UTILIZATION OF THE WORLD WIDE WEB TO DELIVER CARDIAC REHABILITATION AT A DISTANCE

by

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or

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Abstract

Cardiovascular disease (CVD) is a growing epidemic and economic burden in Canada and North America. *Cardiac Rehabilitation Programs* (CRP) have been proven to reduce CVD risk, decrease health care cost and decrease mortality by 25%. With current waitlists of 2 to 5 months and the inaccessibility of CRP to suburban and rural patients, conducting cardiac rehabilitation through the Internet will decrease barriers related to distance and service delivery and allow patients from around the province to interact with cardiac rehabilitation specialists, essentially *bridging the treatment gap*. The virtual cardiac rehabilitation program (vCRP) was a randomized controlled trial (n=15) investigating a 12-week web-based CRP. Outcome investigated were changes in exercise capacity, physical activity participation, lipid profiles, diet composition and level of self-efficacy. Significant findings within the intervention group included the lipid values for HDL-C ($p. < 0.025$), TG ($p. < 0.012$), TC/HDL-C ratio ($p. < 0.012$), self- efficacy ($p. < 0.018$) and physical activity participation ($p. < 0.018$). There was also a *clinically* significant finding with an increase in exercise capacity. Other reported outcomes from patient interviews indicate overall satisfaction with the program and noted positive behaviour change.

Keywords: *cardiac rehabilitation, telehealth, cardiovascular disease, exercise capacity, rural health, virtual cardiac program*

Executive Summary

Cardiovascular disease (CVD) is a growing epidemic and economic burden in Canada and North America. In Canada (2001) approximately 35% of all deaths were related to CVD with 80% of Canadians at risk for CVD development. *Cardiac Rehabilitation Programs* (CRP) have been proven to reduce CVD risk, decrease health care cost and decrease mortality by 25%. However, despite the benefits of these programs, it is believed that as little as 10%-25% of eligible patients actually attend. Barriers to this reported low attendance include accessibility and availability of programs. With current waitlists of 2 to 5 months and the inaccessibility of CRP to suburban and rural patients, conducting cardiac rehabilitation through the Internet will decrease barriers related to distance and service delivery and allow patients from around the province to interact with cardiac rehabilitation specialists, essentially *bridging the treatment gap*. The virtual cardiac rehabilitation program (vCRP) was a randomized controlled trial (n=15) investigating a 12-week web-based CRP. The vCRP website was designed to include interactive heart rate, blood pressure and exercise upload components, live chats with specialists and weekly education sessions. The primary outcome investigated was change in exercise capacity. Secondary outcomes included changes in physical activity participation, lipid profiles, diet composition and level of self-efficacy. Patient interviews were also conducted to evaluate user satisfaction. Significant findings within the

intervention group included the lipid values for HDL-C (p. <0.025), TG (p. < 0.012), TC/HDL-C ratio (p. < 0.012), self- efficacy (p. <0.018) and physical activity participation (p. < 0.018). There was also a *clinically* significant finding with an increase in exercise capacity (58 second increase in GXT equivalent to l MET)(this finding is similar to changes we see in current face to face CRP). There were no statistically significant findings between groups. Other reported outcomes from patient interviews indicate overall satisfaction with the program and noted positive behaviour change. Therefore, it is safe to speculate that the vCRP is comparable with current CRP clinical outcomes. Future directions include further investigation and development in the delivery of telehealth services for cardiac rehabilitation and other chronic conditions.

Dedication

I would like to dedicate this work to my family and friends for their unremitting support throughout my endeavours. To my parents, thank you for my strong upbringing and values towards life. You have taught me to always strive to be a better person and that hard work and perseverance results in endless possibilities.

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Abbreviations

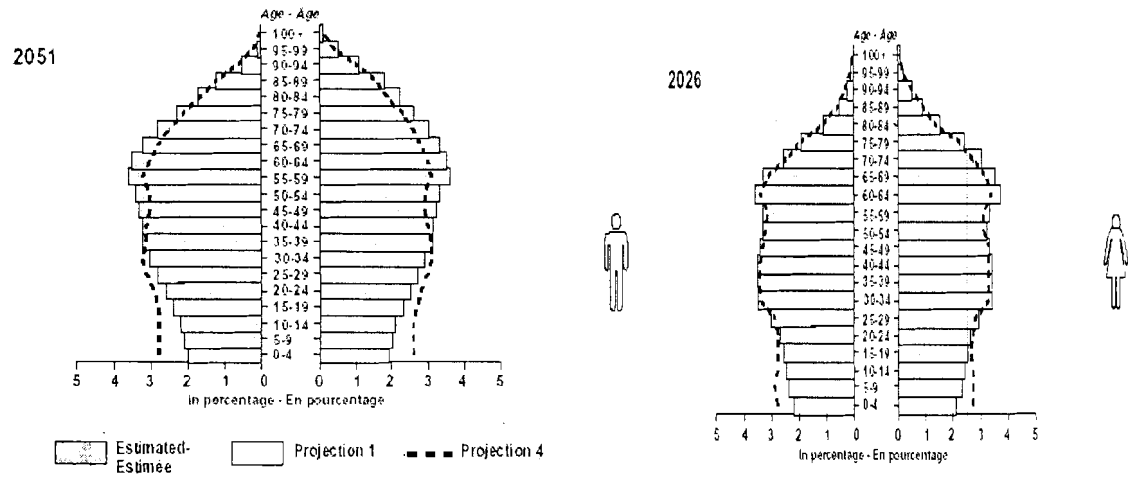
ACE-Inhibitor	Angiotensin Converting Enzyme Inhibitor
BP	Blood Pressure
CABG	Coronary Artery Bypass Grafting
CCU	Critical Care Unit
CHF	Congestive Heart Failure
CR	Cardiac Rehabilitation
CRP	Cardiac Rehabilitation Program
CVD	Cardiovascular Disease
ECG	Electrocardiograph
ES	Exercise Specialist
HHP	Healthy Heart Program
HIUS	Household Internet Use Survey
HR	Heart Rate
IHD	Ischemic Heart Disease
IV	Intervention Group
LPTA	Leisure Time Physical Activity Questionnaire
MI	Myocardial Infarction
NCM	Nurse Case Manager
PTCA	Percutaneous Transluminal Coronary Angioplasty
RD	Registered Dietician
SPH	St. Paul's Hospital
UC	Usual Care Group
VCRP	Virtual Cardiac Rehabilitation Program
WHO	World Health Organization
WWW	World Wide Web

1 Introduction

1.1 Cardiovascular Disease

Cardiovascular disease (CVD) (diseases of the heart and/or blood vessels, valves, muscle, arteries, or electrical system) accounts for the death of more Canadians than any other disease (1,2). The high prevalence rate of risk factors continues to contribute to this growing epidemic of CVD in Canada.

Figure 1.1: Projected Canadian Population Pyramids 2026 and 2051



Data source: Statistics Canada

A major part of the growing burden of CVD will result from the "greying of Canada". Between 1991 and 2001, the population aged 80 years and over rose 41% to 932,000 and is expected to increase an additional 43% between 2001 and 2011, surpassing an estimated amount of 1.3 million (Figure 1)(2). The

population between forty-five and sixty-four years of age increased 36% between 1999 and 2001, due to the entry of the baby boomers into this group (2).

1.2 Prevalence and Costs of Cardiovascular Disease

In 1999, in Canada, there were 78,942 deaths attributed to CVD (2,3). Among men of all ages, 35% of deaths in 1999 were attributable to CVD, while women were reported slightly higher at 37% (2,3). In 2000, more than 450,000 Canadians were hospitalised for CVD. Cardiovascular disease is the leading cause of death in Canada (36%) with Ischemic Heart Disease (IHD) accounting for the greatest percentage (20%) where about 60% of these deaths were among men and 50% among women (3). The total number of CVD deaths were equal for both men and women, more men died from IHD and acute myocardial infarction (MI) and more women died from cerebrovascular disease and chronic heart failure. (3,4).

Cardiovascular disease is the most costly disease in Canada. In the 1998 issue, *Economic Burden of Illness in Canada,* Health Canada estimated the total cost of CVDs on the health sector of the Canadian economy to be $18.5 billion (11.6% of the total cost of all illnesses) (4). The economic cost is now estimated to be over 20 billion dollars in 2005 (5).

1.3 Cardiovascular Disease in British Columbia

Although BC has the lowest mortality rate from cardiac disease when compared to other Canadian provinces, in the year 2000 more than 9,000 British

Columbians deaths were attributed to CVD (5). It has been estimated that more than 1 in 2 British Columbians has at least one risk factor and that almost 1 in 20 British Columbians has CVD. Based on the continued high prevalence of risk factors, the aging population, and the net growth of the B.C. population through immigration, it is predicted that by 2016 the number of people in B.C. with clinical CVD will total 200,000. In B.C. alone, in the year 2001 CVD cost the province $532.5 million in hospital care, $192.5 million in drugs, $95.4 for physician care, $394.8 for long-term disability, $41.8 for short-term disability and as a cost of premature death, $939.7 for mortality (3,4,5). Although mortality rates have been declining for all CVD for both men and women, the actual number of cases has increased.

1.4 Risk Factors

The risk factors for CVD are well known and widely prevalent in our population. The World Health Organization (WHO) defines a risk factor as "an aspect of personal behaviour or lifestyle, environmental exposure, or inborn or inherited characteristic, which, on the basis of epidemiologic evidence, is known to be associated with a health-related condition considered important to prevent" (6). Common risk factors associated with CVD include obesity, diabetes, family history (genetics and heredity), age, gender, ethnicity, smoking, physical inactivity, hypercholesterolemia and hypertension (1,2,3,4,5,6). The Framingham Heart Study, initiated in 1948, found that changing patterns of cigarette smoking, nutritional habits and exercise patterns as well as changes in other aspects of

lifestyle and advances in medical care may all influence future morbidity and mortality rates for cardiovascular disease (3,7).

The risk of CVD and stroke increases with an increasing number of risk factors. Canadians run a high risk of developing CVD, nearly eighty percent of the Canadian population has at least one modifiable risk factor for CVD; with one-third having two risk factors; and another 11% having three or more risk factors (6).

1.5 Cardiac Rehabilitation

Cardiac rehabilitation (CR) is an important management strategy in patient's with CVD. It has become an important aspect of management in patients with coronary artery disease, especially after a MI, CABG or coronary angioplasty (8).

Cardiac rehabilitation is the process by which patients with cardiac disease are restored to their optimal physical, medical, psychological, social, emotional, vocational and economic status, with the objective to minimize potential future cardiac risk by encouraging modification of cardiac risk factors (9). The WHO has defined CR as "...The sum of activity required to ensure cardiac patients the best possible physical, mental and social conditions so that they may, by their own effort, regain a normal place in the community, and lead an active life." (6)

The benefits of CR have been demonstrated in both population studies and mortality and morbidity studies. A recent meta-analysis concluded that

overall mortality, cardiovascular mortality and rates of sudden death were significantly decreased in patients who were active in CR with exercise, as compared with control subjects (9). As a treatment modality, cardiac rehabilitation is cost effective; similar to that of CABG for left main coronary artery disease, and can reduce mortality by up to 25% (9,10,11,12). According to recent evidence-based guidelines, CR is beneficial as soon as CVD is established or as late as after multiple infarctions complicated by congestive heart failure (9,11,12). In addition, CR has now been shown to be a beneficial adjunct to drug therapy for congestive heart failure from any cause and is widely prescribed after cardiac transplants. (10,11,12,13)

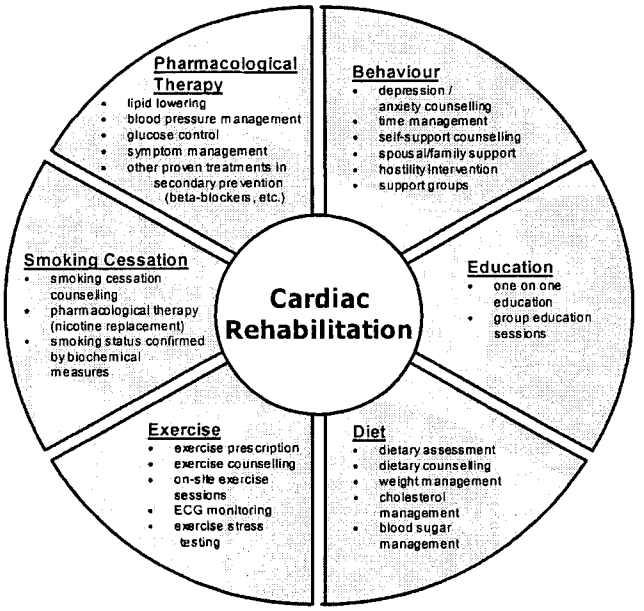
Cardiac Rehabilitation Programs (CRP) are aimed towards increasing one's quality of life and reducing cardiovascular risk through medical therapy, exercise, education and counselling. In general, CR consists of three phases of intervention designed for inpatients recovering from a recent cardiac event such as a MI, CABG, angioplasty, valve surgery, cardiac transplant, stable angina and coronary artery disease risk factor patients to outpatients in the community (13,14,15). The overall goal of the three phases is to guide the patient from an inpatient to outpatient, to the community, undertaking a wide range of activities and adopting life management skills for the future.

The first phase begins in hospital when patients are recovering from a recent event; therefore most of the intervention consists of education about the disease process, treatment options and risk factor modification. However, due to

shorter hospital stays, the amount of education possible is limited. The program also introduces low-level exercise to assist the patient in becoming ambulatory.

The second phase of CR is a supervised outpatient exercise program and risk factor modification/lifestyle management education. At the beginning of the second phase an exercise test is conducted to determine the patient's baseline exercise capacity. This treadmill test (or bicycle if patient is symptom limited) provides results of aerobic capacity, blood pressure response, heart rate levels and electrocardiograph (ECG) adaptations in response to exercise. From these results an exercise prescription is made and the patients are supervised by an exercise specialist while exercising 2-3 times per week for an average of 12 weeks duration. The focus of these 12 weeks is to improve muscular endurance and cardiovascular fitness while educating about chronic disease and lifestyle management. A typical CRP (Figure 2) offers medical evaluations, risk factor evaluation and stratification, individually based exercise prescription, a personalized exercise program, education and support for risk factor modification, dietary counselling, smoking cessation, stress management and vocational consoling. Patients attending CRP's are referred by their family physician or specialist, in some cases a nurse-facilitated referral is also used.

Figure 1.2 Model for Cardiac Rehabilitation



The third and final phase of CR involves long-term lifestyle management. The objectives include improving and maintaining physical fitness while promoting a lifetime commitment to health.

In summary, CRP involves multidisciplinary teams that work together focusing on education, individually tailored exercise, risk factor modification and the optimization of functional status and mental health (12,13,14,15).

There are limitations to cardiac rehabilitation. As excellent as CRP's are seen to be, as little as 10% to 25% of eligible patients actually complete the program (12,14,15). Cardiac rehabilitation programs are limited to large urban

areas, therefore restricting access to those in smaller communities with limited availability of formal programs or community centres without involving travel, resulting in an inequity of care (12,14,15,16). Accessibility to these programs presents a major problem to CVD patients. A recent review investigating the factors associated with CR attendance indicated that psychological, demographic and biological variables are all factors associated with failure *to attend* a cardiac rehabilitation course despite eligibility and opportunity (12,17). Regardless of age, gender or psychosocial variables, accessibility, program availability and distance are the underlying significant barriers to low attendance (12,14,17,18).

In addition, current CRP's may have waiting lists of about 2-5 months. King, Humen and Teo (1999) examined the influence of cardiac patient's demographic and health characteristics on physicians' cardiac rehabilitation referral practice and patient's attendance to such programs (15). Analysis indicated that patients, who live in rural areas, are elderly (70 years of age or older), non-English speaking and those undergoing PTCA alone were less likely to be referred to and subsequently attend CRP's (18). Barriers that affect access and availability are critical determinants of health resource utilization. Distance from and difficulty traveling to a CRP can pose substantial barriers for both rural residents and elderly patients (18). Clearly, CR delivery needs to be considered to meet the heart health needs of people living in rural and remote communities (9).

