association, Society of Thoracic Surgeons. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services endorsed by the american college of chest physicians, american college of sports medicine, american physical therapy association, canadian association of cardiac rehabilitation, european association for cardiovascular prevention and rehabilitation, inter-american heart foundation, national association of clinical nurse specialists, preventive cardiovascular nurses association, and the society of thoracic surgeons. J Am Coll Cardiol 2007 Oct 2;50(14):1400-33.

76. Kinney MR, Burfitt SN, Stullenbarger E, Rees B, DeBolt MR. Quality of life in cardiac patient research: A meta-analysis. Nurs Res 1996 May-Jun;45(3):173-80.

77. Lim LL, Valenti LA, Knapp JC, Dobson AJ, Plotnikoff R, Higginbotham N, Heller RF. A self-administered quality-of-life questionnaire after acute myocardial infarction. J Clin Epidemiol 1993 Nov;46(11):1249-56.

78. Valenti L, Lim L, Heller RF, Knapp J. An improved questionnaire for assessing quality of life after acute myocardial infarction. Qual Life Res 1996 Feb;5(1):151-61.

79. Hofer S, Benzer W, Alber H, Ruttmann E, Kopp M, Schussler G, Doering S. Determinants of health-related quality of life in coronary artery disease patients: A prospective study generating a structural equation model. Psychosomatics 2005 May-Jun;46(3):212-23.

80. Salmon P. Effects of physical exercise on anxiety, depression, and sensitivity to stress: A unifying theory. Clin Psychol Rev 2001 Feb;21(1):33-61.

81. Shen BJ, Avivi YE, Todaro JF, Spiro A,3rd, Laurenceau JP, Ward KD, Niaura R. Anxiety characteristics independently and prospectively predict myocardial infarction in men the unique contribution of anxiety among psychologic factors. J Am Coll Cardiol 2008 Jan 15;51(2):113-9.

82. Garratt A, Schmidt L, Mackintosh A, Fitzpatrick R. Quality of life measurement: Bibliographic study of patient assessed health outcome measures. BMJ 2002 Jun 15;324(7351):1417.

83. Jenkinson C, Layte R, Lawrence K. Development and testing of the medical outcomes study 36-item short form health survey summary scale scores in the united kingdom. results from a large-scale survey and a clinical trial. Med Care 1997 Apr;35(4):410-6.

84. Jenkinson C, Layte R, Jenkinson D, Lawrence K, Petersen S, Paice C, Stradling J. A shorter form health survey: Can the SF-12 replicate results from the SF-36 in longitudinal studies? J Public Health Med 1997 Jun;19(2):179-86.

85. Failde I and Ramos I. 2000. Validity and reliability of the SF-36 health survey questionnaire in patients with coronary artery disease. J Clin Epidemiol 53(4):359-65.

86. Seki E, Watanabe Y, Sunayama S, Iwama Y, Shimada K, Kawakami K, Sato M, Sato H, Mokuno H, Daida H. Effects of phase III cardiac rehabilitation programs on health-related quality of life in elderly patients with coronary artery disease: Juntendo cardiac rehabilitation program (J-CARP). Circ J 2003 Jan;67(1):73-7.

87. Bohannon RW, Maljanian R, Landes M. Test-retest reliability of short form (SF)-12 component scores of patients with stroke. Int J Rehabil Res 2004 Jun;27(2):149-50.

88. Ware JE. SF-36® health survey update. 2nd ed. Massachusetts, USA: Medical Outcomes Trust; 2002. .

89. Dempster M, Donnelly M. Measuring the Health-Related quality of life of people with ischaemic heart disease. Heart 2000 Jun;83(6):641-4.

90. Yu CM, Li LS, Ho HH, Lau CP. Long-term changes in exercise capacity, quality of life, body anthropometry, and lipid profiles after a cardiac rehabilitation program in obese patients with coronary heart disease. Am J Cardiol 2003 Feb 1;91(3):321-5.

91. McDowell I. *Measuring health: A guide to rating scales and questionnaires*. 2nd ed. New York: Oxford University Press; 1996. .

92. Jenkinson C, McGee H. *Health status measurement: A brief but critical introduction*. Oxford: Radcliffe Medical Press; 1998. .

93. Smith HJ, Taylor R, Mitchell A. 2000. A comparison of four quality of life instruments in cardiac patients: SF-36, QLI, QLMI, and SEIQoL. Heart 84(4):390-4.

