

**REMOTE MANAGEMENT OF CHRONIC HEART FAILURE
PATIENTS USING INTERNET SUPPORTED
TECHNOLOGY**

by

Biljana Maric
B.H.K., University of British Columbia 2005

THESIS SUBMITTED IN PARTIAL FULFILLMENT OF
THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

In the
School of Kinesiology

© Biljana Maric 2008

SIMON FRASER UNIVERSITY

Fall 2008

All rights reserved. This work may not be
reproduced in whole or in part, by photocopy
or other means, without permission of the author.

APPROVAL

Name: **Biljana Maric**
Degree: **Master of Science**
Title of Thesis: **Remote Management of Chronic Heart Failure Patients
Using Internet Supported Technology**

Examining Committee:

Chair: **Dr. S. Robinovitch**
Associate Professor, Kinesiology, SFU

Dr. S. Lear
Senior Supervisor
Associate Professor, Kinesiology, SFU

Dr. G. Tibbits
Supervisor
Professor, Kinesiology, SFU

Dr. A. Ignaszewski
Supervisor
Clinical Associate Professor, Div. of Cardiology, Dept. of
Medicine, UBC

Dr. A Wister
External Examiner
Professor and Director, Gerontology, SFU

Date Defended/Approved:

November 20th, 2008

DECLARATION OF PARTIAL COPYRIGHT LICENCE

The author, whose copyright is declared on the title page of this work, has granted to Simon Fraser University the right to lend this thesis, project or extended essay to users of the Simon Fraser University Library, and to make partial or single copies only for such users or in response to a request from the library of any other university, or other educational institution, on its own behalf or for one of its users.

The author has further granted permission to Simon Fraser University to keep or make a digital copy for use in its circulating collection (currently available to the public at the "Institutional Repository" link of the SFU Library website <www.lib.sfu.ca> at: <<http://ir.lib.sfu.ca/handle/1892/112>>) and, without changing the content, to translate the thesis/project or extended essays, if technically possible, to any medium or format for the purpose of preservation of the digital work.

The author has further agreed that permission for multiple copying of this work for scholarly purposes may be granted by either the author or the Dean of Graduate Studies.

It is understood that copying or publication of this work for financial gain shall not be allowed without the author's written permission.

Permission for public performance, or limited permission for private scholarly use, of any multimedia materials forming part of this work, may have been granted by the author. This information may be found on the separately catalogued multimedia material and in the signed Partial Copyright Licence.

The original Partial Copyright Licence attesting to these terms, and signed by this author, may be found in the original bound copy of this work, retained in the Simon Fraser University Archive.

Simon Fraser University Library
Burnaby, BC, Canada



SIMON FRASER UNIVERSITY
THINKING OF THE WORLD

STATEMENT OF ETHICS APPROVAL

The author, whose name appears on the title page of this work, has obtained, for the research described in this work, either:

(a) Human research ethics approval from the Simon Fraser University Office of Research Ethics,

or

(b) Advance approval of the animal care protocol from the University Animal Care Committee of Simon Fraser University;

or has conducted the research

(c) as a co-investigator, in a research project approved in advance,

or

(d) as a member of a course approved in advance for minimal risk human research, by the Office of Research Ethics.

A copy of the approval letter has been filed at the Theses Office of the University Library at the time of submission of this thesis or project.

The original application for approval and letter of approval are filed with the relevant offices. Inquiries may be directed to those authorities.

Bennett Library
Simon Fraser University
Burnaby, BC, Canada

ABSTRACT

Background: Heart failure results in high morbidity and mortality rates and is increasing in prevalence. Symptom and weight monitoring is essential as it has been associated with improved outcomes for patients.

Purpose: To investigate the use of a website for the telemonitoring of heart failure patients, to assess its uptake, and evaluate its effect.

Methods: Twenty patients were recruited and entered their daily weight and symptoms onto the website for six months. Patients were remotely monitored by a nurse and contacted as required.

Results: Trends toward improvement were observed on the maintenance ($p=0.039$) and confidence subscales of the Self-Care of Heart Failure Index ($p=0.069$), Minnesota Living With Heart Failure® Questionnaire ($p=0.337$), six-minute walk test ($p=0.124$) and NT-proBNP ($p=0.210$). Participants and nurses demonstrated a favourable uptake of the website.

Conclusions: The website was favourably accepted by both patients and nurses and its use is associated with improved outcomes.

Keywords: Heart failure; telemonitoring; self-monitoring

Subject Terms: Heart failure; telemonitoring

DEDICATION

To my parents and my brother. Mom, Dad – you have taught me to work hard, to work honestly and to never give up. A lot of that came from watching you. Thank you. To my brother - words cannot express what you mean to me. I love you.

ACKNOWLEDGEMENTS

I would like to extend my thanks to the many individuals who have supported me throughout my endeavours. First and foremost I would like to extend a heartfelt thank you to my family and friends. To my parents and my brother, who have supported me throughout the years, I wish to say thank you and I love you. To the rest of my family who have provided their support and encouragement, thank you. To my friends, I want all of you to know that you are amazing individuals. Thank you for all of your support and for all the times we have shared.

I would like to extend a huge thank you to my senior supervisor Dr. Scott Lear. Thank you for giving me the opportunity to further my education and pursue my passion. Without you, many of the successes that I have achieved in the past several years would not have been possible. Thank you for all of the guidance and support that you have provided. I cannot express how grateful I am for this opportunity.

A special thank you goes out to my supervisory committee members Drs. Andrew Ignaszewski and Glen Tibbits for agreeing to assist me in this endeavour. Your support is very much appreciated.

To Ms. Annemarie Kaan, thank you for all of the help and support that you have provided for the duration of this project. You were so very integral in the creation and planning process and of great assistance throughout. Your

determination and passion to get this project off the ground is very much appreciated. To Ms. Jen Kealy, the study nurse, thank you for the work, time and effort you put into this project.

I would additionally like to extend my sincerest thanks to all of the physicians, nurses and staff at the Heart Function Clinic at St. Paul's Hospital for all of their assistance during the recruitment process.

I also wish to acknowledge all of the physicians, staff and fellow students at the Healthy Heart Program at St. Paul's Hospital. It was a pleasure meeting all of you. And finally to everyone else, including the many wonderful teachers and professors, who I have met along the way, thank you !!!

TABLE OF CONTENTS

Approval	ii
Abstract	iii
Dedication	iv
Acknowledgements	v
Table of Contents	vii
List of Figures	x
List of Tables	xi
Glossary	xii
Chapter 1: Literature Review	1
Heart Failure Prevalence and Impact.....	1
What is Heart Failure?	2
What is Self-monitoring?.....	5
Is There Evidence to Support the Effectiveness of Self-monitoring?	7
Telemonitoring/Telehealth	8
Previous Intervention Studies	8
Telephone-Based Intervention Studies.....	8
Intervention Studies Utilizing Other Modalities	10
Self-management/Telemonitoring Interventions for Other Fields	17
Chapter 2: Rationale	19
Chapter 3: Research Design	22
Purpose... ..	22
Primary Hypothesis.....	22
Specific Aims	22
Study Population.....	23
Inclusion/Exclusion Criteria.....	24
Inclusion Criteria.....	24
Exclusion Criteria.....	25
Chapter 4: Description of Intervention	26
Participant Interface/Requirements.....	26
Nurses' Role in the Intervention.....	32
Other Features of Website	37

Chapter 5: Data Collection Protocols	42
Participant Intake Assessment.....	42
Follow-up Assessments	42
Minnesota Living with Heart Failure® Questionnaire	43
Self-Care of Heart Failure Index	44
NT-proBNP Test	44
Six Minute Walk Test	45
Leisure Time Physical Activity Questionnaire	45
Demographic Data	45
Computer Use Data	46
Anthropometric and Other Measures	46
Participant Interviews.....	47
Staff Interview	48
Chapter 6: Analysis Plan	49
Primary and Secondary Outcomes	49
Sample Size.....	49
Data Analysis	49
Chapter 7: Ethical Considerations	51
Chapter 8: Individual Role	52
Chapter 9: Results	53
Participant Recruitment and Demographics.....	53
Computer Usage Information.....	57
Alert Generation.....	58
Primary Outcomes	61
Secondary Outcomes	62
Participant Interviews.....	63
Staff Interview	66
Chapter 10: Discussion	69
Primary Outcomes	70
Secondary Outcomes	74
Comparison to Other Studies Using the Internet	75
Advantages Over Other Telemonitoring Modalities.....	77
Participant and Nurse Responses and Website Usability	78
Chapter 11: Lessons Learned	82
Chapter 12: Study Limitations	84
Chapter 13: Future Direction	87
Power Calculations	88
Chapter 14: Conclusions	91
Appendices	92
Appendix A: Participant Consent Form	93

Appendix B: Minnesota, Self-Care of Heart Failure and Leisure Time Physical Activity Questionnaires	99
Appendix C: Participant Demographic Data, Computer Use Data and Anthropometric Measurement Collection Forms	109
Appendix D: Participant Instructions	120
Appendix E: The Study Nurse's Role with Heart Helper Participants.....	147
Reference List	152

LIST OF FIGURES

Figure 1: Study Patient Flow24

Figure 2: Login Page.....27

Figure 3: Data Entry Page.....28

Figure 4: Data Entry Page Continued29

Figure 5: No Alert Generated Message.....30

Figure 6: Sample Alert Generated Message31

Figure 7: Alert Resolution Protocol.....32

Figure 8: Nurse Homepage Showing which Participants Have Generated Alerts.....33

Figure 9: Nurse Interface Showing a Single Participant Record with Alerts Generated34

Figure 10: Nurse Interface Showing Single Participant Record with Progress Chart.....35

Figure 11: Nurse Interface Showing Single Participant Record with Alert History36

Figure 12: Participant Interface Showing Progress Chart38

Figure 13: Participant Interface Showing 'My Profile' Page.....39

Figure 14: Participant Interface Showing 'My Profile' Page Continued40

Figure 15: Participant Interface Showing 'Resources' Page41

Figure 16: Participant Recruitment.....54

Figure 17: Number of Alerts Generated per Participant59

LIST OF TABLES

Table 1: Clinical Signs and Symptoms of Heart Failure and Their Manifestation.....	5
Table 2: Participant Demographic Characteristics at Baseline.....	55
Table 3: Participant Demographics at Baseline Stratified by Gender.....	57
Table 4: Computer Usage Information	58
Table 5: Alerts Generated	60
Table 6: Primary Outcome Measures.....	61
Table 7: Primary Outcome Measures Continued	62
Table 8: Secondary Outcome Measures.....	63
Table 9: Number of Participants Needed in Each Group	88
Table 10: Number of Participants Needed in Each Group Continued	89

GLOSSARY

ACC	American College of Cardiology
AHA	American Heart Association
BC	British Columbia
EF	Ejection Fraction
LV	Left Ventricle
NYHA	New York Heart Association
SEM	Standard Error of the Mean

CHAPTER 1: LITERATURE REVIEW

Heart Failure Prevalence and Impact

Heart failure is associated with high rates of morbidity and mortality and is increasing in prevalence in Canada, presumably due to the aging population and the improved survival rates among individuals with coronary artery disease [1]. Data from the Canadian Institute for Health Information indicate that for the fiscal years 1997/1998 to 1999/2000 a total of 83,406 patients were newly hospitalized nationwide with the illness, with approximately 27,802 new patients being admitted annually. Of the patients hospitalized during this time, 42,375 were women, 41,031 were men and approximately 85% were aged 65 years or older [2]. In-hospital mortality averaged 9.5 deaths per 100 hospitalized cases. Among those who survived the initial index hospitalization, readmission rates were 8.7% at 30 days, 14.1% at 90 days and 23.6% at one year [2]. When the burden of heart failure is compared with other major illnesses, it is associated with the second highest total number of hospital days and the third highest number of patients affected [1].

Although only British Columbia (BC) will be discussed below, for an excellent overview of regional variation in hospitalization and mortality rates, refer to the study by Lee et al [2]. In 2002 statistics from the Ministry of Health Services indicated that more than 40,000 people had been diagnosed with heart failure in BC [3] and in 2000/2001 the costs of hospitalization and service fees for

heart failure patients was over \$96 million dollars in that province [3]. During 2000/2001 there were 7,382 cases of hospital admission in BC with the primary diagnosis being heart failure and a resulting 56,042 hospital days with an average of 7.6 hospital days per case [4]. During that same time, the Ministry of Health Services reported that over 40% of the heart failure readmissions that occurred in the province took place less than 15 days from hospital discharge [3].

What is Heart Failure?

A joint statement by the American College of Cardiology (ACC) and American Heart Association (AHA) [5] provides the following definition for heart failure.

Heart failure is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. The cardinal manifestations of [heart failure] are dyspnea and fatigue, which may limit exercise tolerance and fluid retention, which may lead to pulmonary congestion and peripheral edema. Both abnormalities can impair the functional capacity and quality of life of affected individuals, but they do not necessarily dominate the clinical picture at the same time.....[b]ecause not all patients have volume overload at the time of initial or subsequent evaluation, the term “heart failure” is preferred over the older term “congestive heart failure”.

The clinical syndrome of [heart failure] may result from disorders of the pericardium, myocardium, endocardium, or great vessels, but the majority of patients with [heart failure] have symptoms due to an impairment of LV myocardial function. Heart failure may be associated with a wide spectrum of LV functional abnormalities, which may range from patients with normal LV size and preserved EF to those with severe dilatation and/or markedly reduced EF. In most patients, abnormalities of systolic and diastolic dysfunction coexist, regardless of EF.

As stated, heart failure may result from various dysfunctions. These dysfunctions may be grouped into six broad categories including 1) increase in resistance to ejection of blood from the ventricles, 2) increase in the volume of blood to be pumped, 3) impaired atrial emptying, 4) reduced myocardial contractility, 5) reduced myocardial relaxation and 6) increased demand for blood by peripheral tissue [6].

Heart failure may be described as left sided, right sided, or bilateral [6]. Left sided heart failure is 30 times more common than right sided and usually is a result of myocardial infarction, valvular disease or hypertension. When the left ventricle is unable to pump the blood it receives, the blood will accumulate in the left atrium and pulmonary vasculature resulting in an alteration in pressure. Eventually fluid will enter the interstitium and accumulate in the alveolar spaces causing pulmonary edema. The pulmonary edema results in the characteristic symptoms of heart failure including dyspnea, orthopnea, and paroxysmal nocturnal dyspnea. Right sided heart failure usually occurs after left sided heart failure due to the increase in pulmonary pressure and resulting increased right heart afterload, however pure right sided failure may occur as a result of cor pulmonale, bronchitis, emphysema, pneumoconiosis, pulmonary emboli, myocardial infarction, diffuse myocarditis, or pulmonary vascular sclerosis. Right sided heart failure results in minimal pulmonary congestion and edema, but the peripheral edema that results is more severe than in left sided failure. The rate of fluid loss is increased and fluid may leak into the peritoneal cavity (ascites). Right ventricular dilatation and hypertrophy also result. Bilateral heart failure

results when the two sides of the heart fail at the same time or as the progression from one sided heart failure. In the former, a variety of pathologies may be responsible, including toxic conditions, infections, radiation injury, diffuse malignancies, pericardial disease, myocardial ischemia and arrhythmias. Heart failure may also be classified as low output or high output heart failure as well as forward or backward heart failure [6], but for the purposes of this thesis, the focus will be on left sided heart failure.

Heart failure severity is frequently described by assigning patients to a New York Heart Association (NYHA) functional class [7]. Patients assigned to class one (I) have cardiac disease but no resulting limitation in physical activity, and ordinary physical activity does not result in symptoms of heart failure. Patients in class two (II) have cardiac disease and experience a slight limitation in their physical activity. They are comfortable at rest but ordinary physical activity results in fatigue, palpitations or dyspnea. Class three (III) patients have cardiac disease and experience a marked limitation to physical activity participation. They are comfortable at rest but less than ordinary physical activity causes fatigue, palpitations or dyspnea. Patients in class four (IV) are most severely affected. They have cardiac disease, which results in an inability to engage in any physical activity without experiencing discomfort. They present with symptoms upon minimal exertion or even at rest.

It is important to have a good grasp of the underlying mechanisms, signs and symptoms of heart failure, as a worsening in signs and symptoms may

indicate a deterioration and may necessitate medical attention. An explanation of symptoms is found in Table 1.

Table 1: Clinical Signs and Symptoms of Heart Failure and Their Manifestation

Symptom	Manifestation
Dyspnea	Difficulty or uncomfortable awareness of breathing, occurs upon rest or exertion
Orthopnea	Difficulty or uncomfortable awareness of breathing, occurs when patient is supine
Paroxysmal Nocturnal Dyspnea	Sudden, patient awakens suddenly from sleep with difficulty or uncomfortable awareness of breathing
Angina	Chest pain or pressure, jaw pain, arm pain, other equivalent pain indicative of cardiac ischemia
Syncope	Sudden loss of consciousness
Weight gain or loss	Increase or decrease in weight
Swelling	Swelling or puffiness in extremities, abdomen or other areas
Fatigue	Tiredness, inability to perform usual activities

[7]

What is Self-monitoring?

As stated above, because changes in symptoms and increases in weight may indicate a worsening of clinical status, it is crucial that heart failure patients engage in self-monitoring as it may prevent further deterioration. Wright et al. [8] define self-management “as an active cognitive process undertaken by the patient to manage their heart failure, typically the adoption of practices such as self weighing and monitoring of symptoms and the interpretation of changes in weight and symptoms”. This definition touches upon the indicators of deterioration in heart failure, that is, worsening symptoms or increases in weight, and frames self-monitoring as a tool for detecting such deterioration.

Chriss et al. [9] instead entitle the concept as 'self-care' and state that it "is an active, deliberate, cognitive, decisional process that is lay-initiated and self determined". For those with chronic illnesses, self-care is divided into two components: maintenance and management. Self-care maintenance is the process of routinely monitoring symptoms and adhering to treatment. In heart failure, it entails daily weighing, following a low salt diet, exercising or remaining active, keeping medical appointments and taking medication as prescribed. Self-care management concerns the decision-making that is inherent in symptom recognition, evaluation, and treatment as well as treatment evaluation, the cumulative goal of which is to respond to symptoms before decompensation and hospitalization occur. For the purposes of this thesis self-management, self-monitoring and self-care will be used interchangeably.

Riegel et al. [10] frame self-management in the context of chronic illness as consisting of four stages. Stage one includes the recognition that a change in signs and symptoms from baseline is related to the illness. The second stage consists of cognitive evaluation of the change during which the patient attempts to ascertain whether the change is important to their health status. Stage three entails the implementation of a treatment strategy or displaying a specific behaviour in response to the observed change. Finally, stage four involves evaluating the effectiveness of the chosen treatment. Although the stages may occur in the stated order, patients may experience several stages simultaneously, pass through the stages quickly or omit stages based on past experience with that symptom.

Is There Evidence to Support the Effectiveness of Self-monitoring?

Wright et al. [8] investigated the uptake of self-management strategies among 197 heart failure patients who were randomized to the management or usual care group. Usual care patients received normal post discharge care. Management group patients received a clinical review within two weeks of hospital discharge as well as 6-weekly visits for the 12 months of the study. Visits consisted of one on one patient counselling, heart failure education, optimization of medical therapy and liaison with the patient's family and primary care providers. Patients in the management group were given a diary with a list of medications, clinic contact details, schedule of appointments and education sessions, and a calendar-based record to monitor weight. Patients were instructed to take action if weight deviated more than two kilograms from a predetermined goal. Intervention patients also attended three education sessions which explained signs, symptoms, importance of daily weight monitoring and diary use, plan of action if weight changed, effects of medications, importance of compliance and recommendations regarding exercise and diet. The management intervention was associated with a decrease in total bed days, multiple readmissions and improved quality of life but had no effect on mortality. Of the 100 patients in the management group, 76 used the diary. Of these patients, eight died, while 11 of the 24 patients who did not use the diary died. Among those using the diary, 51 patients weighed themselves at least once a week, and this was associated with fewer hospital admissions and greater days alive. Thus the management intervention was associated with decreased

readmissions; more specifically use of the diary with self weighing was shown to be most effective in decreasing readmission and mortality rates.

Telemonitoring/Telehealth

Self-monitoring among heart failure patients can be assisted through the use of telehealth. Health Canada [11] defines telehealth as

The use of information and communications technologies to enable health care and health information services activities. Telehealth is a general, inclusive term referring to a variety of electronic-based health service activities such as actual physician-patient interactions via telemedicine; the provision of education and information services designed to increase awareness of diagnoses, medical conditions, treatments, and good health practices; or clinical decision and diagnostic interactions between health professionals.

More specifically they define telemonitoring as “the use of information and communications technologies to enable monitoring of patient health status between geographically separated individuals” [11]. Here, the two terms will be used interchangeably.

Previous Intervention Studies

A number of studies utilizing various modalities have examined the effects of telehealth among heart failure patients.

Telephone-Based Intervention Studies

Dunagan et al. [12] looked at a year-long, nurse administered, telephone-based management program in which they randomized 151 heart failure patients into a usual care or an intervention group. Both groups received an education

package describing causes, treatment principles, patients' role in their care and monitoring, and appropriate management strategies. Intervention group patients received scheduled telephone calls from nurses, which included education and promotion of self-management skills. Patients were telephoned within three days of hospital discharge or program enrolment, then at least weekly for two weeks, then as needed. Nurses screened patients for heart failure exacerbations and recommended appropriate action. Those in the intervention group had a longer time to encounter (either a hospital readmission or emergency department visit), fewer all cause hospital readmission (mean of 0.9 vs. 1.3, $p=0.010$) and heart failure specific readmission (mean of 0.4 vs. 0.7, $p=0.13$), fewer total hospital days (mean of 7 vs. 8.7, $p=0.019$) and lower hospital costs (mean \$9,155 vs. \$11,225, $p=0.012$) during the first six months, however, differences were not statistically significant after one year.

The DIAL trial [13] randomized 1518 heart failure patients into a usual care group with 758 patients and a telephone-based intervention group with 760 patients for a mean of 16 months. Both groups were treated according to their attending cardiologists' criteria and received a follow-up visit at least every three months. Intervention patients received an educational booklet and telephone calls from a nurse. The first call occurred within seven days of randomization and the first four calls were made every two weeks, then calls occurred as required. Nurses questioned patients regarding diet, drug treatment, monitoring of symptoms, signs of edema, etc. and determined appropriate action. Intervention group patients had a significant reduction in admissions to hospital

for heart failure (29% relative risk reduction, $p = 0.005$) and better quality of life measured by the Minnesota Living With Heart Failure® questionnaire (mean of 30.6 vs. 35, $p = 0.001$), but mortality was similar in the two groups.

The drawback of the above interventions is that they do not provide measures of the uptake of self-management. Despite this, they indicate the potential for benefit from self-monitoring in conjunction with telemonitoring through nurse telephone calls.

Intervention Studies Utilizing Other Modalities

Various other telemonitoring modalities have been used with heart failure patients and many of these studies have more objective measures of self-management uptake than the above mentioned telephone interventions.

Artinian et al. [14] conducted a three month pilot study on a non-random sample of 18 patients with symptomatic left ventricular dysfunction. Patients were randomized to a usual care group or a web-based intervention group which received the Med-eMonitor device in addition to usual care. This device is approximately the size of a video cassette and contains five separate compartments for medications. An alarm reminds patients when to take medications, which pills and how many of each to take and a record is created each time a pill compartment is opened. The monitor additionally contains reminders or questions concerning medication, symptoms, weight, blood pressure, salt intake, etc. The device transferred patient data daily via telephone to an Internet accessible database which could be accessed by clinicians. At

three months, the intervention group demonstrated an improvement in quality of life compared to baseline ($p = 0.002$) while the usual care group did not ($p = 0.113$). Both groups showed improvement in their Heart Failure Self-Care Behavior Scale and differences between groups were not significant. According to daily logs, compliance with daily weight and blood pressure monitoring was lower in the usual care group, but differences between groups were not significant.

Several studies have been conducted using the AlereNet monitoring system which consists of an electronic scale and an individualized symptom response system called the DayLink Monitor. The DayLink Monitor is linked via phone line to a computerized database monitored by nurses employed by Alere, Incorporated [15, 16]. In a study by Cordisco et al. [15] 30 patients with severe heart failure received the monitor, while 13 patients who refused telemonitoring, three non-English speaking patients and 35 ambulatory patients awaiting cardiac transplant served as the comparison group. Intervention patients were required to weigh themselves daily and answer the following questions: 1) Did you wake up short of breath?, 2) Are your feet more swollen?, 3) Do you feel more tired than usual?, 4) Are you more breathless than usual?, and 5) Did you take your medications? Nurses monitored the data daily and contacted the patient's physician for a weight change of five lbs or more or symptoms of paroxysmal nocturnal dyspnea. Patients in the comparison group were instructed to weigh themselves daily and contact the clinic for a weight gain of greater than five lbs. Results showed that 22% of patients in the comparison group had emergency

room visits and 71% required at least one hospitalization, while in the monitored group these values were 3% and 43%, respectively. Both differences were significant at $p < 0.05$. Time to first hospitalization or emergency visit tended to be longer for the monitored group, however this difference was not statistically significant.

The WHARF trial [16] used the DayLink Monitor to follow patients for six months. Patients were randomized as follows: 142 in the standard care group and 138 in the intervention group. Results showed that there were 26 deaths in the standard care and 11 in the intervention group representing a 56.2% difference in mortality ($p < 0.003$). There were no differences between groups in terms of overall time to death, first rehospitalization, first emergency department visit, total number of emergency department visits, total number of cardiovascular hospitalizations, inpatient length of stay or cardiac intensive care unit days. Both groups demonstrated non-significant improvements from baseline in their Minnesota Living with Heart Failure®, SF-12 and Health Distress scores.

de Lusignan et al. [17] investigated the compliance and effectiveness of one year's home telemonitoring. Twenty heart failure patients were randomly allocated to two groups of ten. The comparison group received standard treatment while the telemedicine group received pulse and blood pressure measurement devices, scales and the Via TV-phone for video consultation. The intended video consultation rate was weekly for three months, then every two weeks for three months and then once a month unless the patient was unwell, although the actual rate varied and declined as the study progressed. Data from

the devices were transferred by radio to a box under the patient's telephone then transmitted to a telemonitoring server, which was monitored by nurses on weekdays for changes. Additionally, all patients were seen three times by a cardiologist. Intervention patients, however, reported that they did not find teleconsulting to be useful, that the picture quality was not good, that they would rather have seen a nurse face to face and that they did not perceive video consulting to be more advantageous than a telephone conversation with the nurse. The telemonitored group showed high rates of self-monitoring and medication compliance. There were no significant differences in quality of life (General Health Questionnaire) or Chronic Heart Failure symptomatology questionnaire scores between groups.

Jerant et al. [18] randomized 12 patients to usual care, 12 to telephone care and 13 to a home telecare group. Patients received an in home visit from a nurse after hospital discharge and approximately 60 days later. The interventions were in place during the 60 days between the two nurse visits. Usual care patients received care provided by their primary care physician, telephone group patients received scheduled phone calls and home telecare group patients received telephone-based video conferencing via an Aviva SL1010 Personal Telecare unit (American TeleCare, Eden Prairie, MN). This unit included a microphone, a camera and an electronic stethoscope. Patients were tracked for 180 days, starting with the initial in home nurse visit. Both intervention groups exhibited significantly fewer emergency department visits and charges, fewer heart failure related and all cause readmissions, lower all cause

hospitalization charges, shorter mean hospital lengths of stay and fewer all cause emergency department visits. Despite the \$5,500 cost of each telecare unit, readmission charges were 86% (\$5,850) lower in the telecare group and 84% (\$7,320) lower in the telephone group than in the usual care group (\$44,479), although differences were not significant.

Cleland et al. [19] randomized 426 patients, with 85 in a usual care, 173 in a nurse telephone support and 168 in a home telemonitoring group. Primary physicians of all patients received individualized management plans describing pharmacological treatment. Patients in the telephone support group additionally received monthly telephone calls from a nurse who assessed symptoms and medication and provided appropriate feedback. Home telemonitoring patients received the same telephone intervention, as well as an electronic weigh scale, an automated sphygmomanometer and a single lead electrocardiogram which were connected to the telephone line and transferred data to a web server. Patients were instructed to monitor their weight, blood pressure, heart rate and rhythm twice daily and values that fell outside of pre-programmed limits caused automatic notification of nurses. An interim analysis at 240 days revealed that home telemonitoring patients tended to display a greater number of hospital admissions with heart failure than telephone support patients, however there was a significant reduction in the average duration of those admissions among those in the home telemonitoring group. Those in the home telemonitoring group also had a reduced number of days in hospital for other causes. Patients in the usual care group had the poorest outcomes, predominantly due to poorer survival rates

and due to this further recruitment of patients into the study ceased. Two hundred and seventy one patients were followed for 450 days and it was found that there were no significant differences between the telephone support and home telemonitoring groups in terms of days lost due to death or hospitalization, however those in the telephone support and home telemonitoring groups had significantly decreased rates of mortality and thus fewer days lost to death or hospitalization than patients in the usual care group.

Delgado et al. [20] investigated the use of an interactive Internet site as a tool for the management of heart failure. Sixteen patients with a heart failure diagnosis and Internet access in their home or at their workplace or who had a caregiver who could access the Internet for them were recruited from the heart failure clinic at the Toronto General Hospital. An "Internet communication Web site" (www.heartfunction.com) was developed and served as an information source which provided access to relevant clinical trials and links to organizations such as the AHA. The website also served as a daily communication method between patients and staff at the heart clinic. The website allowed patients to track weight, medication, goals of therapy and allowed for communication of non-urgent issues, as patients were instructed not to use the website for urgent issues. Patients were instructed to enter their morning weight, heart rate, blood pressure and questions they might have into the website. A nurse reviewed patient responses on weekdays and sent back individualized replies which included items such as adjustment to diuretic doses, information regarding clinic tests and education concerning salt restriction, exercise, weight and symptom

management. At three months, significant differences were found for the Minnesota Living with Heart Failure® questionnaire as compared to baseline assessment. Furthermore, all patients reported high levels of satisfaction with the website, thus showing that uptake of an Internet based heart failure management intervention is favourable and is associated with improved quality of life, but the small sample size should be noted.

Wu et al. [21, 22] examined the same website (www.heartfunction.com) among 58 heart failure patients who entered their symptoms, weight, blood pressure, heart rate and comments daily. Clinicians reviewed patient responses and provided appropriate feedback. Participants could continue using the website until the study end date, and total patient follow up was 109 patient-years. 'Users' (those using the website at least 3 months on average once per week) were compared to 'nonusers'. It was found that there was greater hospitalization in the 'user group' due to planned hospitalizations for procedures such as pacemakers, defibrillators and tailored inotropic therapy compared to the 'nonuser group'.

Kashem et al. [23] examined the use of a website (InSight Telehealth Systems) compared to usual care. Twenty four patients were randomized to a usual care group and another twenty four to the intervention group. Patients in the intervention group reported their weight, blood pressure, heart rate, symptoms and comments on the website. Care providers reviewed data and provided appropriate feedback using the website with either a standard message or a message tailored to the patient. Patients were followed for one year.

Emergency visits, hospital admissions and total hospital days were lower for the intervention group compared to usual care.

The previously conducted heart failure telemonitoring studies indicate that telemonitoring does hold promise. Telemonitoring using various modalities results in a number of benefits including improved quality of life, decreased emergency room visits and hospitalizations and decreased costs. However, there does not appear to be a consistent pattern of benefit, as not all studies reported benefits, and the benefits that were reported varied between studies. Part of this may be explained by the use of different modalities and protocols, and many of the studies additionally had a small sample size. It is difficult to determine if any one modality provides greater benefit than the others but the question of accessibility should be considered. When a specialized modality must be provided to the patient, would it be feasible to provide large numbers of patients with the necessary equipment? Cost may be a prohibitive factor and may therefore affect how many patients can receive the equipment. Use of a website would eliminate the need for the purchase of specialized equipment and potentially allow a larger number of patients to be monitored. Given that previous studies have demonstrated favourable uptake and improved outcomes using the Internet, this modality may be a more feasible option.

