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I am submitting herewith a dissertation written by Robin Faust Harris entitled "Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients." I have examined the final electronic copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Nursing.

Kenneth D. Phillips, Major Professor

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(Original signatures are on file with official student records.)

Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients

A Dissertation Presented for the
Doctor of Philosophy
Degree
The University of Tennessee, Knoxville

Robin Faust Harris
August 2012

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Dedication

I dedicate this dissertation to my wonderful family, who provided continual love and support throughout my doctoral education. To my husband John, your never-ending love and encouragement helped me throughout this journey. To my children, John Carter, Lauren, and Meredith, you are amazing young people and I am so proud of each of you. To all my family, I thank you for your patience and understanding during this time. I would not have been able to complete my doctoral education without you.

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Abstract

Patients experience decreased functional capacity from chronic symptoms associated with heart failure. Exercise increases activity tolerance and quality of life in heart failure patients. Physiologic responses to exercise in heart failure patients have been well-documented. In contrast, the effects of exercise on an individual's perception of degree of disability due to chronic illness and their adaptive responses to heart failure have not been studied. The purpose of this randomized controlled trial was to examine the effects of a 12-week home-based combined aerobic and resistance training exercise intervention on an individual's perception of degree of disability and adaptive responses to chronic illness. Seventy-one participants were randomized to receive the combined aerobic and resistance training exercise intervention or usual heart failure care. Repeated measures ANOVA and nonparametric tests were used to test the hypotheses that participants in the 12-week home-based low intensity combined aerobic and resistance training intervention would have decreased perception of illness disability, improved physiologic and psychosocial adaptation to chronic illness, and have fewer hospitalizations than the control group. Findings showed participants who received the exercise intervention had increased distance walked on the 6-Minute Walk Test ($p = .03$), they increased their Average Daily Pedometer Steps ($p = .02$), and they had fewer hospitalizations than the control group. NYHA Functional Class III participants in the intervention group showed the most improvement in NYHA Functional Class (41.2%, $p = .03$), and had decreased perception of illness disability with lower scores on the Illness Perception Questionnaire-Revised. Both the intervention and control groups showed

improvement in psychosocial adaptation with lower scores on the Sickness Impact Profile. No exercise-related adverse events occurred. Thus, a home-based low intensity combined aerobic and resistance training exercise program is safe for NYHA Functional Class II and III heart failure patients and improves physiologic and psychosocial adaptation to chronic illness and supports the adaptation to chronic illness theory.

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Chapter One

Introduction

Heart failure is a chronic illness condition that can affect an individual's functional capacity due to physical limitations from symptoms which occur as a result of altered pump function and reduced cardiac output. Common symptoms of heart failure include fatigue, dyspnea, edema, cough, orthopnea, and nocturnal dyspnea (O'Rourke, Walsh, & Fuster, 2009). As a nurse practitioner working in an outpatient heart failure clinic, I have seen heart failure patients in clinical practice experience difficulty with adaptation to change in functional ability due to the symptoms associated with this chronic illness. Patients often become less physically active due to chronic symptoms of fatigue and dyspnea. As a result of decreased physical activity, individuals become deconditioned and more sedentary. Exercise in heart failure patients has been shown to be safe and beneficial in increasing physical activity tolerance. The effect of exercise on adaptation to chronic illness for heart failure patients has not been studied within the adaptation to chronic illness theory. In this chapter, I will present an introduction and statement of the problem, a summary of the adaptation to chronic illness theory used to guide this study, theoretical definitions of concepts, the research hypotheses, study variables, measurement instruments, research assumptions, study limitations and delimitations, and significance of the study for nursing practice.

Background

Heart failure is characterized by altered heart pumping function which affects cardiac output to vital organ systems in the body. Individuals who have been diagnosed with heart failure often experience decreased activity tolerance as a result of symptoms associated with decreased cardiac output. Heart failure is the only major cardiovascular disorder on the increase due to

improvement in cardiac care resulting in higher survival rates from life-threatening cardiac events (American Heart Association, 2010). Currently, over 6 million people have been diagnosed with heart failure in this country with approximately 670,000 new cases diagnosed each year (American Heart Association). The cost of heart failure care continues to increase with an estimated cost in 2010 of $39.2 billion dollars (Centers for Disease Control and Prevention, 2011). Heart failure remains the most common hospital discharge diagnosis for individuals over age 65 (American Heart Association). One of every five individuals with heart failure will die within the first year of their diagnosis (Centers for Disease Control and Prevention).