94. Hawkes AL, Nowak M, Speare R. 2003. Short form-36 health survey as an evaluation tool for cardiac rehabilitation programs: Is it appropriate? J Cardiopulm Rehabil 23(1):22-5.

95. Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, Jones DW, Kurtz T, Sheps SG, Roccella EJ, Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. Recommendations for blood pressure measurement in humans and experimental animals: Part 1: Blood pressure measurement in humans: A statement for professionals from the subcommittee of professional and public education of the american heart association council on high blood pressure research. Hypertension 2005 Jan;45(1):142-61.

96. Ware JE. User's manual for the SF-36v2 health survey. 2nd ed. London: Quality Metric; 2007. .

97. Orpana HM. Using the national population health survey to identify factors associated with patterns of psychological distress over 10 years. Healthc Policy 2008 May;3(4):55-63.

98. Denis C, Fouquet R, Poty P, Geyssant A, Lacour JR. Effect of 40 weeks of endurance training on the anaerobic threshold. Int J Sports Med 1982 Nov;3(4):208-14.

99. Bandura A. Self-efficacy: Toward a unifying theory of behavioral change. Psychol Rev 1977 Mar;84(2):191-215.

100. McAuley E, Courneya KS, Lettunich J. Effects of acute and long-term exercise on self-efficacy responses in sedentary, middle-aged males and females. Gerontologist 1991 Aug;31(4):534-42.

101. Glazer KM, Emery CF, Frid DJ, Banyasz RE. Psychological predictors of adherence and outcomes among patients in cardiac rehabilitation. J Cardiopulm Rehabil 2002 Jan-Feb;22(1):40-6.

102. Atlantis E, Chow CM, Kirby A, Singh MF. An effective exercise-based intervention for improving mental health and quality of life measures: A randomized controlled trial. Prev Med 2004 Aug;39(2):424-34.

Document **A-1**.
Physician Referral Form

Heart Institute
Brock University

Physician Referral Form
Fax: (905) 378-5724

For completion by Referring Physician
Name of referring physician:
I wish to refer my patient to the Brock University Heart Institute for the purpose of cardiac rehabilitation, which includes exercise stress testing and aerobic and resistance training.
Certification Statement: I have received authorization from this patient to release the information below and to permit the staff of the Brock University Heart Institute to contact him/her directly for follow-up. *(Physician signature required below)*
Physician Signature: _____ **Date:** _____

Patient Information	
Name:	Date of Birth:
	Telephone:

Reason for Referral - Primary Prevention ☐			
☐ Dyslipidemia	☐ Hypertension	☐ Obesity	☐ Diabetes

Reason for Referral – Secondary Prevention ☐

☐ **Post MI:** Date:			☐	Q Wa☐	Non Q	
	Location:	☐ Anterior	☐ Inferior	☐ Lateral	☐ Posterior	☐ Rt. Vent
☐ **Cardiac Surgery:** Date:			☐ CABG	☐ Valve	☐ Other _____	
☐ **Coronary Angioplasty:** Date: Stent				Vessel (s):		☐

Reason for Referral – Spousal Support ☐

Fax referral form to: (905) 378 - 5724

Document **A-2**.
BUHI Questionnaire Battery (Inclusion of Sections Only Pertinent to this Research Project)

BUHI Questionnaire

Demographic Information

1) Male____ Female_____
2) Birthday YYYY/MM/DD _____/_____/_____

3) Please Check the answer that represents your current living situation:

☐ Alone ☐ With Others (Please specify)
☐ With Spouse/Partner _____

4) How do you plan on getting to the clinic?

☐ Drive
☐ Ride the Bus
☐ Walk
☐ Bike
☐ Get a ride from a friend/ family member
☐ Other (Please explain) _____

5) Approximately how long does it take you to get to the center (in minutes)?
_____

6) What is the highest level of education that you have obtained? (Check one of the following)

☐ Less than Grade 6
☐ Grade 6
☐ Grade 7
☐ Grade 8
☐ Grade 9
☐ Grade 11
☐ Grade 12
☐ High school graduate/GED
☐ Partial college (at least 1 year) or specialized training
☐ Standard college or university (undergraduate

☐ Grade 10	degree) ☐ Graduate or professional training (graduate degree)
7) Are you currently... (pick one of the following)	
8) What is your current or previous occupation?	

K-6

During the past month, that is, from one month to yesterday, about how often did you feel.....