Self-management/Telemonitoring Interventions for Other Fields

A number of other health conditions have also used telemonitoring. Finkelstein et al. [24] had asthma patients perform self-testing at home using a portable spirometer and palmtop computer. After three weeks, a medical

professional visited patients and observed them performing a spirometry test. Self testing was found to be valid and comparable to that performed in the presence of the medical professional and 87.1% of patients were strongly interested in using asthma telemonitoring in the future. Gammon et al. [25] looked at parent-child interactions using a prototype mobile phone which automatically transfers blood glucose readings from a monitor to the parents' mobile phone. Both children and parents felt the automatic transfer of blood glucose measurements was a good thing (80% and 93% respectively) and that living with diabetes was to some extent easier (73% and 80% respectively). These studies lend support to telemonitoring, its utility in a variety of situations and with varying patient demographics.

CHAPTER 2: RATIONALE

Heart failure patients experience a number of characteristic signs and symptoms including dyspnea and changes in weight [7], the monitoring of which, both through telephone and through the use of various telemonitoring modalities has been shown to result in improved outcomes. However, the question of accessibility must be considered as it may not be feasible to have nurses telephoning all patients on a daily basis. Additionally the provision of specialized equipment to all patients who may benefit may not be feasible. Use of a website is advantageous in both respects as patients who experience changes in symptoms can be flagged and the nurse need only contact them, and because it does not require the provision of specialized equipment to patients.

According to the Household Internet Use Survey from Statistics Canada, the percentage of Canadian households who had a head of household older than age 65 having Internet access was 10.1% in 1999 and 24.9% in 2003 [26]. More recent data from Statistics Canada from the Canadian Internet Usage Survey, which looks at the individual Internet user, indicates that in 2005, among individuals 65 and older, 23.8% reported using the Internet in the previous 12 months for personal non-business use from any location and 22.5% reported using the Internet from home [27]. As currently approximately 85% of heart failure patients are aged 65 years or older as reported in the study by Lee et al. [2] an Internet based intervention is feasible for this population. Given that there

is also an increase in Internet usage in the population in general [26], which combined with aging 'baby boomers' who are more likely to utilize the Internet than those who are currently older than them, Internet usage is likely to continue increasing. This may be an indication that the typical heart failure population in ten or 15 years will be even more amenable to Internet based interventions. Additionally, initiatives such as the British Columbia Premier's Technology Council, which in conjunction with Telus, is helping connect more communities to high speed Internet access [28], will increase access for individuals living in rural areas and lend further support to the feasibility of Internet-based monitoring interventions.

A website where heart failure patients record their weight and symptoms may be an ideal modality to assist them in self-monitoring as patients may lack the knowledge and understanding to appropriately self-monitor and respond to a deterioration of their health status. Telemonitoring can assist the patient by, for example, having a nurse or physician instruct them to adjust their medication which may help avert a potential crisis. A website can help avoid the purchase and replacement of expensive monitoring equipment and also serve as an avenue to reach a large number of patients. The major cost of such an intervention would be related to the creation and maintenance of the website, and hiring the appropriate individuals to monitor patient responses. The website could ignore 'normal' or 'unchanged' responses and only inform the nurse/physician of the patients who have demonstrated changes. This would

allow one nurse/physician to monitor a larger number of patients including those living in areas that do not have extensive health care facilities.

CHAPTER 3: RESEARCH DESIGN

Purpose

The purpose of this study is to investigate the feasibility of an Internet-based, telemonitoring intervention which utilizes the concept of self-monitoring among chronic heart failure patients. As very few studies [20-23] utilizing a website based telemonitoring tool to help heart failure patients monitor their condition have been conducted, this study is intended to serve as a pilot to help guide future research in the field.

Primary Hypothesis

Patients who self monitor their weight and symptoms on a daily basis, via an Internet based medium for six months, will undergo significant improvements in self-management, quality of life and health status as compared to baseline.

Specific Aims

- To assess the impact that the intervention has on patient quality of life, self-care and health status.
- To determine patient uptake and staff acceptance of the intervention via an exit interview.
- To assess the safety and feasibility of the intervention.

Study Population

Patient charts of all men and women, who were newly referred to the Heart Function and Pre-transplant Clinics at St. Paul's Hospital, were screened for study inclusion criteria. The clinic is a specialty clinic which provides extensive care to patients with heart failure. Nurses and physicians provide education, medical management and follow up to patients from all over the province of BC. The clinic has new referrals each week, although the number may vary. Patients who met initial criteria were briefly informed of the study and asked if they have daily Internet access and the ability to weigh themselves. Patients who indicated that they meet these criteria and were interested in participation received a detailed description of the study as well as a consent form to read over. If patients indicated that they were interested in participating, the attending cardiologist/fellow at the Heart Function Clinic was asked to give final approval, indicating whether the patient was an appropriate candidate for participation. A total of 20 patients meeting the inclusion/exclusion criteria who received final approval from the Heart Function Clinic cardiologist/fellows were enrolled as participants. The study was conducted according to the format presented in Figure 1.

All new referrals to
Heart Function or
Pre-transplant Clinics

20 new referrals to Heart Function or Pre-
transplant Clinic (HF diagnosis, informed
consent, no life threatening co – morbidities,
Internet access)

Intake
Assessment

3 Month
Follow-up

6 Month
Follow-up

Figure 1: Study Patient Flow

Inclusion/Exclusion Criteria

Inclusion Criteria

- New referral to the Heart Function or Pre-transplant Clinic at St. Paul's Hospital.

- Positive diagnosis of heart failure (systolic heart failure defined as the presence of signs and symptoms of heart failure with a documented ejection fraction of less than 40%).
- Access to the Internet at home and the ability to use it daily (either personally or through a caregiver).
- Ability to provide informed consent, which includes the ability to read and write English.

Exclusion Criteria

- Presence of cognitive impairments, depression (untreated) and/or complex co-morbidities such as end stage heart failure.
- Patients who have a planned surgical intervention scheduled during the study's duration or who are on the heart transplant list.
- Patients who have plans to leave the treatment area for a prolonged duration such as for an extended vacation.
- The presence of any other medical condition (not heart failure), which in the clinic physician's opinion makes the participant's survival for the duration of the study unlikely, or which would interfere with optimal participation in the study or produce a significant risk to the patient.

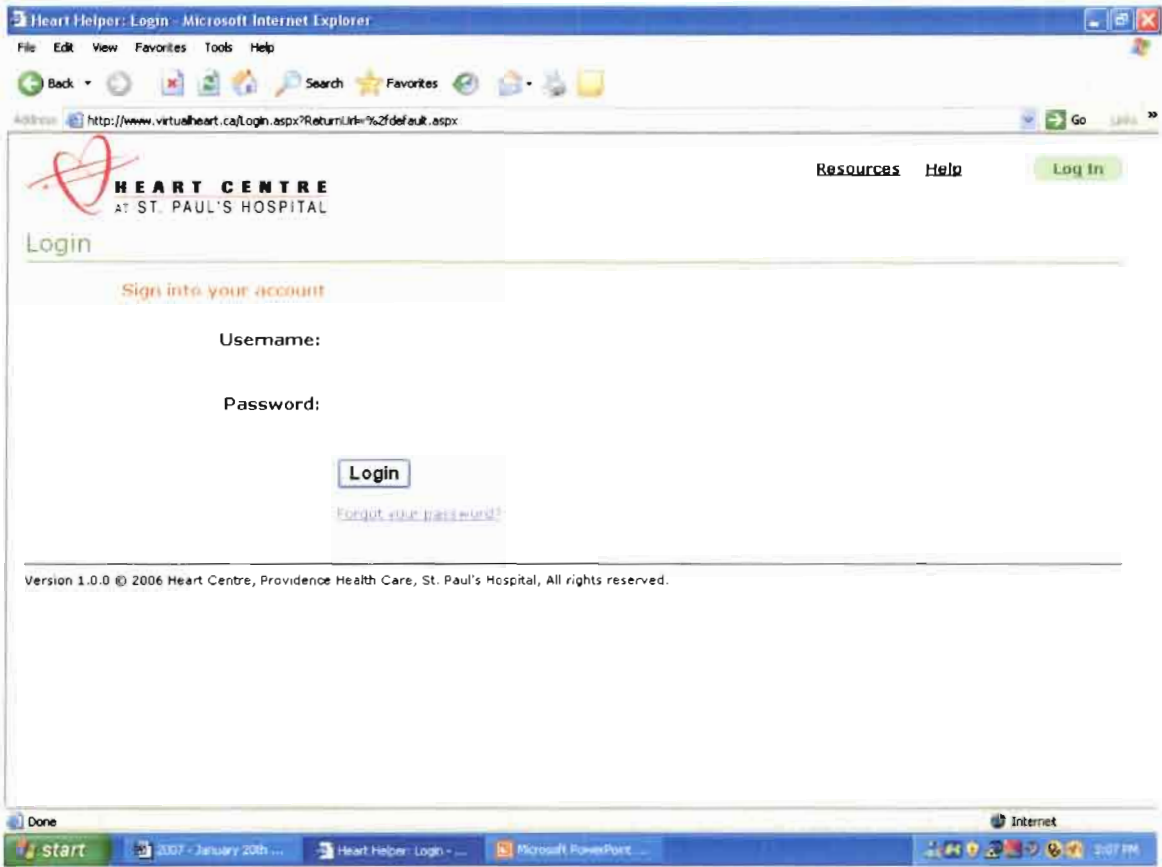
CHAPTER 4: DESCRIPTION OF INTERVENTION

Participant Interface/Requirements

The intervention entails having participants enter their weight and symptoms daily onto the website. A nurse accessed the website on working days to provide additional telemonitoring as will be described below. Participants were reminded that the website is not meant to take the place of, or to serve as a form of, medical care and that if at any time they are feeling unwell that they should seek appropriate medical attention. It was reinforced that the nurse is not on duty all day and that they should not wait for her/him to telephone if they are feeling unwell. The website intervention will be referred to as 'heart helper' or 'virtual heart' throughout.

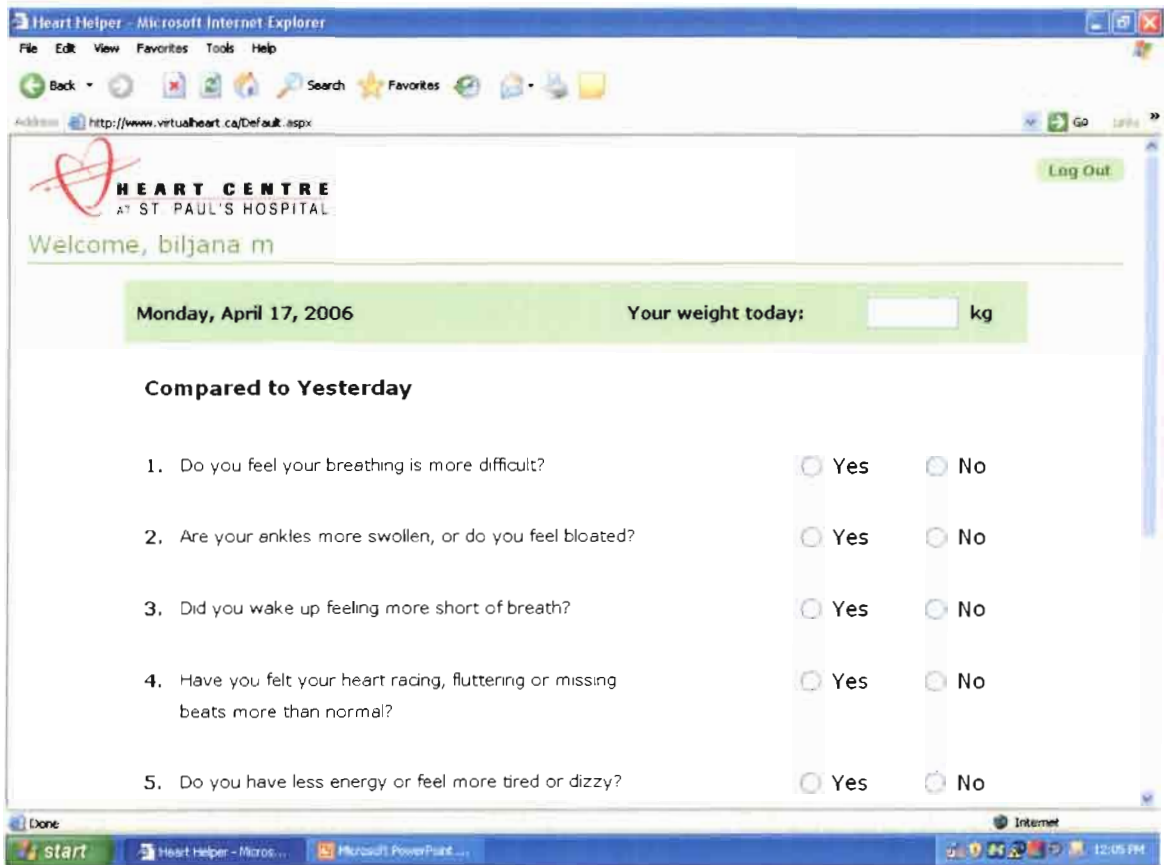
At the time of their intake visit, participants were given a login ID and password to access the website and provided with training on its use. The website runs on a Windows® platform. Participants were also given a booklet (Appendix D) with extensive illustrated instructions on the use of the website. Participants were asked to login every day (Figure 2) and enter their weight and answer five 'Yes'/'No' questions related to their heart failure symptoms (Figures 3 and 4). They were instructed to assess their symptoms and weigh themselves in the morning, after using the bathroom, but before having breakfast and to enter their data at this time. In the event that this was not possible, participants were instructed to assess their symptoms and obtain their weight at a consistent

time each day. The data entry screen reminded participants that the website is not a replacement for medical care and that if at any time they are feeling unwell they should seek appropriate medical attention (Figure 4). Please note that in figures illustrating the intervention, participant data is not used to protect confidentiality. The data shown is demonstration data generated by the researcher.



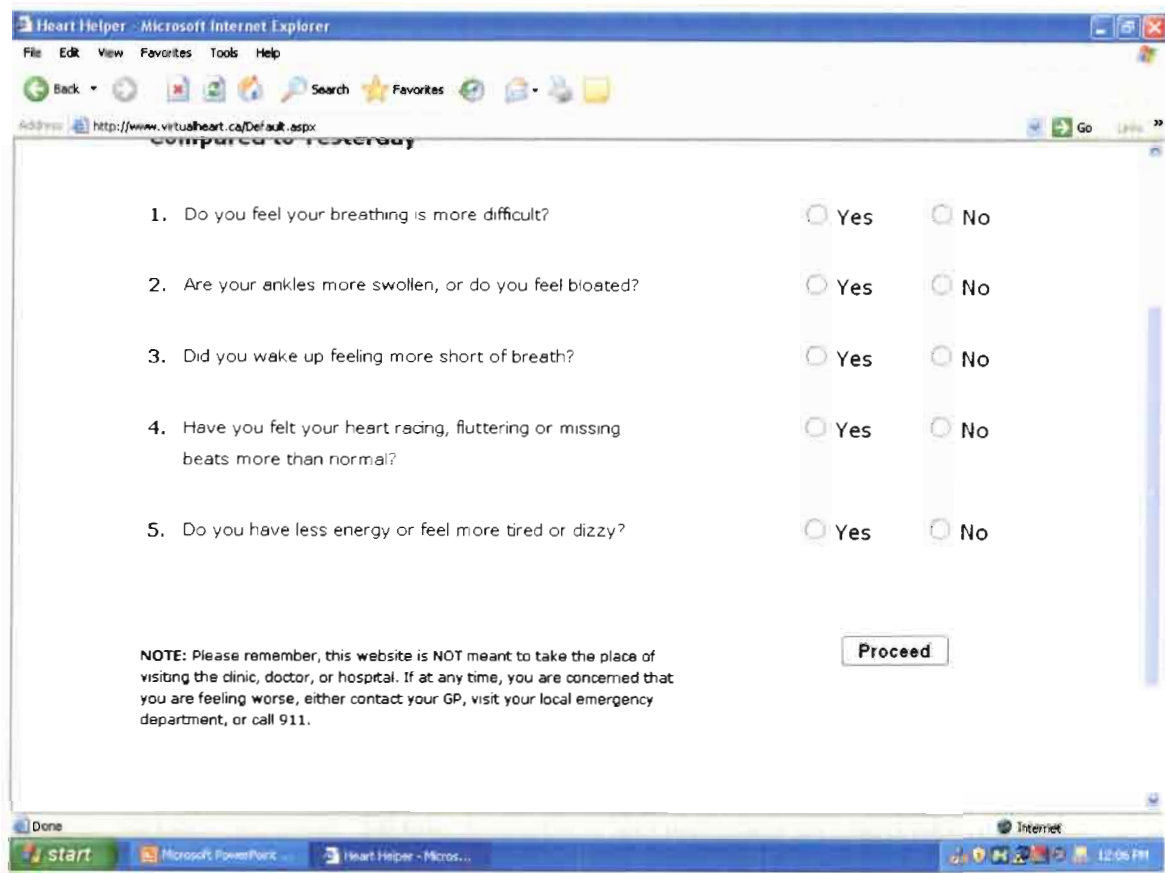
Participants were given a unique username and password which they enter on the login page so that they can access the website.

Figure 2: Login Page



Upon logging on to the website, participants were directed to the data entry page and were required to enter their weight and symptoms.

Figure 3: Data Entry Page

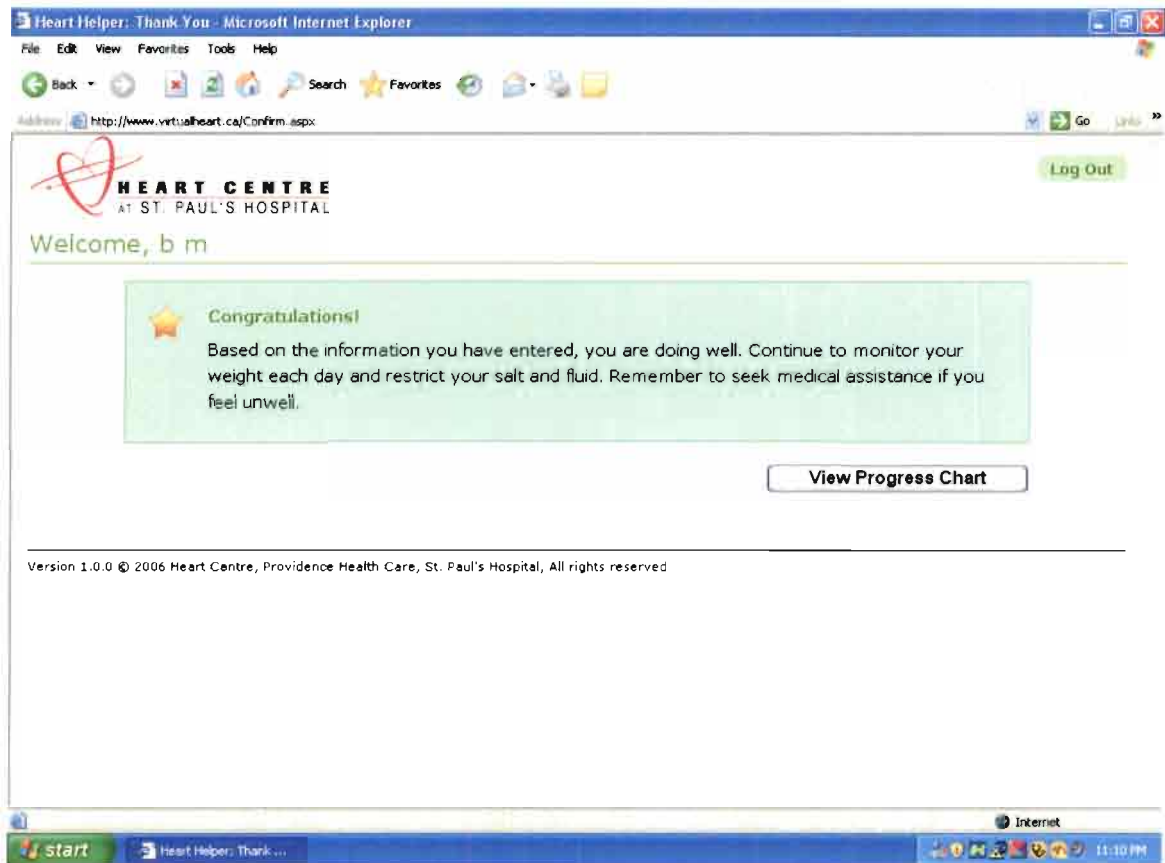


At the bottom of the data entry page, participants must click on the proceed button to enter their data onto the website. A note is displayed stating that this intervention is not meant to replace medical care and that participants should seek medical attention if necessary.

Figure 4: Data Entry Page Continued

Once participants clicked on the 'Proceed' button (Figure 4), their answers were sent to a secure web server. The website was programmed to trigger an alert if the participant's weight changes two kilograms or more in two days, five kilograms or more in seven days or if they answer 'Yes' to any one of the five questions. An automatic alert was triggered if participants did not enter data for three consecutive days. If the participant's weight did not change more than the

trigger value and if they answered 'No' to the five questions, they did not trigger an alert. These participants received a message stating that they are doing well according to the responses they had entered, but that they should seek medical assistance in the event that they feel unwell (Figure 5).

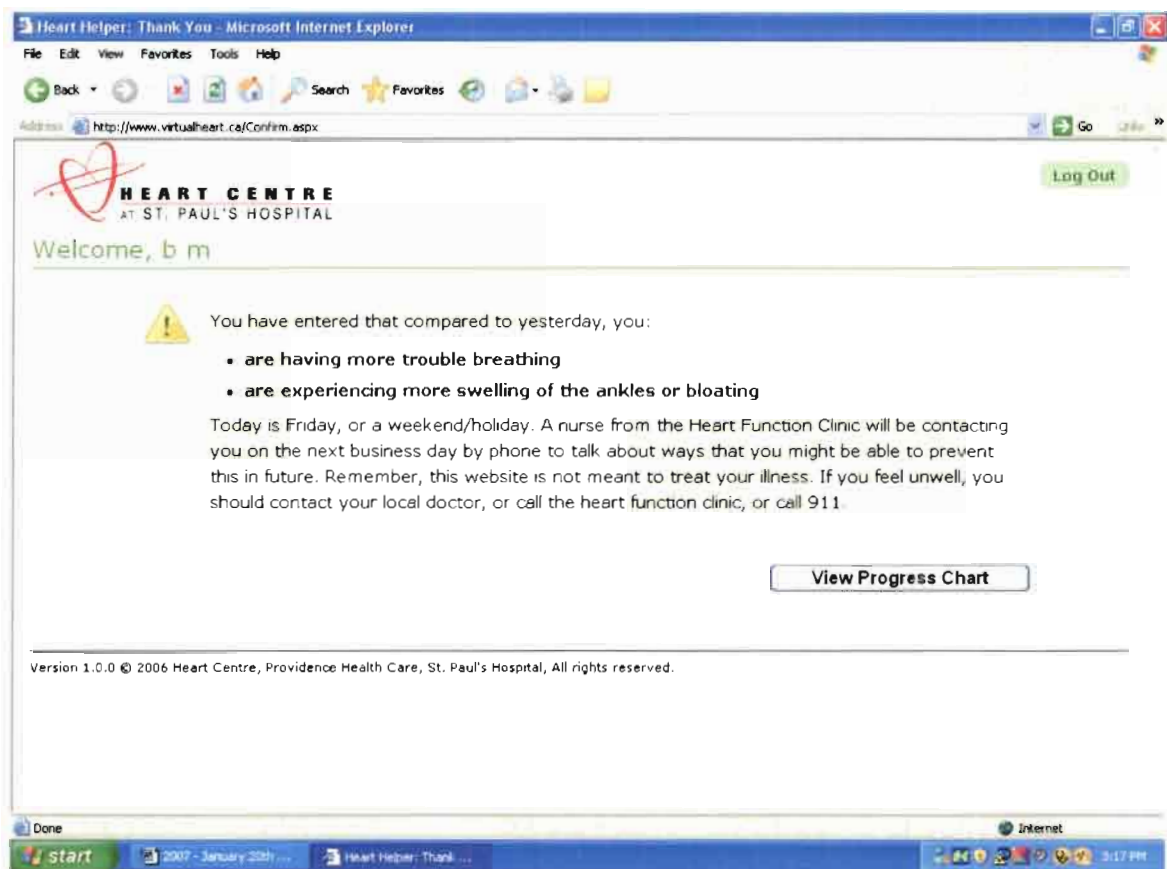


If participants weight does not change and if they answer 'No' to all five questions they will receive a message stating that they appear to be doing well, but to seek medical attention if necessary.

Figure 5: No Alert Generated Message

If the participant's entered weight varied more than the trigger values or if they answered 'Yes' to any of the questions, they received a message, reiterating their responses and indicating that the research nurse would contact them by

telephone within the next business day for follow-up. If the alert was triggered on a non-working day, the message also reminded participants that it was a weekend/holiday and that the nurse would contact them on the next business day. The message also told the participant that if they feel unwell or worried, they should contact their family physician, nearest emergency room or dial 911 (Figure 6).



If participant's weight changed more than the trigger values or if they answered 'Yes' to any of the five questions, they received a message reiterating their responses and informing them that the study nurse would contact them. The message reminds participants to seek medical attention if necessary.

Figure 6: Sample Alert Generated Message

Participant data was reviewed according to the following protocol (Figure 7).

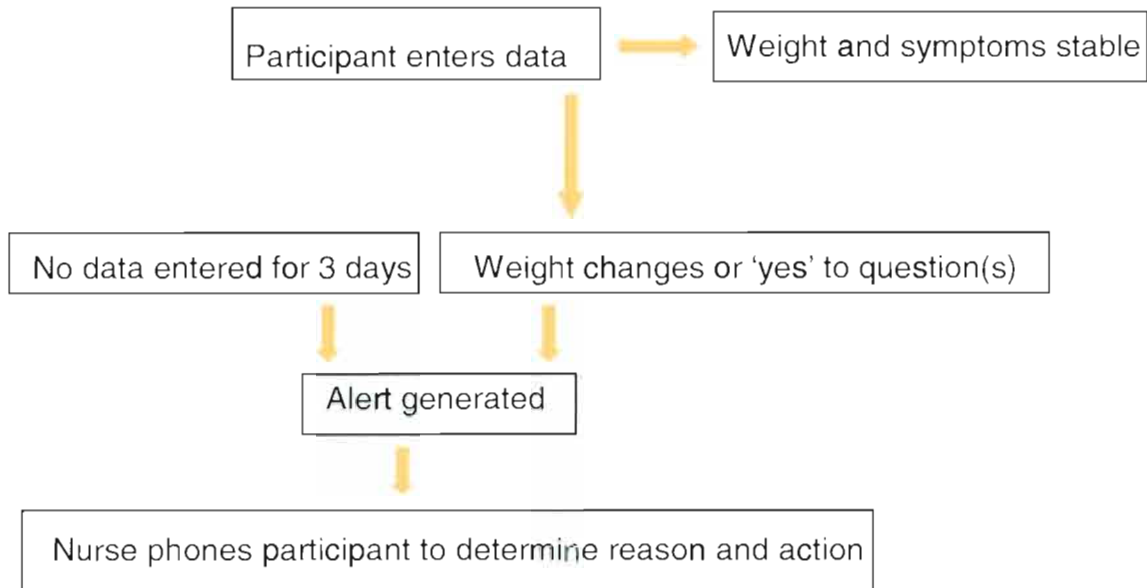


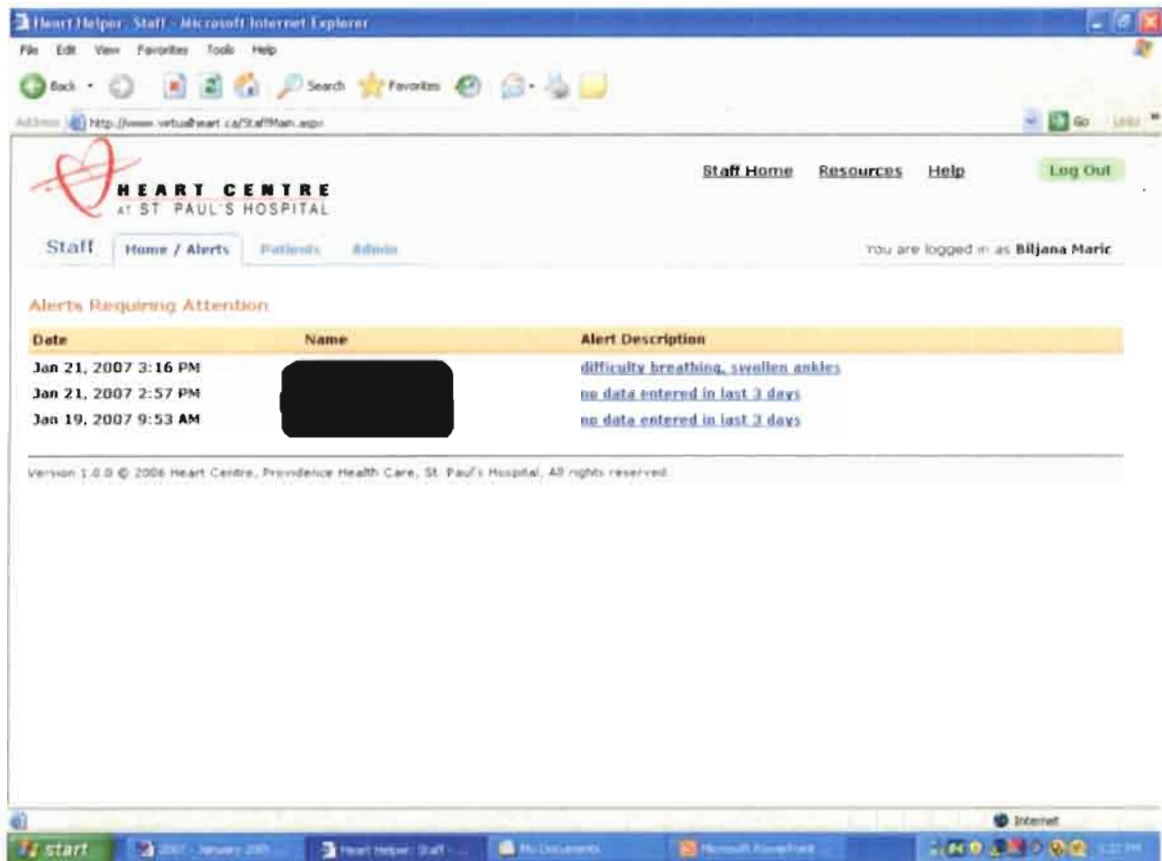
Figure 7: Alert Resolution Protocol

Nurses' Role in the Intervention

Upon enrolment, the study nurse telephoned the participant to review the nurses' role and establish a rapport. The nurse reviewed the website and alerts once every business day and resolved each alert within 24 hours or on the next business day if it was a weekend or holiday.