In a recent review "broadening the reach of cardiac rehabilitation (CR)", investigators Dollard, Smith, Thompson and Stewart (2004) conclude that there

is "no CR model specifically developed for rural or remote areas (19)." Within their review it is indicated that of the 14 studies designed for remote cardiac rehabilitation, 11 were non-conventional comprehensive CR methods. Of those 11, all CR was provided in a home-based setting with health professionals providing support via telephone or home visits (17). None of the studies were designed to investigate the effectiveness of a remote program based upon conventional CR methods. According to the review, "home-based CR is less costly to health care funding organizations and patients than rehabilitation based in a gym (Australia $1169 and $1933 respectively) and providing home-based care can significantly reduce health service costs (Australia $5100 and $10600) per patient in metropolitan areas (17)."

1.6 Telehealth

Over the past decade, the use of the Internet has increased rapidly - more individuals are accessing the World Wide Web (WWW) as a means of researching information for health and education purposes, business, conducting online banking services, communicating through 'real time' chat programs, emailing, shopping, travel and many other resourceful reasons. Recently, it was noted that the number one reason people use the Internet is for health related information (19, 20, 21,22), commonly referred to as "telehealth" or "e-health".

In Canada, telehealth is a consistently growing approach to delivering care and information to the population. Over the past 10 years, Canadian households continue to become more connected to the Internet for computer

communications. An estimated 7.9 million (64%) of the 12.3 million Canadian households had at least one member who used the Internet regularly in 2003, either from home, work, school, a public library or another location. This was a 5% increase from 2002, but well below the annual gains of 19% and 24% observed in 2000 and 2001 (20, 22, 23). Internet use was the highest at home.

Of all Canadian provinces, British Columbia, Alberta and Ontario have the greatest number of household Internet access. In British Columbia alone, Internet use in the home went up from 58% to 62 % in one year (2003-2003). British Columbia is already one of the most connected provinces in Canada with access to broadband being available in communities containing 89% of the population (23). Seventy two percent of provincial homes have Internet connections, more than half of which are high-speed or broadband connections. In smaller towns and communities, Internet connection speed and level of service is vastly different than in larger cities. This creates a "digital divide" (23).

On April 7, 2005 B.C.'s premier Gordon Campbell and TELUS announced that *'as part of its plan to make B.C. the best educated.....the province is partnering with TELUS to expand and bring broadband access to 366 B.C. communities by December 2006'* (23). Referred to as the "digital divide", this 350 million dollar investment to improve telecommunication services is expected to unleash the power that the Internet brings to the world of exciting new health care, educational and economic opportunities (23). By improving community access, residents in rural and remote communities will be able to receive

services on-line, develop or access telehealth services, increase their education opportunities and participate in the new knowledge-based economy (23).

The Internet is a widely used resource, and even though there can be lots of unfiltered and unnecessary information obtained through the Internet, when used for an educational source the availability of online resources and information is vast. Using the google.ca search engine and typing "health" as a keyword over 109 million results were provided in less than 10 seconds. With periodical online 'searches' using the same search engine numbers increased after 3 months later to 231 million results in .20 seconds, and 5 months later to 248 million in .19 seconds. After 1 year the numbers were more then double at 474 million in .23 seconds. Again, close to 2 years later, 868 million results were brought up in .11 seconds. This digital revolution is rapidly improving health care services by converting online patient medical records, hospital billing records, physician procedure codes, pharmacy records, and other financial, administrative, and clinical data into electronic information (24).

Telehealth has been developing since the Internet was deregulated in the early 1990's (25). The existence of telehealth can be traced back to the first uses of the telephone in the late 1800's (24, 25, 26). It is best defined as the use of communications and information technologies to deliver health services and transmit health information over both long and short distances (21,22,24,27). It involves various formats for getting the information to the public including Internet services, telephone hotline services, video conferencing and other telecommunication technologies. There are two types of telehealth, or E-health,

used for current online healthcare. This includes bricks-and-mortar companies that are web-enabled and companies that use the Web as their primary corporate environment (28). In 2004 over 15,000 healthcare sites already exist online but only a few hundred are exclusively web-based. This technology is making information readily accessible to many healthcare patients with the common goal of expanding health information networks in real time communication, therefore becoming less reliant on phone, fax, mail, files and indecipherable handwriting (24). Telehealth is about the adoption of technology that compliments and supports health public policy and enhances the delivery of quality health services within a regional health model. It can help eliminate distance barriers and improve access to services that otherwise are not available in rural communities (27).

The growing public interest in health and wellness information stems from many sources, including social changes related to consumer's rights to women's health movements, and to economic changes brought about by the managed health care revolution (29). Telehealth faces different challenges depending on the needs of various sectors in healthcare. Patients demand that telehealth improve the quality of care and access to specialists (26). Healthcare providers want telehealth to be not only cost effective and manageable but also to improve outcomes and prevent disease. The "information superhighway" could be an effective tool for relaying health information to patients about risk factors and disease management if access to telecomputing equipment and training were available to those with an information need (29).

Currently in Canada, telehealth is an area of growing interest in almost every province and territory. Many projects are being introduced including the implementation of provincial sectors and agencies. Recently New Brunswick adopted a province wide medical hotline to reduce unnecessary emergency department visits; Nova Scotia and Quebec announced a similar implementation with hopes of saving $300 million annually in costs (29). British Columbia has encouraged liaisons between industrial, educational and public sector organizations to study technological advances in telecommunications as they apply to their field of interest (29). Healthnet B.C. is the overall framework for health information sharing within the province of British Columbia, compromised of applications, databases, computer technology, communication networks and necessary supporting services (20) (Appendix). The overall goal of implementing this type of system is to allow health system patients to access all the information they need to effectively do their jobs (20,25,26,28,30).

At a recent conference (2002) the Association of Telehealth Service Providers introduced innovative and impending telehealth technology related to health services. Many two-way transmission devices were introduced including the Health Buddy System which acts as a health monitoring/surveillance device for patients with mental and chronic conditions, including CHF. These devices act as a record keeper with daily reminders and health tips for the patient. Staff and 'red flags' monitor the Health Buddy data or indicators are given when a patient entry is perceived as abnormal or needs attention. In 2004, using this device with CHF patients showed hospital readmissions to decrease by 20% (31).

The impact that telecommunication-based interventions have on individuals with chronic conditions and other disease is still somewhat unknown. The evaluation of telehealth and its effectiveness is limited. Those studies that do exist though provide supportive results indicating that it has a positive effect on health and lifestyle (17,18,31). A study evaluating a health education program with telephone follow-up during CR, indicated that patients who participated in the education sessions and telephone follow-ups showed a significantly greater decrease in smoking and unhealthy eating habits and a significantly greater increase in physical activity than patients with no participation (32). Recent analysis investigating telehealth and chronic medical conditions showed overall results that suggested that telecommunication-based interventions may be an efficient and effective way of providing services for chronically disabled populations, even for those who have no previous experience with the technologies (24,28). To provide an example of telehealth and chronic disease, a website was designed as an information resource and communication tool for congestive heart failure (CHF) patients and health care providers. This was a pilot study to investigate an interactive Internet site for the management of patients with CHF (18). Overall findings indicated that quality of life improved including relationships with family and friends, house and yard work, reduced side effects of medication and also high levels of satisfaction with the website (18).

Further investigations evaluating real life implementation of telehealth with chronic conditions collectively conclude overall effectiveness (33-35), with the

ultimate goal of moving the scope beyond routine health care while expanding services to rural areas. Many issues are addressed in most reviewed telehealth articles with regards to effectiveness and economic benefits.

Recently published articles have reported on the use of the Internet for public health intervention such as diabetes control or weight loss programs (36-40). All three studies provided Internet based communication as a medium for health care professionals to interact with their patients; however there was no "real time" communication. Methods of communication were data entry of food records or blood glucose recordings and email communication for behavioral counseling (36-40). These investigations demonstrated that the Internet appears to be a viable method for the delivery of health services, however further research is needed to validate both cost effectiveness and treatment outcome.

One of the most exciting developments in health care and rehabilitation today is the growing use of telecommunication technologies to provide health information, assessment, and treatment to those individuals with health concerns, particularly those with chronic disabling conditions. This new field of telehealth has vastly expanded over the past decade in the United States, Canada, Europe and Australia with the potential to expand access, increase the quality of health care while proving cost effectiveness (20). Telehealth is beginning to be used as a substitute or alternative method for traditional forms that are providing health information and services. Ongoing research is investigating the efficacy and cost effectiveness of telehealth.

Chronic diseases, such as CVD, are conditions that have to be dealt with on a daily basis for 10 -20 years by the patient. The decreasing mortality trends and increasing hospitalizations for CVD clearly demonstrate that we are not necessarily dying from CVD but we are living with these conditions for many years. These conditions affect an individual's quality of life. Having the ability to access information online to improve general knowledge, answer queries and support general information, benefits individuals who are diagnosed with these chronic conditions. The idea of telehealth in relation to CVD is not to replace current rehabilitation programs but rather to enhance the area of rehabilitation completely by adding another modality. Having accessible and reliable information available through a hotline or online service acts as a reputable resource for individuals who are faced with distance barriers and access to certain health services.

Cardiovascular disease does not discriminate geographically. Knowing that accessibility and availability barriers are a major problem for attendance in CRP, a web based program that is designed to accommodate patients who are at a distance seems only suitable for the next stage in expanding and improving health services in cardiac rehabilitation. Using web based communication offers an opportunity to shift the focus in health care away from the heart centre or hospital and towards the patients' daily lives at home, but little is still known about the impact of using the web in the clinical care of patients with chronic disease (36-40).

1.7 Telehealth and CVD

Implementing a virtual cardiac rehabilitation program (vCRP) that essentially mimics current CRP programs may help to bridge the treatment gap. Providing cardiac care at a distance through interactive Internet communication, patient education, emails and live chats with dynamic components such as heart rate monitoring through infrared uploads and self monitoring BP cuffs will help to deliver health services to those that would otherwise be inaccessible. With the advancement of technology, designing programs dedicated to make use of the features of telehealth can only improve the quality of health care service provision to patients both in urban and rural communities.

Currently there is limited, if any, evidence of any existing online CRP that compares to the unique components of the vCRP study. Of the limited research investigating *interactive* telehealth the majority of studies focus on weight loss/weight management, diabetes management and the CHF management (36-40). In these trials, the website component can be described as *infomediary*, meaning that the website is designed to gather and organize information or data and acts as an intermediary between those who want the information (i.e. health professionals) and those who supply the information (i.e. patients). The trials are more focused towards providing information about behaviour modification, disease management, email communication and educational components. Little, if any, have "virtual real time" communication or monitoring, they are providing more information resources and database platforms then rehabilitative services. (36,37,38). One article introduces a remote CR service that is currently underway

in northern Alberta (38). Nevertheless, this study is again focused more on the patient education of heart disease in rural populations rather then the actual provision of rehabilitation services. There are similarities with respect to patient population, disease presentation, assessments and the rationale of using telehealth for a cost effective tool, however these studies remain unparalleled to the vCRP website used in this study. All in all, the overall outcomes of these trials provide support for the rationale of this pilot investigation to provide the delivery of CR to the patient in the privacy of their own homes.

In 2004 Ralston and colleagues investigated a diabetes support program based on an interactive electronic medical record through qualitative analysis (33). Patients with Type II Diabetes Mellitus participated in an interactive disease management program that included secure email, blood glucose readings, education, online diary and an electronic medical record. A total of 9 patients completed the program and qualitative analysis was conducted to examine the patients' experience with the web-based program. Results indicated that the patient's experiences support further study of open access to online communication and electronic medical records (33).

One clinical trial that evaluated an Internet based case management system for secondary prevention of heart disease found that such a tool could be used as a cost effective intervention for patients with CVD, either independently or in conjunction with traditional cardiac rehabilitation (41). The investigators developed an alternative Internet based program that allowed nurses to provide risk management, education and monitoring services to patients with CVD (41).

Although there were no statistically significant results in the differences between the two groups in terms of BP, lipid levels, depression, minutes of exercise and dietary habits other results indicated that there were fewer cardiovascular events and a gross cost savings of $1418 per patient. The return on the investment was estimated to be 213% (41). Again, this program was more of a monitoring service rather than interactive in comparison to the vCRP. To my knowledge, this is the only clinical trial to examine the effectiveness of using a web-based program for CVD rehabilitation other than the vCRP trial examined in this thesis.

A 'virtual' CRP (vCRP) may also prove beneficial as a tool for long-term follow-up. It could provide a way to help reinforce healthy behaviour practices and avert patients returning to old habits. It could also serve as a self-management monitoring system for patients post rehabilitation. This pilot research and supplementary investigation is intended to provide supporting evidence for online programs targeting CVD to be implemented with the primary goal of decreasing geographic barriers and program accessibility. It is also intended that these findings support web based health delivery services as a means of eliminating hospital visits for acute events, consequently reducing economic health care costs. Telehealth is an innovative means of delivering health care services and compliments current secondary prevention and tertiary care. The anticipated outcome is that the vCRP could essentially *bridge the treatment gap* by bringing health care into the privacy of the patient's home, specifically in those living in remote, urban demographics.

1.8 Rationale

Cardiac rehabilitation is a rapidly expanding field, in the areas of both research and program development (12). Current research trends in this area include the evaluation of new secondary-prevention modalities and alternative program options, such as home-based rehabilitation (12). As an intervention (home/web based rehabilitation), it is efficacious, cost-effective and accepted as an integral component of cardiovascular care. Cardiac rehabiltiation services can provide an integrating structure for secondary prevention efforts (12). For the survivors of CVD, early rehabilitation and risk-management for these individuals is essential to regain function and reduce the risk of a second adverse cardiac event (11,15).

The following two scenarios can highlight the importance of new strategies to improve services to individuals with CVD throughout the province:

- Mr. S lives in Vancouver and requires cardiac surgery performed at St. Paul's Hospital (SPH). Within a week of discharge, he sees his family physician; within 6 weeks, he sees his cardiologist. He also accesses specialized services such as the SPH Healthy Heart Program and Heart Function Clinic and he proceeds with a satisfactory recovery.
- Mr. J lives in Masset, Queen Charlotte Islands and requires cardiac surgery. He is transferred to SPH for surgery and discharged home. Post-operatively he sees his family physician, but there are no cardiologists in the North. In addition, he cannot access the specialized health services in the Vancouver area essential for long-term management. Faced with many challenges, Mr. J is without support and trained professionals to assist him. The likelihood of Mr. J experiencing complications and being re-admitted are high.

These scenarios highlight that CVD does not discriminate by location- *yet there is a geographic inequity of health services in BC.* This geographic inequity

encompasses the spectrum of cardiac services from prevention to intervention, to secondary prevention, and to the management of severe chronic disease.

The Commission of the Future of Healthcare in Canada (Romanow) highlighted telehealth as a way to improve access to healthcare services for rural and remote communities. Canada presents a strong case for telehealth development with a population of approximately 29 million people spread over 9 976 139 square kilometers. One quarter of the population is located in rural areas across Canada and for three of its 13 provinces and territories, over 50% of the population lives in rural areas. Canada also has a varied and harsh climate and a diverse geography. These hardships present a barrier for many to obtain timely access to necessary health services. "Telehealth will benefit patients, rural and urban physicians, and the provincial health care system...it reduces travel and time away from home and work...the main cost savings to the health care system are measured in reduced ...patient hospital days."(36,42).

In the 2003/2004 fiscal year St. Paul's Hospital Heart Centre (SPH) (primary, secondary, tertiary and quaternary services to both rural and urban communities) carried out approximately 5000 specialized CVD related procedures, including over 1,100 open-heart surgeries. Out of 4 B.C. hospitals that provide specialized procedures, St. Paul's Hospital is the "heart centre" of all locations and 40% of procedures are for patients outside of the Vancouver area. In addition, current waiting lists for CR are anywhere from 2 to 5 months with a large majority of visiting patients being limited to accessibility of CRP in suburban

and rural communities. Therefore, providing CR through the WWW may help to reduce these current inequities of care.