1) ... so sad that nothing could cheer you up? 1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time	**1) ... nervous?** 1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time
2) ... restless or fidgety? 1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time	**2) ...hopeless** 1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time
3) ... worthless? 1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time	**3) ... that everything was an effort?** 1. All of the time 2. Most of the time 3. Some of the time 4. A little of the time 5. None of the time

SF12

Thinking about your own health . . .**Please try to answer the following questions as accurately as you can**

1. In general, how would you say your health is...
   - ☐ Excellent
   - ☐ Very good
   - ☐ Good
   - ☐ Fair
   - ☐ Poor

2. In regards to moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf; does your health now limit you a lot, a little, or not at all?
   - ☐ A lot
   - ☐ A little
   - ☐ Not at all
   - ☐ Do not do activity:

   If you answered 'Do not do activity': Is that because of your health?
   - ☐ Yes, limited a lot
   - ☐ Yes, limited a little
   - ☐ No, Not limited at all

3. In regards to strenuous activities such as climbing several flights of stairs; does your health now limit you a lot, a little, or not at all?
   - ☐ A lot
   - ☐ A little
   - ☐ Not at all
   - ☐ Do not do activity:

   If you answered 'Do not do activity': Is that because of your health?
   - ☐ Yes, limited a lot
   - ☐ Yes, limited a little
   - ☐ No, Not limited at all

4. During the past 4 weeks, have you accomplished less than you would like as a result of your physical health?
   - ☐ Yes
   - ☐ No

5. During the past 4 weeks, were you limited in the kind of work or other regular daily activities you do as a result of your physical health?
   - ☐ Yes
   - ☐ No

6. During the past 4 weeks, have you accomplished less than you would like as a result of any emotional problems, such as feeling depressed or anxious?

- ☐ Yes
- ☐ No

7. During the past 4 weeks, did you not do work or other regular activities as carefully as usual as a result of any emotional problems, such as feeling depressed or anxious?

- ☐ Yes
- ☐ No

8. During the past 4 weeks, how much did pain interfere with your normal work, including both work outside the home and housework?

- ☐ Not at all
- ☐ A little bit
- ☐ Moderately
- ☐ Quite a bit
- ☐ Extremely

9. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities, like visiting with friends or relatives?

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

10. How much of the time during the past 4 weeks, have you felt calm and peaceful?

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

11. How much of the time during the past 4 weeks, did you have a lot of energy?

- ☐ All of the time

- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

12. How much of the time during the past 4 weeks, have you felt downhearted and blue?

- ☐ All of the time
- ☐ Most of the time
- ☐ Some of the time
- ☐ A little of the time
- ☐ None of the time

Document A-3.

Brock University Ethics clearance
Research Ethics Office
Brock University | Brock Research

FROM: Michelle McGinn, Chair

TO: Dr. Deborah O'LEARY, Community Health Sciences

FILE: 09-226 - O'LEARY
Masters Thesis/Project

TITLE: Brock University Heart Institute

The Brock University Research Ethics Board has reviewed the above research proposal.
DECISION: Secondary Use of Data Accepted.

This project has received ethics clearance for the period of **April 6, 2010** to **May 31, 2011** subject to full REB ratification at the Research Ethics Board's next scheduled meeting. The clearance period may be extended upon request. ***The study may now proceed.***

Please note that the Research Ethics Board (REB) requires that you adhere to the protocol as last reviewed and cleared by the REB. The Board must provide clearance for any modifications before they can be implemented. If you wish to modify your research project, please refer to http://www.brocku.ca/researchservices/forms to complete the appropriate form ***Request for Clearance of a Revision or Modification to an Ongoing Application.***

Adverse or unexpected events must be reported to the REB as soon as possible with an indication of how these events affect, in the view of the Principal Investigator, the safety of the participants and the continuation of the protocol.

The Tri-Council Policy Statement requires that ongoing research be monitored. A Final Report is required for all projects, with the exception of undergraduate projects, upon completion of the project. Researchers with projects lasting more than one year are required to submit a Continuing Review Report annually. The Office of Research Services will contact you when this form ***Continuing Review/Final Report*** is required. Please quote your REB file number on all future correspondence.

MM/sp

Niagara Region | 500 Glenridge Ave. | St. Catharines, ON L2S 3A1
brocku.ca | T 905 688 5550 x3035 | F 905 688 0748DATE: April 6, 2010