In heart failure, alteration in the heart pumping function occurs as a result of an index event that results in damage to the myocardium. The index event may be due to a myocardial infarction that results in acute damage to the myocardium, or may be due to a less obvious event such as a genetic disorder that causes changes in the myocardium over time. Initially, the heart can respond to decreased stroke volume by chronic myocyte hypertrophy to increase stroke volume and maintain cardiac output. This results in enlargement of the heart from cardiac hypertrophy and fibrosis. Over time, the heart is unable to maintain stroke volume and cardiac output through this process of chronic myocyte hypertrophy. The influence of neurohormonal activation of the sympathetic nervous system and the renin-angiotensin-aldosterone (RAAS) system in an attempt to maintain cardiac output contributes to remodeling of the left ventricle with further progression of heart failure and decline in cardiac output (O'Rourke, Walsh, & Fuster, 2009).

In healthy individuals, cardiovascular responses to exercise include increased cardiac output from an increase in stroke volume and heart rate. Increased sympathetic stimulation

during exercise results in increase in both heart rate and blood pressure. Blood flow to active skeletal muscles is increased during exercise. Blood flow to visceral organs, such as stomach and intestine, is decreased during exercise. Increased arteriolar vasodilation in skeletal muscle occurs as a result of increased production of nitric oxide in the vascular endothelium (Powers & Howley, 2009). Alterations in left ventricular function in patients with heart failure causes reduced cardiac output from reduced stroke volume and lower maximal heart rate at a lower work demand. Individuals with heart failure may achieve < 50% of maximal cardiac output when compared with healthy participants at peak exercise (Pina et al., 2003).

In heart failure patients, reduced skeletal muscle blood flow from decreased cardiac output causes hypoxia in skeletal muscles during exercise and increases anaerobic metabolism. Hypoxanthine levels have been used as a marker for skeletal muscle hypoxia and have been shown to be higher in heart failure patients at submaximal exercise levels. Hypoxanthine is produced when regeneration of adenosine triphosphate does not occur as a result of decreased oxygen transport during exercise (Hwang, Redfern, & Alison, 2008). In addition to decreased blood flow and oxygenation to the skeletal muscle, endothelial dysfunction in the reduction of nitric oxide production contributes to peripheral vasoconstriction in heart failure patients. Endothelial dysfunction resulting in a reduction in nitric oxide formation and decreased peripheral vasodilation has been correlated with the degree of exercise intolerance and New York Heart Association (NYHA) Functional Class in heart failure patients (Pina et al., 2003). Exercise training has been shown to improve VO_2 max (amount of oxygen uptake by the body), improve endothelial function, and decrease sympathetic response in heart failure patients (Pina et al.).

Management of heart failure includes pharmacologic and nonpharmacologic measures. Extensive research has produced evidence-based guidelines for pharmacologic treatment of heart failure (Jessup et al., 2009). Standard pharmacologic therapy for heart failure management includes: (a) beta blockers, (b) angiotensin-converting enzyme (ACE) inhibitors, (c) diuretics, (d) aldosterone blockers, and (e) addition of digoxin when indicated (Buttaro, Trybulski, Bailey, & Sandberg-Cook, 2008).

In addition to pharmacologic measures, nonpharmacologic measures have been shown to decrease illness exacerbations (Jessup et al., 2009). Nonpharmacologic management of heart failure includes patient education for monitoring of sodium and fluid intake, recording daily weights, knowledge of symptoms of worsening heart failure, and importance of daily physical activity (Buttaro et al., 2008; Jessup et al.). Prior to the initial exercise in heart failure studies in the 1970s, patients were advised not to exercise because of concern that increased demands placed on the heart from physical activity would be harmful (Bartlo, 2007). Exercise training has since been studied in patients with NYHA Functional Classes I - IV heart failure and has been shown to be safe without worsening of heart failure severity or increase in adverse events (Cahalin, Ferreira, Yamada, & Canavan, 2006; Keteyian, 2011).