Currently there are a limited number of studies investigating telehealth and CVD, the majority of these are educational based with limited monitoring. None of the existing studies investigates using the Internet to deliver an interactive 'virtual' CRP. Therefore, a program to deliver CR at a distance was developed with the vision to serve to those individuals who would benefit but do not have access to a standard outpatient CRP. It was anticipated that the program would:

- Provide direction for safe and effective cardiac rehabilitation for each patient
- Increase the resources available to sub-urban and rural CVD patients and their families
- Increase the overall health outcomes of these patients with CVD above usual care for that area.

The outcomes of the pilot study are expected to provide the foundation for further investigation in the form of a randomized controlled trial involving a larger CVD patient population from more remote areas.

1.9 Hypothesis

The utilization of the WWW to deliver cardiac rehabilitation to a randomized group of patients currently on a CRP waiting list will be safe and

result in clinically significant improvements in exercise capacity as measured in total time.

In addition we expect to observe changes within physical activity participation, dietary composition and self-efficacy between and within both intervention and usual care groups.

1.10 Alternative Hypothesis

The utilization of the WWW to deliver CR to a randomized group of patients currently on a CRP waiting list will be safe but will not result in clinically significant improvements in exercise capacity as measured in total time.

1.11 Objectives

The overall aim of the pilot study was to provide data for the development of future studies in order to improve access and reduce barriers cardiac rehabilitation programs. Specific objectives to this trial included:

- a safe delivery of the vCRP to 7 patients
- detectable changes in exercise capacity following 12 weeks of the vCRP within and between groups
- noted observable trends and changes in physical activity participation, metabolic risk factors, dietary composition and self-efficacy within and between groups
- the use of outcome measures to determine variance of change to power a larger study

2 Study Design

2.1 Patient Recruitment

All St. Paul's Hospital (SPH) cardiac patients are referred to the Healthy Heart Program (HHP) for CR through an automated referral system. These patients are referred from the critical care unit and both surgical and medical wards (5A and 5B) upon discharge. Patients are also referred locally through their general physicians or cardiac specialists for both primary and secondary prevention care services.

The HHP includes an initial multifaceted clinical assessment visit, a 12-16 week program of progressive exercise sessions and a final evaluation before an exit clinic. Upon the initial clinical visit, a cardiologist, nurse, registered dietician and pharmacist assess patients. A history, physical examination, required exercise/stress testing and appropriate blood work are all completed at this time. Based upon the patient's symptoms and test results, an individualized exercise program is prescribed for the patient. Exercise sessions include twice weekly, 75 minute long aerobic exercise sessions utilizing a variety of aerobic and resistance exercise equipment. The exercise sessions are supervised by a registered nurse/case manager and assisted by an exercise specialist and exercise leader. Each exercise session consists of 12-15 patients; presently twelve exercise sessions per week are scheduled with an attendance capacity of

180 patients per week. In addition to the scheduled exercise sessions within the hospital, individualized home exercise programs are designed for each patient based upon their functional capacity, skill level and exercise preferences. Every four weeks patient's responses to dietary counseling, treatment and exercise are reviewed and revised accordingly. In the final weeks of the clinic, patients are re-evaluated with a similar assessment as the initial intake clinic. Upon exiting the clinic, patients are encouraged to either continue their exercise sessions in a community program or at home. Some patients, depending on their progression and reported symptoms are extended in the CRP.

Current incoming referrals for the hospital HHP were reviewed weekly and patients were screened for eligibility. Eligible patients were mailed a general letter of invitation and consent form outlining the pilot research study and requesting their participation (Appendix). Upon acknowledgment of the letter or direct contact with patients, a further assessment was completed over the telephone to ensure that the patient was eligible for an intake assessment. Inclusion and exclusion variables can be reviewed below in Table 1. A patient recruitment flowchart can be seen in the Appendix.

MIdway through recruitment, new methods of obtaining participants were developed due to a slow response rate from patients. This stage of recruitment became more aggressive in order to obtain the other half of the sample population required for study completion and projected time frame. For those mailed letters, a telephone follow up call was conducted one week after the mail

out. The purpose of the telephone call was to follow up with the patients and to provide further explanation of the research study and commitment involved.

In addition to the telephone follow up, we also started to screen patients that were scheduled for intake clinics at the HHP. A letter was attached to the files of those patients that were eligible for the study. The intake staff, including a case manager nurse, dietician and cardiologist determined a patient's eligibility through the intake assessment. At that time, if the patient was interested in participating they would see the cardiologist for a short time and then have the first study assessment that same day.

Table 2.1: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Recent referral to the HHP	Patients with significant co-morbidities that would either limit the effectiveness of the intervention or require them to enter the HHP at an earlier then expected time, or place them at increased medical risk with distance supervision of exercise according to CRP guidelines
No previous experience with CRP	Patients unable to provide informed consent
Residence within 60 km radius of SPH in order to facilitate with initial setup, technical support and communication	Patients, who in the opinion of the investigators have physical or mental disabilities that would limit their ability to utilize a home computer
	Positive exercise stress test **
	Abnormal ECG's ***
	Uncontrolled diabetes

** Positive Stress Test – ST depression > 2 mm indicating positive ischemia, any exercise induced arrhythmia, left bundle branch block, hyper/hypotensive response, chronotropic impairment, symptoms upon exertion, heart block with exercise, functional capacity < 5 METS, any orthopaedic FC.
*** Abnormal ECG – atriofibrillation or atrioflutter, ST depression > 1 mm, left bundle branch block, left ventricular hypertrophy with strain, any heart blocks – except 1°, complex ventricular arrhythmia, ventricular bigemny/trigemny

Eligible patients were then scheduled for an initial study assessment, which was conducted at the HHP. During the initial assessment, the study was outlined and reviewed. Patients were then asked to provide informed consent. Within the assessment, patients also underwent a history profile, resting ECG, BP recordings, resting HR, weight, waist circumference measurement and completed the required study forms (Appendix). Patients were then scheduled for a graded exercise stress test at the Cardiology Lab at SPH and given blood requisitions forms. Each patient underwent a similar assessment upon completion of the study (Appendix)

2.2 Randomization

A total of 16 patients were recruited. Following the baseline assessment and stress test, eligible patients were randomly assigned to either the usual care or intervention through random number generation. The research coordinator (Ms. Amber Zutz) provided an assigned patient identification number to Dr. Scott Lear for randomization purposes. Dr. Lear was blinded to the patient identity while Ms. Zutz was blinded to the patient randomization in efforts to eliminate any bias or patient coercion.

2.3 Usual Care/Control Group

After recruitment and baseline assessment, patients in the control group returned to usual care and continued on the waitlist. Patients who agreed to participate and signed the consent form understood that they would not enter into

the HHP for 12 weeks. With most patients, waitlists are currently 3 months; therefore no additional delay for entry into the St. Paul's Hospital HHP-CRP was anticipated. To avoid any possibility of delay, once randomized, an intake assessment was automatically scheduled for the patients 12 weeks ahead of time in order to avoid any complication with the transition from research to the HHP.

Patients underwent a final assessment at 12 weeks prior to CRP entry for comparison to baseline. All control patients received a Polar Heart Rate monitor at the end of Assessment 2 prior to their entry into the HHP-CRP to show appreciation for their time commitment and participation in the research.

2.4 Intervention Group

Patients randomized to the intervention group (vCRP) received a laptop, HR monitor, BP monitor and other software devices necessary for CR. All patients participated in a computer tutorial session(s) at either SPH or in the privacy of their own home during initial setup. This was to familiarize the patient with the laptop computers, general use of the software and to provide an overview of the virtualheart.ca website. After the training session, patients were set up with their vCRP laptop computer, HR and BP monitors and additional software components. Patients were also assigned personal vCRP e-mail address and allowed free unlimited Internet access for the 12-week period.

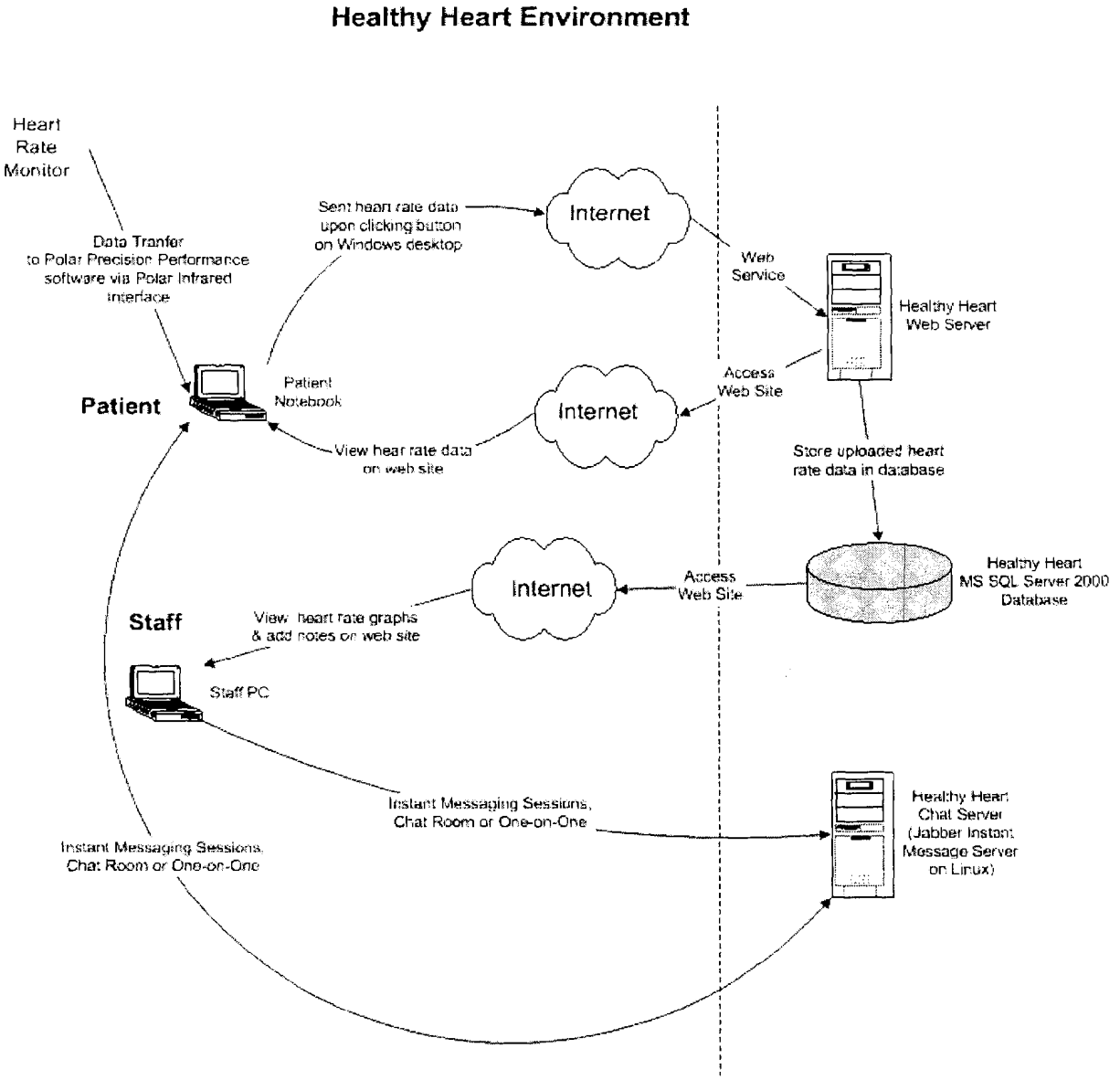
2.5 Virtualheart Website

The website was designed as an interactive, web-based program that essentially mimics the HHP at SPH. It consisted of:

- Videos outlining appropriate HR monitor device operations, dietary advice and angina symptom management
- Risk factor and lifestyle assessment forms
- Individual virtual chats with the nurse, dietician and exercise specialist
- Monthly group chats with cardiac rehabilitation health professionals from the Healthy Heart Program
- Outcome assessments conducted by the nurse-case manager
- Downloadable exercise HR monitoring
- Question of the week education series (with interactive questions and answers)
- Ask-an-Expert chat (scheduled once a month)
- Email access to the nurse case-manager, dietitian, exercise specialist and research staff (tech support) for additional feedback and communication
- Resources page with helpful links and contacts

- Data tracking, comprehensive BP, weight and HR reports

Figure 2.1 Healthy Heart Environment



3 Patient Timeline and Research Responsibilities

3.1 Intervention Group

During Week 1, patients completed an online risk factor, lifestyle assessment and dietary analysis. The online risk factor assessment and lifestyle assessment (Appendix) evaluated current and reported symptoms, medical history, risk factor history, patient medications and provided baseline data. These forms essentially served as a electronic health record for the patient profile, with the addition of progress notes for the vCRP staff to record throughout. Results from the patients' exercise stress test and blood lipid profile were entered onto the website by the appropriate team member and were accessible by staff and patients. The online dietary history assessed the patient's physical measurements (height, weight), 3-day food intake and food frequency. During weeks 1-12 participant were asked twice a week to enter HR data that was taken before and after each exercise session.

Patients received a personal vcrp@telus.net email address that was active during their participation. Patients were informed of scheduled discussion sessions as well as any other necessary communications through email. It was expected that patients check their email a few times per week to schedule weekly chat session with vCRP staff. Throughout the duration of the study, group and

individual chat sessions were scheduled so that patients could discuss cardiovascular health topics with the research team and other patients. The discussions were monitored through rotation between the case manager, exercise specialist and the dietitian (Figure 3). These sessions were pre-scheduled and lasted approximately one hour. Patients were informed of the session prior to the scheduled date and time through the website posting and email. In addition to the private chats and weekly group discussions there was to be an "Ask the Expert" session held once a month. This session was to take the place of a group chat session and last approximately 1 hour in total duration. Again, these talks were rotated through the vCRP team and included discussion topics within their expertise and knowledge. However due to patient activity in the vCRP, these group chats did not occur because of limited online patients at that current time. All transcripts of online chat sessions and emails were saved for future analysis.

Figure 3.1: vCRP Patient Flow

Week	Online Risk Assessment	Online Diet History	Vital Signs#1				Vital Signs#2				Online Private Chat Session with HHP Staff			Week	Online Chat (General)	"Ask An Expert" Chat	Question of the Week
			HR	BP	BS	Wt	HR	BP	BS	Wt	NCM	RD	ES				
1	▲	▲	▲	▲	▲	▲	▲	▲	▲	-	▲	▲	▲	1	▲		▲
2			●	●	●	-	●	●	●	-	●		●	2	●		●
3			●	●	●	-	-	-	-	-	-	●	-	3	●		●
4			●	●	●	●	-	-	-	-	●	-	-	4		●	●
5			-	-	-	-	-	-	-	-	-	-	●	5	●		●
6			-	-	-	-	-	-	-	-	-	●	-	6	●		●
7			-	-	-	-	-	-	-	-	-	-	-	7	●		●
8			●	●	●	●	-	-	-	-	●	-	-	8		●	●
9			-	-	-	-	-	-	-	-	-	-	●	9	●		●
10			-	-	-	-	-	-	-	-	-	-	-	10	●		●
11			-	-	-	-	-	-	-	-	-	-	-	11	●		●
12			●	●	●	●	-	-	-	-	●	●	●	12		●	●

Key: HR: Heart Rate; BP: Blood Pressure; BS: Blood Sugar (*for patients with diabetes*); Wt: Weight, NCM: Nurse Case Manager; RD: Registered Dietitian; ES: Exercise Specialist.