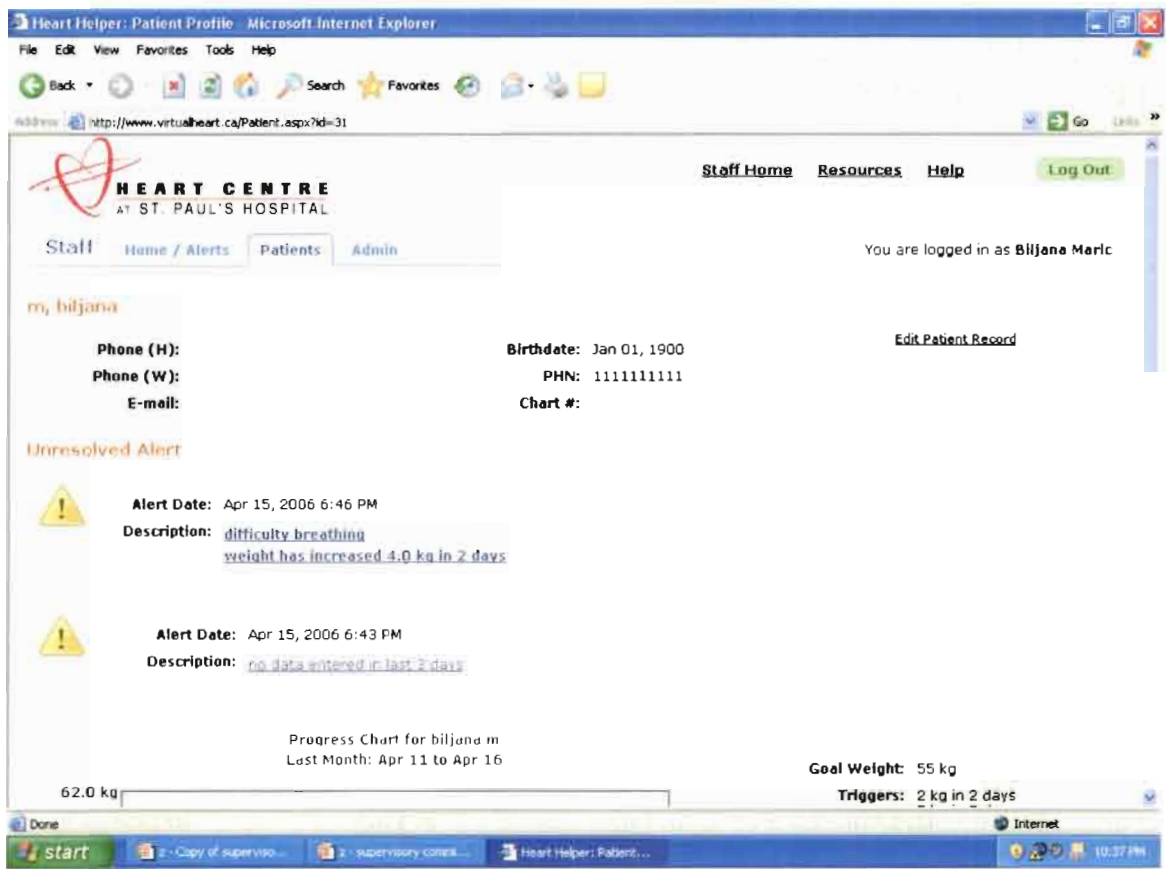
Upon logging on to the website, the nurse was directed to a screen indicating which participants have triggered alerts (Figure 8). The nurse then reviewed the alert data and undertook the appropriate action via the pre-specified intervention protocol (Appendix E). To complete this, the nurse clicked on the participant's name/alert. S/he was then directed to that particular participant's

record which displays a progress chart, written record of progress and alerts generated (Figures 9, 10 and 11). Because the nurse only received notification for those participants who triggered alerts and for those who were not entering data, there was no need to review the data of those participants who have not generated an alert, thus decreasing the amount of time required for participant monitoring.



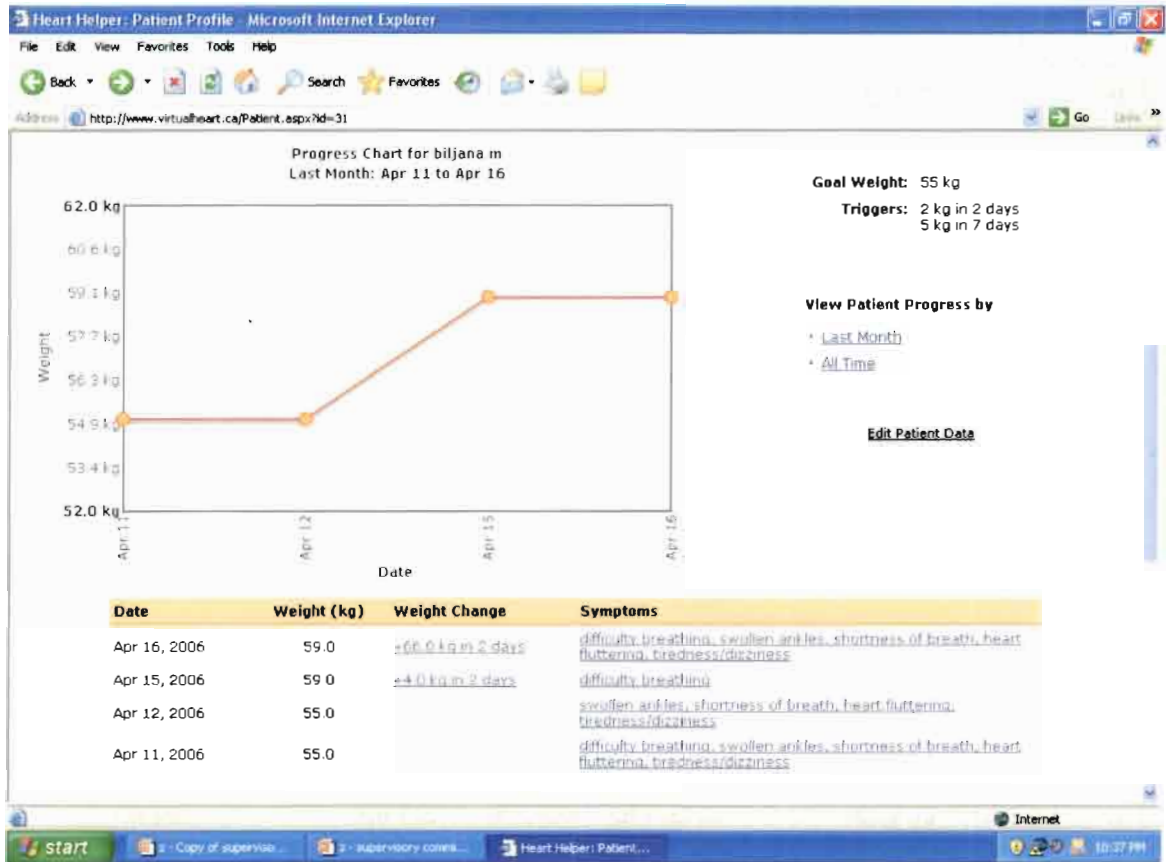
Upon logging on to the website, the nurse was directed to a homepage which indicated any participants who have triggered alerts. To resolve the alert, the nurse clicked on the participant's name or alert description.

Figure 8: Nurse Homepage Showing which Participants Have Generated Alerts



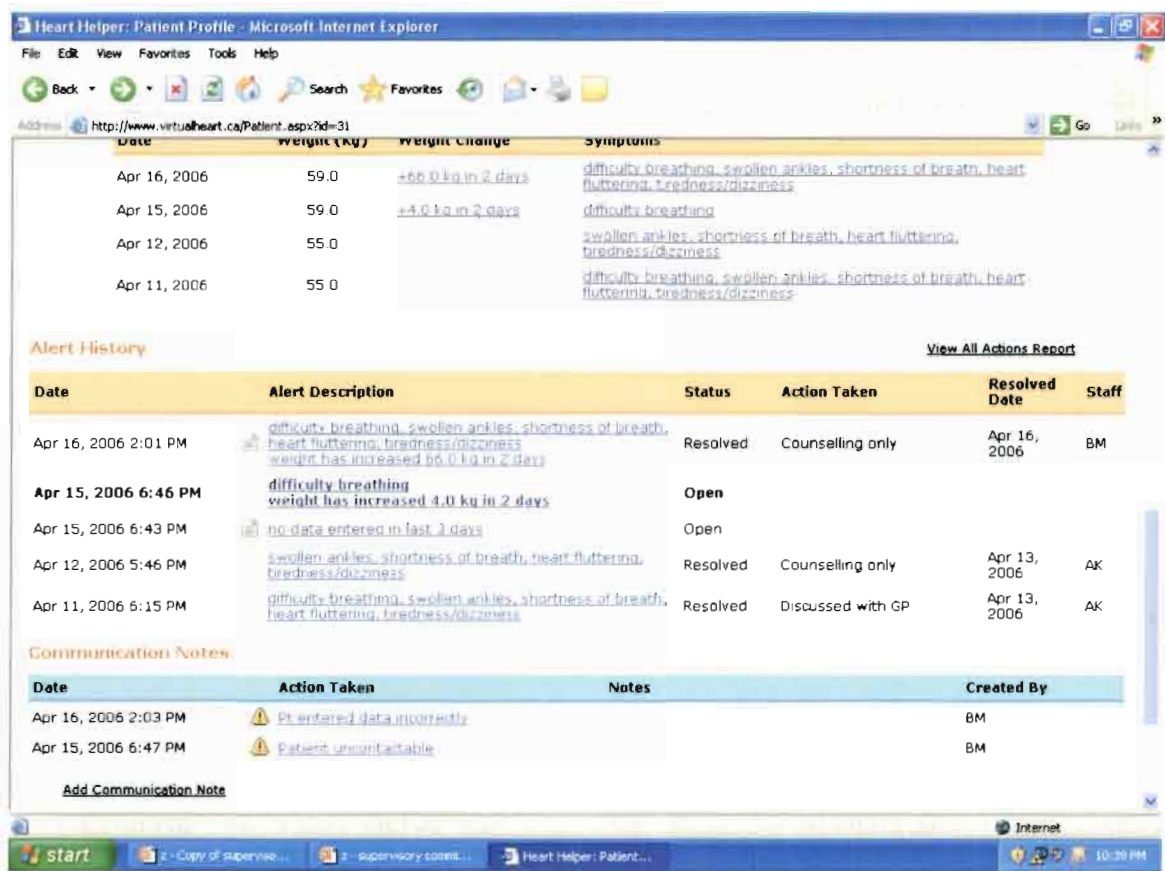
Upon clicking on the required participant, the nurse was directed to that participant's record which displays any alerts that s/he has generated. If present, unresolved alerts were displayed at the top of the page as above.

Figure 9: Nurse Interface Showing a Single Participant Record with Alerts Generated



The nurse interface of the participant record displays a progress chart which indicates the participant's weight. If the nurse clicked on any of the dots in the chart which indicate data entry points, the participant's weight and symptoms would temporarily be displayed next to the dot. Alternatively the nurse could view alerts generated, including symptom and weight changes, further down the page in text form.

Figure 10: Nurse Interface Showing Single Participant Record with Progress Chart



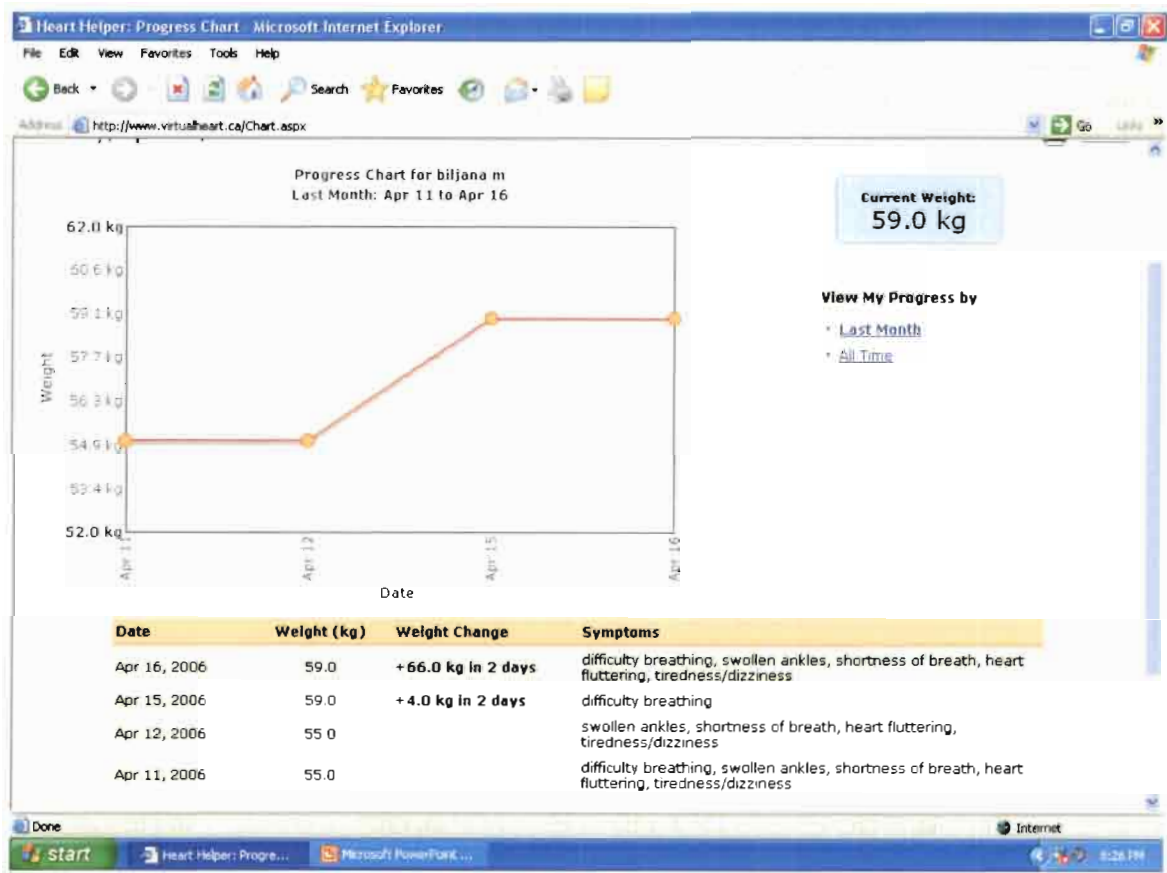
Upon scrolling down further in the participant's record, the nurse could view the alert history which contains a history of alerts generated as well as the actions taken to resolve each alert. At the bottom of the page the nurse could add or view any additional notes that were made regarding that participant.

Figure 11: Nurse Interface Showing Single Participant Record with Alert History

After the appropriate action as indicated by the intervention protocol was implemented, the nurse updated the participant's record on the website by 'resolving' the alert. This was repeated for all participant alerts. In the event that the participant had entered data incorrectly, the nurse was able to make the necessary corrections as seen in Figure 11 where the demonstration participant entered that they had gained 66 kg in two days.

Other Features of Website

The website allowed participants to track their progress over time by viewing a progress chart and a list of changes in their weight and symptoms (Figure 12). If participants realize that changes in weight and symptoms may be indicative of a deterioration in their health status when they view this on the graph or list, they may realize that they need to react to any decompensation that does occur.



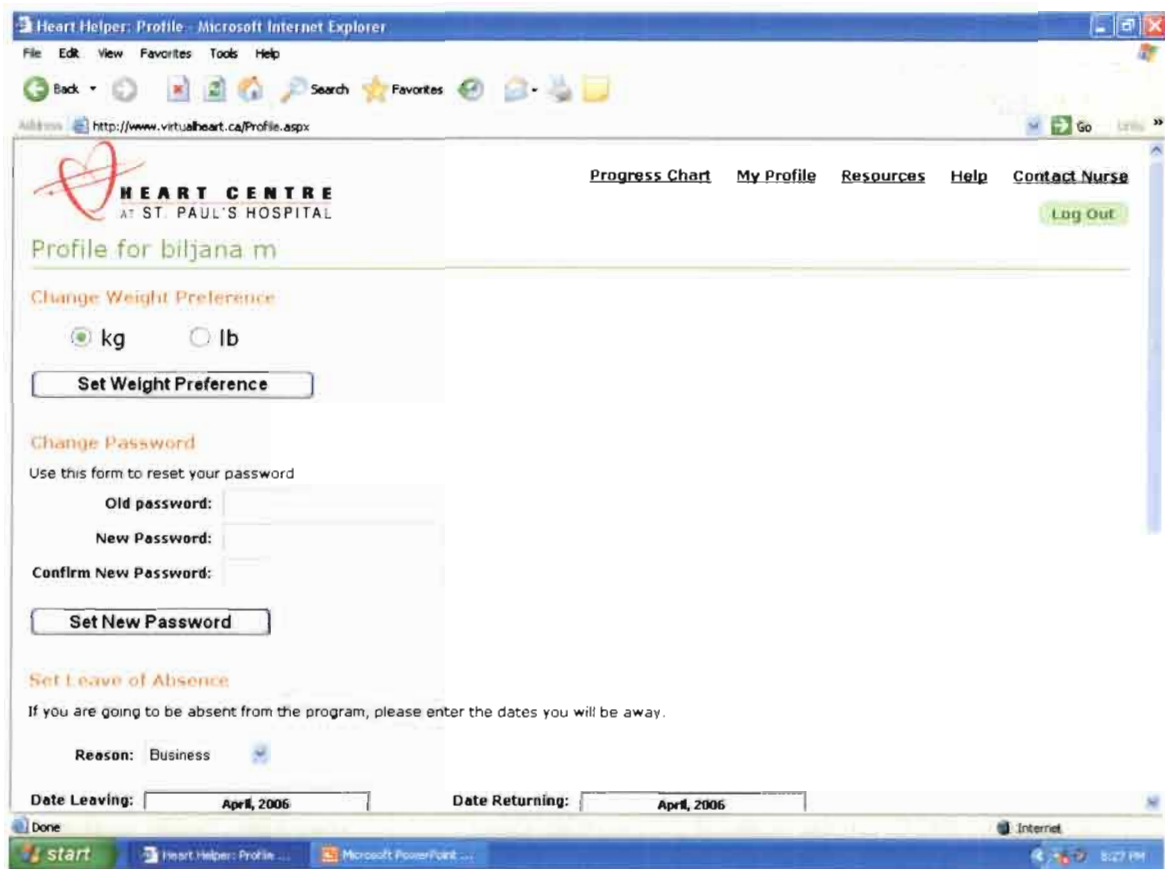
Upon logging on to the website the participant may view a chart indicating their weight throughout the intervention. If s/he clicked on any of the dots on the chart, which indicate data entry points, their weight and symptoms for that day would be displayed. The participant could also view their weight and symptom progress over time in text form below the chart.

Figure 12: Participant Interface Showing Progress Chart

Participants could customize their preferences on the 'My Profile' page as to whether they wished to enter their weight in lbs or kilograms and change their password whenever they wished. They could enter a leave of absence if they would be going away for more than three days so that the nurse would not receive alerts for lack of data entry (Figures 13 and 14). They could also contact the nurse via a 'Contact Nurse' link and view a 'Help' page containing the contact

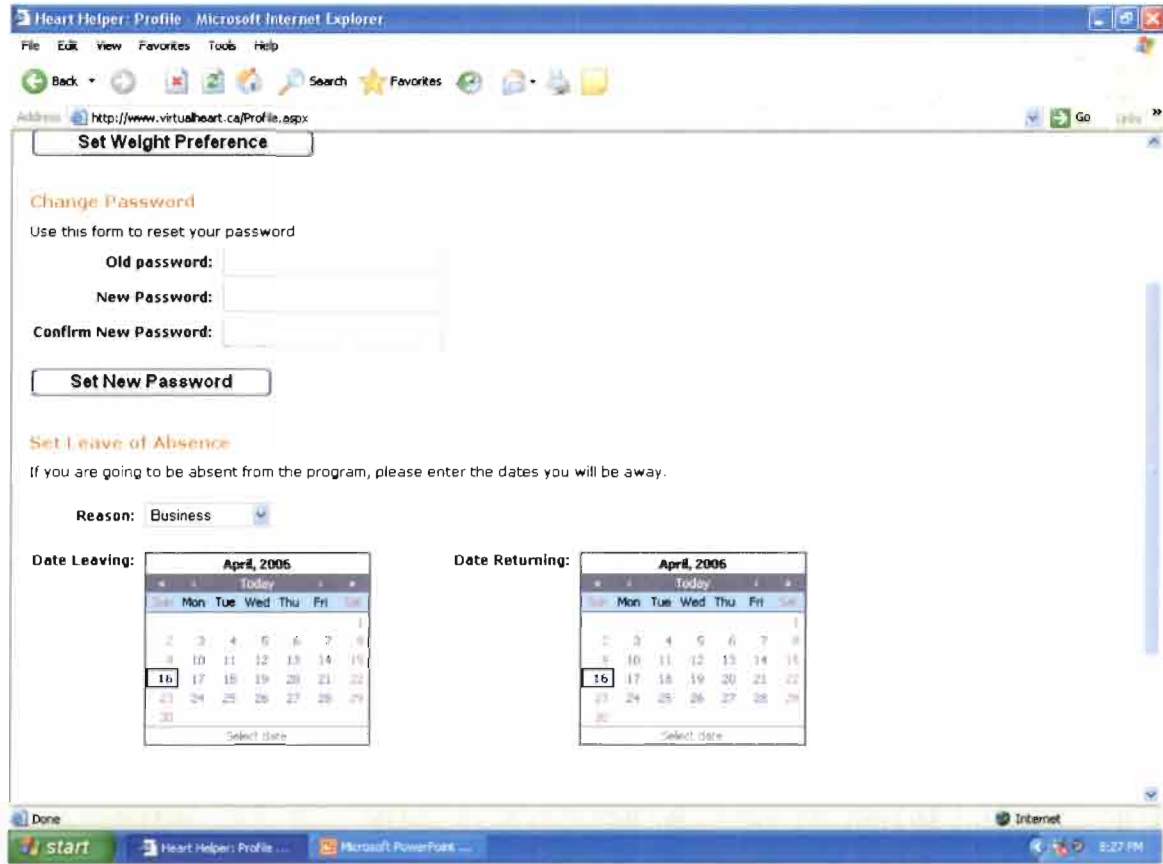
information of the research assistant and the document with instructions for use.

A 'Resources' page with various links was also available (Figures 13, 14 and 15).



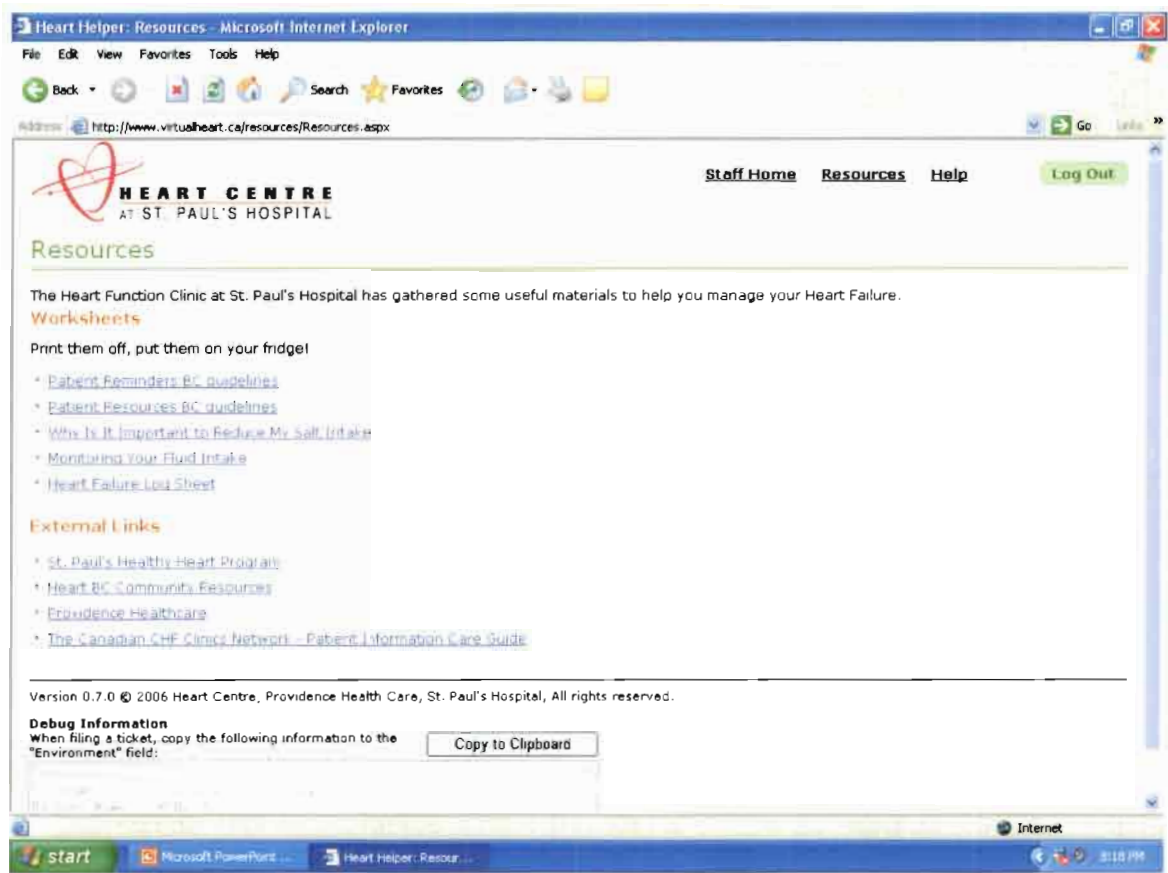
The participant could change their weight preference and their password on the 'My Profile' page. Participants could navigate through the various parts ('Progress Chart', 'My Profile', etc) of the website by clicking on the appropriate section as labeled at the top of the page.

Figure 13: Participant Interface Showing 'My Profile' Page



If the participant was going away for more than three days they could enter a leave of absence so that the nurse would not receive alerts for lack of data entry.

Figure 14: Participant Interface Showing 'My Profile' Page Continued



The participant could view a number of resources on the 'Resources' page. Participants may navigate through the various parts ('Progress Chart', 'My Profile', etc) of the website by clicking on the appropriate section as labeled at the top of the page.

Figure 15: Participant Interface Showing 'Resources' Page

CHAPTER 5: DATA COLLECTION PROTOCOLS

This study was conducted at St. Paul's Hospital Heart Function Clinic in Vancouver, BC. Ethics approval was obtained from the Simon Fraser University Office of Research Ethics as well as the UBC-Providence Health Care Research Ethics Board.

Participant Intake Assessment

Participants were required to provide informed consent (Appendix A) before enrolment. During the intake, they underwent a baseline assessment consisting of demographics, medical history, medications, blood pressure, heart rate, height, weight, hip and waist circumference measures, NT-proBNP (a natriuretic peptide), six-minute walk test, Self-Care of Heart Failure Index, Minnesota Living With Heart Failure® questionnaire and the Leisure Time Physical Activity questionnaire. As NT-proBNP testing is frequently conducted as part of routine clinic care, those with a recent test result were not required to have that test repeated.

Follow-up Assessments

Approximately three months from the intake assessment, participants underwent a follow-up consisting of blood pressure, heart rate, weight, hip and waist circumferences, current medication list, six-minute walk test as well as the Self-care of Heart Failure Index, Minnesota Living With Heart Failure®

questionnaire and the Leisure Time Physical Activity questionnaire. At this time participants were asked about their health resource utilization including items such as Heart Function Clinic visits, family physician visits, emergency room visits and hospitalizations. Another follow-up assessment was conducted approximately six months after the initial intake visit. The 6 month follow-up is identical to the three month follow-up, except that an NT-proBNP test was also performed at the six month follow-up.

A semi-structured interview was conducted at the six month follow-up to assess participant uptake of the intervention.

Staff who assisted in the management of study participants were interviewed at the conclusion of the study to assess their uptake of the intervention.

Minnesota Living with Heart Failure® Questionnaire

The Minnesota Living with Heart Failure® questionnaire [29] is a reliable and valid questionnaire assessing quality of life in patients with heart failure [30]. It contains 21 items and utilizes a Likert scale to assess how the individual has been affected by their heart failure in the previous four weeks. This questionnaire was administered according to the instructions provided by the Regents of the University of Minnesota [31]. The questionnaire can be found in Appendix B.

Self-Care of Heart Failure Index

The Self-Care of Heart Failure Index [32] measures a patient's ability to self-manage their condition. It uses a Likert scale with specific questions about important self-management skills required to live with heart failure at home. For this study a modified version of the questionnaire was used. The language of the questionnaire was simplified to facilitate understanding among patients.

Permission was obtained from the creator of the questionnaire to modify it to suit study purposes. Instructions for completion were explained to participants and the participants were required to complete the questionnaire on their own. The questionnaire can be found in Appendix B.

NT-proBNP Test

NT-proBNP is a natriuretic peptide that is produced by the ventricular wall of the heart in response to stretch, ventricular dilation or fluid overload. Its production, and therefore, its concentration in the plasma, is increased in individuals with heart failure [33]. Furthermore, it has been found that higher NT-proBNP levels are correlated to poorer survival among heart failure patients [34]. This test is often performed as part of standard care during clinic intake and when required by the patient's physician. When recent NT-proBNP results were not available for a participant, the individual was asked to have another sample drawn. This test was conducted in St. Paul's Laboratory as per the protocol provided by Roche Diagnostics [35].

Six Minute Walk Test

The six-minute walk test is used in patients with heart failure and requires them to walk as far as they can in a six minute time span. Distance walked is positively correlated with patient survival. The test was performed according to the instructions provided by the American Thoracic Society Guidelines [36] in a straight hallway at St. Paul's Hospital.

Leisure Time Physical Activity Questionnaire

The Leisure Time Physical Activity Questionnaire [37] assesses participation in physical activity by asking subjects to recall activities that they have participated in during the previous four weeks. Instructions for completion were explained to the participants and the participants were required to complete the questionnaire on their own. The questionnaire can be found in Appendix B.

Demographic Data

A questionnaire was developed to assess the demographic variables of participants (Appendix C). It assesses items such as income, education level, country of birth, etc. Demographic variables were collected by interview. In the event that this was not possible, participants were instructed on how to complete the questionnaires on their own. In such instances, the researcher reviewed participants' answers and asked for clarification in the event that it was necessary. A current list of participants' medications was obtained from the Heart Function Clinic whenever possible, otherwise, participants were asked to provide this information.

Computer Use Data

The computer usage questionnaire (Appendix C) assesses items such as type of computer, frequency of use, type of use (e.g. email, web surfing), etc. This information was obtained in the same fashion as the demographic variables.

Anthropometric and Other Measures

Weight was measured using the Seca scale that is utilized by the Heart Function Clinic. Participants were asked to remove their shoes and items from their pockets as well as any extra or heavy clothing prior to being weighed. Weight was recorded in kilograms and lbs. Height, in centimetres, was obtained using a stadiometer. Participants were required to stand upright, without shoes, looking straight ahead with hands at their sides. A sliding bar was lowered until it reached the top of the participant's head and the indicated height was recorded. Waist circumference was obtained via a flexible tape measure at the narrowest part of the torso, as seen from the posterior. Hip circumference was obtained using a flexible tape measure at the greatest protuberance of the gluteus as seen from the side. Blood pressure and heart rate readings were obtained using the BPtru monitor (VSM MedTech Ltd. Vancouver, Canada). The monitor takes six blood pressure measurements, discards the first, and displays the average of the last five measures [38]. Patients were also asked about their current medications, recent doctors visits, smoking status and alcohol consumption. A copy of the anthropometric and medical record data collection sheet can be found in Appendix C.

Participant Interviews

At study completion, a semi-structured interview was conducted to assess patient uptake of the intervention. The interview was tape recorded and then transcribed. It was comprised of the following questions:

- What was it about the study that interested you to participate?
- Overall, did you find it useful participating in the self-management program? How so/why or why not?
- Do you feel that you benefited from participating in this program? (How so weight loss, dietary changes, feeling better etc)
 - How has this increased your interest in heart health/lifestyle management?
 - Has this affected your ability to monitor your symptoms or affected your health, or awareness of health/symptoms?
- How, if at all, did this program help improve your knowledge of how to manage your heart failure?
- How comfortable were you using the website?
 - What did you like the most?
 - What did you like the least?
- How important/useful was it to log on to the website every day as time passed?
- How was the time commitment level? (for data entry, data collection, nurse telephone calls etc)
- Would you participate in something like this again?
- What would help/promote patients like yourself to use a program such as this?
- How could we improve this type of delivery for heart failure care?
- Is there anything else that you feel we should know about this intervention or do you have any other comments, recommendations, etc?

Staff Interview

As with the participant interviews, the staff interviews were tape recorded and then transcribed. It was comprised of the following questions:

- Overall, how did you find being involved with the intervention?
Was it useful to you? How so / why / why not?
Was it useful to your patients? How so / why / why not?
- What were the benefits of this program?
- What were drawbacks/downfalls of this program?
- How comfortable were you using the staff interface of the website?
What did you like the most?
What did you like the least?
- Suggestions for improvement of website?
- How was the time commitment level? (consulting with research/clinic nurse, contacting patients, reviewing data on website)
Is there a way to make this process better/more efficient?
- Which segment of the patient population do you think this intervention would be most/least beneficial for?
- Would you use something like this with your patients? Why / why not?
- How could we improve this type of delivery for heart failure care?
- Is there anything else that you feel we should know about this intervention or do you have any other comments, recommendations, etc?

CHAPTER 6: ANALYSIS PLAN

Primary and Secondary Outcomes

The primary outcomes for this intervention are changes in the Minnesota Living with Heart Failure® questionnaire, the Self-Care of Heart Failure Index, six-minute walk test results and NT-proBNP levels between intake and the six-month follow up. The secondary outcomes are other participant variables including heart rate, systolic and diastolic blood pressure, hip and waist circumference, weight and uptake of the intervention.