The HF-ACTION trial is the largest randomized controlled trial to date on exercise in heart failure patients (n= 2,331). Participants in that study included New York Heart Association (NYHA) Functional Class II, III, and IV patients with systolic heart failure and ejection fraction (EF) less than 35% (O'Connor et al., 2009). Study participants completed symptom-limited graded exercise test with expired gas spirometry at baseline, and again at 3 months, 12 months, and 24 months. There were 2,037 participants who completed at least one of the follow-up graded exercises tests (Keteyian et al., 2009). Study findings revealed no increase in test-related

deaths, worsening of heart failure, or development of angina symptoms resulting in hospitalization due to myocardial infarction, stroke or transient ischemic attack. Two episodes of ventricular arrhythmias were reported in that study, one each of ventricular fibrillation and sustained ventricular tachycardia. Researchers reported findings of zero deaths per 1,000 exercise tests and 0.45 nonfatal cardiovascular events per 1,000 tests in the HF-ACTION trial (Keteyian et al.).

The Exercise in Left Ventricular Dysfunction and Chronic Heart Failure (ELVD-CHF) Trial evaluated the effects of combined supervised and home-based aerobic exercise program in stable patients with NYHA Functional Class II or III heart failure (N = 90) (Giannuzzi, Temporelli, Corra, & Tavazzi, 2003). The purpose of that trial was to: a) examine the physiological effects of exercise training on left ventricular volume and function, and b) evaluate safety of an aerobic exercise program in stable heart failure patients in a multi-center randomized controlled trial. Participants randomized to the intervention group attended exercise sessions at least three times weekly for supervised continuous 30-minute bicycle ergometry for 60% of peak VO_2 obtained at baseline exercise stress testing. Participants in the intervention group also completed a 30-minute daily walk and 30 minutes of calisthentics of non-supervised home-based exercise as part of the exercise protocol. Participants randomized to the control group received heart failure education but no specific exercise instruction or protocols.

Findings from that study showed fewer clinical events in the treatment group (9%) vs. control group (15%) (Giannuzzi et al., 2003). In the treatment group, two participants were hospitalized due to worsened heart failure, and two participants developed worsening heart failure but did not require hospitalization. In the control group, one patient was hospitalized due to worsening heart failure, six patients developed increased symptoms but did not require

hospitalization, and one patient died of sudden cardiac death one month after enrollment into the study. Findings also showed exercise training improved left ventricular function with a 16% increase in ejection fraction in the treatment group vs. no improvement in the control group, and lowered both end-diastolic and end-systolic volumes in the exercise group vs. control group ($p < 0.001$) (Gianuzzi et al.)

In a review of published exercise studies using either aerobic exercise or combined aerobic and resistance training, Keteyian (2011) reported there was no increase in exercise-related deaths or cardiac events in published multi-center trials. There was also no increase in all-cause mortality or hospitalizations from exercise training in heart failure patients. Findings from this review showed exercise in heart failure improves: a) physiologic effects of increased cardiac demand, b) exercise capacity, and c) overall health status and quality of life. Exercise in heart failure patients is safe and has not been shown to increase sudden cardiac death or adverse clinical events (Keteyian).

Safety of exercise in heart failure patients was examined in a meta-analysis of 81 published exercise studies involving exercise training in 2,382 patients (Smart & Marwick, 2004). Exercise protocols included aerobic training (n = 40), resistance training (n = 3), combined aerobic and resistance training (n = 13), and inspiratory muscle training (n = 1). All study participants had an ejection fraction of less than 40% and were primarily NYHA Functional Class II or III, although some studies did include NYHA Functional Class I and IV. Over 60,000 patient hours of exercise training were recorded with no exercise-related cardiac deaths, which is comparable with exercise-related deaths in healthy individuals and cardiac populations. Study findings also showed reduction in composite endpoint of death and adverse events in exercise vs. control groups in randomized controlled studies (Smart & Marwick).

In spite of evidence to support the benefits and safety of exercise for heart failure patients, no universal guidelines for specific exercise protocols in this patient population currently exists (Pina et al., 2003). Recommendations for exercise in heart failure patients from the American Heart Association (2012) and the Heart Failure Society of America (2012) are nonspecific and encourage 30 minutes of activity per day, which may be done in shorter interval several times a day, on most days of the week. The lack of agreement among experts on universal guidelines for exercise recommendations in this patient population is due in part to variability in exercise protocols studied in clinical trials (Pina et al.). Exercise training can improve physical activity tolerance and increase an individual's ability to adapt to physiological and psychological aspects of living with a chronic illness. Improved physical activity tolerance allows the patient to maintain activities of daily living, independence, and quality of life (McConnell, 2005).