Online Private Chat Session with HHP Staff	Online private chat session with one of the HHP Staff. An email will be sent by the staff member to notify the patient with the possible times when to have the private chat.
Online Group Chat*	A moderated ~2hr chat room, to be held every week on Wednesday at 7pm. Participants are encouraged to join other patients for an open session to discuss topics of interest.
"Ask An Expert" Chat*	An online ~2hr chat session to be held once a month on Wednesday at 7pm (in lieu of the regular Online Group Chat). Participants are encouraged to join other patients and ask HHP staff questions that would appeal to all patients. Check the website for details.
Question of the Week*	Participants are encouraged to participate the weekly learning session. A different learning session will be held each week. There are 12 sessions that rotate each week.

**Note: Online Group Chat, "Ask An Expert", "Question of the Week" sessions are arranged by calendar week independent of when a patient joins the program. For instance, a patient's "Week 1" may correspond to Week 6 for Group Chat and Question of the Week.*

Upon logging into the website, patients were directed to their current active Week with information for the week (chats, uploads, entries). Each week patients were asked to record the pre and post exercise HR and BP data. Patients recorded and entered their HR and BP 2x/week for Week 1-2, 1x/week for Week 3-4, 2x for Week 5-7, 1x/week for Weeks 8 and 12 with the remainder Weeks 9-11 without entries.

Patients were also asked to upload their exercise data files twice weekly, through Weeks 1-12, to the website for the vCRP team to review and monitor. In addition to uploading exercise HR data, patients were also asked to send a brief email on a weekly basis to the exercise specialist outlining the specifics of their exercise logbooks including time, duration, type of activity, intensity and any reported symptoms or concerns.

Patients were also expected to go through a weekly "Question of the Week" flash media slide-show presentation developed by research team members. Each presentation contained informative slides and graphics to discuss various heart health topics including disease, exercise, diet and medications. These were based on the HHP educational sessions. At the end of each presentation there were a few slides with interactive multiple-choice questions that were designed to assess patient's comprehension.

In addition, a resources page was available on virtualheart.ca that had valuable links to various websites and organizations that are dedicated to heart health. Patients were encouraged to use the unlimited Internet access to search

through these recommended resources on the virtualheart.ca to help answer any questions and expand their heart health knowledge. This was also designed with the intentions that patients would actively search for health information to improve knowledge and awareness regarding their conditions and healthy lifestyle management.

After the 12-week intervention patients were interviewed to evaluate their experience with the online vCRP and to gather feedback for future development. The interview consisted of 12 questions designed to conceptualize the overall response to the program (Appendix). The interview questions examined overall patient enjoyment and satisfaction, technical components (user friendliness, chats, software, website design), time commitment, overall health status, self-efficacy and method of delivery of care. Patients were also encouraged to provide constructive feedback that was used as qualitative data for future study.

3.2 Nurse Case Manager

Every 4 weeks patients underwent an online risk factor and lifestyle review that was assessed by the nurse case manager (NCM). The NCM was responsible for initial patient contact and was scheduled for online private chat sessions during Weeks 1,2, 4, 8 and 12. The NCM was primarily responsible for providing professional information and advice about the patient's heart condition and to monitor the course of their condition over the study duration.

In addition, the NCM would review 4 pre/post exercise HR and BP. If the reported BP was in normal limits the patients were required to self-track BP and

report any symptoms. If the BP was not within normal limits two additional BP checks were conducted at the nurse's discretion. If after three checks the BP was still outside of normal limits the NCM asked the patient to continue to record HR and BP and enter the values online for evaluation. If necessary, patients were put on 24 hour monitoring to further assess BP.

3.3 Registered Dietitian

The registered dietitian (RD) worked with patients to discuss initial blood work, BMI and dietary habits. Upon assessment, weight and dietary goals were individually developed for each patient. The online dietary analysis filled out by the patient was evaluated by the RD and used throughout the study for progress review as needed. The RD scheduled private online chats during Weeks 1,3,6 and 12 (Appendix). Upon completion of the study, patients and the RD reviewed final blood work, goals and other variables to continue working on after exit of the virtual CRP.

3.4 Exercise Specialist

The exercise specialist (ES) was responsible for reviewing the stress test results with each patient as well as developing a personal exercise prescription, plan and goals. At the end of each week, the ES reviewed the uploaded HR data and emails from each patient. If there were any serious concerns they were evaluated at that time and discussed with the patient and GP if necessary. The ES evaluated the patients exercise progression weekly. Near completion of the

study the exercise specialist discussed long-term maintenance plans for continued exercise commitment as well as a final exercise prescription and discussion of any participants concerns and questions. The ES scheduled private online chats during Weeks 1,2,5,9 and 12 (Appendix).

4 Methods of Assessment

4.1 Outcomes (primary and secondary)

This study was designed as a pilot to provide the foundation for a larger study. A primary concern of the research project was to ensure the safety of the patients. Measurable outcomes were assessed at baseline and 12 weeks later.

Comparisons were made within and between the intervention and control groups. The change in exercise capacity of the vCRP from baseline to completion of the 12-weeks between the two groups served as the primary outcome. In addition to the primary outcome, secondary outcomes included the changes in exercise capacity, physical activity participation, metabolic risk factors, lipid values, dietary composition, reported self efficacy, heart knowledge and server data from entry into the study to entry into the HHP (within and between randomized groups).

All outcome measures were evaluated with instruments that have been previously validated and are currently used in other studies with CR patients at the HHP.

4.2 Exercise Capacity

Exercise capacity is regularly used as an indicator for overall improvement after 12 weeks of CRP, it is the cornerstone of CR. (12,33,42). It has been an important procedure in cardiovascular medicine and disease diagnosis for decades. Exercise stress testing is an inexpensive and non-invasive tool that provides valuable cardiopulmonary information in healthy and diseased populations (45). It is the gold standard in measuring functional capacity following a cardiac event, throughout rehabilitation, or following any procedure such as post CABG, revascularization (angioplasty) or other cardiac event (45). Exercise capacity increases maximal attainable VO2 max uptake capacity while decreasing risk for exercise induced MI in patients with CVD (12,46). Exercise capacity was determined by a symptom limited treadmill exercise stress test using the Bruce Protocol and reported as the total time in minutes. Test termination was based from the patient exercising to volitional fatigue or self reported symptoms (Appendix).

4.3 Physical Activity Participation

Physical activity participation was measured using the 4 week modified Leisure Time Physical Activity (LTPA) questionnaire and presented as kilocalories per week (46,47). The LTPA was used to measure physical activity and exercise compliance throughout the study. The LPTA requires participants to identify activities that they participated in, based on recall, over the previous four weeks. The questionnaire captures information related to structured exercise

activities (walking, running etc) and less structured physical activities (home repair, gardening etc) (46,47,Appendix). Leisure time physical activity was reported as the average weekly kilocalories (kcal/wk) expended through physical activity and exercise. The questionnaire has been validated through comparisons to measures of exercise capacity and use of accelerometers. (46,47)

4.4 Dietary Assessment

A standardized three-day food questionnaire was used to evaluate diet composition and eating habits. The 3-day food record is considered to be the most practical way of assessing the quality of an individual's diet (44). All participants were asked to complete the 3-day food record over a two weekday and one weekend day at home where all food and drink consumed over this duration was recorded including amounts and preparation. The food record was analyzed by a registered dietitian using Nutritionist IV Diet Analysis software and reported as values of average percent daily kilocalories (kcal) of protein, carbohydrates, total fat, saturated fat and unsaturated fats (44) (Appendix).

4.5 Other Recorded Variables

Screening - Depression Scale

The Center for Epidemiologic Studies Depression Scale (CES-D) was used as a screening tool upon intake only and was recorded as a depression score (48)(Appendix). This was used only as a screening tool to identify patients who may be suffering from a serious psychological condition requiring other

professional intervention. Patients with an score indicating clinical depression were excluded from the study (48).

Heart Rate and Blood Pressure

Two consecutive radial artery HR measures were taken at each assessment. Each HR was taken 2 minutes apart following 5 minutes of seated rest.

Two consecutive readings of BP were measured and recorded 2 minutes apart following 5 minutes of seated rest using a manual sphygmomanometer and reported in mmHg. The appropriate sized adult cuff was used with each individual patient.

Body Mass Index

Body Mass Index (BMI) was calculated from weight (kg) divided by height (m) squared. Weight was measured to the nearest 0.1 kg using a balance scale with participants in street clothing. Patients were instructed to remove any footwear, jackets and over excessive garments including any heavy items on themselves. Height was measured to the nearest 0.5 cm with the participant standing erect in front of an extendible measuring device. Height was only measured at the baseline assessment with that same value being used throughout other assessments for subsequent BMI calculations.

Waist Circumference

Waist circumference was measured directly over the skin (to the nearest 0.1 cm) at the point of maximal narrowing of the trunk as viewed from the

anterior with the patient standing upright (48). This measure was recorded following a normal expiration with the average of two successive measures documented.

Self Efficacy

Self-efficacy was reported as both a general score and an exercise specific self-efficacy score with maximal scores of 48 and 84 respectively based on Likert scoring (50) (Appendix). The general self-efficacy questionnaire assesses an individual's perception of their ability to successfully achieve a range of health-related behaviours (ie. diet, exercise, medications, etc.). The exercise-specific self-efficacy questionnaire assesses an individual's perception of their ability to successfully participate in structured exercise in the presence of various potential barriers (ie. family obligations, social events or weather conditions.) These questionnaires have been modified by Dr. Wolfgang Linden (registered psychologist) of the Department of Psychology, University of British Columbia and have been used in-house for a number of projects (33,50).

Heart Health Knowledge

An in-house questionnaire focusing on factors directly related to cardiac health and rehabilitation assessed the patient's knowledge and understanding of cardiac events and rehabilitation (51)(Appendix).

Laboratory Measures

Blood samples for laboratory measures were collected from patients after a 12-hour fast and 72 hour cessation of alcohol. Blood samples are drawn from either B.C. Bio Medical or MDS labs and sent to SPH laboratory for analysis. The blood analysis includes a fasting glucose (FGS), complete lipid profile (Total Cholesterol, H-LDL, L-LDL, C: HDL ratio, triglycerides) and a homocysteine (Hcy) result.

5 Statistics and Analysis

As this was a pilot study, it was expected that patient numbers would be too low to allow for statistically significant results or appropriate multivariate analysis, however trends were investigated. The overall outcome from the analysis was to investigate the potential of treating patients through a virtual setting. The objectives were designed to provide the experience and data to power a larger randomized controlled trial to support multivariate analysis.

All comparisons were made using an intent-to-treat analysis. Data was analyzed using SPSS 12.0 statistical software and presented as means and standard deviations for continuous variables and descriptive statistics such as percentages and frequencies for categorical variables. Both quantitative and qualitative data outcome analysis was conducted.

Data was analyzed using non-parametric statistics. For dependent paired samples, analysis was performed using the Wilcoxon test. For independent samples the Man Whitney test was performed to compare outcome measures between groups. To test the primary hypothesis, changes in exercise capacity of both groups (intervention and control), including means and difference between means, was analyzed for significance ($p. < 0.05$). As seen in current HHP protocol, an observed change of >10% increase in exercise capacity or improvement of I MET performance was considered to be clinically significant.

Transcribed interviews and scored questionnaires are presented for descriptive purposes to develop an understanding of issues related to accessibility, time commitment, acceptance, use of the Internet, perception of the website and overall effectiveness perceived by patients. Analysis was conducted on the server data, used only for descriptive purposes, to determine and quantify utilization of the website

5.1 Power Analysis

For this pilot study a sample size of convenience (n=16) was used. In addition to the above statistical analysis, results of the study were used to determine population sample size estimates for future investigations. To calculate and estimate sample sizes for future studies we will be using the variance of the observed changes of exercise capacity, blood lipid results, and anthropometric measurements, using a power of 80-90 and an alpha set at .05.

6 Ethics and Confidentiality

Study approval was received from both St. Paul's Hospital Ethics Committee and the Simon Fraser University Ethics Board. All participants have read and signed the informed consent form (Appendix). All patient information is strictly confidential and only available to the research team. All communications through the website was monitored and collected on a confidential server line.

All data obtained throughout the study was stripped of personal identifiers and kept confidential. The data was entered into the database with subjects identified by a unique identifier only. The website was only accessible through personal password protected login identification to prevent any unauthorized access from offsite locations.

7 Results

Between November 2003 and February 2005 a total of 860 patients were screened with a total of 544 men and women who met the study criteria that were invited to participate in the study. Of the 860 patients screened, 22% were ineligible as they had resided out of the set 60 km radius for this research, were current smokers and/or had uncontrolled diabetes. Of the 544 sent letters, 34 responded through telephone contact. However, 18 of those respondents did not meet study inclusion criteria after further assessment. As of February 2005 total patients recruited and randomized into the study was 16. Initially, a total number of 20 patients were to be recruited and enrolled into the vCRP study. Due to the low rate of recruitment and time restraints, which can be attributed to a low response rate, stringent inclusion criteria and screening process (CRP automatic referral and limited telephone follow up due to pilot study protocol), recruitment was ended after the 16^{th} patient was randomized. Possible reasons for the low response rate to the recruitment letters include: failure to return contact after receiving the initial consent form, location, incorrect address (moved), upcoming intake appointments in CRP program and/or lack of interest.

Of the 16 patients initially recruited, 2 patients in the usual care (UC) group did not complete the study, patient 1 withdrew immediately after completion of the baseline assessment due to personal reasons (this patient was

removed prior to analysis) and patient 2 was unavailable for contact after several attempts were made for the exit assessment, after following up, this patient also did not participate in the St. Paul's Hospital CRP program.

As seen in Table 10.1 of baseline descriptives, the gender distribution between subjects was 5M: 2F randomized into the UC group and 7M: 1F into the intervention (IV) group. A mean age of 58 years was seen within both groups. Table 10.1 outlines disease presentation, current medications, menopausal status for female patients and baseline data. There were no significant differences between the usual care and intervention group for age, gender, medications or disease presentation. However there were significant clinical differences noted for lipid results, fasting glucose, GXT time and workload (METs), level of current physical activity and difference in disease presentation and some medications.

Table 7.1: Baseline Patient Descriptives

	Usual Care (n=7)	Intervention (n=8)
Male Female	5 2	7 1
Age	58.5 ± 12.34	57.8 ± 4.04
Disease Presentation		
Initial MI	29 %	38%
PTCA	57%	13%
Other Diagnostic	0%	25%
CABG	50%	14%
High Risk	14%	13%
Diabetes Mellitus	14%	13%
Medications		
Lipid Lowering	80%	100%
Beta Blockers	80%	75%
ACE Inhibitors	20%	62%
ASA	100%	83%
Hypoglycaemic	33%	0%
Nitrates	40%	13%

	Usual Care (n=7)	Intervention (n=8)
Diuretics	0%	13%
Cardiac Glycosides	40%	13%
Angiotensin II Receptor	0%	13%
Ca + Blocker	0%	13%
Menopausal Status (% women)	50%	100%
Total cholesterol (mmol/L)	4.00 ± 0.97	3.80 ± 0.68
LDL-C (mmol/L)	2.31 ± 0.79	3.08 ± 0.55
HDL-C (mmol/L)	1.06 ± 0.35	1.09 ± 0.44
Triglycerides (mmol/L)	1.37 ± 0.64	1.33 ± 0.48
TC/HDL-C	4.31 ± 1.82	3.86 ± 1.41
Homocysteine	11.25 ± 5.75	9.45 ± 1.31
Fasting Glucose	6.63 ± 1.77	5.39 ± 0.74
Weight (kg)	78.3 ± 7.52	78.3 ± 9.11
Height (cm)	168 ± 7	173 ± 6
Waist Circumference (cm)	92.0 ± 9.05	87.0 ± 1.88
BMI	28 ± 3	26± 4
Resting HR 1	71 ± 8	66 ± 10
Resting HR 2	69 ± 4	65 ± 10
Avg SBP1 (mmHg)	120 ± 7	123± 14
Avg DBP1 (mmHg)	76 ± 7	81 ± 10
Exercise Capacity (minutes)	8:16 ± 2:34	11:07 ± 3:55
Max HR	146. ± 25	143 ± 30
RPP	18702 ± 4486	19025 ± 4468
Workload (METs)	10 ± 3	11± 3
Self Efficacy 1 (General) Self Efficacy 2 (Exercise)	42.2 ± 5.8 61.8 ± 10.8	43 ± 3.3 68.5 ± 6.2
LPTA (kcal/wk)	2386 ± 2207	987 ± 351
Knowledge Questionnaire (30)	25 ± 5	26 ± 2

**For definition of abbreviations please see Table in Prefix Section

Tables 10.2, 10.3 and 10.4 outline actual patient logins that were compared against the expected number of login times (Table 10.2), completion of weekly tasks (Table 10.3) and HR upload compliance for the vCRP (Table 10.4) The expected patient logins were calculated based upon weekly task completion, HR uploads, scheduled chat sessions and online chart filling from Week 1.