Sample Size

This study is meant to serve as a pilot, and as such a sample size of twenty participants was chosen for reasons of convenience. Due to time constraints a comparison group could not be included and a retrospective chart review was attempted. However, the matched comparisons did not have the required information with respect to Minnesota Living With Heart Failure® questionnaire and NT-proBNP at the time intervals required.

Data Analysis

Means and standard deviations for anthropometric data including waist and hip circumference, weight, heart rate and blood pressure were analyzed for changes over time using a repeated measures ANOVA using SPSS software [39]. Minnesota Living with Heart Failure® questionnaire, Self-Care of Heart

Failure Index and six-minute walk test results were also analyzed for changes using repeated measures ANOVA. NT-proBNP results were analysed using a Wilcoxon Signed Ranks test. Demographic and computer usage data are also reported. If applicable, all data are reported as significant at $p < 0.10$. A significance level of 0.10 was chosen because of the nature of the intervention, as it is looking at outcomes such as quality of life. As such, if an observed improvement in quality of life, for example, is found, even if it is due to chance, it is unlikely to be detrimental to participants.

Participant adherence to the intervention is reported. The number of alerts including those for lack of data entry and the reasons were examined and are reported. Participants who did not enter data were not considered drop-outs. They had to request to discontinue with the study to be considered a drop-out. Characteristics of those who dropped-out are compared to remaining participants.

Participant and nurse interviews were evaluated qualitatively using grounded theory to allow for the investigation of trends, comments, etc. and these are reported as part of the results.

CHAPTER 7: ETHICAL CONSIDERATIONS

To address ethical concerns, ethical approval was obtained from the Simon Fraser University Office of Research Ethics as well as the UBC-Providence Health Care Research Ethics Board. Upon enrolment into the study, participants were assigned a unique, confidential identification number. The participant's name appeared on only one of the data collection forms. For the purpose of the study, the study nurses and study coordinators were aware of subject identity. The participant's name and study identifier were stored on the website. This website was secure and encrypted, with NetNation (<http://www.netnation.com/>) providing the hosting services. Each subject, nurse and study coordinator required a unique login password to access the website. Additionally, transcripts of interviews did not contain personal identifiers. Participant identity will remain confidential in the data analysis and any publications that may arise from this research.

CHAPTER 8: INDIVIDUAL ROLE

As the only researcher collecting data for this project, my role consisted of patient recruitment and assessment which included the following components: screening patient charts for eligibility, approaching patients and ascertaining if they fit eligibility criteria, obtaining approval for participation from the Heart Function Clinic cardiologists/fellows, collecting all participant data including anthropometric measures, questionnaires, administering the six-minute walk test, data management as well as the final data analysis and interpretation. I was also responsible for instructing participants on appropriate use of the website and providing technical assistance when necessary.

CHAPTER 9: RESULTS

Participant Recruitment and Demographics

A total of 140 potentially eligible patients were approached. Of these 44 patients did not have daily Internet access, two claimed they would be away for extended periods of time, three had an improved EF, one patient was non-ambulatory and one patient was not going to be followed by the Heart Function clinic for 6 months, thus 51 patients (mean age = 66.5, SD=12.4, 36 male) were deemed ineligible. Of the remaining 89 patients (mean age = 61.6, SD=10.6, 65 male), 26 were not interested, 10 could not come for follow-up, nine stated they were “too busy”, 11 refused participation for a variety of other reasons, and a further seven either could not be contacted or chose not to enrol for non-specified reasons. Six interested patients were denied participation by the physicians for various reasons: sickle cell anemia (n=1), dialysis (n=1) and cognitive issues (n=4). Twenty participants, representing approximately 20% of the 89 potentially eligible patients, were enrolled (Figure 16). A total of 17 participants completed the study and were followed for an average of 194 days (SD=25.4).

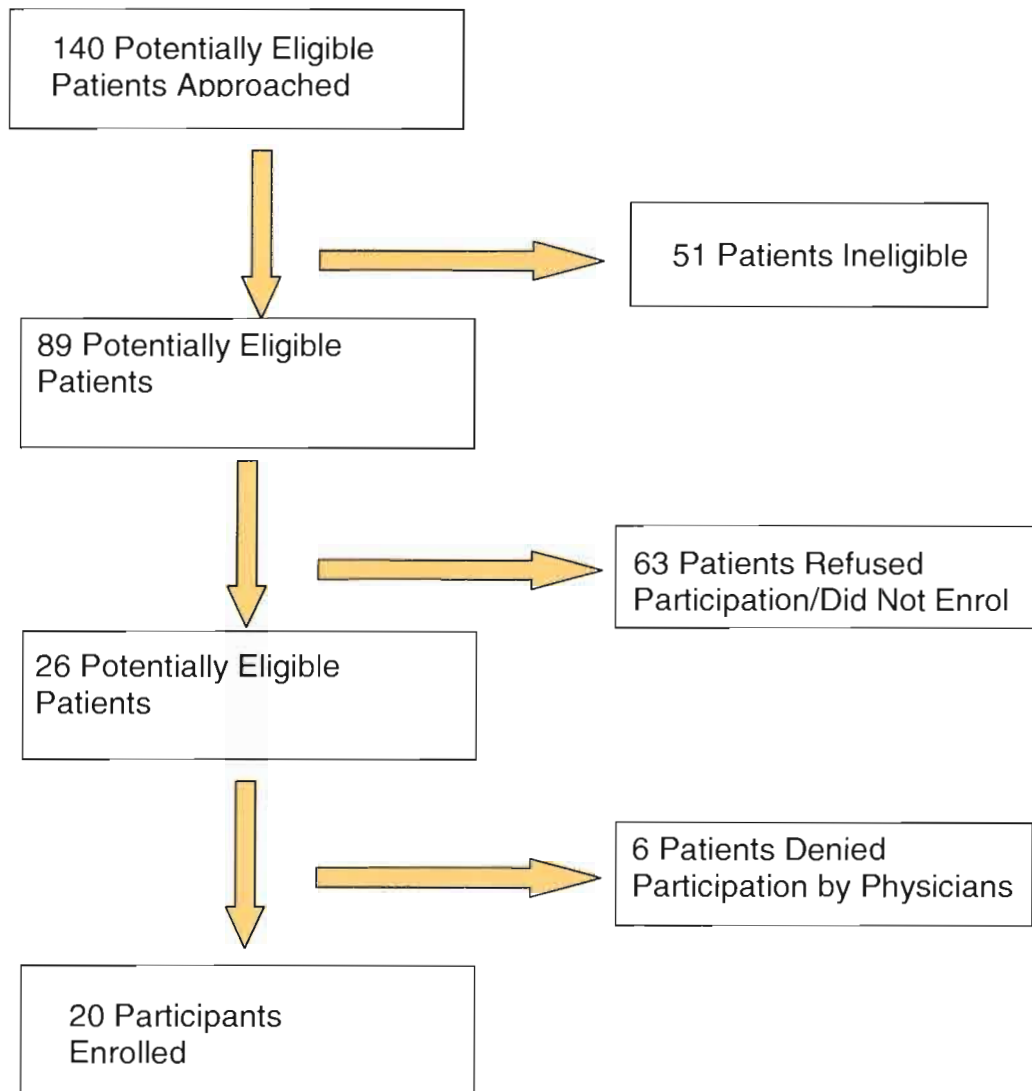


Figure 16: Participant Recruitment

The average age was 61.2 (SD=9.7) years for all 20 enrolled participants, and 62.3 (SD=9.6) years for the 17 remaining. Of the 17 participants who completed the study most were NYHA class II, and had an ejection fraction between 21 – 30%. The majority of these participants were married or living in a common law relationship, retired, and held a post secondary degree or diploma.

Baseline demographic data for participants can be found in Table 2 below. Data are presented for all 20 participants as well as for the 17 that completed the study.

Table 2: Participant Demographic Characteristics at Baseline

	Data for n=20	Data for n=17
Age (years)	61.2 (SD=9.7)	62.3 (SD=9.6)
Gender		
Male	14 (70%)	11 (64.7%)
Female	6 (30%)	6 (35.3%)
NYHA Class		
I	5 (25%)	4 (23.5%)
II	10 (50%)	8 (47.1%)
III	5 (25%)	5 (29.4%)
Ejection Fraction		
0 – 10 %	1 (5%)	1 (5.9%)
11 – 20 %	2 (20%)	2 (11.8%)
21 – 30 %	10 (50%)	8 (47.1%)
31 – 40 %	7 (35%)	6 (35.3%)
Marital Status		
Married/Common Law	14 (70%)	12 (70.6%)
Divorced/Separated	4 (20%)	4 (23.5%)
Other	2 (10%)	1 (5.9%)
Educational Status		
Less than high school	3 (15%)	3 (17.6%)
High school graduate	3 (15%)	3 (17.6%)
Some post secondary education	3 (15%)	1 (5.9%)
Post secondary degree or diploma	9 (45%)	8 (47.1%)
Post graduate education	1 (5%)	1 (5.9%)
Trade	1 (5%)	1 (5.9%)
Employment Status		
Retired	8 (40%)	7 (41.2%)
Full time job	4 (20%)	2 (11.8%)
Other	8 (40%)	8 (47.1%)

Three male participants dropped out with no pattern evident in the dropouts. The average age for the three males that dropped out was 54.0 years (SD=8.7), one was NYHA class I and two were in class II, two had an EF between 21 – 30% and one had an EF between 31 – 40%. Two of these participants asked to withdraw from the study. In one instance the participant was consistent with data entry but asked to withdraw after the three month follow-up due to a change in schedule, which he felt would interfere with data entry. In the other instance the participant only entered data on two occasions despite repeated telephone calls from the study nurse for lack of data entry and did not show up for the scheduled three month appointment. When contacted to reschedule, the participant requested to withdraw from the study. One male participant did not show up three times for the scheduled six month follow up, although he was consistent with data entry, and was considered lost to follow up.

For the 17 participants that completed the study, data are displayed in Table 3 stratified by gender.

Table 3: Participant Demographics at Baseline Stratified by Gender

	Males (n=11)	Females (n=6)
Age (years)	64.5 (SD=9.3)	58.3 (SD=9.6)
NYHA Class		
I	1 (9.1%)	3 (50%)
II	5 (45.5%)	3 (50%)
III	5 (45.5%)	0 (0%)
Ejection Fraction		
0 – 10 %	0 (0%)	1 (16.7%)
11 – 20 %	1 (9.1%)	1 (16.7%)
21 – 30 %	6 (54.5%)	2 (47.1%)
31 – 40 %	4 (36.4%)	2 (35.3%)
Marital Status		
Married/Common Law	9 (81.8%)	3 (70.6%)
Divorced/Separated	2 (18.2%)	2 (23.5%)
Other	0 (0%)	1 (16.7%)
Educational Status		
Less than high school	3 (27.3%)	0 (0%)
High school graduate	2 (18.2%)	1 (16.7%)
Some post secondary education	0 (0%)	1 (16.7%)
Post secondary degree or diploma	4 (36.4%)	4 (66.7%)
Post graduate education	1 (9.1%)	0 (0%)
Other	1 (9.1%)	0 (0%)
Employment Status		
Retired	5 (45.5%)	2 (41.2%)
Full time job	1 (9.1%)	1 (16.7%)
Other	5 (45.5%)	3 (50%)

Computer Usage Information

Many of the participants were regular computer users with 8 (47.1%) of the 17 participants that completed the study reporting that they were the primary computer user. Eight (47.1%) of these participants reported that they access the Internet on a daily basis. Most participants reported that they knew how to send emails, search for web pages, search for health related information and print documents. Baseline computer usage information is presented in Table 4 below.

Table 4: Computer Usage Information

		n=17
Main Computer User		
Participant	8	(47.1%)
Spouse/Common Law	4	(23.5%)
Child/Children	2	(11.8%)
Participant/Spouse/Common Law equally	2	(11.8%)
Participant/Child/Children equally	1	(5.9%)
Do you know how to		
Send email?	15	(88.2%)
Search for web pages?	14	(82.4%)
Search for health information?	13	(76.5%)
Print documents?	13	(76.5%)
Other?	6	(35.3%)
How often do you use the Internet in a week?		
7 days/week	8	(47.1%)
4 – 6 days/week	4	(23.5%)
1 – 3 days/week	3	(17.6%)
< 1 day/week or never	2	(11.8%)
What do you use the Internet for?		
General searching	13	(76.5%)
Searching for health information	12	(70.6%)
Bill payment	9	(52.9%)
Banking	9	(52.9%)
Other	8	(47.1%)

Alert Generation

For the 17 participants that completed the study, 456 alerts were generated and 295 (64.7%) of these were for lack of data entry. The number of total alerts generated per participant ranged from one to 87 and the number of alerts generated per participant for lack of data entry ranged from zero to 67. The number of alerts generated per participant can be found in Figure 17 below. Patient identifiers have been changed.

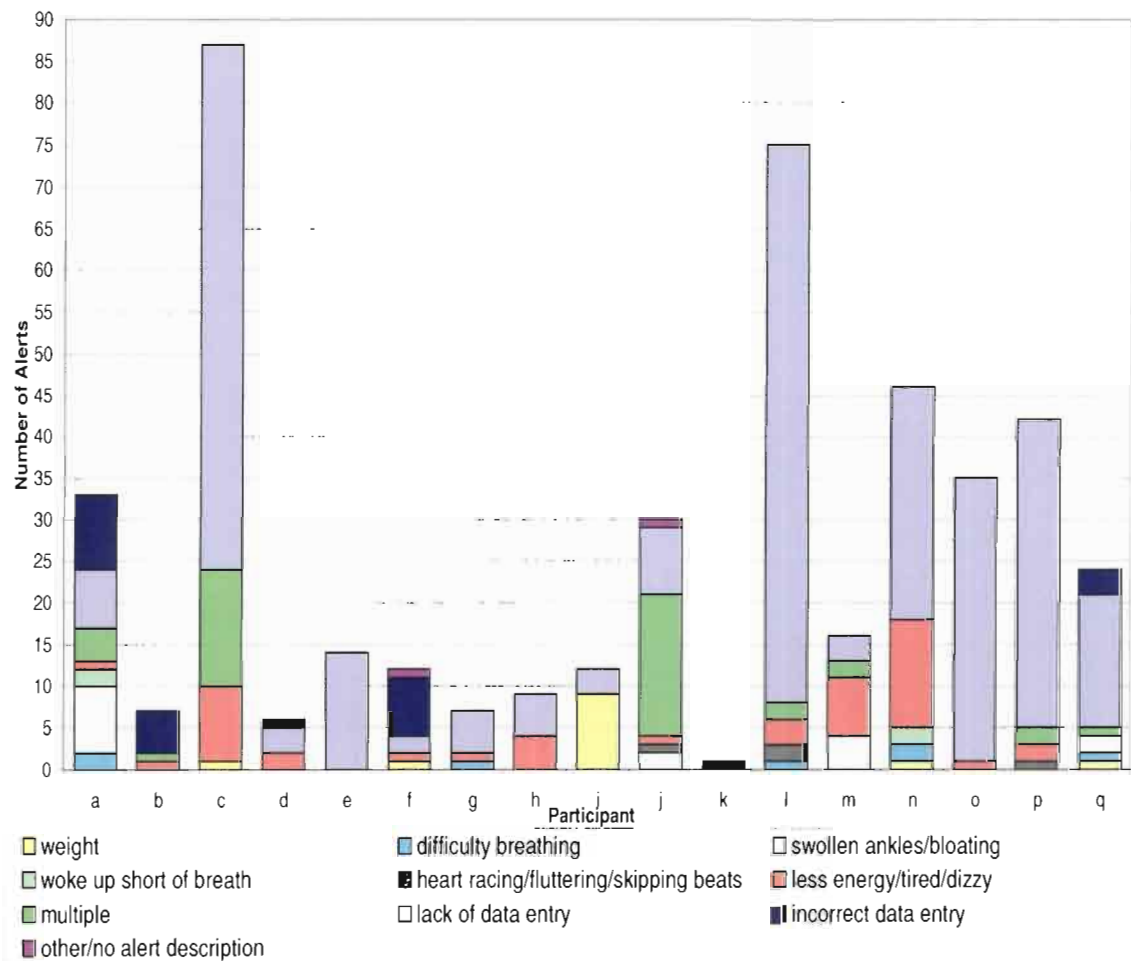


Figure 17: Number of Alerts Generated per Participant

Several factors contributed to the number of alerts generated for lack of data entry. In one instance the participant generated 63 alerts for lack of data entry, many of which were generated because he was unable to weigh himself due to a broken scale. Another participant generated 67 alerts for lack of data entry. This participant did not enter data consistently, as she felt that the website did not fully capture the essence of her condition and all of the events occurring

in her life which she felt affected her. After consultation with the participants, on several occasions the study nurse entered a leave of absence for these participants, as well as for one of the participants that dropped out, to prevent the generation of alerts for no data entry. An additional contributing factor is that participants sometimes entered data every several days, such that often an alert was generated early in the day, with the participant subsequently resuming data entry later in the day. Furthermore, on several occasions participants omitted to enter a leave of absence, thus further contributing to the number of alerts generated. The breakdown for alert number and reason can be found in Table 5 below.

Table 5: Alerts Generated

Alert Reason	n=17	
Total alerts generated	456	
Change in weight	13	(2.9%)
'Yes' to one symptom question	77	(16.9%)
- difficulty breathing	7	
- swelling of the ankles or bloating	16	
- woke up feeling short of breath	4	
- heart racing, fluttering or skipping beats more than normal	4	
- less energetic or more tired or dizzy	46	
Multiple reasons ('Yes' to multiple symptom questions or change in weight plus 'Yes' to one or more symptom questions)	43	(9.4%)
Lack of Data Entry	295	(64.7%)
Incorrect Data Entry	26	(5.7%)
Other/No Alert Description	2	(0.04%)

Primary Outcomes

For the 17 participants who completed the study, significant changes were observed with respect to the maintenance ($F=3.602$, $p=0.039$) and the confidence ($F=2.916$, $p=0.069$) subscales of the Self-Care of Heart Failure Index (Table 6). A non-significant trend toward improvement in six-minute walk test results was also observed ($F=2.482$, $p=0.124$). Changes in the Minnesota Living with Heart Failure® questionnaire ($F=1.126$, $p=0.337$) and the management subscale of the Self-Care of Heart Failure Index ($F=1.513$, $p=0.239$) were not significant. Although the change in NT-proBNP level was not significant ($z=-1.254$, $p=0.210$), the mean value decreased from a level of 1654 picograms/millilitre ($SD=2074.1$) at intake, to a mean level of 1181 picograms/millilitre ($SD=1075.6$) at six months follow up (Table 7).

Table 6: Primary Outcome Measures

Variable	Intake	3 months	6 months	F	p
Minnesota Living With Heart Failure® Questionnaire	44 (24.2)	41 (20.6)	38 (24.4)	1.126	0.337
Self-care maintenance	74.1 (16.0)	80.9 (10.9)	78.2 (11.9)	3.602	0.039
Self-care management	63.5 (18.5)	69.1 (19.2)	69.3 (21.3)	1.513	0.239
Self-care confidence	62.9 (10.0)	65.1 (13.8)	72.1 (12.7)	2.916	0.069
Six-minute walk test (meters)	428.1 (95.8)	463.5 (73.0)	460.8 (79.4)	2.482	0.124

Table 7: Primary Outcome Measures Continued

Variable	Intake	6 months	z	p (two tailed)
NT-proBNP (picograms/millilitre)	813 (389.5, 2176.5)	1017 (397.0, 1704.0)	-1.254	0.210
	1654 (2074.1)	1181 (1075.6)		

Values represent median (25th, 75th) and mean (SD).

Primary outcomes were stratified by gender to assess if there were any significant changes within each gender. Women demonstrated a significant change on their self-care maintenance (p=0.075). Men (p=0.059) demonstrated a significant change on their self-care management.

Due to a number of incorrectly filled-out questionnaires, Leisure Time Physical Activity scores are not reported.

Secondary Outcomes

There was a significant change observed for diastolic blood pressure. There were no significant changes for the other secondary outcomes of systolic blood pressure, heart rate, weight, and hip and waist circumference. The outcomes are reported in Table 8 below.

Table 8: Secondary Outcome Measures

Variable	Intake	3 months	6 months	F	p
Systolic Blood Pressure (mm Hg)	109 (16.9)	111 (14.3)	105 (11.7)	1.797	0.182
Diastolic Blood Pressure (mm Hg)	68 (9.4)	71 (9.2)	64 (10.1)	4.384	0.021
Heart Rate (beats/minute)	67 (15.8)	66 (11.6)	63 (10.7)	0.940	0.401
Weight (kgs)	86.0 (22.5)	86.0 (21.6)	86.8 (22.7)	0.563	0.575
Waist Circumference (cm)	99.7 (18.5)	99.0 (17.7)	98.7 (17.5)	1.256	0.298
Hip Circumference (cm)	109.2 (15.3)	107.8 (13.7)	107.6 (14.4)	2.219	0.125

Participant Interviews

A total of 13 participants were formally interviewed. Additionally, the two participants that requested to withdraw from the study were questioned over the telephone regarding their experiences. The remaining participants were not interviewed as it was decided that saturation was reached and no new themes were emerging from the interviews.

Uptake of the intervention was favourable with 12 of the 15 interviewed participants stating that they would participate in a similar program in the future, another stating yes depending on their time commitments and one further participant stating yes if the website was 'tweaked'. Some participants also expressed a desire to continue with use of the website. A number of benefits were reported by participants in particular that the program made them more

aware of, and caused them to make a conscious effort to monitor their weight and symptoms. Remarks such as the following were often made. One participant stated:

It made me understand to look for any of the symptoms I used to shrug off as just something else. Now I'm more concerned with what my body is actually doing. So that I'm more aware of whether my heart is really bothering me or whether it's something else.

Another participant stated:

I found it very useful because the one thing is that it helped me correlate my checking my weight. It also helped me to remind myself to watch my water intake, my fluids. It helped me to see what happens when I do fluctuate between weight. And sometimes some of the symptoms that I do have. It made me see also too that there was always somebody on the end watching that as well so that if they were concerned about something, they would give me, they would let me know. So it was great in that way.

Participants reported additional lifestyle changes including paying greater attention to their salt and fluid intake, which is essential in the maintenance of heart failure. Participants found the weight graph useful for this purpose, and some reported undertaking exercise programs, and reported that they could also track changes in weight due the exercise programs using the graph. One participant stated:

It was nice to sort of keep track of my weight, it forced me to do it every day at the same time and I was conscious of my weight and I was actually conscious of what I ate because I didn't want my weight to go up. It was kind of fun having the chart to look at.

A participant who had been dealing with longstanding heart health/heart failure, stated that the program

...certainly makes your interest pique and you know keeps you focused on your health.

Participants reported that they found reassurance in knowing that if they triggered an alert, there was someone who would be calling to check in with comments such as the following:

it was nice to know that if there was a problem there was nurse that would get a hold of me immediately if any like flags came up on it.

Several participants stated that the website made them feel connected, and that even though it was a study nurse making the telephone calls, if something needed to be addressed, the nurse was able to communicate with clinic nurses or cardiologists, thereby connecting the participant with these health care professionals. Additionally, the website was seen as an alternative to contacting a doctor with one participant in particular stating

I enjoyed it, I found it useful and I thought somebody out there is looking at it you know and giving me a call [if] something is wrong... you wouldn't normally phone a doctor and say my foot is swelling a bit, I know how to look after it, take an extra water pill and watch it and make sure that it goes down. But the nurse phoning me and telling me that is just that much better. I wouldn't go to a doctor. I wouldn't go and phone a doctor and get an appointment to tell him... so I find this very convenient.

Similar comments were reiterated among several participants, in that this was a way of receiving additional care, which they would not normally seek out themselves.

In terms of suggestions for improvement, several participants commented that it would be useful to have a free text comment box where they could explain their answers for that day, for example, if they were tired due to lack of sleep,

and not their heart problems. Participants felt that this would help the nurse to have a better understanding of their condition and any changes being reported. As such, several participants sent a number of emails to the study nurse to communicate the reason for their answers. One participant in particular felt that the way the website worked was passive, and suggested the addition of a 'blog' type feature, where participants could further detail their behaviour in regards to diet, exercise, etc to see how these factors affect their health status. She additionally suggested the integration of an interactive component where participants could interact with each other as well as the inclusion of additional educational components and links to educational materials or organizations. Some participants suggested that different questions be available for different patients, which are more specifically tailored to their condition, while others suggested that they would like the questions reworded so that it was not 'compared to yesterday'.

Participants reported that the website was simple to use and that it required minimal time. The two participants who dropped out also reported that the website was simple to use.

Staff Interview

The primary study nurse, a secondary study nurse and two clinic nurses were formally interviewed, while one clinic nurse provided written responses to the questions. The clinic nurses reported that they saw the utility of the intervention, but that it did add some time to their workload. The primary study nurse reported that the phone calls she placed were a useful way to reinforce

what the participants had learned at the clinic and may have forgotten since their visit. The major concern that came up was the communication between and integration of the study and clinic nurses, as the study nurse had to consult with clinic nurses regarding participant responses. It was suggested that it would be more efficient if the nurses responsible for patient care in the clinic were the ones who followed that patient via the website, or that there be one person dedicated to monitor the website, but who would be able to deal with patient issues and recommendations without having to consult with clinic nurses.

Nurses also felt that because many participants were dealing with a number of comorbidities that such a modality should attempt to be tailored to each patient's particular condition and that there should be some sort of integration between the heart specialists, the GP and others when necessary. It was suggested that a nurse practitioner might be a good candidate to serve as the nurse responsible for monitoring the website, titrating patient medications, and then interacting with the other health care professionals.

Another issue raised by the nurses was the reporting of symptoms not related to heart failure. Like the participants, nurses recommended that there be some sort of comment box where participants could explain their answer to help save nurse time. Nurses speculated that some patients may generate alerts because they want the reassurance and social aspects of a nurse telephoning them, even though they are not feeling any worse compared to yesterday.

Nurses reported that although most patients would benefit from participating in a similar program, patients who do not have access to a heart

function clinic would probably reap the most benefits from the reinforcement and contact with the study nurse. Time constraints were a concern for the nurses, it was suggested that if such a system was implemented into routine care, the patients who are unstable could be enrolled and then as they are optimized they could be taken off the program, or be able to enter data less frequently.

Nurses felt that if they were dedicated to particular patients the website would be useful for tracking patient weight changes that occur slowly over time and may be of concern. Additionally, nurses reported that they often have telephone or email interaction with certain clinic patients as well, so having these patients on a website may be beneficial to such patients.

CHAPTER 10: DISCUSSION

Heart failure is a prevalent condition among the elderly and results in high rates of hospitalization and high health care costs. Interventions that entail monitoring the signs and symptoms of heart failure have demonstrated improved outcomes including decreased hospitalization and improved quality of life. Frequently these interventions involve extensive follow up by health care practitioners or the use of specialized equipment where participants enter their signs and symptoms for practitioners to review. This can prove to be time intensive if it is applied to large numbers of patients, and the provision of specialized equipment to all patients who need it may not be feasible. An alternative is the use of a nurse-monitored website. Patients enter their signs and symptoms and the nurse follows up with those who experience changes. With increasing Internet usage among the elderly [27], use of the Internet for telemonitoring of heart failure patients requires investigation.

The purpose of this study was to investigate the feasibility and effect of a website designed to assist heart failure patients in self-monitoring. As few similar studies have been conducted [20-23], results from this investigation provide valuable information in regards to the benefits and utility of an Internet-based self-monitoring intervention. Results indicated that this website was favourably accepted by heart failure patients as a tool to monitor their condition. Significant changes were observed on two subscales of self-monitoring ability. There was

also a significant change observed for diastolic blood pressure. Patients indicated high levels of satisfaction with the website, with most expressing that they would participate in a similar program in the future and some even expressing a desire to continue with use of the website. Nurses also reported a favourable uptake of the intervention.

Primary Outcomes

The changes demonstrated by the participants are favourable and lend support to the hypothesis that the use of the website would result in improved outcomes, although not all investigated variables improved significantly. Participants experienced significant improvements on the self-care maintenance and self-care confidence subscales of the Self-care of Heart Failure Index. The maintenance subscale questions participants regarding self-care behaviours such as how likely they are to weigh themselves daily, to keep their weight down and to eat a low salt diet. All of these behaviours are aspects of heart failure self-management [9, 10] and most specifically, daily weighing was an integral part of the use of the website. Previous data from Wright et al. [8] indicate that patients who did not adopt self-management strategies including self-weighing were at high risk of death or readmission. The change experienced on this subscale (mean levels of 74.1, 80.9 and 78.2 at baseline, three and six months respectively) indicates that participants were more likely to engage in these and the other behaviours investigated by the subscale as time progressed. The confidence subscale investigates how confident participants are that they can evaluate their symptoms and the effects of the action they take to remedy the

situation. These aspects are also integral to the concept of self-management [9, 10] and the participants demonstrated an improvement from 62.9 to 65.1 to 72.1 points from baseline to three and six months. The authors of the tool [32] cite differences of 4 and 6 points on the maintenance and confidence subscales as being statistically significant in individuals who have been diagnosed less than two months prior to assessment as compared to those diagnosed more than two months prior to assessment. The changes observed from intake to six months in this study were equal to four and nine for the maintenance and confidence subscales respectively. As the website was designed to assist participants in self-monitoring their condition, the changes in their self-care abilities coincide with reports that they felt the website allowed them to become more aware of their signs and symptoms.

In regards to the management subscale of the Self-Care of Heart Failure Index, no significant changes were observed. This scale evaluates the recognition of changes in signs and symptoms, and the patients knowledge that they are related to heart failure [32], however, scores are affected by which symptoms participants did or did not experience, thus this subscale is not as applicable as the remaining two. If participants have not had trouble breathing or ankle swelling they would be unable to answer some of the questions and thus the scores on the scale would be lower, even though they did not experience a deterioration in their management skills. Conversely, if they did experience these symptoms, participants could answer all questions, and may have a higher score even though their management skills may not have changed.

Although non-significant, trends on the Minnesota Living With Heart Failure® questionnaire indicate improved scores at follow up. The score fell from 44 to 41 to 38 from baseline to three and six months respectively, thus the change was approximately 6 points suggesting trends toward improvement in quality of life. Although statistically non-significant, the clinical significance of this change is somewhat more difficult to determine. According to an overview of the questionnaire [30] some investigators have suggested that a change of one standard error of the mean (SEM) may be clinically significant. Estimates for the SEM for the tool are approximately six to seven points, and the change demonstrated by the participants in this study are approximately equal to that and may be viewed by some as being clinically significant. It has been previously reported that scores on the questionnaire are correlated with number of hospital admissions in the previous year and functional class [40]. Although the reported results are based on a Spanish population, scores on the questionnaire are associated with disease severity, and this may likely apply to participants in this study.

Participants also demonstrated non-significant trends toward improvement with respect to NT-proBNP levels. Although this change was not statistically significant, the drop was equal to approximately 28%, changing from a mean of 1654 picograms/millilitre at intake, to a mean of 1181 picograms/millilitre at six months follow up. Several studies have reported increased mortality and hospitalization with higher NT-proBNP levels [41, 42] as well as higher NYHA classification [43]. Petretta et al. [34] reported that there was a difference of

2386 picograms/millilitre between survivors and non-survivors over a year and a half, and that NT-proBNP level was greater in higher NYHA classes. With respect to the clinical significance of a change, Bayes-Genis et al. [44] examined serial NT-proBNP levels in heart failure patients. NT-proBNP was measured at intake, then weekly for four weeks and at three months unless a primary event occurred. Primary endpoints were cardiovascular events. Baseline NT-proBNP concentrations were not statistically different between patients with and without events. No significant decrease was found in patients who experienced events, while there was a significant decrease in those patients that did not experience events during follow up. In patients who did not experience events the NT-proBNP level decreased by 30%, 36%, 34% and 37% at one, two, three and four weeks from baseline and each relative decrease was a statistically significant predictor of events. It is difficult to compare the results of the Bayes-Genis study to the results observed in the current study, as in the current study levels decreased by approximately 28% over a period of six months. Irrespective of this, NT-proBNP levels did show a trend toward decreasing, and may suggest improved outcomes among the participants.