The average number of logins for patients was 50, which accounted for >100% above the expected 43 logins. The majority of patients (75%) completed greater than 50% of their required weekly tasks throughout the 12 weeks. Fifty percent of the patients were compliant with their HR uploads.

Table 7.2 Patient Login Reports

Patient ID	Number of Logins	Patient Logins compared to Expected Login (43 logins)
ID26	86	200 %
ID27	55	130 %
ID28	73	170 %
ID29	28	65 %
ID31	48	116 %
ID32	27	63 %
ID33	26	60 %
ID36	57	133 %
Average Logins	50	116 %

Table 7.3: Patient Completion of Weekly Tasks

Patient ID	Weekly Input	% of Completion
ID26	1,1,2,2,3,4,8,12	100 %
ID27	1,1,2,2,3,4,8	87.5 %
ID28	1,1,2,2,3,4,8,12	100 %
ID29	1,2,2,3,4	62.5 %
ID31	2,2,3,4,8,12	75 %
ID32	1,3,12	37.5 %
ID33	1	12.5 %
ID36	2,2,3,4	50 %

Table 7.4: Patient Heart Rate Upload Compliancy

Patient ID	HR File Uploads (minimum 24)	% of Upload Compliance
ID26	24	100%
ID27	9	37.5
ID28	31	129%
ID29	28	116%
ID31	24	100%
ID32	7	30%
ID33	3	12.5%
ID36	6	25%

There were no significant findings within or between groups reported mean change values for the primary outcome improvement in patient exercise capacity (UC 36 second, IV 94 second). However, there were findings that indicated individual changes and clinical relevance when compared to current CRP outcomes. There was an improvement in both groups with exercise stress test performance with the intervention group improving by 2.9 METs (58 second improvement beyond the UC) from baseline (Table 10.5). The UC group also improved however it was less than 1 MET change in overall time and not considered clinically significant. It was also noted that there was a greater improvement in the intervention group with the exercise stress test sub-values, these included max HR (+ 12 bpm), rate pressure product and workload. Trends that can be noted included overall group improvements and clinical relevance within the observed changes for the IV group.

Table 7.5: Exercise Stress Test Results Baseline and Exit

	Usual Care (n=5)		Intervention (n=8)	
	Baseline	Exit	Baseline	Exit
Exercise Capacity (min)	8:50 ± 2:24	9:26 ± 2:10	11:07 ± 3:55	12:41 ± 3:35
Max HR	150 ± 25	147 ± 22	143 ± 29	155 ± 13
RPP	18442 ± 4965	20525 ± 3093	19025 ± 4678	21614 ± 4527
Workload (METs)	10.5 ± 2.5	11.0 ± 2.0	11.0 ± 3.0	13.9± 4.0 **

** P value < 0.05 (within group significance)

The secondary outcomes that were measured included anthropometrics, metabolic (lipids) and behavioural components, respectively represented in Tables 10.6, 10.7 and 10.8. In Table 10.6 we can see that there was weight loss in both groups, there were no significant findings between group changes were

indicated. It can be noted that the IV group had a greater change (2 cm) in waist circumference and resting HR (8 bpm) when compared to the UC.

Table 7.6: Anthropometrics Baseline & Exit

	Usual Care (n=5)		Intervention (n=8)	
	Baseline	Exit	Baseline	Exit
Weight (kg)	78.34 ± 8.41	76.51 ± 10.51	78.31 ± 9.11	76.63 ± 9.34
Waist Circumference (cm)	88.8 ± 5.1	88.8± 9.2	86.7± 1.9	84.7 ± 6.4
BMI	28.14 ± 3.08	27.48 ± 3.54	26.14 ± 3.66	25.76 ± 2.36
Resting HR 1	70 ± 8	64 ± 4	66 ± 10	58 ± 8
Resting HR 2	69 ± 5	66 ± 6	65 ± 10	58 ± 10
Avg SBP (mmHg)	121 ± 8	117± 8	123 ± 14	127 ± 27
Avg DBP (mmHg)	75 ± 8	71 ± 7	81 ± 10	80 ± 12

Table 10.7 outlines the baseline and exit lipid values between usual care and intervention patients. There were no significant findings found between the groups. Significant findings within the intervention group only included the lipid values for HDL-C (p. <0.025), TG (p. < 0.012) and TC/HDL-C ratio (p. < 0.012). These findings are also consistent with current CRP clinical outcomes.

Table 7.7: Lipid Measurements: Baseline and Exit

	Usual Care (n=5)		Intervention (n=8)	
	Baseline	Exit	Baseline	Exit
Total cholesterol (mmol/L)	4.13 ± 1.02	4.01 ± 0.37	3.80 ± 0.68	3.52 ± 0.56
LDL-C (mmol/L)	2.44 ± 0.80	2.20 ± 0.41	2.08 ± 0.55	1.82 ± 0.34
HDL-C (mmol/L)	1.05 ± 0.40	1.15 ± 0.25	1.09 ± 0.44	1.22 ±0.43**
Triglycerides (mmol/L)	1.38 ± 0.73	1.36 ± 0.83	1.33 ± 0.48	0.83± 0.18 **
TC/HDL-C	4.58 ± 1.90	3.62 ± 1.00	3.86 ± 1.41	3.06 ± 0.98**
Homocysteine (Hcy)	11.73 (n=3)	8.51 ± 2.05	9.44 ± 1.31	8.25 ± 2.11
Fasting Glucose	6.68 ± 1.97	5.94 ± 0.78	5.39 ± 0.74	5.71 ± 0.88

** P value < 0.05 (within group significance)

In table 10.8 the questionnaire assessment data shows no significant findings between groups and no significant findings within the UC group. It was

noted that the IV group had a substantial increase in their recorded physical activity (LTPA), increasing five times by the recorded baseline value. This improvement in physical activity participation is considered to be a clinically relevant. There were significant improvements found for reported self- efficacy (p. <0.018) and physical activity participation (p. < 0.018) within the IV groups. Both groups improved in all questionnaire data, but neither showed significance.

Table 7.8: Questionnaires: Baseline and Exit

	Usual Care n=5		Intervention n=8	
	Baseline	Exit	Baseline	Exit
Self Efficacy 1 (general) Self Efficacy 2 (exercise)	42.2 ± 5.8 61.8 ± 10.8	43.2 ± 3.8 69.2 ± 6.7	43 ± 3.3 68.5 ± 6.2	44.3 ± 3.1 73.1 ± 5.2**
LTPA	2386 ± 2207	2444 ± 4176	987 ± 351	5111 ± 4839**
Knowledge Questionnaire	26 ± 2	29 ± 2	25.5± 2.5	27 ± 1.5

** P value < 0.05 (within group significance)

Table 10.9 reports patients' medication use throughout the study duration. There was no reported change in medications from baseline to exit.

Table 7.9: Patient Changes in Medication

	Usual Care Baseline		Intervention Exit	
Lipid Lowering Drugs	87.5%	87.5%	57%	57%
Beta Blockers	62.5%	62.5%	71%	71%
ACE Inhibitors	62.5%	62.5%	28.5%	28.5%
ASA	87.5%	87.5%	28.5%	28.5%

	Usual Care Baseline		Intervention Exit	
Hypoglycaemic	0%	0%	28.5%	28.5%
Nitrates	12.5%	12.5%	0%	0%
Diuretics	12.5%	12.5%	0%	0%
Cardiac Glycosides	12.5%	12.5%	0%	0%
Angiotension II Receptor Antagonists	12.5%	12.5%	0%	0%
Ca + Blocker	12.5%	12.5%	0%	0%

Table 10.10 outlines the IV group responses from their final exit interview. These interviews were conducted to evaluate the overall effectiveness of the program. Interview responses were generally positive with respect to overall acceptance of the program. Patients found the program enjoyable, rewarding, user-friendly and beneficial to their recovery. From patient feedback, the most effective components of the vCRP included the collective interactive components (62.5%), ability to view personal records (53%) and the scheduled chat sessions (50%). The components of the program that were reported to require the most improvement included the server connection (75%) which can be related to the 37.5% response to improve the interactive component, as those who had connection problems experienced uploading problems as well.

Table 7.10: Intervention Group Final Interview Responses

Categorical Questions	IV Group Responses (n=8)
Overall Enjoyment	100%
Health Improvement	100%
Website – User Friendly	87.5 %
Best Component	

Education Professional chats Interactive components Website design Personal records	37.5% 50% 62.5% 25% 53%
Weak Component Education Professional/group chats Interactive components Website/server connection	12.5% 12.5% 37.5% 75%
Beneficial Chat Sessions	100%
Suggested Improvements Website Server connection Program Delivery	 25% 25% 50%
Reasonable Time Commitment	100%
Participate again?	100%
Patient Benefit	100%
Heart Health Improvement	100%
Overall confidence	100%

8 Discussion

Despite the known benefits of structured CRP, many patients fail to attend. Accessibility to such CRP is a primary barrier to patient participation. If we look at cardiac disease as a three step process where a patient undergoes: 1) diagnosis 2) treatment and rehabilitation and 3) lifestyle management, we are essentially putting up a blockade for some to complete the process. Many patients undergo treatment options and are then limited to access to care to educate and rehabilitate into the next CR phase of lifestyle management. The vCRP research project is the first to our knowledge to investigate the provision of CR at a distance through using the Internet as the delivery modality.

Safety of the patients was the number one concern as the study population had diagnosed cardiac disease and had been recently referred for medically supervised exercise. Although rate of coronary events in rehabilitation settings are significantly low it was still important for us to provide a safe environment with symptom monitoring to assure no problems during remote treatment (52). Safety concerns included a possible increased risk with exercise (from home) without direct monitoring. To address this issue, we had a established criteria for inclusion into the study, which included a final 'consent to participate' by one of the HHP cardiologists after evaluating the patient's stress test results. In addition to the cardiologist approval we also monitored patient's

symptoms during exercise, along with the HR and BP recordings. By having these metabolic measurements and patient reported symptoms we were able to flag any problems that arose during the study. Throughout the duration of the study there were no reported incidents of any patient problems that occurred with exercising from home with remote monitoring. Any symptoms that were reported were evaluated and addressed by the exercise specialist and/or nurse case manager with individual exercise prescription changes.

8.1 Primary Outcomes

The primary outcomes was to a change in exercise capacity, as assessed by total time on Bruce protocol treadmill test, following 12 weeks of vCRP within and between groups. An improvement of greater then 1 MET in performance on patient's exercise stress test was considered to be a significant improvement from a clinical perspective as accepted by both HHP cardiologists and exercise specialist. Exercise capacity was chosen as the primary outcome because it has been previously demonstrated to improve consistently with CR (52).

Exercise capacity is a known prognostic factor with CVD patients. It is well established that exercise capacity and activity status help to predict cardiovascular and overall mortality (53,54,55). It is a helpful clinical tool that is inexpensive and diagnostically relevant as it provides information for exercise prescription and rehabilitation. Cardiac rehabilitation has significant effects on exercise tolerance, symptoms and coronary events. After a full CRP exercising training at an intensity of 70-85 percent of maximal heart rate, exercise tolerance

increases by 30-50%, peak oxygen consumption by 15-20%, HDL levels improve by 8-23%, and overall TC: HDL-C ratio increases 5-26% (52). Patients also reported a decrease in symptoms.

Exercise stress tests showed no significant improvements between (p value < 0.49) or within groups. From baseline to exit, the intervention group exercise performance was better than that of the UC group. This was demonstrated by an increase in exercise capacity of 58 second, equivalent to 1 MET, in total time at the exit performance (IV $p < 0.063$ and UC $p < 0.068$). Within group significance was noted for the workload in the IV only ($p. < 0.012$) indicating that these patients significantly improved their exercise capacity over the 12 weeks of the vCRP (Baseline 11 METS to Exit 13.9 METS). This improvement of > 1 MET in the IV group is considered clinically significant.

8.2 Secondary Outcomes

Secondary outcomes were physical activity participation, self-efficacy, anthropometric measurements, metabolic (lipid) values and dietary composition. Our results indicated there were no significant findings between groups for lipid profile, anthropometric measurements or group lifestyle measures. There were minimal nutrition summaries returned upon exit and it was not statistically evaluated.

There were significant findings within the intervention group from baseline to exit for changes in lipid values (HDL-C $p < 0.025$; TG $p < 0.012$ and TC: HDL-C ratio $p < 0.012$). This demonstrates that even within a small population we

observed improvements in patients' lipid profiles during the 12- week intervention. As medications within the intervention group did not change from baseline to exit the change in lipids can be attributed to lifestyle changes.

Significant findings were also noted within the intervention group with decreases in resting HR from baseline to exit ($p. < 0.018$) improvement in self-efficacy ($p. < 0.018$) and level of physical activity participation ($p. <0.018$). This increase in self-efficacy and physical activity participation is seen in a similar study from Delgado et al when investigating a remote based program for cardiovascular patients (18). Resuts from Delgado et al showed significant differences at three months with a noted increase in level of self-efficacy, relationships with friends and family and level of physical activity (18). Although the quality of life scores did not achieve statistical significance there was a trend towards improvements in self-efficacy, physical activity, heart health knowledge and overall patient satisfaction (18). Conclusions from Deglado indicated that internet-based communication is a feasible tool for the management of heart failure patients, providing an effective medium for health care professionals to interact with their patients with an overall improvement of patient quality of care and quality of life (18).

There were no significant findings within the usual care group, which help to support the hypothesis that a 12-week virtual program is beneficial to patients waiting for cardiac rehabilitation.

8.3 Patient Interviews

Patient feedback that we received during the exit interviews was noteworthy. Each patient described in detail their own personal experience with the vCRP program and communication with the staff. Overall the analysis between the chat programs and staff interaction indicated a general acceptance and benefit from the scheduled chat sessions. Aside from the technical difficulties with the HR uploading software, the novel concept was generally accepted and found useful by the patient as they felt more 'self managed' and in control of their exercise. This allowed for patients to keep track of their exercise regimens, eating habits and overall lifestyle habits which in turn allowed them to see where necessary changes and recommendations were coming from with the staff chats.

Of all 8 IV patients interviewed, 100 % agreed that they would participate in something like this again if ever encountered with another cardiac event. Individuals made lifestyle changes and individual improvements from the 12-week intervention including weight loss, improved heart and lifestyle knowledge; improved diet; improved self-efficacy; and motivation towards a healthier life style. Some positive patient comments included:

- **Patient 1:** *"the nutrition portion was extremely valuable and a constant reminder of what you should and should not be doing. That also gave just more incentive to continue with the program and continue to go down this road of a changed lifestyle and all physiotherapy sessions were extremely useful as well. Things occurred from day to day and week to week and they could be very easily answered in the chat sessions."*
- **Patient 2:** *"I think everything was great. The uploading of the HR was pretty easy.. that was pretty good. Being able to look at that chart*

after, gives you a visual aspect of what you have entered of the blood pressure and additional exercise information. The resources, I went in and read a lot of them and that were actually quite informative. The questions of the week, I found, were very good informative."