The improvement in the six-minute walk test scores by approximately 33 meters, from 428.1 to 463.5 to 460.8 meters, from intake to three to six months, was not statistically significant. Several studies have reported on the association of lower distances walked with increased mortality and hospitalization [45, 46]. One study [47] comparing the use of Perindopril to placebo found an increase of 37.1 meters in the Perindopril group compared to a decrease of 0.3 meters in the

placebo group, with the difference between the two groups being significant. At follow-up the groups differed by 34.9 meters, and this is in line with the change observed in this study. However, they were investigating medication and the length of follow-up was 10 weeks. In comparison, the Artinian study [14] also reported an improvement of 49 feet (approximately 15 meters) in the mean score for the six-minute walk test for their monitored group, which is less than half of the value observed in this study. However, they used a different modality and the follow-up was three months in length. Additionally, their usual care group improved to a greater degree (137 feet or approximately 42 meters) than did the monitored group. Given the improvement demonstrated by participants in this study, it is likely that the change is indicative of improved outcomes.

Although not all measured variables improved with use of the website, there is a clear trend towards improvement on virtually all primary outcomes and there was no deterioration observed on any of the variables measured.

Secondary Outcomes

With respect to secondary outcomes only diastolic blood pressure demonstrated a significant change from 68 to 71 to 64 mm Hg from baseline to three to six months. Interestingly, diastolic blood pressure was slightly higher at the three month follow up than at intake but then dropped down to a lower level at the six month follow up. There was no change in either weight or waist circumference, indicating that the intervention was useful in preventing weight gain. This is in agreement with participant reports that the graphs helped them to keep track of their weight.

Comparison to Other Studies Using the Internet

It is important to consider that this study was a pilot and that it used a sample size of convenience. The small sample size may have made it difficult to detect differences in the other variables investigated. However, like the previously conducted studies, this study lends support to the fact that telemonitoring is beneficial for heart failure patients. Although it is difficult to compare the results of this study to the results of most previous studies utilizing specialized devices for telemonitoring, several comparable studies using websites exist. The study by Delgado et al. [20] found significant differences on the Minnesota Living with Heart Failure® questionnaire, which fell from a mean of 59.75 at baseline to 49.87 at three months, and high levels of satisfaction with the website among participants. This is in agreement with our results, in that there was a trend towards improvement in quality of life and high levels of satisfaction among participants. However, the methodology used by Delgado et al. differed somewhat from this study. Their nurse reviewed each patient's data and sent back individualized responses using the website whereas in this study nurses only reviewed the responses of participants who generated alerts.

Wu et al. [21, 22] also examined the use of the same website as Delgado et al. and found that there was greater hospitalization in the 'user' group (n=26) of patients who utilized the website regularly, compared to the 'non-user' group (n=36), due to planned hospitalizations for procedures such as pacemakers, defibrillators and tailored inotropic therapy. Although the hospitalization rates increased, it should be noted that they increased because the patients were

receiving planned treatment and not due to unplanned hospitalizations resulting from decompensation. However, the protocol for the study by Wu et al. was somewhat different from the one used in the current study, as they did not have a set follow up period, participants were permitted to use the website as long as the study was ongoing and clinicians used the website to respond to patient data.

A study by Kashem et al. [23] investigated a different website and reported decreased emergency visits, hospitalizations and total hospital days among their participants. It is difficult to say whether this intervention would have resulted in changes in hospitalization as there was no comparison group, however, participants did not report any hospitalizations associated with use of the website.

Irrespective of the differing methodologies between studies, there appears to be a benefit associated with the use of telemonitoring using the Internet among heart failure patients. Together these studies indicate that heart failure patients are willing to use a website to assist in monitoring their condition and that its use is associated with some changes in quality of life. This study further suggests that a nurse need not monitor the responses of all participants as has been done in previous interventions. This may prove to be a more time effective protocol and may allow for the monitoring of a greater number of patients. Thus Internet based telemonitoring of heart failure patients does hold promise, but due to the small number of studies in this area, further work is warranted before conclusive benefits can be fully determined.

Advantages Over Other Telemonitoring Modalities

With respect to other telemonitoring modalities, a website has clear advantages over supplying participants with specialized devices in terms of feasibility, as participants have their own computers and Internet access and no extra equipment is needed. A website eliminates the need for the purchase of extra equipment and potentially allows for an unlimited number of patients to be enrolled, with availability of a nurse to monitor the website being the determining factor of how many participants are enrolled. A website will have costs associated with it, such as development, maintenance, and hosting, but has clear advantages also because patients cannot 'break' or 'lose' the website such as they could a specialized device. It may be arguable that use of the telephone also has similar advantages over specialized devices but the telephone also has limitations with respect to providing participants with feedback regarding their condition. In an intervention in which participants enter their signs and symptoms via telephone, participants cannot view graphs or progress reports of their status and changes in their condition. A website allows participants to graphically view changes in their status over time and may help them to examine the effect of actions taken and the effect they have on signs and symptoms. This evaluation is a key component of self-monitoring and in fact, it was reported by participants in this study that the website made them aware of the importance of tracking their weight and symptoms.

Although not all people with heart failure use or have access to the Internet, trends in Internet usage indicate an increase, including among older

populations, with younger age groups indicating greater usage. Thus it can be presumed that currently non-elderly individuals who do not have heart failure but may develop it in the future, are more likely to be familiar with and have access to the Internet than individuals who currently have the illness. This in combination with the favourable uptake reported by participants may indicate that use of a website for monitoring may hold even more promise in the future.

The alert system used in this study, whereby only participants who have experienced changes in weight and symptoms generate alerts and are contacted by the nurse, clearly has the potential to be more time effective than the systems used in most previous studies, where all participant data was reviewed. If 100 participants are enrolled, and the data of each one have to be reviewed, it can take hours, assuming that one to two minutes are required to review the data for each participant. Clearly a system where nurses only review the data of and contact those participants who trigger an alert is advantageous in terms of time requirements compared to interventions where all participant data are reviewed even if stable.

Participant and Nurse Responses and Website Usability

The favourable uptake demonstrated by participants is encouraging as it lends credibility to the use of the Internet to provide an intervention to heart failure patients. A total of 14 out of 15 participants interviewed, including one of the participants that dropped out, expressed that they would participate in a similar program in the future. The remaining participant stated that he could not get himself into using the website despite repeated nurse reminders to enter

data. Although the participants in this study were younger than the typical heart failure population [1] (62.3 (SD=9.6) vs. 76) they were willing to use the website for monitoring. Participants reported that the website made them aware of the importance of tracking their weight and symptoms, which is essential to the concept of self-monitoring. The participants provided a number of suggestions for improvement of the website and these are discussed in the following sections.

With respect to usability of the website, participants felt that it was simple to use and required a minimal time commitment. More information in this regard can be obtained from patient data entry patterns. Although there was a large number of alerts for lack of data entry, 456 alerts were generated and 295 (64.7%) were for lack of data entry, 130 of these alerts can be attributed to two participants, only one of whom was not entering data due to reasons associated with the website. Additionally many of the remaining alerts generated for lack of data entry could be explained by the various reasons discussed previously. In practice such alerts and the reasons behind them should be explored to ascertain if they can be resolved, for example by placing the participant on a leave of absence. Thus it can be concluded that it was not factors intrinsic to the website, but rather factors intrinsic to the participants that most likely account for the remaining lack of data entry alerts. This also appears to be the case with the participants who dropped out of the study. Two of the participants entered data regularly and generated seven and 11 alerts respectively for lack of data entry. One of these participants cited a change in schedule for their decision to withdraw and in the other instance the participant did not show up for follow-up.

This suggests that factors intrinsic to the participants and not the website are related to their decision to withdraw from the study. The third participant entered data on only two occasions despite repeated nurse reminders, and when questioned stated that he could not 'get himself into it'. Interestingly this participant also did not attend his scheduled appointment at the clinic on the day he was scheduled for follow-up, further confirming that intrinsic factors likely played a role in his non-adherence.

Only one participant reported technical difficulties with the website. At times when attempting to logon she would receive an error message stating 'object moved here'. When this occurred, she would logon again. The website developers attempted to troubleshoot the problem but were unable to determine a cause. Despite this, the participant was able to successfully enter data. None of the participants reported any hospitalizations or emergency room visits that they would attribute to use of the website.

Clinic nurses indicated that in practice they at times telephone patients to assess their medical condition and that such a website could be a useful tool for determining when patients should be contacted. Instead of placing telephone calls to patients to ask about their weight and symptoms, the nurses could easily look up patients on the website to keep track of them, and if these patients generate alerts the nurses would automatically be notified. Additionally, nurses could have access to patient information using the website, even if the patient is not near a telephone, thus the nurse would not have to repeatedly try to contact the patient simply to enquire about weight and symptoms.

The nurses also stated the website could be a useful tool for patients, particularly those who are unstable or do not have access to health care services. As the number of hospital readmissions after discharge is high among heart failure patients, a website may be an ideal monitoring tool to utilize after hospital discharge until patients stabilize. If a patient is newly diagnosed with heart failure they may not be aware of the importance of tracking weight and symptoms. The website could be used to assist the patient in the period when they are newly diagnosed or unstable and have not had the chance to visit a heart failure specialty clinic. Additionally, a website may be a useful tool for patients who live in remote areas and do not have access to specialty clinics. By providing these patients with the website, they would be receiving a level of care above what is normally available to them, thus enhancing the ability to detect deterioration in their condition. With the website, changes can be detected quickly and appropriate action can be initiated, potentially helping to avoid hospitalization. As the patient stabilizes, they can decrease the frequency of data entry and slowly wean off when stable. With respect to this, patients can even be monitored by their family physician using the website.

Clearly the use of a website to monitor heart failure patients is favourably accepted by both participants and nurses and holds promise for improving self-care ability and other outcomes.

CHAPTER 11: LESSONS LEARNED

Several issues arose for the duration of this study in regards to website design and intervention implementation. In regards to website design, participants reported that the website was easy to use, however, their suggestions for improvement need to be considered. Some participants recommended rewording of the symptom questions so that they are not 'compared to yesterday'. Two possible solutions are asking 'yes' or 'no' questions such as 'Are you feeling short of breath?' or providing a likert scale and posing questions in the form of 'How short of breath are you?'. With the former option an algorithm would have to be developed to determine which score on the likert scale would require the nurse to telephone the patient. Participants also suggested a comment box where they could explain their signs and symptoms. Again with such an option an appropriate algorithm would have to be developed to determine when nurses should contact patients. A check box can be included where patients tick off 'please do not contact me as I am feeling fine'.

Nurses suggested that there could be a confirmatory screen after patients enter their data, stating 'you have entered that ... is this correct?' to help avoid incorrect data entry. Nurses also recommended a change to the process of alert resolution. Because the study nurse was not a clinic nurse, she was required to consult with clinic nurses as per protocol, which required additional time. As nurses suggested, a nurse practitioner may be an ideal candidate to serve as the

nurse that monitors the website, or alternatively, the nurses responsible for patient care can monitor the website. This would allow optimization of nurse time required to address patient alerts. The website could also be set up so that each participant is monitored by their family physician who can then contact the specialist clinic when the participant is experiencing signs and symptoms that require attention.

CHAPTER 12: STUDY LIMITATIONS

Due to the nature of the intervention, all patients who do not have daily Internet access were excluded from participation. Data indicate that Internet usage is associated with age, income and education [26] thus, participants may be younger, more educated, and in a higher income bracket than those patients who do not have Internet access. Indeed, when looking at the 51 patients who were deemed ineligible, most due to lack of Internet access, the average age was 66.5 (SD=12.4) compared to 61.6 (SD=10.6), $p=0.014$, for the 89 who were potentially eligible. The average age of the participants was lower than that of average heart failure patients [1] (62.3 (SD=9.6) vs. 76) and this too might indicate that the recruited participants might not be representative of the typical heart failure population. Additionally, there is the possibility of a healthy volunteer bias. It may be the case that the patients who were approached and chose not to participate may have been experiencing more severe heart failure than those who chose to participate. These factors may affect the external validity and generalizability to a typical heart failure patient demographic. Thus the ability to extrapolate the results obtained to other patients may be affected.

The other major limitation to this study is the lack of a control group. A control group was not included in this study and thus the effect of the intervention could not be compared to the effect of usual care. An attempt was made to conduct a retroactive chart review and compare participants to matched controls

from the Heart Function Clinic but no adequate matches were found who had the desired measures (Minnesota Living With Heart Failure Questionnaire and NT-proBNP) conducted at similar intervals as in the intervention. However, because this study is meant to serve as a pilot for future research, the assessment of patient and staff uptake of the intervention are of use. Additionally, patients who attend the heart function and pre-transplant clinics receive the 'gold standard' treatment. They are evaluated, treated and followed up by nurses and cardiologists and it is difficult to determine whether the changes observed among study participants are due to the treatment they receive from the heart function and pre-transplant clinic or the intervention.

A further limitation is the small sample size. Due to the nature of the study and time constraints a convenience sample was chosen. As such it may have an effect on the ability to detect statistically significant differences. Additionally the participants may not be fully representative of the typical heart failure population. As this study was a pilot a significance level of 0.10 was chosen. This is higher than the typical significance level of 0.05. The higher significance level was chosen for a number of reasons. The study was meant to examine the usability and the feasibility of the website for the telemonitoring of heart failure patients. Additionally, the nature of the outcomes measured was not such that participants would experience negative outcomes if the improvement they demonstrated occurred due to chance. With the higher significance level there is a greater possibility that the improvements experienced by participants may have been due to chance. However, even if improvements in the outcomes measured were

due to chance, they would not be detrimental and do not affect the usability of the website. Thus the higher significance level is justifiable.

CHAPTER 13: FUTURE DIRECTION

The use of a website for the monitoring of heart failure patients shows promise and as such future direction should focus on conducting randomized, controlled trials assessing the impact of the website. Participants using the website can be compared to usual care, but also to participants using another telemonitoring modality. This would allow for the determination of the advantages of telemonitoring compared to usual care, but also the advantages of one modality over the other. A number of outcomes can be investigated including quality of life, self-care ability, six-minute walk test, NT-proBNP, hospitalization and mortality rates, and cost of the intervention. The cost of monitoring, as well as the cost of website maintenance and system wide implementation should be compared to the cost of the usual care and other modalities to determine if using the modalities results in cost savings and whether one modality is more economical than the other.

Patients who are newly diagnosed, who are being managed by their family physicians and who have not yet been referred to a specialty clinic may be ideal to investigate. Because these patients are not receiving the enhanced level of care provided by specialty clinics they may benefit from a website that assists them with self-monitoring. Patients living in remote areas without access to health care can also be included as such an intervention can provide a level of care that may otherwise not be available to them.

Power Calculations

Using the results obtained, power calculations were conducted using the Power and Sample Size Calculation program [48]. The minimum sample size needed to observe statistically significant differences are reported in Table 9 below. The results were obtained by entering the desired power level of 0.80, with a $p=0.05$. The standard deviation was obtained for the change from intake to six months observed in this study. For NT-proBNP this value was 1460 picograms/millilitre and for the six-minute walk test it was 94.9 meters. There do not appear to be any guidelines for a clinically significant change in NT-proBNP and six-minute walk test. Thus the observed difference from a previous study which was noted to be statistically significant for NT-proBNP was 2386 picograms/millilitre [34] and was used in the calculation. For the six-minute walk test Hutcheon et al. [47] powered their study to detect a difference of 10 meters and the same value was used in the calculation reported in Table 9.

Table 9: Number of Participants Needed in Each Group

Variable	Standard Deviation	Difference	p value	Power	n
NT-proBNP	1460	2386	0.05	0.80	7
Six-minute walk test	94.9	10	0.05	0.80	1415

NT-proBNP and six-minute walk test were chosen as the outcomes to power future studies because they are well validated and relatively objective. Clearly there is a large discrepancy between the two measures for the number of participants needed in each group. The large difference reported by Petretta et

al. [34] with respect to NT-proBNP is quite large, perhaps larger than can be expected in some patients, and causes the calculated sample size to be quite small. Seven participants per group may be too small to realistically detect differences between groups. Conversely the small change used by Hutcheon et al. [47] with respect to the six-minute walk test may not be clinically significant and results in a large calculated sample size. Realistically, 1415 participants per group may be too many to recruit. As such several different calculations were conducted to determine the sample size when varying differences were used and can be found in Table 10 below. The power level used in the calculations was 0.80 and the p value was 0.05. The standard deviation used for NT-proBNP was 1460 picograms/millilitre and for the six-minute walk test it was 94.9 meters.

Table 10: Number of Participants Needed in Each Group Continued

NT-proBNP		Six-minute walk test	
Difference	n	Difference	n
500	135	20	354
1000	34	35	116
1500	16	50	58

When the observed difference of 34.9 meters reported by Hutcheon et al. [47] was used in the calculation, the calculated sample size was 117 participants per group. Given that this study noted trends towards improvement with 20 participants, it is likely that a study with fewer than 117 participants per group would detect statistically significant changes. Accordingly, a randomized controlled trial should be conducted to assess the outcomes mentioned above. If

possible, researchers should be blinded to group assignment to help decrease bias.

CHAPTER 14: CONCLUSIONS

This investigation of a website for the monitoring of heart failure patients is a relatively novel concept with few previously published studies in the area. As such it provides a number of valuable results.

- The use of a website for the monitoring of heart failure patients is feasible. Participants were willing to use the website and reported a favourable uptake of the intervention. Nurses also reported a favourable uptake.
- Use of a website for the monitoring of heart failure patients is safe. The participants did not report any adverse events associated with use of the website.
- Use of a website for monitoring of heart failure patients is associated with improved outcomes. Statistically significant changes were observed for self care ability.

The favourable results from this pilot study lend credibility to the use of a website for the telemonitoring of heart failure patients and should be used to power a large scale, randomized study investigating its use.

APPENDICES

Appendix A: Participant Consent Form



St. Paul's Hospital



**SIMON FRASER
UNIVERSITY**

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)
Academic Director, HHP: Jiri Frohlich, MD, FRCP(C)
Program Coordinator: Sandra Barr, RN

Remote Management of Patients with Chronic Heart Failure Using Internet Supported Technology Intervention Group Consent Form

Investigators:

Dr. Scott Lear	604-682-2344 ext 62778
Ms. Annemarie Kaan	604-806-8976
Dr. Andy Ignaszewski	604-806-8605
Ms. Biljana Maric (primary contact)	604-682-2344 ext 63052
Dr. Cindy Patton	604-268-6887

The above investigators would like to invite you to participate in the following research study as you have chronic heart failure and are currently attending the Heart Function Clinic. Participation is entirely voluntary and you may decide to refuse to participate or withdraw from the study at any time.

Purpose:

Patients with heart failure who take an active role in managing their symptoms through fluid and salt restriction (self-management) tend to have an improved quality of life and reduced complications. The purpose of this study is to see if the Internet can help patients with managing their illness at home. We will use a website designed for patients with chronic heart failure (CHF). We hope that using this website will help patients to understand their symptoms and what to do about them. In order to decide if using the Internet helps patients, we need to see how people using the website ("intervention" group) do compared to a similar group who don't use the website ("standard" group). You are being asked to be in the "intervention" group for this study.

Voluntary Participation

Your participation is entirely voluntary. You have the right to refuse to participate in this study. If you decide to participate, your decision is not binding and you may choose to withdraw at any time without negative consequences to the medical care, education, or other services you may receive from St. Paul's Hospital and Providence Health Care.

Who can participate in this study?

Patients with heart failure who have been recently referred to the St. Paul's Hospital Heart Function Clinic and who have and use the Internet may be eligible for this study.

What does your participation involve?

Upon providing consent to this study, you will be asked to undergo an initial assessment which includes getting basic information about you, your medical history, measurement of height, weight, blood pressure, heart rate and waist circumference as well as a six minute walk test, and three questionnaires (one for each of quality of life, self-management, and activity patterns). You will be asked to return 3 and 6 months from now for a repeat of all the measures described above. At this time you will also be asked about hospital and emergency room visits since your last assessment. For those who report hospital and emergency room visits, we will need to get information from your medical records from that institution. You will need to sign the attached sheet to give us permission to access these records. A blood test will also be done at the time of your first assessment and at the end of the study. This blood test is often done as part of the care you receive from the Heart Function Clinic, and we will use these results whenever possible. As a member of the "intervention" group, you will have access to the self-management website for six months and will need to complete an interview when the study is finished. You will continue with your regular visits with the Heart Function Clinic. After the 6-month assessment, your participation in the study will be done.

You will be given training on how to use the website during the first visit and get a username and password to access the website. You will need to enter your weight and answer 5 questions about your symptoms on the website, every morning, unless the nurse says that you may enter your answers less often, for six months. The website allows you and the nurse to monitor changes in your weight and symptoms over time.

Based on your weight and the answers to your questions, the website may show a message either saying everything is fine or giving you a warning,

informing you of your answers and that a nurse will be contacting you on the next business day. This message will also be sent to a nurse who will monitor your responses on business days. If the nurse receives an alert in his/her email inbox, he/she will telephone you within approximately 24 hours (unless it is a Friday, weekend or holiday) to discuss your weight and symptoms and provide further education on salt and fluid restriction and/or he/she may tell you that it is probably best for you to visit your physician for the symptoms you are having.

THIS WEBSITE IS NOT MEANT TO TAKE THE PLACE OF MEDICAL TREATMENT. IF AT ANY TIME YOU FEEL UNWELL, YOU SHOULD PHONE OR SEE YOUR G.P., LOCAL HEART FUNCTION CLINIC, OR CALL 911. THIS WEBSITE IS NOT MEANT TO PROVIDE MEDICAL TREATMENT FOR YOU. IT IS TO HELP YOU UNDERSTAND HOW TO MANAGE YOUR ILLNESS BY WATCHING YOUR WEIGHT AND RESTRICTING YOUR SALT AND FLUID.

You will continue with your regular visits to the Heart Function Clinic. At the end of the study you will be asked to complete an interview to give your opinion on your experience with the website, how it was useful and suggestions for improvements. The interviews will be tape-recorded for analysis, however, your name and any personal information will not be recorded on the tape. For this study, you will need to commit a regular time for the entire six-month period (we think the TOTAL time it will take for the whole 6 months is about 48 hours). This time estimate is based on 3 data collection meetings and spending approximately 10 to 15 minutes each morning on the website. We will make every effort to coordinate your study visits with your routine clinic visits.

How will we protect your confidentiality?

Protecting your privacy is very important to us. For the purpose of this study, you will be given a “unique identification number”. Your name and this number will be stored separately and only the study investigators and the nurse will have access to both. As a member of the “intervention” group, you will have a login password so that you can access the website because it is secure and cannot be accessed by anyone who does not have a password. Only you, the study nurse and investigators listed above will have access to your information. The information will be analyzed at the end of the study, but patient identity will always remain confidential. If you wish, you may contact us for a copy of the final results.

What are the costs of participation?

The costs of participation are limited to those associated with travelling to and from St. Paul’s Hospital to participate in the study assessments. You will not

be reimbursed or compensated for your participation. We will make every effort to ensure that the data collection meetings are scheduled at the time of your regular Heart Function Clinic visits.

What are the benefits of participation?

While not everyone may benefit from this study, we expect that those in the intervention group will benefit from the additional monitoring performed throughout the study and the feedback with respect to symptom self-management.

What are the risks of participation?

We do not anticipate that participation in this study will pose any risks, however there are risks associated with the blood collection for this study. This is the same manner in which blood is usually collected and may result in bruising of the skin (hematoma) and in very rare instances, infection (phlebitis).

Remember, **THE WEBSITE IS NOT A MEDICAL TREATMENT** and that **THE NURSE IS NOT ON DUTY ALL DAY**. If you are feeling concerned or unwell **DO NOT WAIT FOR THE NURSE TO TELEPHONE YOU. YOU SHOULD CONTACT YOUR GP, GO TO THE EMERGENCY ROOM OR DIAL 911.**

If you have any questions

If you have any questions or would like any more information about this study, please feel free to contact the investigators.

If you have any concerns regarding your rights as a research subject

If you have any concerns about your treatment or rights as a research subject, you may telephone the Director, Office of Research Services at the University of British Columbia, at 604-822-8598 or The Chair of the UBC/Providence Health Care Research Ethics Board at 604-628-2344 local 62325. Alternatively you may contact Dr. Hal Weinberg, Director of Research Ethics at Simon Fraser University at 604 268 6593, or the Director of the School of Kinesiology at Simon Fraser University at 604-291-4062.

Authorization: I, _____, have read the above information and I have had an opportunity to ask questions to help me

understand what my participation would involve. I freely consent to participate in the study and acknowledge receipt of a copy of the consent form. I also understand that I may refuse to participate in the study or withdraw from the study AT ANY TIME. My refusal to participate or withdraw from the study will not affect my medical care at St. Paul's Hospital or Providence Health Care

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 B: Minnesota, Self-Care of Heart Failure and Leisure Time Physical Activity Questionnaires

Study ID: _____ Date: _____ D.O.B. _____

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	No	Very Little				Very Much
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

©1986 Regents of the University of Minnesota, All rights reserved. Do not copy or reproduce without permission. LIVING WITH HEART FAILURE® is a registered trademark of the Regents of the University of Minnesota.

SELF-CARE OF HEART FAILURE INDEX[®]

All answers are confidential.

Study ID: _____

Date Completed _____

Date of Birth _____

SECTION A:

Listed below are common recommendations for persons with heart failure. How often do you do the following?

	Never or rarely	Sometim es	Frequent ly	Always
1. Weigh yourself daily?	1	2	3	4
2. Eat a low salt diet?	1	2	3	4
3. Take part in regular physical activity?	1	2	3	4
4. Keep your weight down?	1	2	3	4
5. Get a flu shot every year?	1	2	3	4

SECTION B:

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past three months, have you had trouble breathing or ankle swelling? Circle one.

- 1) No
- 2) Yes

6. The **LAST TIME** you had trouble breathing or ankle swelling,
(circle **one** number)

	Have not had these	I did not recognize it	Not Quickly	Somewhat Quickly	Quickly	Very Quickly
how quickly did you see it as a symptom of heart failure?	N/A	0	1	2	3	4

Listed below are remedies that people with heart failure use. If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies?

(circle **one** number for each remedy)

	Not Likely	Somewhat Likely	Likely	Very Likely
7. Reduce the salt in your diet	1	2	3	4
8. Reduce your fluid intake	1	2	3	4
9. Take an extra water pill	1	2	3	4
10. Call your doctor or nurse for guidance	1	2	3	4

11. Think of a remedy you tried the last time you had trouble breathing or ankle swelling,

(circle **one** number)

	I did not try anything	Not Sure	Somewhat at Sure	Sure	Very Sure
how <u>sure</u> were you that the remedy helped or did not help?	0	1	2	3	4

SECTION C:

	Not Confident	Somewh at Confident	Very Confident	Extremel y Confident
12. How confident are you that you can <u>work out whether your symptoms are important or not?</u>	1	2	3	4
13. Generally, how confident are you that you can <u>recognize changes</u> in your health if they occur?	1	2	3	4
14. Generally, how confident are you that you can <u>do something</u> that will make you feel better?	1	2	3	4
15. How confident are you that <u>what you do to make yourself feel better works or not?</u>	1	2	3	4

THANK YOU !



Study number: _____

Birthdate: _____

Date Completed: _____

Leisure Time Physical Activity Questionnaire

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

Activity	Check those activities that you have done in the past 4 weeks.	Check each week in which you performed the activity.							MET Values
		Week 1	Week 2	Week 3	Week 4	Average times/week	Average Duration (min)		
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)								
Swimming (beach)								
Scuba diving								
Snorkeling								
Section D: Winter Activities.								
Snow skiing (downhill)								
Snow skiing (x-country)								
Ice/roller skating								
Tobogganing								

		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 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									
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								
Other 3								

**Appendix C: Participant Demographic Data, Computer Use Data
and Anthropometric Measurement Collection Forms**



Healthy Heart Program

St. Paul's Hospital

St. Paul's Hospital, B180-1081 Burrard Street, Vancouver BC V6Z 1Y6
• Phone: 604-806-8591 • Fax: 604-806-8590
• Web: www.healthyheart.org



SIMON FRASER
UNIVERSITY

Medical Director, HHP: Andrew Ignaszewski, MD, FRCP(C)
Academic Director, HHP: Jiri Frohlich, MD, FRCP(C)
Program Coordinator: Sandra Barr, RN

Remote Management of Patients With Chronic Heart Failure Using Internet

Supported Technology

Name: _____

Today's Date: _____

Date of Birth: _____

Study Number: _____

Gender: Male Female

Address: _____

Phone Number: _____

Cell Phone Number: _____

Email address: _____

USERNAME: _____

1) What is your relationship status?

- | | | | |
|------------|--------------|----------|--------|
| Married | Widowed | Divorced | Single |
| Common Law | Other: _____ | | |

2) What is your highest level of education attained?

- | | |
|-------------------------------|--------------------------------------|
| Less than high school | High school graduate (or equivalent) |
| Some post secondary education | Post secondary degree or diploma |
| Post graduate education | Other: _____ |

3) What is your current employment status?

Full time job Full time homemaker Part time job
Unemployed Retired Disability Other: _____

4) What is your annual household income?

<\$ 20,000 \$ 20,000 to \$ 30,000 \$ 30,000 to \$ 40,000
\$ 40,000 to \$ 50,000 \$ 50,000 to \$ 60,000 > \$ 60,000
Other: _____ Refused

5) Who do you live with?

Spouse/Common Law Child/Children Relative Friend
Other: _____

6) How many people live in your household including yourself?

7) What is your country of birth?

Canada USA China India Other: _____

8) What is your mother tongue?

English French Cantonese Mandarin
Punjabi Other: _____

9) Which of these heart failure symptoms have you experienced in the last week?

Fatigue Palpitations Angina Swelling (legs or abdomen)
Lightheadedness or dizziness Dyspnea (shortness of breath)
Paroxysmal Nocturnal Dyspnea (shortness of breath while sleeping)
Orthopnea (shortness of breath while lying down) Other: _____

10) Do you have any illnesses or medical conditions other than heart failure? Check all that apply and write down any others that you have which we did not include on the list.

Kidney/Renal conditions Diabetes HIV/AIDS COPD

Asthma Emphysema

Other: _____



St. Paul's Hospital



**SIMON FRASER
UNIVERSITY**

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)
Academic Director, HHP: Jiri Frohlich, MD, FRCP(C)
Program Coordinator: Sandra Barr, RN

Remote Management of Patients With Chronic Heart Failure Using Internet Supported Technology

Computer Use Information

Today's Date: _____

Date of Birth: _____

Study Number: _____

1) Who is the main user of your computer?

Me Spouse/Common Law Child/Children Other: _____

2) Is your home computer a desktop or a laptop?

Desktop Laptop

3) What brand is your computer? (For example Hewlett Packard, Sony etc)

4) What operating system does your computer use?

5) What year was the computer purchased?

6) Who purchased the computer?

Me Spouse/Common Law Child/Children Other: _____

7) What was the main reason that the computer was purchased for?

Interest Need Other _____

8) Do you know how to do the following with your computer? Please check all the items that you know how to do.

Send/Receive Email Search for web pages

Search for health related information Print documents

Other: _____

9) What do you use your computer for? Please check all the items that apply.

Email Searching/browsing for information on the Internet

Personal uses Printing documents Other: _____

10) In the average week or month, please indicate how often you use the Internet.

_____ days per week

or

_____ days per month

11) What do you use the Internet for? Please check all items that apply.

General searching/browsing Searching for health related information

Bill Payment Banking Other: _____

12) What time of day do you usually use the computer?

Morning Afternoon Evening Nighttime

13) Where in your home is your computer located?

Computer room/Den/study Living Room Family Room

Bedroom Other: _____

14) a) Do you ever use a computer outside of your home?

Yes No

14) b) If you answered yes to 14) a), where else do you use a computer?

Library Community Centre Work
Friend's or relative's home Other: _____

15) a) Do you have a printer?

Yes No

15) b) If you have a printer, do you ever use it?

Yes No

16) Who will be entering your daily data onto the computer for this study?