- **Patient 3***: "I think that the 12-week program was really good because I could do it at my own timings using my own home gym and monitor everything my way with the polar equipment monitor situation where you can actually see the graph and see the progression of your heart rate and against the timeline really helps create goals. I felt that really, really useful being able to just see your own blood pressure and do all that and correlate and put all the data together and see how it works before and after an exercise program, which was great too. The issues that I had with it that, I believe, it needs to be more easily accessible from where ever you are."*

8.4 Staff Interviews

The vCRP was widely accepted by staff, There were a few suggestions for future improvements. The staff were excited to participate in such an innovative program and felt that there would be many benefits to the patients. There were some concerns with technical difficulties and patient adherence, but the majority of the staff feedback indicated a positive experience between the staff and patient. The technical suggestions for improvement were directed towards having a stable server connection and consistent HR uploads from patients.

A steep learning curve for the staff members was expected, depending on computer experience and willingness to experiment with a remote virtual web based program staff members were provided with additional support with the vCRP. When asked if this type of health care service should be implemented to offer CRP to out of town patients, the staff was in 100% agreement that it would be beneficial and worthwhile. Staff expressed concerns about time issues if the

patient flow were to be larger. Given such a scenario it would be realistic to have a specialized team that would be involved and dedicated with providing this specific service of care.

- *"It would be great to be able to offer vCRP to patients outside of the lower mainland without access to Cardiac Rehab. The technical difficulties will need some work, obviously, but I think the communication and education opportunities are very helpful. This is definitely a useful tool!"*

- *"Technical difficulties aside, some patients did benefit from this program. As with general outpatient cardiac rehabilitation, it is not suitable for everyone, but there will always be some who benefit. I was able to detect an arrhythmia in one patient that was consistent with his exercise symptoms just from reading the HR upload graphs. I have never come across any such finding before, through HR monitoring, in the outpatient based HHP to this date!! A unique first time finding that was useful to adjust exercise prescription accordingly and continue with the program successfully."*

8.5 Adherence and Usability of the Website

We used observational analysis to investigate the overall usability of the website and patient adherence. Since this is the first study to look at a specific 12 week CRP program including the dynamics of HR uploads and chat sessions, reporting the patient usage, determined by he number of total logins, is a good measure of adherence to the program. The expected time commitment for the 12 week program was not extensive; it was more a matter of familiarizing oneself with the website and the components. Therefore it was expected that the within the first few weeks there would be a steep learning curve.

In Table 10.2 we can see the patient logins varied from lack of access to an abundance of logins which could either indicate that the patient did adhere to

the weekly commitments in phases or that they were logging into the computer to gain additional information. It was calculated that the average patient login for the 12-week duration would be approximately 43 times. This number was calculated by using minimal logins expected to complete weekly tasks, this included 2 logins per week for uploading information (24 logins), 17 logins for scheduled chats with vCRP staff and 2 additional logins during Week One for patient history and assessment forms.

When comparing actual patient logins to the expected logins we see a wide range in the frequency of program use of 60-200%. When patient ID's were matched and evaluated, the patients recording > 100% expected login commitments were the patients that showed the most improvement through the 12-week intervention. It was also observed in the interview that these same patients had expressed their gratitude for the great care and professional advice they had received from vCRP staff. The patients with lower adherence (< 70% of expected) were the patients that had difficulties with the program commitments. Even though several tutorials and one on one advice was given with regards to logins, chats and HR uploads some patients seemed to have difficulty with the technical portion and commitment. Methods to overcome these commitment difficulties could include weekly follow up and email reminders to patients, 24-hour technical support line and a more in depth tutorial upon set up. When further investigated, two of the three patients with lower logins had reportedly withdrew from the follow up 12- week CRP at the HHP, while the third patient never attended classes.

Table 10.3 demonstrates the expected weekly commitment from patients. This input included risk factor analysis, patient history reports, scheduled chat sessions and bi-weekly uploads of HR data. In total, patients should have completed 16 tasks over the vCRP duration (2 x 8 specific weeks). There was a wide range of completion seen with patient input. Only two patients had 100% completion of weekly tasks, 3 patients had greater then 60% completion and the remaining 3 patients with < 50% task completion. This result may be indicative of technical problems with the HR uploads that we experienced throughout the program and possible inconveniences due to server connections. We experienced several technical problems. The server connection and support from the host environment had the most effect. In the initial stages of the study there were several times where we could not establish a connection due to programming error and host server error (server disconnection during weekly 'backup' from the provider, disregard of server re-connection after upgrades; and year transition programming problems (ie. 2004 to 2005)). With these technical problems it was not always possible for the HR uploads to be completed bi-weekly. Many patients had to upload information 5-10 files at a time due to programming error or unstable server connection. It was noted that lag times for uploads ranged from 3 minutes to the upward of 20 minutes. Therefore, it was sometimes seen to disconnect before successfully uploading data files to the website. Table 10.4 outlines specific HR uploads and patient compliance. We can clearly see that only 3 particular patients had problems with fulfilling the completion of uploading their HR information. Again, these are the repeated

patients that had general adherence issues with the 12- week vCRP commitment initially. In retrospect, the uploading of information was difficult to track as some patients would upload single HR components and others would upload weekly which would include 2 or more exercise files with each. Therefore there was some duplication of HR uploads along with additional exercise sessions.

As reported in Table 10.3, patients with ID 32, 33 and 36 had reported low completion with minimal weekly input. This possibly suggests that the patients were non-compliant to the program. Interviews with these patients suggest that HR problems and busy schedules may have hindered their participation in the program due to affected motivation levels. Patient ID 33 was unable to adhere to the HR upload and BP recordings, in addition to attending scheduled chat sessions. The lack of adherence of ID 33 is thought to be due to motivation, scheduling and health status at that time. Coincidently, with follow up it was seen that these three patients did not attend the Healthy Heart CRP at St. Paul's Hospital, which could possibly reflect an overall low compliance (i.e. they may be unlikely to attend any program).

From these tables we can speculate that patient compliance varies within this sub population. Reasons for compliance can likely be attributed to: lack of interest, lack of motivation, technical ability and general health. For patients with low adherence it is most likely that these patients would demonstrate similar traits given an outpatient CRP. It is possible that patient perception and experience with the vCRP was negative, which transferred to the HHP, however

interview feedback tends to provide evidence that this is an unlikely reason for adherence.

For interest purposes and further analysis concerning adherence issues, a random sample of originally screened patients (n=58) was selected to gauge attendance from the initial referral to the HHP. Using an onsite patient database program we were able to determine that 38% of those randomly selected did attend the HHP with a successful completion while 7% that began attending the program but did not successfully finish. The remaining 54% did not attend the HHP. This reported lack of attendance (54%) portrays potential adherence issues and provides possible explanations to the initial low response rate and troubles with recruitment. Low response rate and recruitment difficulties could possibly be attributed to the known fact that only 10-25% of eligible patients actually participate in CRP and that there maybe have been some initial apprehension regarding a computer based CR program.

8.6 Noted Trends

There are limited studies that investigate a home-based rehabilitation program using exercise capacity as a significant outcome. Many of the current technology based studies are looking at more qualitative information and trends that are seen with differences in populations specific to diabetes management, weight management and heart failure patients.

Many observed trends were reported in this pilot study allowing us to speculate possible outcomes with a larger randomized trial. Being a pilot study

we are dealing with low numbers, which essentially makes it difficult to obtain significant findings or differences within groups. There were several values that came close to our p value of < 0.5 that we speculate would have been significant given a larger sample size.

Noted trends in the primary and secondary outcomes that indicated favourable outcomes of the vCRP study. Within the intervention group we saw notable trends with patient waist circumference and exercise capacity (p value < 0.091 and p. < 0.063). A change was noted within the usual care group as well for exercise capacity (p. < 0.068) however the intervention group showed slightly more improvement. Two of the eight patients in the IV group improved so considerably that the original intended 12 week CRP program at the HHP was not necessary upon cardiologist review.

Given a larger sample size these numbers would likely demonstrate more significant changes both within group and between groups for exercise capacity, lipid profiles and lifestyle management. See section 11.9 for power calculation.

There were additional trends that showed clinical significance including a change in both waist circumference (decrease 1.69 cm, p < 0.09 exercise capacity (increase 58 sec in total time, p< 0.063), workload (from 11-13.9 METS) and lipid values (TC decreased 0.28 mmol/L, LDL decreased 0.26 mmol/L, TG decreased 0.50 mmol/L and TC: HDL-C ratio decrease 0.96 mmol/L) seen in the intervention group. The usual care lipid values had slightly decreased values from baseline to exit, however they were not as clinically significant as the

intervention group. There was a non-significant change seen in total time of the usual care group of 32 seconds ($p < 0.068$).

These reported clinically significant values for lipid changes and exercise capacity for the IV group are similar to the changes that we see in patients who have gone through a face to face cardiac rehabilitation program. Using the Extensive Lifestyle Management Intervention (ELMI) trial for comparable values, the changes we see in current CRP include an increase in exercise capacity (> 1 MET), increase in HDL (0.06 mmol/L), decrease in LDL (0.19 mmol/L) and overall decrease in TC: HDL ratio (0.31 mmol/L) (Lear et al. 2001). When compared to vCRP results for the intervention we see similar, if not greater, clinically significant improvements for the same outcome measures. With this comparison, it is safe to believe that the results of the vCRP are similar to the outcomes seen in current CR intervention with a bricks and mortar face to face programs.

In addition to notable trends seen in outcome measures, it also appears that the vCRP may be more suitable for a specific cohort. It appears that the patients who had greater benefit with the vCRP were between 47-52 years of age, currently employed (some with required travelling) technically inclined and also motivated by their current health concerns. It is possible that the vCRP might appeal to the lower end age range of cardiac patients that are referred for rehabilitation. With the greying population and an upcoming highly computer orientated generation, it is possible that patients entering CRP in future years would choose an Internet based program over a traditional face to face CRP.

8.7 Limitations of research

Identified limitations of the study include participation, computer attitudes and skills of patients, computer knowledge and motivation towards telehealth and computer mediated services. While this was not a requirement of the study, we recognize some people did not respond due to being intimidated by computers.

There were many technical problems that were encountered in the initial stages of the study. With our first patient starting in December 2003 we started to experience problems with the web server with the change of the year into 2004. After investigation the problem was rectified within 3 weeks, however we experienced the same problem the following year with the transition from 2004-2005 year. This was easily corrected with some simple reprogramming into the patient laptops. These problems affected not only the patients and their computer access, but also the staff with their access to patient files and uploaded information. Other technical problems that were experienced included difficulties in uploading HR information, periodic times with limited or no access to servers, unstable connection to the chat server for scheduled chats and access to the saved chat conversations. Most issues seemed to relate back to programming errors or downtimes from the server connection and were overcome through technical support from both the vCRP and service provider.

There was an anticipated learning curve for the staff and patients involved in this project; however it seemed that in some patients their desire or motivation was minimal with respect to learning the technical portion of the expected weekly

tasks leading to incomplete data uploads upon exit. There were several scheduled visits for both staff and patient training to try to accommodate for this learning curve in addition to technical support information available on the website itself. It was observed that most patients were able to push through the first couple weeks to learn how to use the new software however, there were two patients that made little attempts resulting in low login reports, low task completion and overall lower outcome results of improvement. As a novel design, these technical hitches provide useful feedback for future design of virtual programs. It would be essential to include user-friendly software and additional scheduled patient tutorials to make the program easier to use and eliminate unnecessary frustrations.

Another notable reason for no significant outcomes between the groups might be attributed to differences in the patient population at baseline. Randomization eliminates any bias that may occur between the groups. However, at baseline the intervention group had an overall higher exercise stress test time when compared to the usual care. While most cardiac patients present with baseline stress test performance averaging 8 minutes, the intervention group in this study had an average value of 11 minutes at baseline. There was minimal room for significant improvement considering that 15 minutes performance time on a stress test is usually indicative of athletic condition. With small number, randomization (such as this pilot study) is less likely to result in a matched group. However, if we have a larger sample size we can speculate that

it might turn out to be a more even representation of the population with limited bias in the group assignment.

Given these aforementioned limitations, it was the main objective of the pilot study to provide the experience and data for the design of a larger randomized controlled trial to support full statistical analysis. With the results of this study, we can develop power models for further development and investigation including a larger patient population (sample size) and increased geographical distance.

8.8 Supporting Evidence

To my knowledge, throughout the duration of the research there were no new studies that investigated a CRP at a distance with such specific components as the vCRP. There are several existing telehealth initiatives that have been identified as alternative health service delivery methods for rural patients; however there is little information in the literature about outcomes or further development after initial pilots.

Of existing Internet based trials, the main focus has been on weight loss and diabetes management. Within these trials most outcome measures indicated no significant findings. Womble et al. (38) investigated a commercial Internet weight loss program in 47 women over a 1-year period of time. Outcome measures included weight loss, metabolic measures, behaviour adherence and quality of life. Patients were randomly assigned to one of two groups: a web based program membership for one year or a weight loss manual. Overall

findings did not reach significance in cardiovascular risk factors or quality of life. In comparison to the vCRP this study had limited "interactive" components available to subjects. The intervention in this study was conducted through a non-interactive web based program. There was minimal live interaction between the patient and staff, and most communication was through email and generated response messages. The conclusions from Womble et al. support our general conclusions as well in that the findings suggest that successful Internet interventions incorporate practice – record keeping, personalized feedback and accountability (38).

Another study investigating a weight loss program via the Internet examined changes in subjects (n=91) who were randomly assigned to a 6 month weight loss program through one of delivery methods, Inter-education or Internet behaviour therapy (39). Significant findings included a greater weight loss in the behaviour group vs. the education group ($p < 0.005$) and changes in waist circumference ($p > 0.001$). The findings and conclusions in this study are also supportive of our overall conclusions in that structured treatment programs delivered through the Internet with weekly contact and individualized feedback proved to have better outcomes vs. a non-interactive delivery. Tate et al. also studied this effect in Type II Diabetics with respect to an Internet program vs. a combined Internet program with behaviour counselling. As with the findings of the other weight loss trials, more weight loss occurred in the behavioural counselling group compared to basic Internet intervention alone (39).

Other supporting evidence of remote monitoring is found with Delgado's clinical study investigating an interactive Internet site for managing CHF patients (18). Although Delgado had a small sample (n=16), outcomes indicated that an interactive Internet based communication is a feasible tool for management in CHF patients by providing an effective means of interaction between professionals and patients, ultimately improving patient quality of care and quality of life. Home telemonitoring of cardiac patients with severe congestive heart failure have been shown to be well-accepted in this population, and to produce cost savings from decreased health care utilization (56,57)

One clinical trial investigating the use of an internet-based case management system for secondary prevention of heart disease demonstrates similar design components and outcomes to our pilot study (42). To my knowledge, this is the one and only clinical trial investigating cardiac disease and remote monitoring services. Southard et al evaluated an alternative internet-based program provided to patients in an effort to broaden access to CR. The Internet based program was based on risk factor management and education and monitoring services for patients with CVD. The clinical trial involved 104 patients randomised to usual care or intervention groups over a 6-month duration. Results indicated fewer cardiac events amoung the intervention group, a cost savings per patient and program. Similar variables were used for analysis including BP, lipid levels, depression scores, minutes of exercise and dietary habits. Southard concluded that such an Internet based management system could be used as a cost effective intervention to patients either independently or

in conjunction with traditional CR (42). Although this study provides great insight into cost effectiveness of a remote intervention there were several limitations including limited interactive components, validity of the instruments used to assess exercise and dietary habits and a small study sample that may not be representative of the general population of individuals with coronary heart disease (42).

The findings of another study that provided an internet based rehabilitation program for patients (n=16) with COPD suggest that these programs can help to increase access to information and resources for COPD while encouraging day to day management through activities of daily living, improved self efficacy, increased perception of support and improved exercise behaviour (53). This study in comparison to the vCRP has many similarities in both design and analysis. These similarities include a weekly education session, individualized exercise prescription, patient self-monitoring, live chat sessions and the additional provision of support (53). This is the only study to date that has comparable patient interaction. As with the vCRP, the absence of significant differences between groups may be due to limited sample size.

Collectively these findings suggest that these programs demonstrate opportunity to promote self-management in patients with COPD, CVD or other chronic disease. The conclusions of those studies are consistent with the overall conclusions of the vCRP; and help to reveal that in order to achieve a useful telehealth intervention program it is necessary to have essential components that together contribute to effective outcomes. While a static website may provide

information it is speculated that telehealth programs with patient feedback and interactive components, may result in greater improvements in patient behaviour, delivery of care and outcome measures.

8.9 Power Calculation Sample

Since this was a novel concept and pilot design a sample size of convenience was used. From the results of the pilot study we can use the variance of the outcomes to determine an appropriate sample size for a larger study to have an outcome with clinically significant results.

Using the pooled data information and variance of change, Table 11.8.1 shows the estimated sample size from power calculations using the variance of change in exercise capacity, TC: HDL-C ratio for lipid outcomes and BMI for anthropometrics. Collectively these demonstrate effective sample sizes that are practical for possible future studies. All power calculations were computed using a Power and Sample Size Calculation Software program for independent t-test sample size estimates using *a priori* < .05 and a power of .80.

Table 8.1: Estimated Power Sample Sizes

Variable	Observed Change (btw. Groups)	Variance of Change (n=13)	Sample Size (p. <0.05)
Exercise Capacity (seconds)	+58**	± 77	29
TC: HDL-C ratio (mmol)	-.16**	± .29	53
BMI	-.39**	± 1.14	135

** + and – indicate noted increase or decrease in value

9 Conclusions

Based on the findings of this pilot study, several conclusions can be stated.

1) All safety issues were addressed. All patients participated in the vCRP without any reported incidents, risks or concerns.

2) Trends observed from the vCRP demonstrated clinically significant results that are consistent to current outpatient program such as the HHP, indicating the vCRP results comparable to current outcomes after a regular 12 week CRP.

3) Patients in the IV group with higher levels of adherence found the vCRP beneficial, user friendly and an enjoyable option for CR.

4) There was no reported decline in health within the usual care group throughout study duration (which essentially acted as a mimic for the current waitlists to access such programs as the Healthy Heart)

5) There were significant improvements found within the Intervention Group for the metabolic risk factors, exercise capacity (MET level) and self efficacy

6) The chat program and other technical components proved to be user friendly and enjoyable to both the patient and staff.

7) Patients agreed that if offered again they would prefer a virtual program versus an outpatient program due to convenience and time scheduling. From a staff perspective, it was agreed by all participating staff that this vCRP is a useful tool to provide to patients in addition to the current CRP program.

8) Overall outcomes were comparable to current supporting evidence within the literature for similar Internet based studies

Speculations can be made into exercise capacity and lipid profile improvement within the intervention group. Given the trends demonstrated in the vCRP a sample size of 29 participants per group would be needed to show significant differences between groups from. As previously discussed, with the observed clinical significance in the IV group measures, the vCRP is consistent with current CRP outcomes.

Cardiovascular disease is largely preventable through lifestyle modification, education and increased awareness. The feasibility of using the Internet as a communication/rehabilitation tool as part of a conventional multidisciplinary CRP has large potential. It is a viable method of improving communication between patient and health care providers while also extending services to remote areas that currently no disease management programs. We have the scientific knowledge to create a world in which most CVD and stroke could be eliminated. Implications for action to improve CVD and prevent further

disease include the use of outpatient services, therapy and rehabilitation programs, increased education and awareness and the development of more cost effective programs in the community.

Whatever the reasons are for poor referral and attendance at CRP's, it is imperative to improve patient access to rehabilitation programs through initiatives such as home-based management, online/virtual rehabilitation programs to assure that all those who may benefit from cardiac rehabilitation interventions have the opportunity to do so. By targeting large barriers such as accessibility, both patients in both rural and urban locations will have comparable opportunities for available health services. Cardiac rehabilitation programs play a significant role in enhancing recovery following a primary cardiac event and in encouraging behaviour aimed at secondary prevention of CVD (15).

Lessons from other telehealth implementation projects identify telehealth initiatives, both in B.C. and worldwide, as an alternative health service delivery for rural patient. B.C. has several advantages in moving in this direction of Internet based telehealth strategies including high computer ownership with Internet access in addition to the overall availability of high-speed Internet access.

With the advances in technology and delivery of health services there is endless opportunity to increase the accessibility and efficiency of healthcare through the using telehealth approaches. Once an Internet based program model is established there will be many stages of advancement for improving quality of

care, access to care and provision of care that is available through the WWW. This pilot study is only a stepping-stone to providing any empirical evidence to support the effectiveness of telehealth interventions. Telehealth is the wave of the future and offers tremendous promise to improvements in health care; this virtual program development will not only be directed at cardiac care, but to other chronic disease that can be managed through a virtual based setting.

With the growing burden of heart disease and stroke in North America and worldwide, climbing obesity rates, and the increasing incidence of the metabolic syndrome the question that remains is overall benefit. Isn't it better for a patient to be offered a remote service rather then being offered nothing at all after the onset of cardiac disease?

10 Future Directions

Based on the outcomes of this study and feedback (patient and staff), future investigation into a remote CRP is necessary. It is proposed that with further investigation and implementation of a vCRP program both patients and healthcare professionals a trend indicating significant improvements in this delivery of care will provide a *stepping stone* for developing a successful web based CRP that can be implemented. Improving access to programs through a virtual setting could potentially result in increased knowledge, increased motivation for patients to play an active role in disease management, enhanced health outcomes, improved quality of life and social support. In addition to the patient improvements, we would also expect to see reduced long- term costs to the healthcare system.

Specific developmental improvements to the website could also contribute to the success of a remote program. These developments would include an adequate speed connection/server access with limited interruptions, guided tutorials to help patients with novel software and hardware, accessible help line for trouble shooting, a patient notes section to record any exercise information, symptoms or concerns and a weekly email reminder to update patient on chat appointments and expected weekly tasks.

This pilot work confirms the feasibility of conducting a research study to support intervention through the Internet. It leaves us with the question of what steps or components are necessary to take us towards further investigation or implementation of the program. There are several key factors that would play a crucial role in the actual implementation of the program. Realistically it would need to be a feasible progression and development of the website. Using this pilot as a reference, a larger study could be designed that would target more rural settings and delivery of CR. In British Columbia there is an active initiative in place for development plans to bring broadband connections into communities currently not connected. This initiative in place to provide equal opportunity to rural communities in order to help improve communications, education and information to help to conquer the knowledge gap and essentially bridge the digital divide. With over 70% of British Columbians accessing the Internet daily, it sees feasible to provide such a delivery of service (25,29).

In retrospect, a matched cohort would be more appropriate. Other recommendations for a future study would include establishing a consistent safe and secure connection, trained staff, larger sample size, recruitment changes (outside of automatic referral), technical troubleshooting, patient log books and online symptom management to mention a few. Using preliminary telehealth study results to help with future direction would be an asset.

It is expected that in conjunction with the current telehealth information we have, future studies will help to pave the path towards implementation. The possibilities are endless with where such a program could lead us in the future.

Ultimately, it is thought that this program will provide a template for the implementation and development of chronic disease management tools available through the WWW. With some work, by providing such programs, noting the current challenges and necessary modifications, we can *"bridge the current treatment gap"* that exists with patients that have limited access to rehabilitation and disease management programs.

Appendices

Appendix 1: Forms

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Providence HEALTH CARE
St. Paul's Hospital

HEALTHY HEART
Healthy Heart Program

St Paul's Hospital, B180-1081 Burrard Street, Vancouver, BC V6Z 1Y6
• Phone: 604-806-8591 • Fax: 604-806-8590
• Web: www.healthyheart.org
Medical Director, HHP: Andrew Ignaszewski, MD, FRCP(C)

Utilization of the World Wide Web to deliver cardiac rehabilitation at a distance

INVESTIGATORS:

Dr. Joanna Bates	822-8067
Dr. Andrew Ignaszewski	806-8591
Dr. Scott Lear	682-2344 ext. 62778
Ms. Amber Zutz (Primary Contact)	806-8608

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

Purpose

The purpose of this research is to evaluate a web-based program called Virtualheart that we hope will help provide cardiac rehabilitation for people who do not have access to these hospital-based programs. We hope that this will lead to: modification of cardiac risk factors and lifestyle behaviours, and improved quality of life. We also hope to learn from your experiences with Virtualheart in order to further develop the program.

What is the Virtualheart Web Site?

The Virtualheart web site is an interactive, web-based program that consists of:

- Videos outlining appropriate exercise routines, dietary advice and angina symptom management.
- Live chat with the nurse, dietitian and exercise specialist.
- Monthly, live, email chat with cardiac rehabilitation health professionals from the Healthy Heart Program.
- Outcome assessments conducted by the nurse case-manager.

- Chat-group discussion for participants. This will be monitored by the nurse case-manager, who will only participate at his/her discretion.
- Downloadable exercise heart rate monitoring.
- Question of the week education series.
- Email access to the nurse case-manager for additional feedback.

What does your participation involve?

If you decide to participate, you will undergo an initial screening exam and an exercise stress test for safety assessment conducted by a research assistant and also asked to see your family physician for additional screening. If you meet the safety requirements, then you will be randomly assigned to one of two groups: 1. An intervention group that will be provided access to the virtualheart web site for 12 weeks, or 2. A control group that will undergo observation for the 12 week period. This study will take place prior to your entry into the Healthy Heart Program cardiac rehabilitation program **and may postpone your entry to the Healthy Heart Program depending on the current wait list (usually 1 to 3 months). Upon completion of the 12 week study, you will immediately enter the Healthy Heart Program with no wait.**
During the study we would like you to participate in three outcome assessments to be conducted upon starting the study (the safety screening exam), after 12 weeks and when you finish the Healthy Heart Program. These outcome assessments will consist of an exercise stress test, and psychosocial and lifestyle questionnaires. These assessments should take no longer than 2 hours each and are standard procedures for those participating in cardiac rehabilitation.

Intervention Group

If you are assigned to the intervention group, you will be provided instruction on how to access the Virtualheart web site, its features, and general instruction on the use of a computer (if necessary). You will then be provided with a home computer and free unlimited Internet access with which to access the Virtualheart web site. This will be set up in your home by one of our technical staff. If you already have a home computer, we ask that you only access the Virtualheart web site using the computer we provide. You will then be able to access the Virtualheart web site at your leisure and participate in the interactive sessions. From time to time your nurse case-manager may send you emails or contact you by telephone to let you know of upcoming interactive sessions, discuss your progress or if necessary, discuss why you have not accessed the Virtualheart web site. While the amount of time spent per week accessing the Virtualheart web site will be up to you, we anticipate that 1 to 3 hours of access per week will be adequate to participate in the all of the Virtualheart web site's activities. Your family physician and your cardiologist will be notified about your participation in this project if you agree to participate.Once you have started exercise classes at the Healthy Heart Program, our technical staff will arrange to come to your home and return the computer. In addition, we would like to get your input about the

Virtualheart web site and the Healthy Heart Program through a one on one interview upon starting and completing the Healthy Heart Program, each of these should last no more than one hour.

Control Group

If you are assigned to the control group, **you will receive written materials regarding management of heart disease as well as resource information.** We ask that you attend only the assessments outlined above (total time 2 hours each assessment for three assessments). Upon completion of the 12 week observation period, we will give you a heart rate monitor to thank you for your participation.

How will we protect your confidentiality?

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

What are the costs of participation?

The costs of participation are limited to those associated with traveling to and from St. Paul's Hospital to participate in the study assessments. You will not be reimbursed or compensated for your participation.

What are the benefits of participation?

While not everyone may benefit from this study, we expect that most **intervention** participants will benefit from the additional monitoring performed throughout the study and the use of a home computer for the duration of the study.

What are the risks of participation?

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

If you have any questions about your rights as a research subject you may contact the Director of Research Services, University of British Columbia at (604) 822-8598, or Dr. Steve Shalansky, Chair - UBC/Providence Health Care Research Ethics Board, St. Paul's' Hospital (604) 682-2344 ext. 62325.

Authorization: I,_____, have read the above information and I have had an opportunity to ask questions to help me understand what my participation would involve. I freely consent to participate in the study and acknowledge receipt of a copy of the consent form. I also understand that I may refuse to participate in the study or withdraw from the study AT ANY TIME. My refusal to participate or withdraw from the study will not affect my medical care at St. Paul's Hospital or Providence Health.

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

Yes_____ No___

_____ _____

Date:_____

participant's signature name (please print)

_____ _____

Date:_____

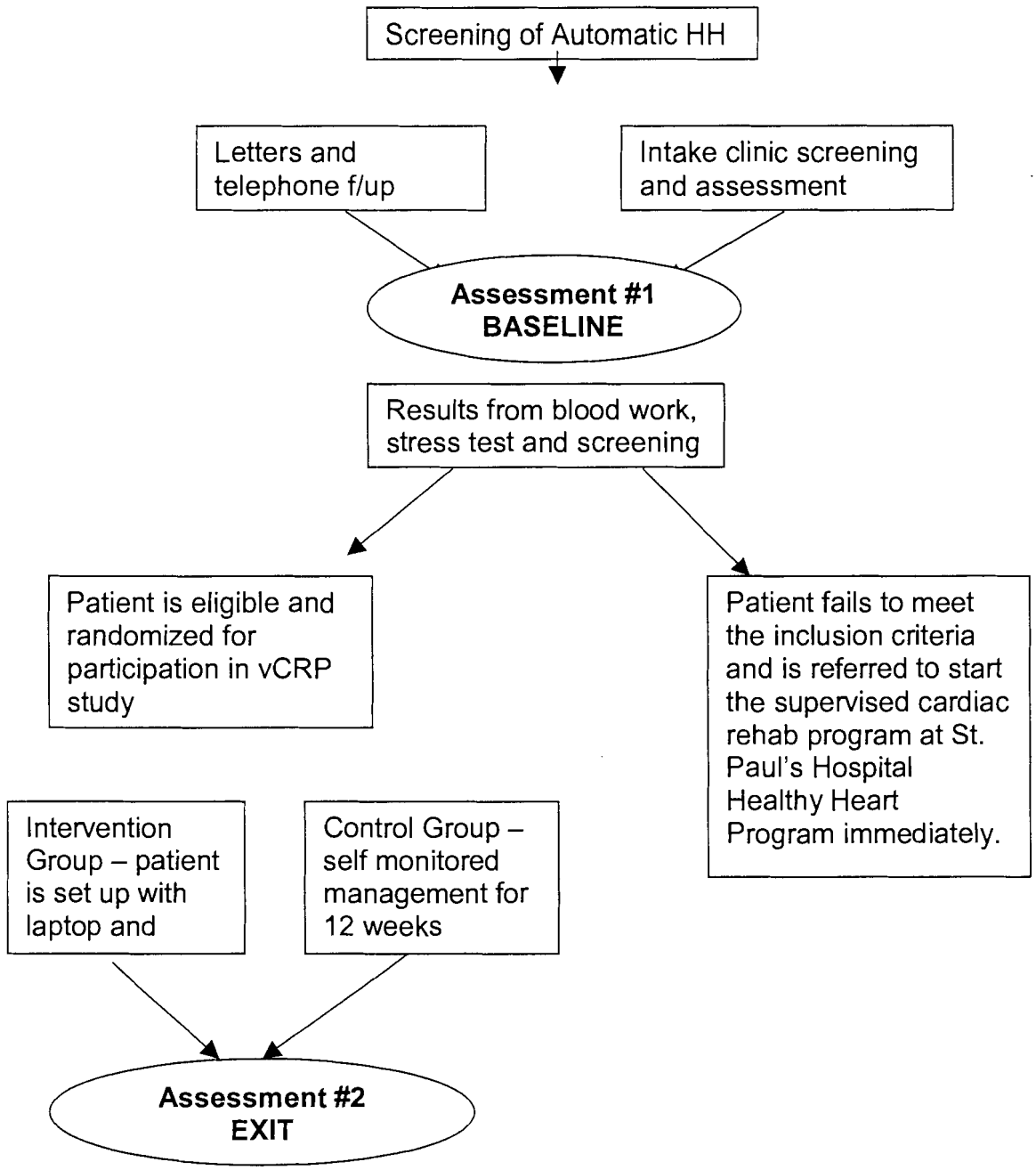
witness' signature name (please print)

_____ _____

Date:_____

principal investigator's signature name (please print)

Appendix 2: VCRP Recruitment Flowchart



Appendix 3: Assessment Descriptions

Assessment Visit #1 (pre vCRP /pre CRP)

- Signed consent form
- Patient history including demographics, medications, reason for referral, current symptoms etc.
- Patient height (cm) and weight (kg) – calculated BMI
- Patient HR and BP readings (2 trials)
- Patient waist circumference
- Self Efficacy Questionnaire
- Depression Scaled Questionnaire
- In House Heart Knowledge Questionnaire
- Stress test requisition
- Blood work requisition
- 3 day dietary analysis
- Internet questionnaire (Leah's social component)
- Lifestyle and Physical Activity Questionnaire

Assessment Visit #2 (post vCRP, pre CRP)

- Basic Anthropometric measurements – BP, HR, height, weight and waist circumference
- Self Efficacy Questionnaire
- In House Heart Knowledge Questionnaire
- 3 day dietary analysis
- Lifestyle and Physical Activity Questionnaire
- ALL Patients undergo INTAKE clinic for Healthy Heart Program (stress test, dietitian, bloodwork etc)
-

Intervention Patients ONLY

- 30 minute interview pertaining to virtual Cardiac Rehabilitation Program

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Medical Director, HHP: Andrew Ignaszewski, MD, FRCP(C)

Utilization of the World Wide Web to deliver cardiac rehabilitation at a distance

3-Day Food Intake Record

Name _____ Study _____

Birthdate _____ Height _____ Weight _____

Please call Scott Lear at 682-2344 (62778) for any questions or concerns.