Me Spouse/Common Law Child/Children Other: _____

17) If you are not entering the data yourself, why do you prefer having someone else enter it? (For example you may simply prefer that someone else does it for you or perhaps you may have difficulty seeing the screen, etc)



St. Paul's Hospital



**SIMON FRASER
UNIVERSITY**

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)
 Academic Director, HHP: Jiri Frohlich, MD, FRCP(C)
 Program Coordinator: Sandra Barr, RN

Remote Management of Patients With Chronic Heart Failure Using Internet

Supported Technology

Today's Date: _____

Date of Birth: _____

Study Number: _____

Test Measures and Questionnaire Scores

MEASURE	SCORE/RESULT
BP Arm: L R	
Heart Rate	bpm
Height	
Weight	Lbs Kgs
Goal Weight	Lbs Kgs
Waist Circumference	Measure 1: Measure 2:
Hip Circumference	Measure 1: Measure 2:
BNP	
MLWHF questionnaire	
Self-care of HEART FAILURE Index	
Leisure Time Physical Activity Questionnaire	
6-Minute Walk test	Meters
NYHA Class	
Ejection Fraction	

Smoking	Never Former: _____ cigs/day _____ years _____ date quite Current: _____ cigs/day _____ years
Drinking	Never/<1 per week 1-5 per week 6-10 per week > 10 per week Other: _____
Females only – Menopausal Status (only if available in chart)	Pre – menopausal Peri – menopausal Post – menopausal Hysterectomy

MEDICATION / VITAMINS / SUPPLEMENTS	DOSAGE

Doctors visits, emergency room visits or hospitalizations

Please Indicate all visits since your last appointment.

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Type of visit: Doctor ER Hospital Heart Function Clinic

Date: _____

Nature of visit: _____

Length of stay for Hospitalization: _____

Appendix D: Participant Instructions



St. Paul's Hospital



**SIMON FRASER
UNIVERSITY**

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)
Academic Director, HHP: Jiri Frohlich, MD, FRCP(C)
Program Coordinator: Sandra Barr, RN

Remote Management of Patients With Chronic Heart Failure Using Internet Supported Technology

Username _____

Password _____

Study Number _____

These instructions are meant to help you use the Heart Helper website. Please write down your username and password and store them in a safe place (where others cannot access them) in case you forget them. You will not be able to change your username once it is entered into the system, but your password can be changed by you (see instructions below) or by the study nurse. You may also wish to write down your study number.

Introduction to Virtualheart/Heart Helper

Patients with heart failure who take an active role in managing their symptoms through fluid and salt restriction tend to have an improved quality of life and reduced complications. The purpose of this study is to see if the Internet can help patients with managing their illness at home. We will use a website designed for patients with chronic heart failure (CHF). We hope that using this website will help patients to understand their symptoms and what to do about them. In order to decide if using the Internet helps patients, we need to see how people using the website (“intervention” group) do compared to a similar group who don’t use the website (“standard” group). You are part of the “intervention” group for this study.

Please remember that This website is NOT meant to take the place of medical treatment. if at any time you feel unwell, You should phone or see your g.p., heart function clinic, or call 911.

If you need medical advice , you should contact the nurse at the Heart Function Clinic – 604-806-8733. Or you can email the clinic using the instructions below.

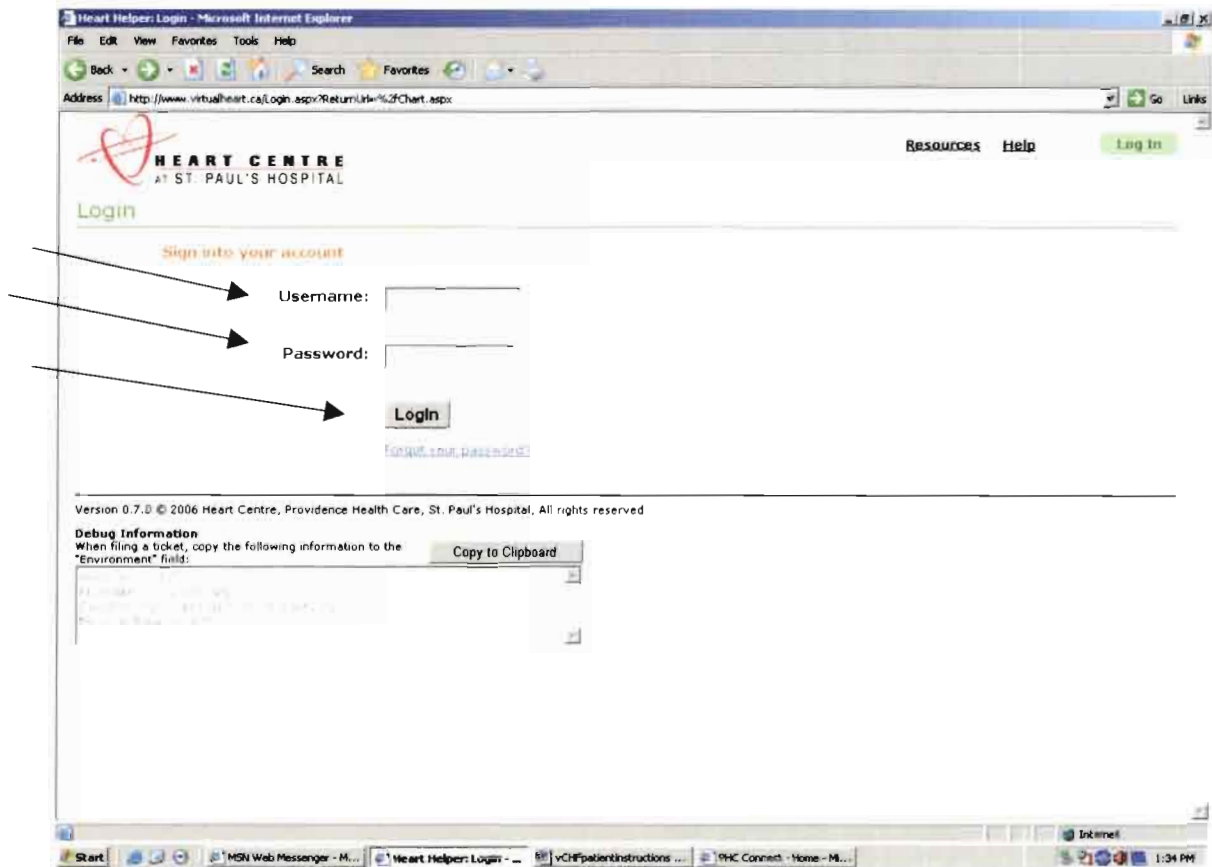
If you need technical assistance with the website, telephone Biljana Maric at 604-682-2344 ext 63052.

Table of Contents

Logging on.....	p. 4
Adding Heart Helper to Your Favorites List.....	p. 5
Entering Your Information.....	p. 7
View Progress Charts/Reports.....	p.10
Printing Graphs.....	p.11
Changing Weight Preference.....	p.12
Changing Password.....	p.14
Forgot your password.....	p.16
Going Away – Setting a Leave of Absence.....	p.17
Downloading Resources.....	p.19
Going to Links.....	p.21
Technical Support.....	p.23
Contacting the Nurse.....	p.24
Logging Off.....	p.25
Logging on Twice in One Day.....	p.26

Logging On

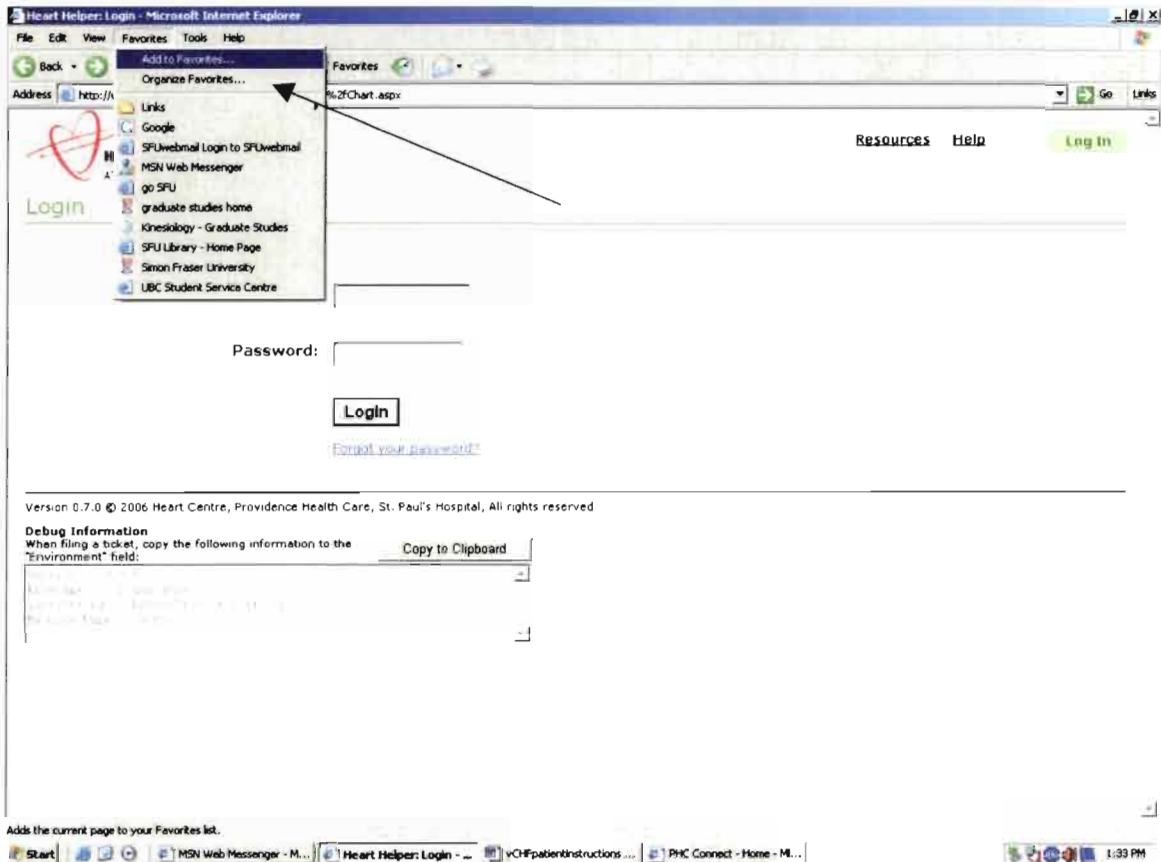
- 1) Open Internet Explorer
- 2) Type <http://www.virtualheart.ca> into the address bar
- 3) Type in your “Username” into the first box
- 4) Then click in the box beside “Password”, and type in your password
- 5) Once you have filled in the two boxes click once on the “Login” button.



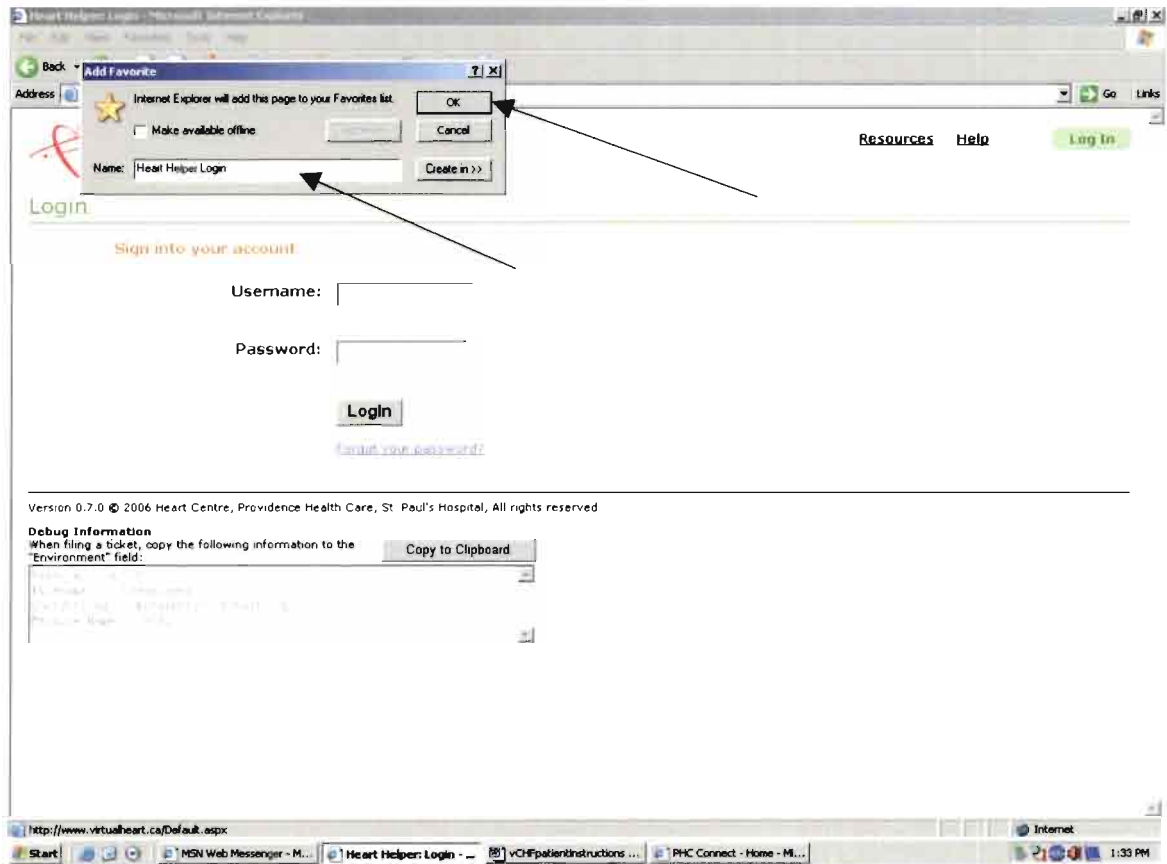
Adding Heart Helper to your favorites list

If you wish, you can add this website to your “favorites” list.

- 1) On the top left you will see the word “favorites”, click on it once
- 2) Click once on “Add to favorites”



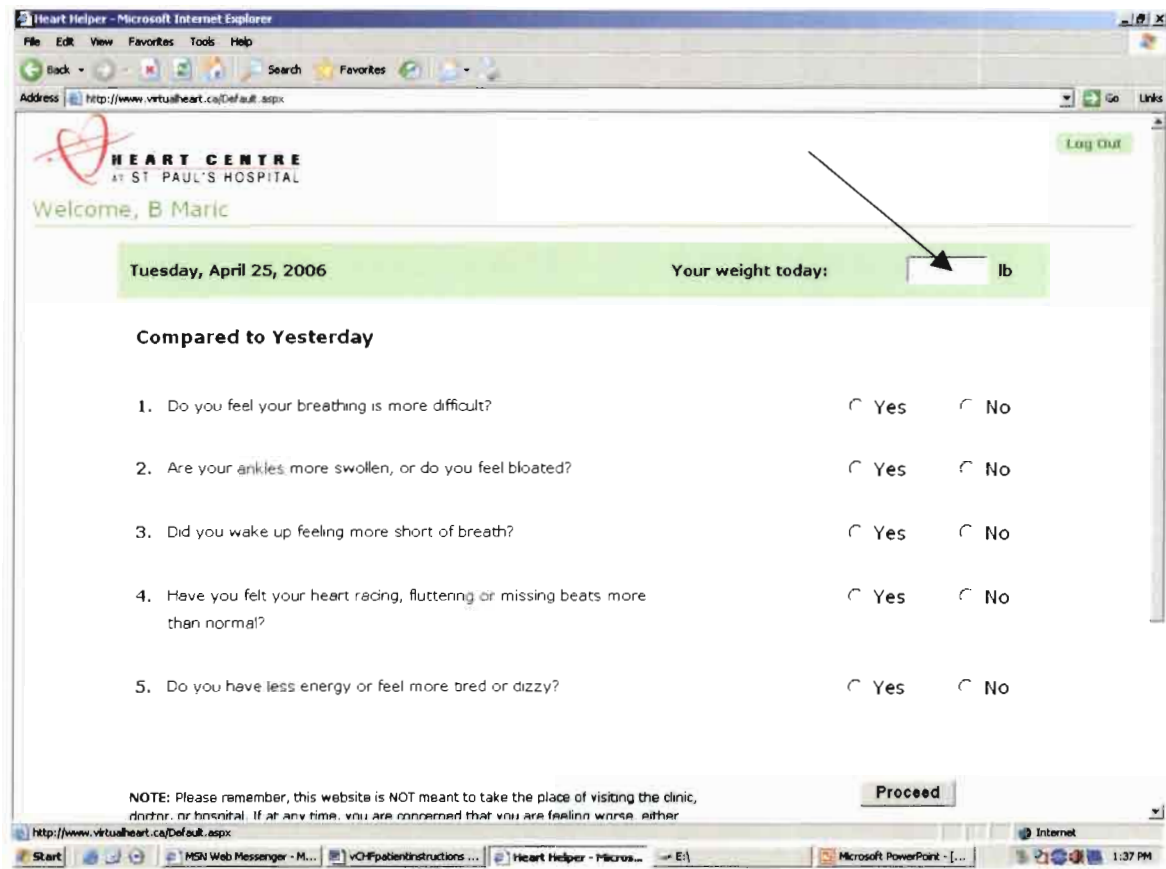
- 3) A box should pop up that says “add favorite”, in the box that says “Heart Helper Login” you can change the name to whatever you wish to call the item or you may leave the name as is
- 4) On the top right side of this box click once on “ok”



5) The next time you want to go to “Heart Helper Login” just click on “favorites” again and click on “Heart Helper Login”

Entering your information

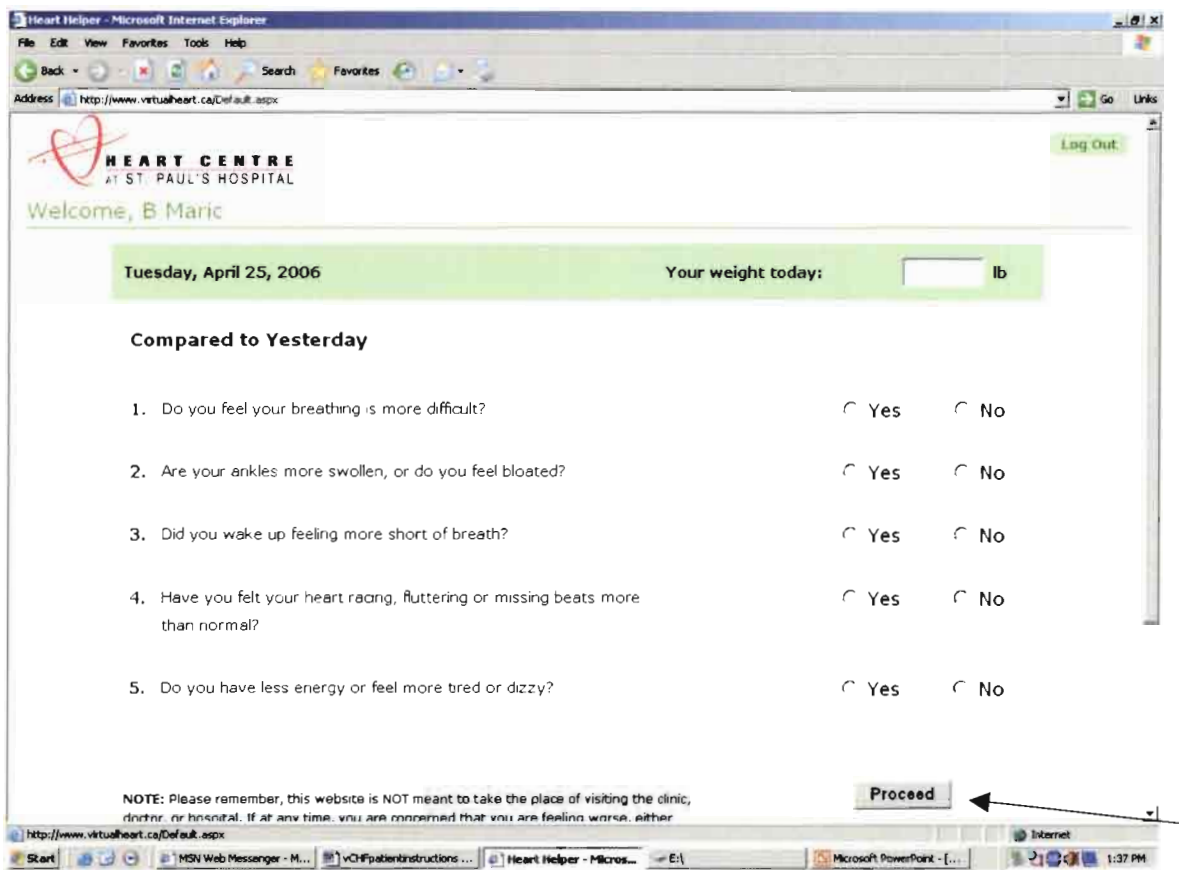
1) After logging in you will be directed to a page that lets you enter your weight and answers to questions regarding your symptoms. Click once in the box next to your “Weight” and type it in. If you want to change the way you measure your weight to lbs or kgs, see instructions below.



The screenshot shows a web browser window titled "Heart Helper - Microsoft Internet Explorer". The address bar shows "http://www.virtualheart.ca/Default.aspx". The page header includes the "HEART CENTRE AT ST PAUL'S HOSPITAL" logo and a "Log Out" button. The main content area displays a green banner with the date "Tuesday, April 25, 2006" and the text "Your weight today:" followed by an input field containing "lb". A black arrow points to this input field. Below the banner, the section "Compared to Yesterday" contains five questions, each with "Yes" and "No" radio button options. A "Proceed" button is located at the bottom right of the form area. A note at the bottom of the page reads: "NOTE: Please remember, this website is NOT meant to take the place of visiting the clinic, doctor, or hospital. If at any time, you are concerned that you are feeling worse, either". The taskbar at the bottom shows several open applications, including MSN Web Messenger, vCHP patient instructions, and Microsoft PowerPoint.

2) The questions are asking you to compare how you feel to yesterday, it is important to keep this in mind when answering the questions. Read each question carefully and answer each question by clicking once on the “Yes” or “No” circle. You can change these if you make a mistake as long as you haven’t clicked on the “Proceed” button.

3) When you have entered your weight and answered all questions to your satisfaction, click once on the “Proceed” Button.

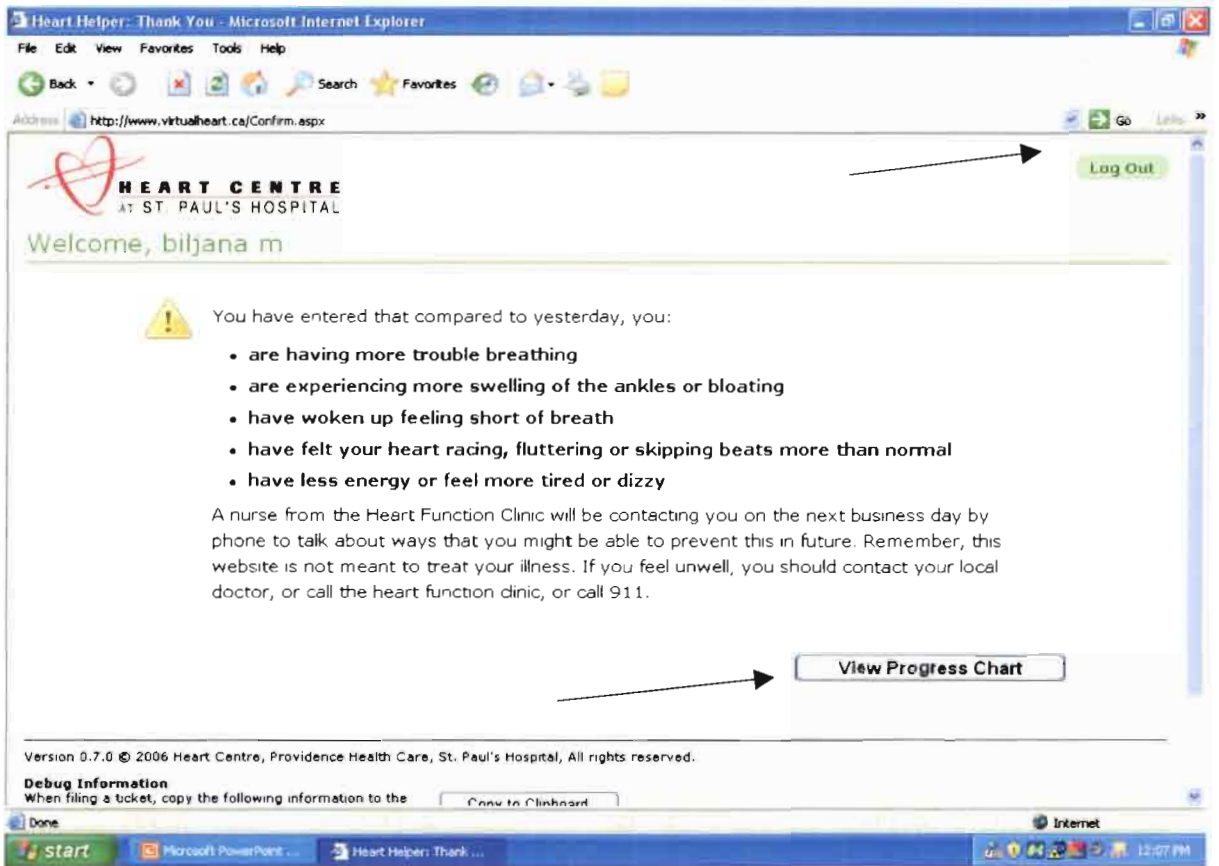


4) If you find you have accidentally entered the wrong information, you should call or email the nurse in the clinic.

5) You will then see a message telling you what answers you have entered.

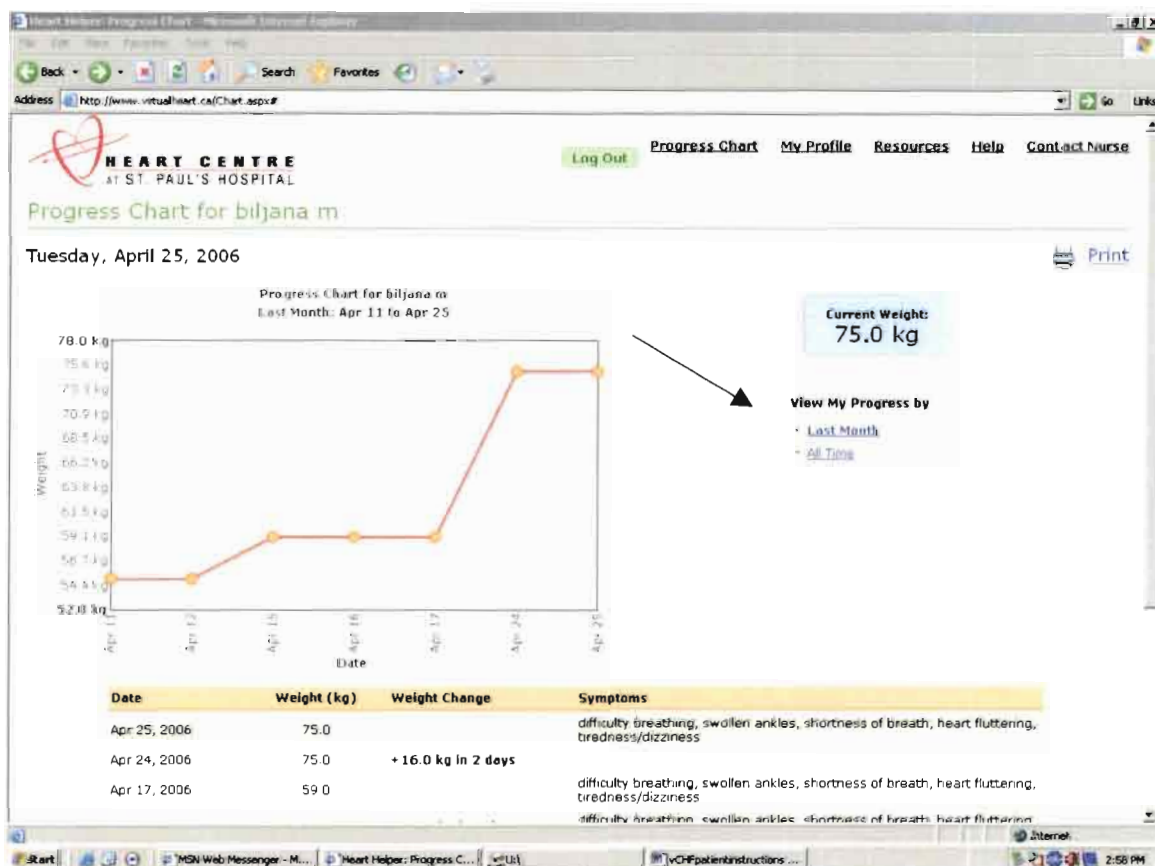
6) If you want to see your progress chart, click your mouse once on the “View Progress Chart” button.

7) If you do not want to see your progress chart, click your mouse once on the green “Log Out” button in the top right hand corner. Remember to always log out.



Viewing Progress Charts/Reports

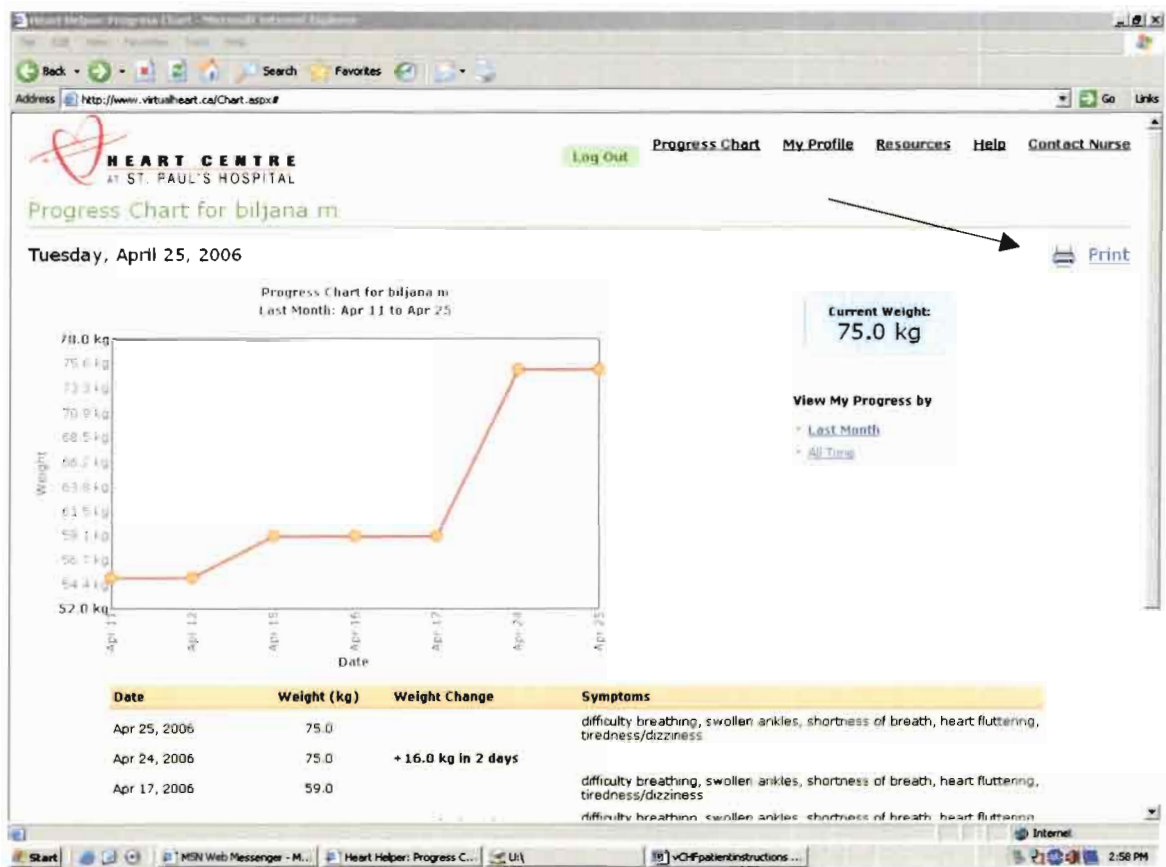
Once you have clicked on the “View Progress Report” button, you will be shown a graph with your progress so far. This graph will have the date, and your weight entered for that date. If you answered yes to any of the questions or if your weight increased more than the preset limits, the data dots on the graph will be larger than normal. If you move your mouse over the dot, it will show you what your symptoms were for that day. The graph can be viewed for either the “last month”, or for “all time”, simply by clicking on the option that you want beside the graph. You can also look below the graph for a list of alerts generated. The date, your weight, weight change, and symptoms will be displayed.