Instructions

Please complete the following food intake record.

- Record what you have eaten for 3 consecutive days using 2 week days and 1 weekend day.
- Record all food and beverages consumed each day.
- Include all snacks eaten throughout the day.
- Include the amount of butter, margarine, oil, mayonnaise, salad dressings, sauces, etc., you have used in preparing the food.
- Estimate food portion sizes as accurately as possible.

Sample descriptions		
Orange juice, unsweetened		½ cup
Tuna	whole wheat bread	2 slices
	water packed tuna	½ cup
	light mayonnaise	1 Tbsp
	soft margarine	2 Tsp
Salad:	lettuce	1 cup
	tomato	1/2
	cucumber	3 slices
	Italian dressing	1 Tbsp

DAY 1	Date		
For Office Use Only Code Quantity	Time of Day	Type of Food include preparation method (ie: boiled, fried, baked)	Amount of Food Consumed

DAY 2	Date		
For Office Use Only Code Quantity	Time of Day	Type of Food include preparation method (ie: boiled, fried, baked)	Amount of Food Consumed

DAY 3	Date		
For Office Use Only Code Quantity	Time of Day	Type of Food include preparation method (ie: boiled, fried, baked)	Amount of Food Consumed

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Utilization of the World Wide Web to deliver cardiac rehabilitation at a distance

This is a questionnaire to assess your recent participation in physical activity. Please check only those activities that you have participated in during the last 4 weeks. If you have any questions please contact Scott Lear at 682-2344 (62778).

		Check each week in which you performed the activity.						
Activity	**Check those activities that you have done in the past 4 weeks.**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Average times/ week**	**Average Duration (min)**	**MET Values**
Section A: Walking and miscellaneous.								
Walking for Pleasure (slowly)								
Walking to and from work								
Walking during work break								
Stairs when elevator available								
Cross country hiking								
Backpacking								
Mountain climbing								
Bicycling (work/pleasure)								
Dancing (ballroom/square)								
Section B: Conditioning Exercise.								
Home exercise								
Health club								
Jogging and walking (briskly)								
Running								
Weight lifting								
Section C: Water Activities.								
Water skiing								
Sailing								
Canoeing/rowing (pleasure)								
Canoeing/rowing (competition)								
Canoeing (camping)								
Swimming (>50' pool)								

		Check each week in which you performed the activity.						
Activity	**Check those activities that you have done in the past 4 weeks.**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Average times/ week**	**Average Duration (min)**	**MET Values**
Swimming (beach)								
Scuba diving								
Snorkeling								
Section D: Winter Activities.								
Snow skiing (downhill)								
Snow skiing (x-country)								
Ice/roller skating								
Tobogganing								
Section E: Sports.								
Bowling								
Volleyball								
Table tennis								
Tennis (singles)								
Tennis (doubles)								
Softball								
Badminton								
Paddle ball								
Racketball								
Basketball (non-game)								
Basketball (game)								
Basketball (officiating)								
Touch football								
Handball								
Squash								
Soccer								
Golf (riding cart)								
Golf (walking with clubs on cart)								
Golf (walking carrying clubs)								
Section F: Lawn and Garden Activities.								
Mowing lawn (riding mower)								
Mowing lawn (power mower)								
Mowing lawn (push mower)								
Weeding and cultivating garden								
Digging/filling/spading garden								
Raking lawn								

		Check each week in which you performed the activity.						
Activity	**Check those activities that you have done in the past 4 weeks.**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Average times/ week**	**Average Duration (min)**	**MET Values**
Snow shovelling by hand								
Section G: Home Repair.								
Carpentry (power tools/workshop)								
Paint/wallpaper/waxing/plumbing								
Carpentry/fences/porch (outside)								
Painting/windows/drains (outside)								
Section H: Fishing and Hunting.								
Fishing from river bank								
Fishing wading in river								
Hunting (birds)								
Hunting (small game)								
Hunting (large game)								
Section I: Other Activities.								
Other 1								
Other 2								

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• Web: www.healthyheart.org
Medical Director, HHP: Andrew Ignaszewski, MD, FRCP(C)
Academic Director, HHP: Jiri Frohlich, MD, FRCP(C)
Program Coordinator: Sandra Barr, RN

Utilization of the World Wide Web to deliver cardiac rehabilitation at a distance

This questionnaire assesses how confident you are in making healthy lifestyle changes. Please answer the following questions as accurately as possible by circling one of the four numbers below such that '1' means 'Not at all true' and '4' means 'Very much true'. If you have any questions please contact Scott Lear at 682-2344 local 62778.

	Not at all true	Barely true	Moderately true	Very much true
1. If I intend to take up a healthy diet, I know that I can stick to it.	1	2	3	4
2. When I understand why a medication is needed, I know that I will take it as instructed.	1	2	3	4
3. I doubt that I can manage to really carry through with a low fat, healthy diet.	1	2	3	4
4. Often I am unable to organize my day so that I can take all my pills on time.	1	2	3	4
5. I usually can't resist the temptation of delicious but unhealthy food.	1	2	3	4
6. Often I am unable to find the patience necessary for cooking a healthy meal.	1	2	3	4
7. I often get confused about how to take my medication.	1	2	3	4
8. I know for sure that I can stick to my medication routine.	1	2	3	4
9. I know for sure that I can stick to a	1	2	3	4

	Not at all true	Barely true	Moderately true	Very much true
healthy diet when I really want to.				
10. Often I don't succeed to take the time necessary for buying fresh, healthy groceries.	1	2	3	4
11. I doubt that I can take all my medications exactly when and how I am supposed to take them.	1	2	3	4
12. I know for sure that I can take all my prescribed medication at the right times.	1	2	3	4

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

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

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HEALTHY HEART
Healthy Heart Program

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Utilization of the World Wide Web to deliver
cardiac rehabilitation at a distance

Heart Knowledge Questionnaire

TRUE/FALSE

1. High blood cholesterol is one of the risk factors for heart disease that you can do something about.
2. To lower your blood cholesterol level you should eat less saturated fat, total fat, and cholesterol, and lose weight if you are overweight.
3. Lowering blood cholesterol levels can help people who have already had a heart attack.
4. The risk factors for heart disease that you *can do something about* are: high blood pressure, high blood cholesterol, smoking, obesity, and physical inactivity.
5. Exercise programs do not require a lot of time to be very effective
6. Most people get enough physical activity from their normal daily routine.

MULTIPLE CHOICE

1. What is the best way to treat and control high blood pressure?

   a.) control your weight and exercise
   b.) eat less salt (sodium) and restrict intake of alcohol
   c.) blood pressure medication
   d.) all of the above

2. Women are:
   a.) both less likely to have a heart attack than men and less likely to survive a heart attack than men
   b.) more likely to have a heart attack than men
   c.) less likely to survive a heart attack than men
   d.) less likely to have a heart attack than men

3. When it comes to LDL and HDL cholesterol, it is best:
   a.) to have low LDL levels and high HDL levels
   b.) to have equal levels of each
   c.) to have low HDL levels and high LDL levels
   d.) to completely eliminate both

4. Which of the following drugs is *not* used to treat high blood pressure?
   a.) antibiotics
   b.) diuretics
   c.) beta blockers
   d.) vasodilators

5. How long does it take before your body experiences "true" physiological changes in response to training?
   a) 1-2 weeks
   b) after one exercise session
   c) 6 months
   d) 4-6 weeks

6. The coronary arteries are the blood vessels that supply oxygen-rich blood to the heart. Which of the following best describes Coronary Artery Disease (CAD)?

   a.) a chronic disease in which the coronary arteries have hardened and narrowed, leaving less room for blood to flow through
   b.) a chronic disease in which the coronary arteries have gradually shortened overtime, so that they no longer reach the heart
   c.) a chronic disease in which fatty cholesterol has softened the coronary arteries, causing chest pain.
   d.) A chronic disease in which high-fat foods have eroded the coronary arteries so that blood is leaking from them and causing chest pain.

7. What percentage of people with heart disease experience no symptoms at all?
   a.) 100%
   b.) 50-60%
   c.) 20-30%
   d.) 0%

8. Which of the following cooking oils contains the least amount of saturated fat?
   a.) canola oil
   b.) coconut oil
   c.) corn oil
   d.) cottonseed oil

9. According to FDA rules for nutritional claims, which of the following is true?
   a.) a "calorie free" food must contain 0 calories per serving
   b.) a "fat free" food much contain 0 grams of fat per serving
   c.) both of the above
   d.) none of the above

10. The body requires about half a gram of sodium (salt) per day. But how much sodium does that average person consume per day?
   a.) six times what the body requires (3 grams)
   b.) ten times what the body requires (5 grams)
   c.) fourteen times what the body requires (7 grams)
   d.) eighteen times what the body requires (9 grams)

11. Angina is a primary symptom of which of the following conditions?
   a.) diabetes
   b.) coronary artery disease
   c.) high blood pressure
   d.) anemia

12. Physical exercise can help prevent or further heart disease by:
   a) reversing the process of atherosclerosis
   b) lowering blood pressure
   c) reducing cholesterol levels
   d) reducing levels of stress and depressions
   e) all of the above

13. Which of the following is not a healthy blood cholesterol level?
   a.) total cholesterol of 180
   b.) LDL cholesterol level of 30
   c.) HDL cholesterol level of 30
   d.) None of the above

14. Exercise can help you do which of the following?
   a.) lower LDL cholesterol
   b.) raise HDL cholesterol
   c.) lower triglycerides
   d.) all of the above

15. What proportion of cardiac rehabilitation participants complete their program?
    a) about 25%
    b) about 50%
    c) about 75%
    d) less then 25%

16. The pain of a heart attack can be:
    a) a crushing pain int he centre of the chest
    b) a pain that radiates down the arm, up in to the jaw, or into the back
    c) not a pain but a feeling of discomfort or pressure
    d) none of the above
    e) all of the above

17. Atherosclerosis is referred to as:
    a) hardening of the arteries
    b) the buildup of plaque on the walls of your blood vessels
    c) a heart attack
    d) high blood pressure
    e) both a and b

18. Infarction is a medical term meaning:
    a) lack of oxygen
    b) a localized area of dead tissue
    c) low blood pressure
    d) high blood pressure

19. An aneurysm is:
    a) a balloon-like swelling of a blood vessel
    b) the narrowing of a blood vessel by plaque
    c) a blood clot
    d) a heart attack

20. A thrombus is:
    a) a baloon-like swelling of a blood vessel
    b) the narrowing of a blood vessel by plaque
    c) a blood clot
    d) heart attack

21. Angioplasty refers to:
    a) the plastic tubing used to make catheters
    b) a non-surgial procedure for widening narrowed blood vessells
    c) a surgical procedure for opening narrowed arteries in the heart
    d) use of a gene therapy to make the heart grow new blood vessels

22. Doctors sometimes refer to bypass surgery on the heart as CABG. What does CABG stand for?
    a) Coronary Arteriosclerosis Bypassing
    b) Cardiac Atherosclerosis Bypass Grafting
    c) Cardiac Artery Bypass Grafting
    d) Coronary Artery Bypass Graft (or Grafting)

23. Chest pain caused by heart disease is referred to as angina pectoris or angina. Why does angina occur?
    a) the heart muscle is not getting enough blood
    b) the natural pacemaker of the heart is not functioning correctly
    c) the brain is sending the wrong signals to the heart
    d) it remains unknown

24. Which of the following is not considered a risk factor for heart disease?
    a) high blood pressure
    b) obesity
    c) diabetes
    d) low triglyceride levels

23. Before you exercise, a warm-up is essential. An appropriate warm-up would be:
    A. Hopping on the spot for 3-5 minutes.
    B. A stretching routine for the major muscles of the body.
    C. 10 minutes of light or easy exercise combined with range of motion activities for the major muscles of the body.
    D. 3 minutes of calisthenics.

24. The purpose of a 'cool-down' is:
    A. to bring the heart rate and blood pressure back to a restful state in a gradual fashion.
    B. To avoid blood pooling in the legs following moderate to somewhat hard exercise.
    C. To help clear away lactic acid (produced by the muscles as a result of fatigue) so your muscles are less likely to be stiff or sore following exercise.
    D. All of the above.

25. During exercise how would you know if you are over-training (over doing it)?
    A.. You are able to breathe and exercise in a comfortable, yet challenged manner.
    B. Your muscles begin to feel a burning sensation but you can tolerate it and continue.
    C. You begin to feel discomfort in the chest accompanied by shortness of breath.
    D. You are sweating and your face appears flushed.

26. Choose the most appropriate activity to combat the 'risk factors' for heart disease.
    A. Walking a minimum of 30 minutes, and as much as 60 minutes 3-6 times a week.
    B. 18 holes of golf
    C. Climbing 12 flights of stairs every other day.
    D. Mowing the lawn and cleaning the garden.

27. Regular exercise is a proven strategy to reduce the risk factors for developing heart disease and can help prevent further cardiac events by:
    A. increasing your HDL cholesterol (good cholesterol)
    B. relieving stress
    C. controlling both blood sugars and weight
    D. all of the above

28. Choose the exercise program that you will derive the most health benefits from.
    A. 3 days a week you go to the community center where you participate in an hour long Yoga class. The other days of the week you walk a small dog for approximately 20 minutes each day.
    B. 4 days a week you walk for 30-40 minutes in the evening. 3 days a week you attend a community center where you ride the stationary bike and walk on the treadmill for 15-20 minutes each. You then spend 15 minutes on strength training with hand held and machines weights.

Providence HEALTH CARE
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IV Group Final Interview

1. Overall, how did you enjoy participating in the 12 week vCRP program?
2. Do you think this program helped you to improve your cardiac health?
3. Did you feel the website and HR upload components were user-friendly?
4. What component of the website did you enjoy the most?
5. What component of the website did you enjoy the least?
6. How did you like the scheduled chat sessions? (private and conference)
7. How could we improve this type of delivery for cardiac care, or other chronic diseases, in the future?
8. How was the time commitment level? Do you think expectations were too demanding?
9. Would you participate in something like this again?
10. Do you feel like your benefited from this pilot program? If so, how? (weight loss, dietary changes, feeling better?)
11. Has this increased your interest in heart health – lifestyle management etc?
12. How do you feel about making changes to your diet, exercise and lifestyle now that you have had cardiac intervention? (motivation? Confidence in ability to make change?)

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