Printing graphs

1) If you wish to print out your progress graph, you must first log in to the system. After you have entered your data and clicked the proceed button, you should then click on the “View Progress Chart”

2) On the top right hand side, you should see a picture of a little printer and the word print beside it, click once on “Print” to print your graphs.



HEART CENTRE
AT ST. PAUL'S HOSPITAL

Progress Chart for biljana m

Tuesday, April 25, 2006

Progress Chart for biljana m
Last Month: Apr 11 to Apr 25

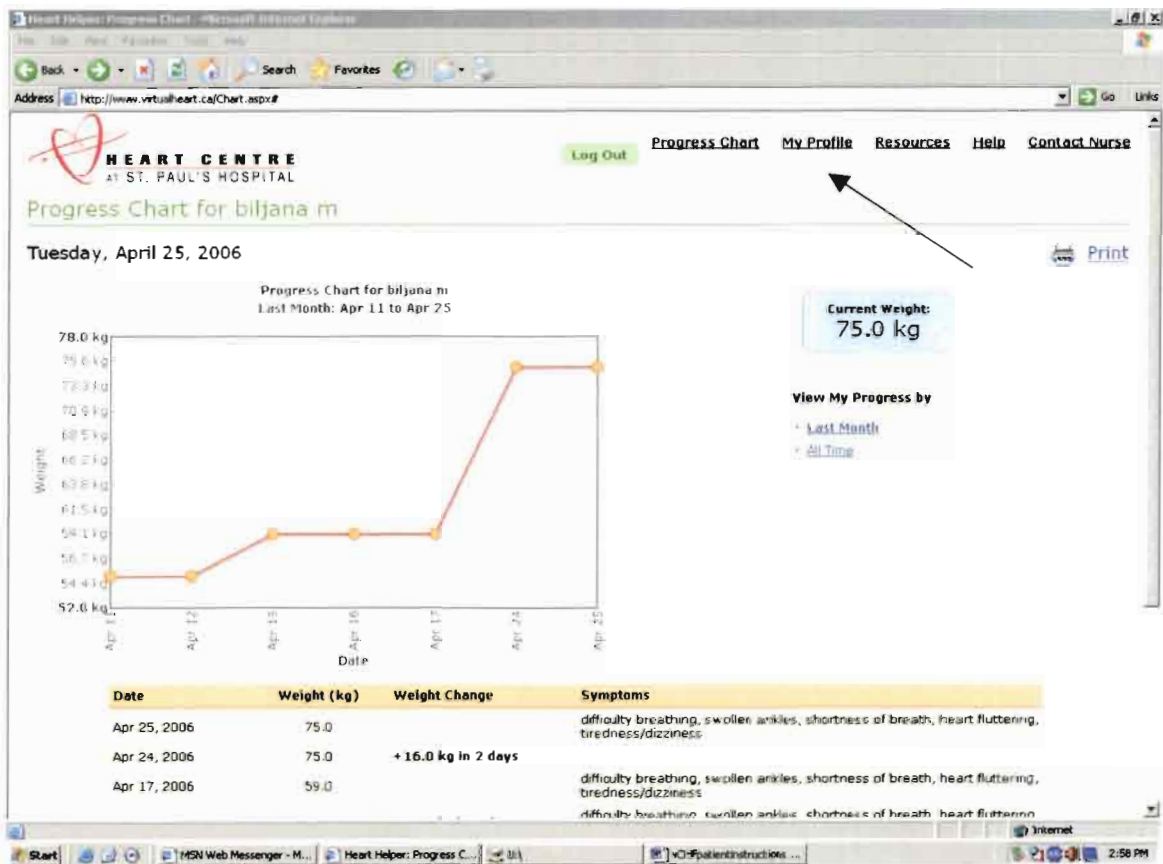
Current Weight: 75.0 kg

View My Progress by
Last Month
All Time

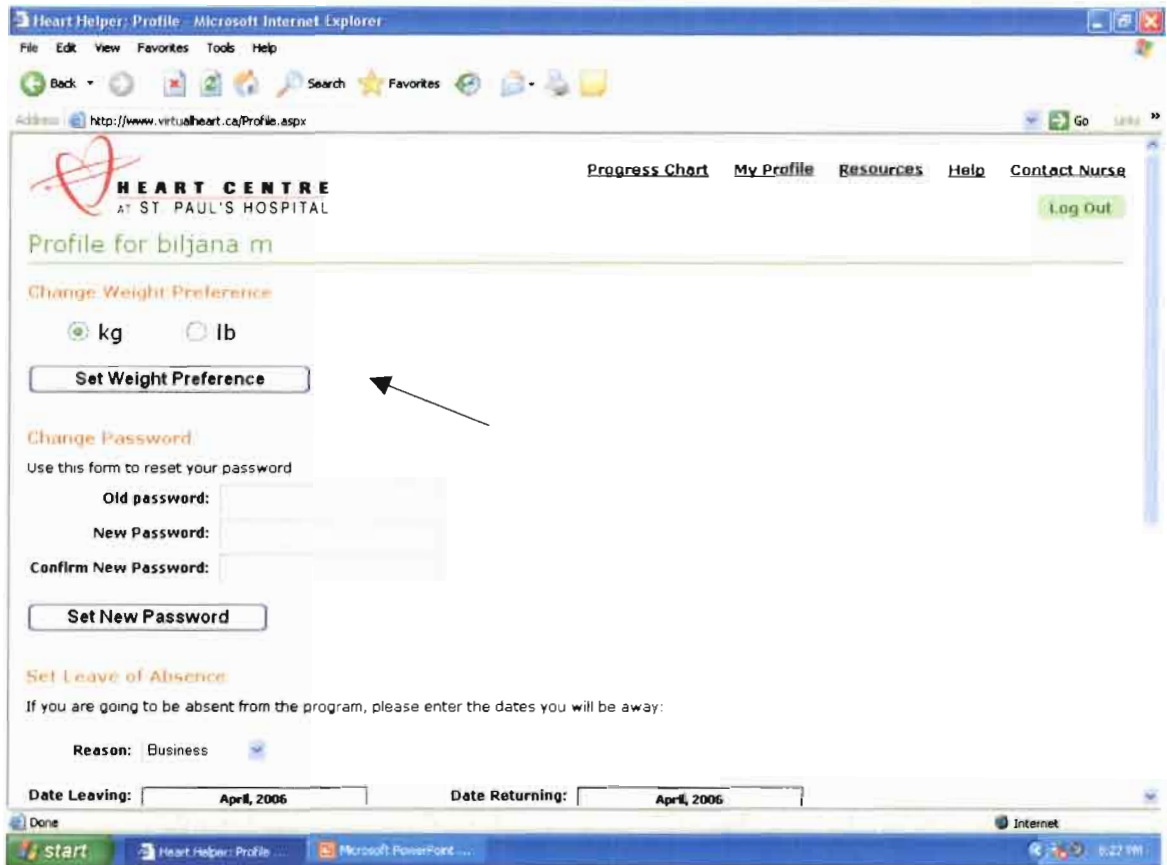
Date	Weight (kg)	Weight Change	Symptoms
Apr 25, 2006	75.0		difficulty breathing, swollen ankles, shortness of breath, heart fluttering, tiredness/dizziness
Apr 24, 2006	75.0	+ 16.0 kg in 2 days	
Apr 17, 2006	59.0		difficulty breathing, swollen ankles, shortness of breath, heart fluttering, tiredness/dizziness

Changing weight preference

- 1) To change your weight preference you must first log onto the system. Once you have entered your answers, click once on the “View Progress Chart” button.
- 2) On the top right side of the screen you will see a “My Profile” link. Click once on “My Profile”



- 3) Under “Change Weight Preference” choose your weight preference and click in the circle next to it (either kg or lb)
- 4) Click once on the “Set Weight Preference” button



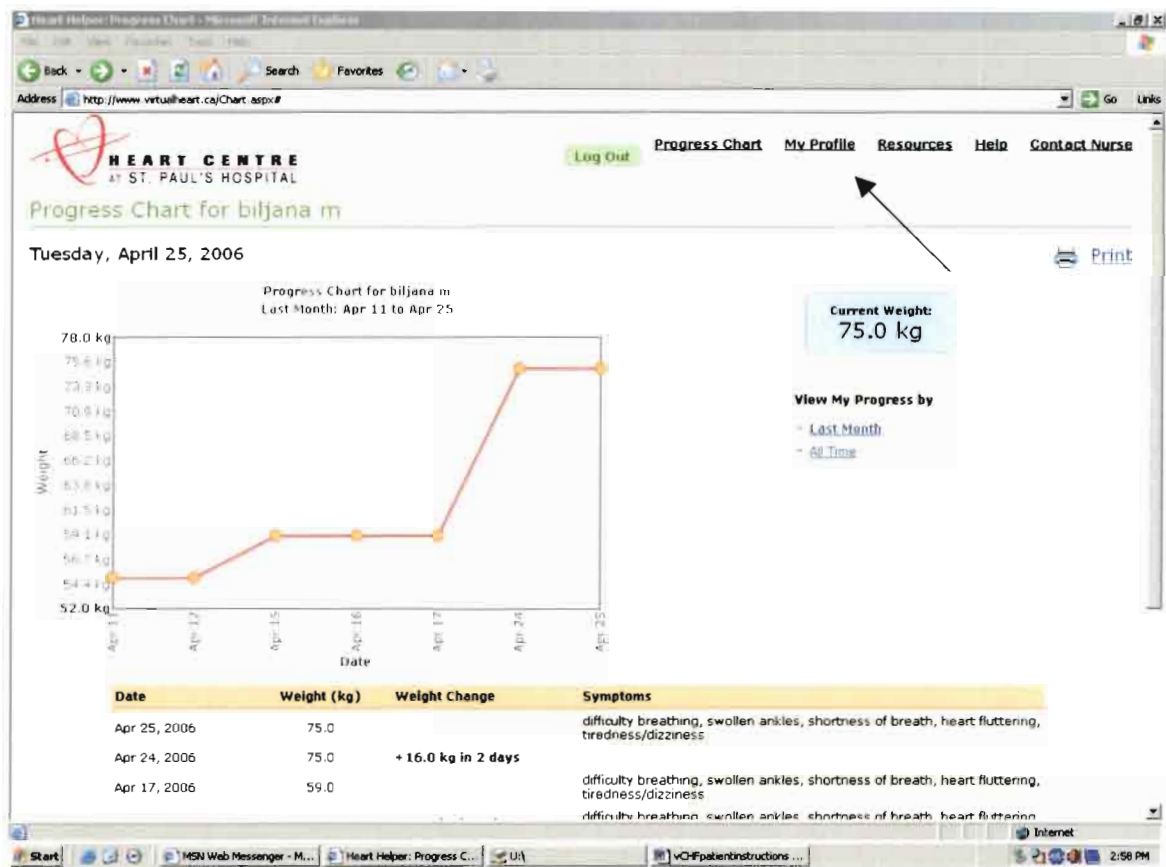
Changing password

1) To change your password you must first log onto the system.

Once you have entered your answers, click once on the “View Progress Chart” button.

2) On the top right side of the screen you will see a “My Profile” link.

Click once on “My Profile”

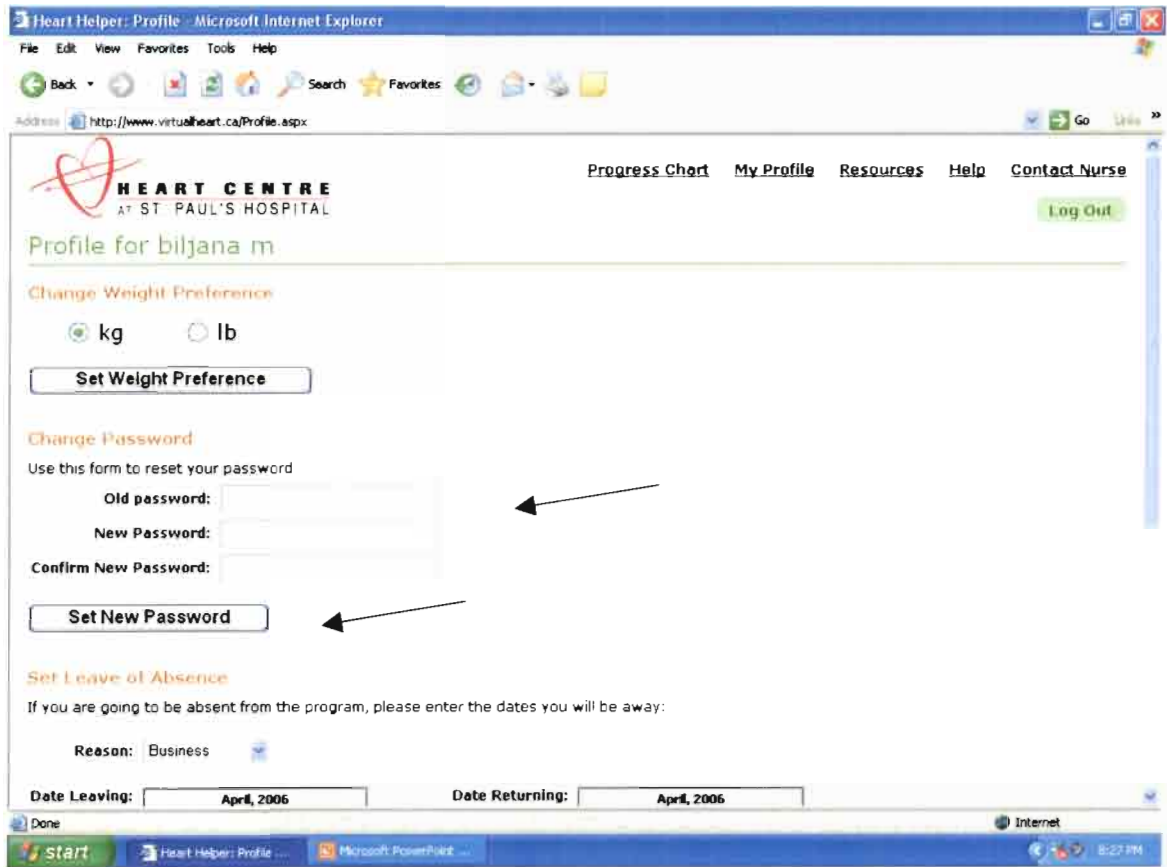


3) Under the heading “Change Password” click your mouse once in the box next to “Old Password” and type in your old password

4) Move your mouse to the box that says “New Password”, click once, and type in your new password

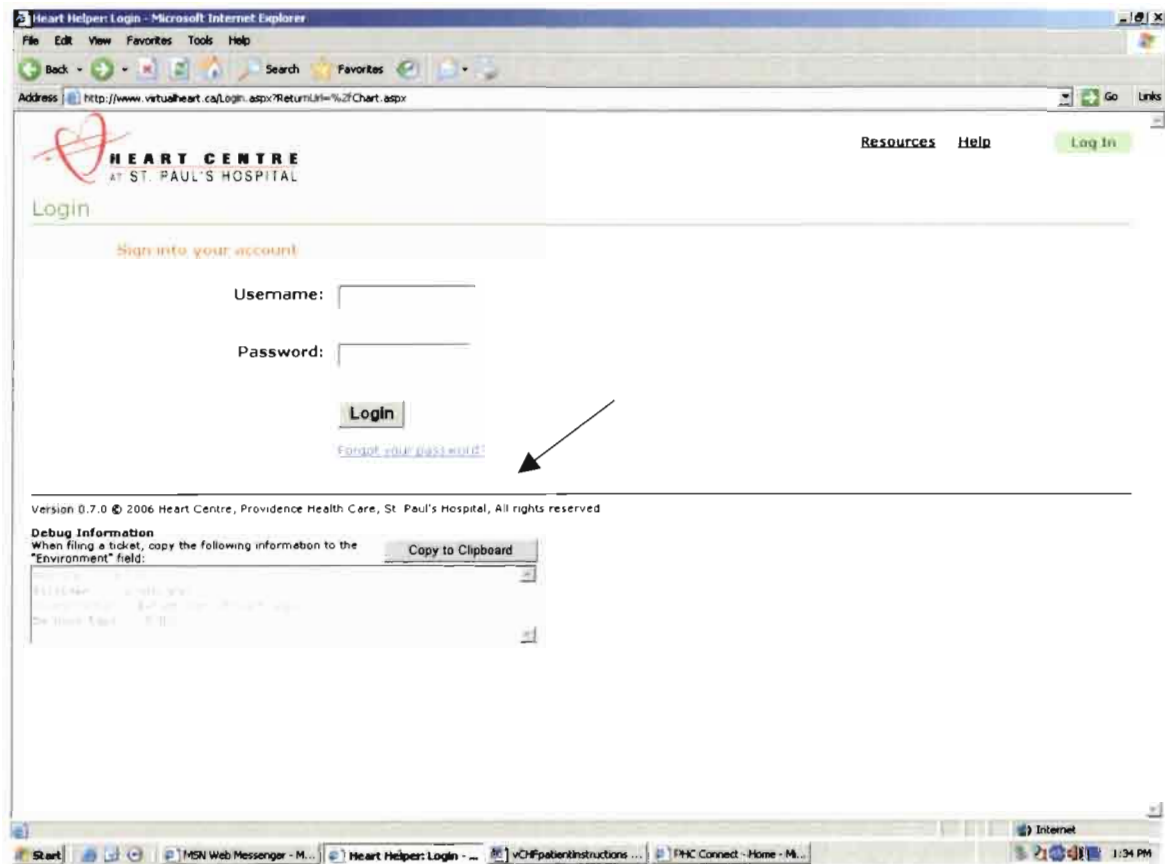
5) Move your mouse to the box that says “Confirm New Password”, click once, and type in your new password again

6) Click once on the box that says “Set New Password”



Forgot your password

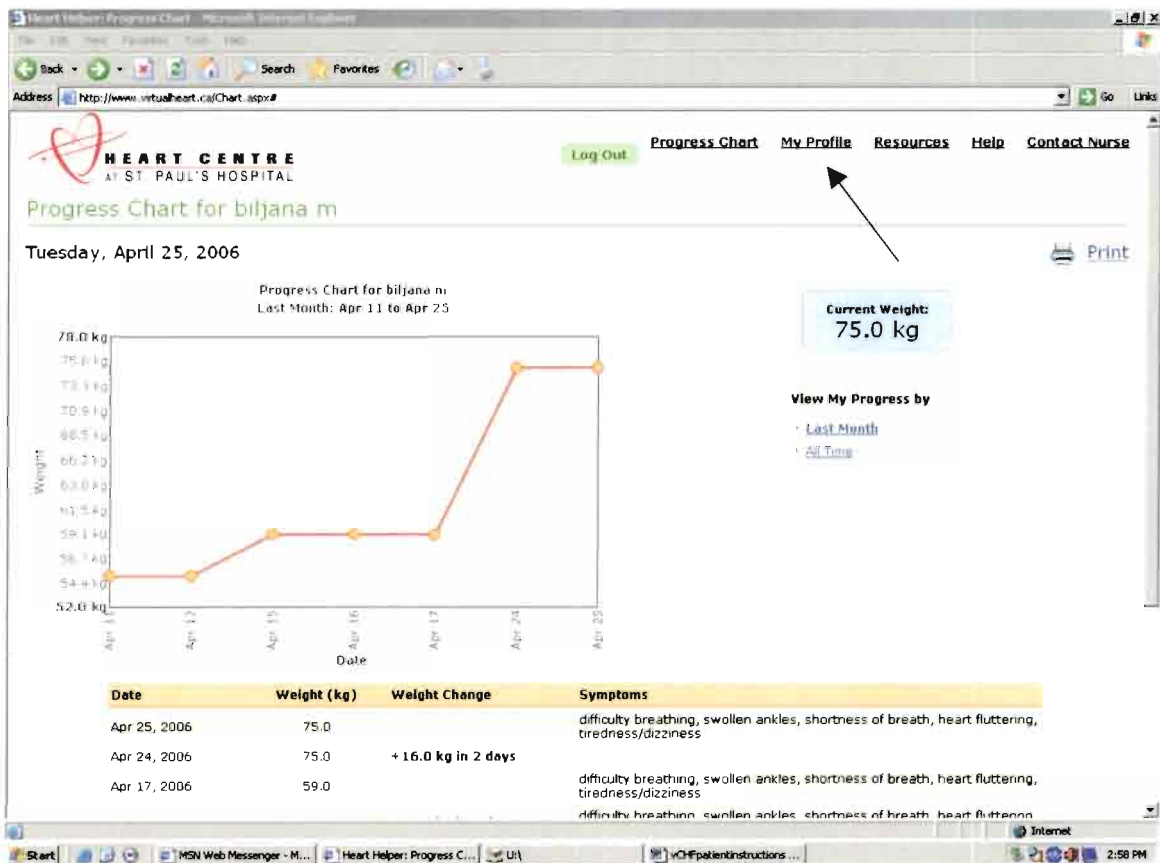
- 1) If you forget your password open Internet Explorer
- 2) Type <http://www.virtualheart.ca> into the address bar
- 3) Click on “Forgot your password?” and your password will be emailed to you
- 4) You may also contact Biljana Maric at 604-682-2344 ext 63052 or email her at bmaric@sfu.ca to get your password



Going away

1) To set a leave of absence if you are going away you must first log onto the system. Once you have entered your answers, click once on the “View Progress Chart” button.

2) On the top right side of the screen you will see a “My Profile” link. Click once on “My Profile”



3) Under the heading “Set Leave of Absence” click once on the down arrow beside the box that says “Reason”

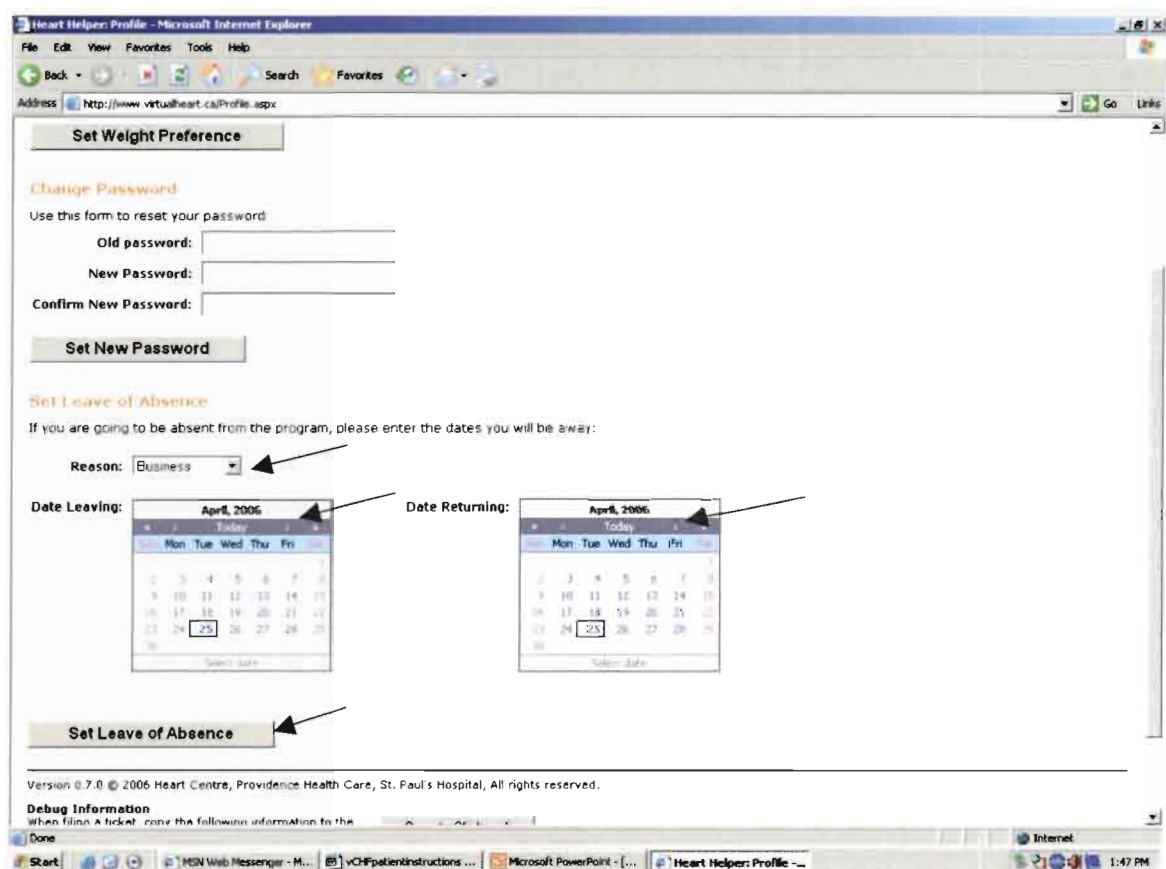
4) Click once on the reason that you would like.

5) On the calendar labelled “Date Leaving” click once on the date that you are planning to leave.

6) On the calendar labelled “Date Returning” click once on the date that you are planning on coming back.

7) If you need to change the month or year that is shown on the calendar, look at the calendar and notice where it says “today”, to the left and right of “today” you will see a single arrow and a double arrow. Click on the single arrow to the right of “today” for the next month, or click on the double arrow to the right of “today” for the next year.

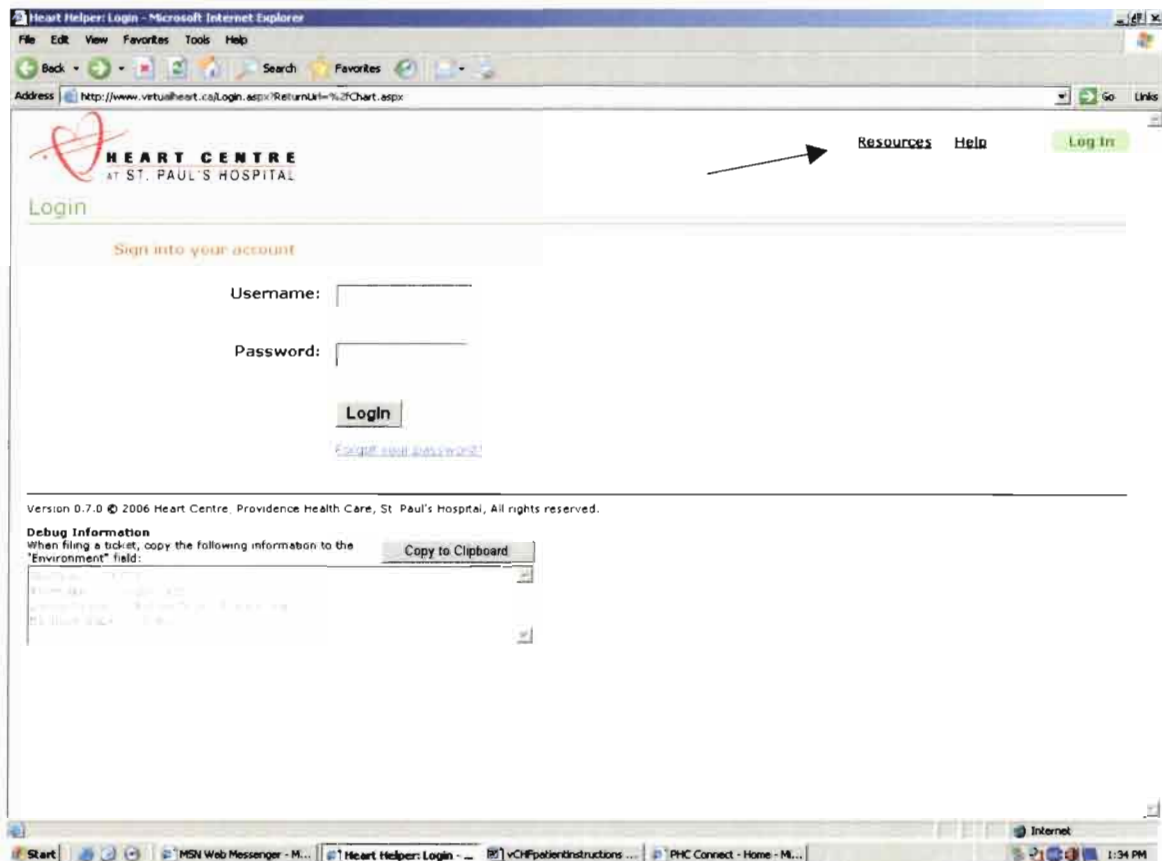
8) Once you have set the right dates, click once on the box that says “Set Leave of Absence”



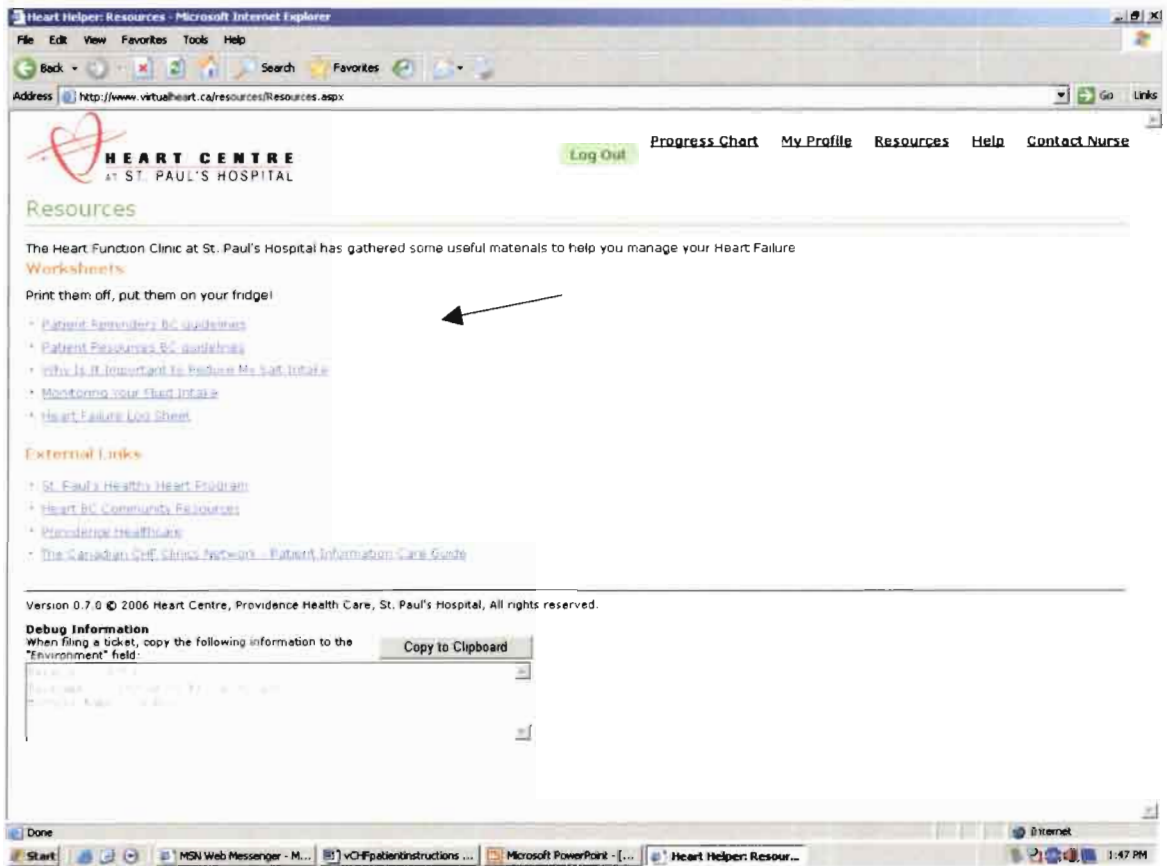
Downloading resources

1) If you wish to download some of the resources that we have for you, simply go to the log in page <http://www.virtualheart.ca>, you can also access resources if you are logged in

2) In the top right you will see a link that says “Resources”, click once on it,

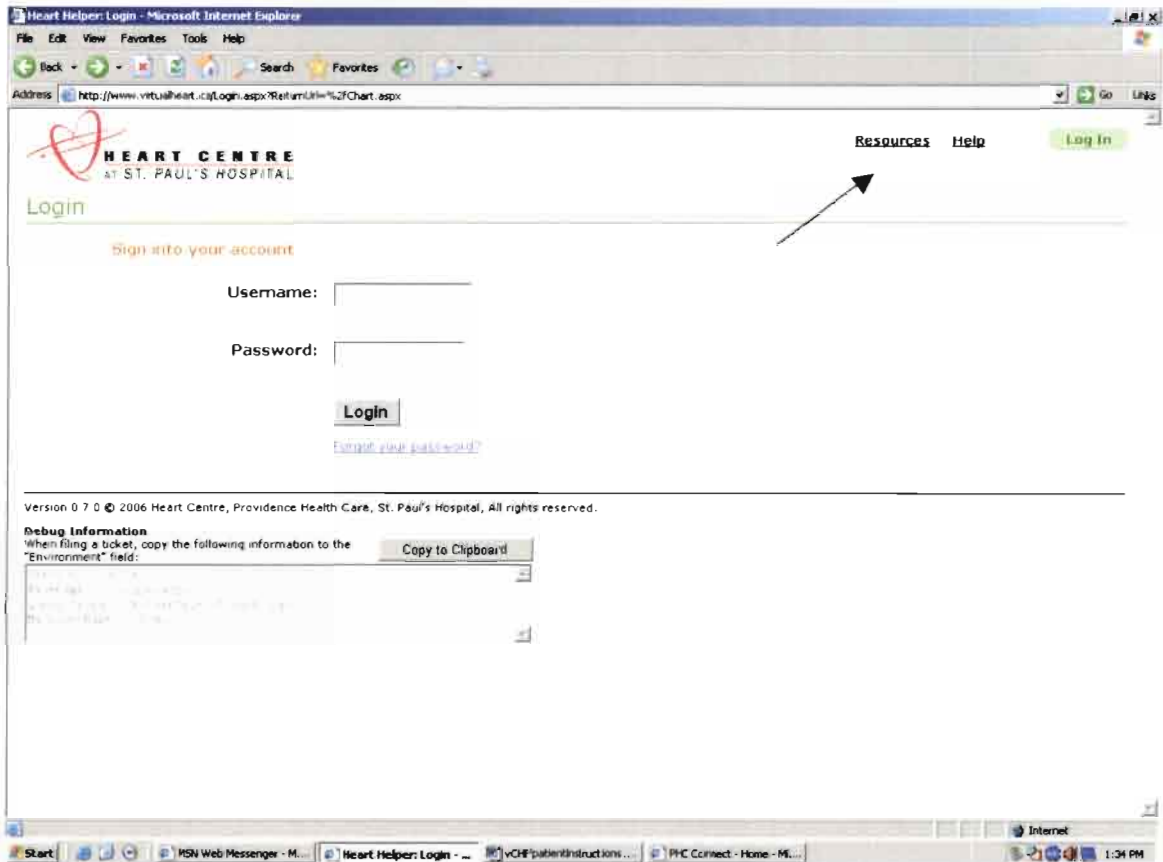


3) In the section that says “Worksheets” click once on the resource you wish to download, the item will come up in a new window for you to view or save as desired.



Going to links

1) If you wish to view some of the links that we have for you, simply go to the log in page <http://www.virtualheart.ca>, or if you are already logged in, on the top right you will see a link that says “Resources”, click once on it




2) In the sections that says “External Links” click once on the link you wish to see

Heart Helper: Resources - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites

Address http://www.virtualheart.ca/resources/Resources.aspx

 **HEART CENTRE**
AT ST. PAUL'S HOSPITAL

[Log Out](#) [Progress Chart](#) [My Profile](#) [Resources](#) [Help](#) [Contact Nurse](#)

Resources

The Heart Function Clinic at St. Paul's Hospital has gathered some useful materials to help you manage your Heart Failure

Worksheets

Print them off, put them on your fridge!

- [Patient Reminders BC Guidelines](#)
- [Patient Resources BC Guidelines](#)
- [Why Is It Important to Reduce My Salt Intake?](#)
- [Monitoring your Fluid Intake](#)
- [Heart Failure 101 Sheet](#)

External Links

- [St. Paul's Health Heart Program](#)
- [Heart BC Community Resources](#)
- [Providence Healthcare](#)
- [The Canadian CHF Clinics Network - Patient Information Care Guide](#)

Version 0.7.0 © 2006 Heart Centre, Providence Health Care, St. Paul's Hospital. All rights reserved

Debug Information

When filing a ticket, copy the following information to the "Environment" field:

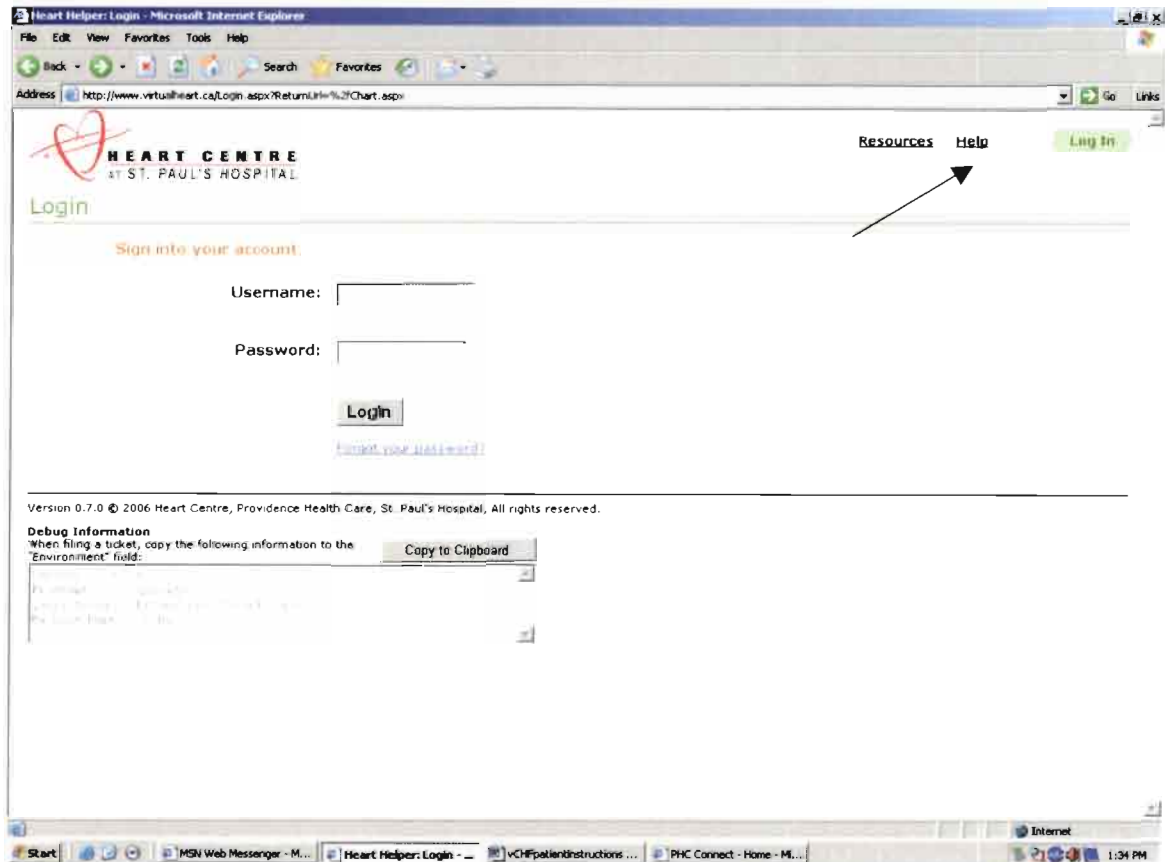
```
Environment:
  User-Agent: Mozilla/5.0 (Windows; U; MSIE 6.0; en-US; rv:1.9.0.5) Gecko/20081028 Firefox/3.0.5
  Accept: text/html,application/xhtml+xml,application/xml;q=0.9,*/*;q=0.8
  Accept-Language: en-US,en;q=0.5
  Accept-Encoding: gzip,deflate
  Referer: http://www.virtualheart.ca/resources/Resources.aspx
```

Done

Start MSN Web Messenger - M... vCHFpatientinstructions ... Microsoft PowerPoint - [... Heart Helper: Resour... 1:47 PM

Technical Support

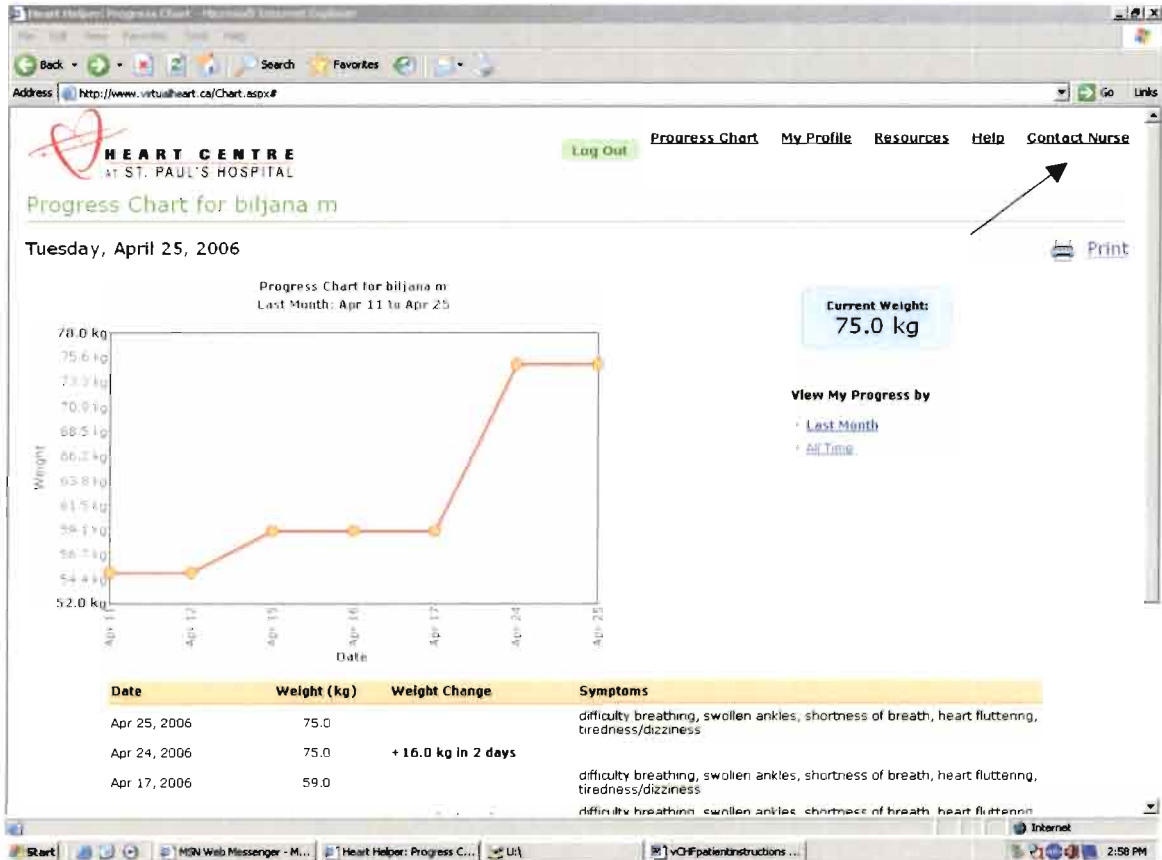
1) If you need instructions on how to use the website, simply go to <http://www.virtualheart.ca>, or if you are already logged in, click once on the “Help” link on the top right.



2) If you need technical assistance please contact Biljana Maric at 604-682-2344 ext 63052 or email her at bmaric@sfu.ca.

Contacting the nurse

1) To contact the nurse via email you must be logged in to the system. On the top right hand side of the screen you will see a link that says “Contact Nurse”, click once on it.



2) An email program should open up, and you can write your email to the nurse. The nurse’s email address is heartfunccln@providencehealth.bc.ca. You can also manually enter the nurse’s email address into whatever email program you use.

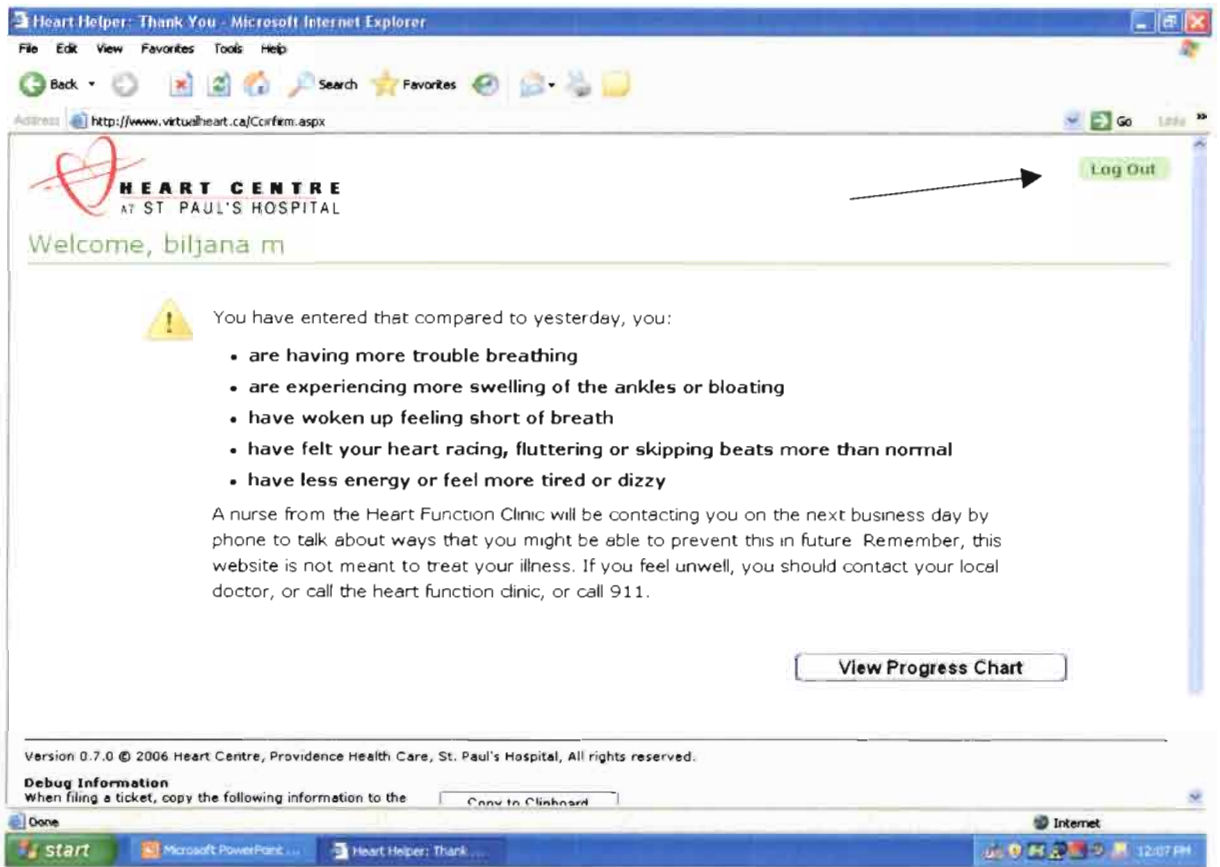
3) If you do not use email, you can telephone the nurse at the heart function clinic at 604-806-8733.

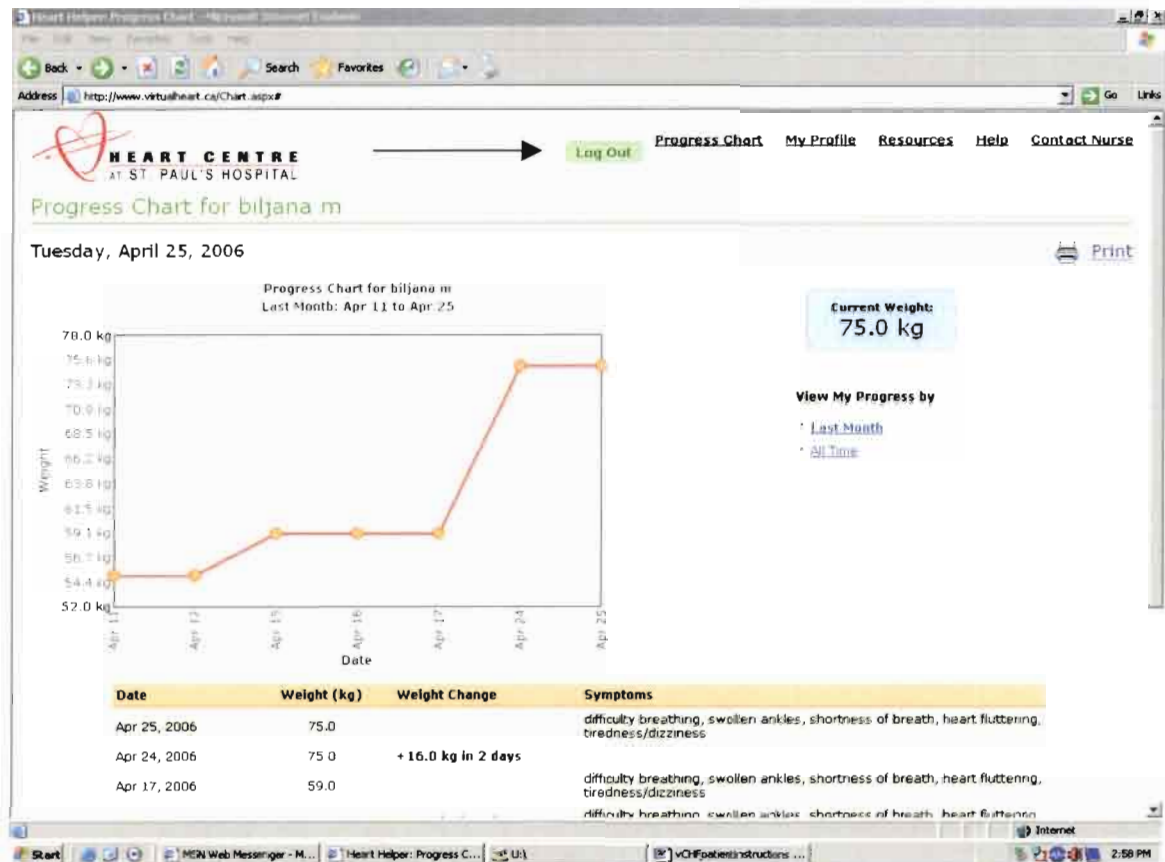
Logging Out

When you are done entering your data and viewing your progress chart, please remember to ALWAYS log off from the system.

Always click once on the green “Log Out” button on your screen.

If you log onto the website, and are inactive for more than 15 minutes, the system will automatically log you out.





Logging on twice in one day

You will only be allowed to enter your answers once a day, so if you make a mistake entering your answers, please contact the nurse.

You can however, log on more than once a day if you want to see your progress charts, email the nurse or look at resources.

Simply log in as you would normally, and you will automatically be taken to your progress chart.

Appendix E: The Study Nurse's Role with Heart Helper Participants

The protocol below provides a framework for the study nurse's actions. If at any time there is any doubt, the study nurse will discuss with the heart function clinic (HFC) nurses.

Heart Helper Protocol for Managing Patient Alerts

Patient Alerts and Protocol:

The patient reported that compared to yesterday, he or she is:

- having more trouble breathing
- experiencing more swelling of the ankles or bloating
- woke up at night feeling short of breath
- felt his/her heart racing, fluttering or skipping beats more than normal
- less energetic or feeling more tired or dizzy

1. The study nurse will review the patient's data and progress chart.
2. The study nurse will contact the HFC nurses and update them on the patient's symptoms. The nurses will assume responsibility for continuing management and documentation.
3. The study nurse will devise an ongoing self-management plan in collaboration with the HFC nurses using the accepted protocols.
4. If indicated, the study nurse will phone the patient and offer self-management counselling. Using the "view progress" option on the Heart Helper website, the study nurse will assist patients in recognizing the correlation between their weight and their symptoms. If appropriate, the study nurse will direct patients to the resource section of the Heart Helper.

5. The study nurse will document the action taken and the immediate outcome on the Heart Helper.

6. The study nurse will document the final outcome, including the action taken by the HFC nurses on a spreadsheet for future analysis

No data was entered for 3 consecutive days

1. The study nurse will phone the patient to determine why no data was entered.

A. If the patient does not answer the phone, the study nurse will make three attempts over 24 hours to contact the patient or caregiver. The study nurse will document the attempts to reach the patient, including messages left on answering machines or with family members. The study nurse will continue daily attempts to contact the patient.

B. If the patient is hospitalized or away, the study nurse will inform the HFC nurses and update the “away” function on the Heart Helper.

C. If the patient is deceased, the study nurse will inform the HFC nurses and the research assistant.

D. If the patient states they no longer want to enter their data every day, the study nurse will discuss this with the patient.

E. If the patient states they no longer want to continue participating in the study (that is, enter their data and receive phone calls from the study nurse), the study nurse will ask the patient if the research assistant can contact them for an exit interview. If the patient does not want the research assistant to contact them, the study nurse will attempt to conduct the exit interview at that time over the phone.

The study nurse will inform the research assistant and discuss the case. The study nurse will inform the HFC nurses and update the Heart Helper website.

F. If the patient states they have forgotten to enter their data or they have another simple reason for not entering data (for example, “too busy”), the study nurse will discuss this with the patient and offer self-management support if appropriate. The study nurse will document the reason for absent data and will resolve the patient alert.

G. If the patient is experiencing difficulties using the system, the study nurse will offer technical support and/or refer the patient to the research assistant.

Weight Trigger (a change in a patient’s weight exceeding the target value)

1. The study nurse will review the patient’s data and progress chart.
2. The study nurse will contact the patient to ensure the correct weight was entered and will ask the patient to weigh him or herself again.
3. If the patient’s weight is accurate, the study nurse will contact the HFC nurses and update them on the patient’s weight change. The HFC nurses will assume responsibility for continuing management and documentation.
4. The study nurse will discuss an ongoing self-management plan with the HFC nurses.
5. If indicated, the study nurse will phone the patient and offer self-management counselling. Using the “view progress” option on the Heart Helper website, the study nurse will assist patients in recognizing the correlation between their weight

and their symptoms. If appropriate the study nurse will direct patients to the resource section of the Heart Helper.

6. The study nurse will document the action taken and the immediate outcome on the Heart Helper.

7. The study nurse will document the final outcome, including the action taken by the HFC nurses on a spreadsheet for future analysis.

Heart Helper Protocol for Managing Patient Emails

Depending on the nature of the email, the study nurse will contact the patient and/or the HFC nurses.

If the email is strictly about education and general management of heart failure through self-care, the study nurse will offer the appropriate support and information.

If the email is about medical management and treatment of heart failure, the study nurse will refer the patient and forward the email to the HFC nurses.

Regardless of the nature of the email, all correspondence shall be forwarded to relevant HFC nurses for their information.

REFERENCE LIST

1. Tsuyuki, R.T., et al., *Contemporary Burden of Illness of Congestive Heart Failure in Canada*. Canadian Journal of Cardiology, 2003. **19**(4): p. 436-438.
2. Lee, D.S., et al., *Regional Outcomes of Heart Failure In Canada*. Canadian Journal of Cardiology, 2004. **20**(6): p. 599-607.
3. HeartBC. *Province Wide Chronic Disease Collaborative for Patients With Congestive Heart Failure in British Columbia: The Collaborative Chapter*. 2003 [cited 2006; Available from: http://www.heartbc.ca/pro/collaboratives/chf/docs/chf_collaborative_chapter.pdf]
4. HeartBC. *Guidelines and Protocols Advisory Committee: Heart Failure Care*. 2003 [cited 2006; Available from: <http://www.heartbc.ca/pro/collaboratives/chf/docs/heartfail.pdf>].
5. Hunt, S.A., et al., *ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: Summary Article: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure)*. Journal of the American College of Cardiology, 2005. **46**(6): p. 1116-1143.
6. BCIT, *Cardiac Pathophysiology Course Manual*. 1996.
7. Radford, M.J., et al., *ACC/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Chronic Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Data Standards (Writing Committee to Develop Heart Failure Clinical Data Standards)*. Journal of the American College of Cardiology, 2005. **46**(6): p. 1179-1207.
8. Wright, S.P., et al., *Uptake of Self-Management Strategies in a Heart Failure Management Programme*. The European Journal of Heart Failure, 2003. **5**: p. 371-380.
9. Chriss, P.M., et al., *Predictors of Successful Heart Failure Self-Care Maintenance in the First Three Months After Hospitalization*. Heart and Lung, 2004. **33**(6): p. 345-353.

10. Riegel, B., B. Carlson, and D. Glaser, *Development and Testing of a Clinical Tool Measuring Self-Management of Heart Failure*. Heart and Lung, 2000. **29**(1): p. 4-15.
11. *Health Care System: eHealth Resources: eHealth Thesaurus*. 2006 [cited 2007; Available from: http://www.hc-sc.gc.ca/hcs-sss/ehealth-esante/res/thesaurus/index_e.html#T].
12. Dunagan, C., et al., *Randomized Trial of Nurse-Administered, Telephone-Based Disease Management Program for Patients With Heart Failure*. Journal of Cardiac Failure, 2005. **11**(5): p. 358-365.
13. GESICA-Investigators, *Randomised Trial of Telephone Intervention in Chronic Heart Failure: Dial Trial*. British Medical Journal, 2003.
14. Artinian, N.T., et al., *Pilot study of a Web-based Compliance Monitoring Device for Patients With Congestive Heart Failure*. Heart and Lung, 2003. **32**(4): p. 226-233.
15. Cordisco, M.E., et al., *Use of Telemonitoring to Decrease the Rate of Hospitalization in Patients With Severe Congestive Heart Failure*. The American Journal of Cardiology, 1999. **84**(7): p. 860-862.
16. Goldberg, L.R., et al., *Randomized Trial of a Daily Electronic Home Monitoring System in Patients with Advanced Heart Failure: The Weight Monitoring in Heart Failure (WHARF) Trial*. Congestive Heart Failure, 2003. **146**(4): p. 705-712.
17. de Lusignan, S., et al., *Compliance and Effectiveness of 1 Year's Home Telemonitoring. The Report of a Pilot Study of Patients With Chronic Heart Failure*. The European Journal of Heart Failure, 2001. **3**: p. 723-730.
18. Jerant, A.F., R. Azari, and T.S. Nesbitt, *Reducing the Cost of Frequent Hospital Admissions for Congestive Heart Failure: A Randomized Trial of a Home Telecare Intervention*. Medical Care, 2001. **39**(11): p. 1234-1245.
19. Cleland, J.G.F., et al., *Noninvasive Home Telemonitoring for Patients with Heart Failure at High Risk of Recurrent Admission and Death: The Trans-European Network-Home-Care Management System (TEN-HMS) Study*. Journal of the American College of Cardiology, 2005. **45**(10): p. 1654-1664.
20. Delgado, D., et al., *An Interactive Internet Site for the Management of Patients With Congestive Heart Failure*. Canadian Journal of Cardiology, 2003. **19**(12): p. 1381-1385.
21. Wu, R.C., et al. (2005) *Pilot Study of an Internet Patient-Physician Communication Tool for Heart Failure Disease Management*. Journal of Medical Internet Research **Volume**, DOI: doi:10.2196/jmir.7.1.e8
22. Wu, R.C., et al., *Pilot Study of an Internet Patient-Physician Communication Tool for Heart Failure Disease Management*. World Hospitals and Health Services, 2006. **42**(3): p. 32-38.

23. Kashem, A., et al., *Managing Heart Failure Care Using an Internet-Based Telemedicine System*. Journal of Cardiac Failure, 2008. **14**(2): p. 121 - 126.
24. Finkelstein, J., M.R. Cabrera, and G. Hripcsak, *Internet-Based Home Asthma Telemonitoring*. CHEST, 2000. **117**: p. 148-155.
25. Gammon, D., et al. (2005) *Parent-Child Interaction Using a Mobile and Wireless System for Blood Glucose Monitoring*. Journal of Medical Internet Research **Volume**, DOI: 10.2196/jmir.7.5.e57
26. *Characteristics of Household Internet Users, by Location of Access*. 2005 [cited 2006; Available from: <http://www40.statcan.ca/l01/cst01/comm10a.htm>.
27. *Characteristics of Individuals Using the Internet 2005* [cited 2007; Available from: <http://www40.statcan.ca/l01/cst01/comm15.htm>.
28. Telus. *Connecting Communities: Connecting BC Communities*. [cited 2007; Available from: <http://about.telus.com/digitaldivide/>.
29. *Minnesota Living With Heart Failure® Questionnaire*. 1986 [cited 2007; Available from: http://www.mlhfq.org/dnld/mlhfq_questionnaire.doc.
30. Rector, T.S. *Overview of the Minnesota Living with Heart Failure® Questionnaire*. 2005 [cited 2007; Available from: http://www.mlhfq.org/dnld/mlhfq_overview.doc.
31. *Minnesota Living With Heart Failure® Questionnaire: Instructions for Data Collection and Scoring*. 2004 [cited 2007; Available from: http://www.mlhfq.org/dnld/mlhfq_scoring_instructions.doc.
32. Riegel, B., et al., *Psychometric Testing of the Self-Care of Heart Failure Index*. Journal of Cardiac Failure, 2004. **10**(4): p. 350-360.
33. Silver, M.A., et al., *BNP Consensus Panel 2004: A Clinical Approach for the Diagnostic, Prognostic, Screening, Treatment Monitoring and Therapeutic Roles of Natriuretic Peptides in Cardiovascular Disease*. Congestive Heart Failure, 2004. **10**(5).
34. Petretta, M., et al., *NT-proBNP, IGF-I and Survival in Patients with Chronic Heart Failure*. Growth Hormone & IGF Research, 2007. **17**: p. 288 - 296.
35. Roche/Cobas, *proBNP N Terminal pro B-Type Natriuretic Peptide - instructions for sample collection*. 2007, Roche/Cobas.
36. *ATS Statement: Guidelines for the Six-Minute Walk Test*. American Journal of Respiratory and Critical Care Medicine, 2002. **166**: p. 111-117.
37. Taylor, H.L., et al., *A Questionnaire for the Assessment of Leisure Time Physical Activities*. Journal of Chronic Diseases, 1978. **31**: p. 741-55.
38. *BpTRU Operator's Manual*. 2002, VSM MedTech Ltd.: Vancouver.
39. SPSS.com, *SPSS® for Windows®*. 2007: Chicago.

40. Parajon, T., et al., *Use of the "Minnesota Living With Heart Failure" Quality of Life Questionnaire in Spain*. *Revista Espanol de Cardiologia*, 2005. **57**(2): p. 155 -160.
41. Hartmann, F., et al., *NT-proBNP in Severe Chronic Heart Failure: Rationale, Design and Preliminary Results of the COPERNICUS NT-proBNP Substudy*. *The European Journal of Heart Failure*, 2004. **6**: p. 343 - 350.
42. Alenhagen, U. and U. Dahlstrom, *Can NT-proBNP Predict Risk of Cardiovascular Mortality Within 10 Years? Results From an Epidemiological Study of Elderly Patients With Symptoms of Heart Failure*. *International Journal of Cardiology*, 2008. **Article in Press**.
43. Anguita, M., et al., *Utility of NT-proBNP for Diagnosing Heart Failure in a Heterogeneous Population of Patients With Dyspnea. Spanish Multicenter Study*. *Revista Espanol de Cardiologia*, 2006. **59**(5): p. 465 - 472.
44. Bayes-Genis, A., et al., *Serial NT-proBNP Monitoring and Outcomes in Outpatients With Decompensation of Heart Failure*. *International Journal of Cardiology*, 2007. **120**(3): p. 338-343.
45. Shah, M.R., et al., *Prognostic Usefulness of the Six-Minute Walk in Patients With Advanced Congestive Heart Failure Secondary to Ischemic or Nonischemic Cardiomyopathy*. *The American Journal of Cardiology*, 2001. **88**: p. 987 - 993
46. Cahalin, L.P., et al., *The Six-Minute Walk Test Predicts Peak Oxygen Uptake and Survival in Patients With Advanced Heart Failure*. *CHEST*, 1996. **110**: p. 324 - 332.
47. Hutcheon, S.D., et al., *Perindopril Improves Six Minute Walking Distance in Older Patients With Left Ventricular Systolic Dysfunction: A Randomised Double Blind Placebo Controlled Trial*. *Heart* 2002. **88**: p. 373 - 377.
48. Dupont, W.D. and W.D.J. Plummer, *PS: Power and Sample Size Calculation*. 2004, Vanderbilt Biostatistics: Nashville.