Assisting individuals with the process of adaptation to chronic illness to achieve optimal level of function to prevent illness exacerbations and reduce healthcare costs is an important aspect of nursing care (Pollock, 1993). Understanding the process of adaptation to chronic illness, including adaptation to changes in activity from functional limitations, assists nurses to develop and implement nursing interventions to facilitate adaptation and optimal health in patients with chronic heart failure. Helping patients adapt to chronic illness to achieve optimal level of physiological and psychological functioning has important implications for nursing practice. Exercise training has been shown to alter physiological consequences of reduced left ventricular function in heart failure patients and improve functional capacity and quality of life (McConnell, Mandak, Sykes, Fesniak, & Dasgupta, 2003). The influence of exercise on

perception of illness and adaptation to chronic illness in patients with heart failure has not been studied.

Statement of the Problem

Heart failure is a chronic illness condition and individuals with heart failure must adapt to chronic physical symptoms that may decrease functional ability and activity tolerance. Individuals who have been diagnosed with heart failure have altered heart pumping function that can influence activity tolerance and functional capacity (Gunn, Smith, McKelvie, & Arthur, 2006). Dyspnea and fatigue are common symptoms that occur as a result of decreased cardiac output in individuals with heart failure (Bartlo, 2007). Limitation in physical activity as a result of symptoms related to decreased left ventricular function and reduced cardiac output often leads to a sedentary lifestyle in patients with heart failure resulting in deconditioning and increased symptoms of dyspnea, fatigue, and breathlessness in heart failure patients. Exercise training has been shown to be beneficial in patients with heart failure to improve endurance and decrease dyspnea (McConnell et al., 2003). Although exercise training has been shown to improve heart failure symptoms and activity tolerance, the individual's perception of the effect of physical exercise on his/her general well-being could be the most significant advantage of exercise training in heart failure patients (Tai, Meininger, & Frazier, 2008).

Study Purpose

While physiologic responses to exercise in heart failure patients have been well-documented in the literature, the influence of an exercise training program on an individual's perception of disability and adaptive responses to chronic illness in heart failure patients has not been well-studied. Therefore, the purpose of this study was to examine the effects of

participation in a structured exercise program on perception of illness impact and adaptation to chronic illness in patients with heart failure.

Philosophical Perspective

This exercise intervention study used quantitative research methodology. Quantitative research methodology is based within the positivist paradigm that absolute truth of knowledge exists and is independent from creation by the human mind (Creswell, 2009; Polit & Beck, 2008). Within the positivist paradigm, objectivity is desired and based on logic and mathematics (Rodgers, 2005). The positivist paradigm emphasizes disciplined, strict procedure and control in research (Polit & Beck). However, strict control in research within the positivist paradigm is difficult when the phenomenon of interest involves the behaviors, actions, or responses of human beings (Creswell). In contrast, the postpositivist paradigm is not based on such rigid, strict controls in the research setting and is used most often in nursing research to gain new knowledge and understanding of nursing care for human beings (Rodgers). In the postpositivist paradigm, objectivity remains a goal with efforts to control bias and maintain neutrality. Understanding of the phenomena and predictions about the phenomena are based on probabilistic evidence, not absolute truth (Creswell; Polit & Beck). This study examined adaptive responses from human participants and was based within the postpositivist paradigm.

Theoretical Framework

The theoretical framework used to guide development of this study on exercise in patients with chronic heart failure is the adaptation to chronic illness theory (Pollock, 1993) derived from the Roy Adaptation Model (Roy, 1984). In the Roy Adaptation Model (RAM), the individual is viewed as a bio-psycho-social being in constant interaction with the environment. According to this model, the person is an adaptive system with two innate subsystems for

adaptation to changing environmental stimuli. These subsystems are the: a) regulator subsystem, and b) cognator subsystem. The autonomic nervous system influences reflex responses to environmental stimuli through the regulator subsystem. Major components of the regulator subsystem include: a) neural, b) endocrine, and c) perception-psychomotor. Through the cognator subsystem, the individual is able to process information from stimuli for adaptation. Components of the cognator subsystem include: a) perception/information processing, b) learning, c) judgment, and d) emotion (Roy & Andrews, 1991).

In the RAM, adaptation to focal, contextual, or residual stimuli occurs from regulator (physiologic) or cognator (psychologic) processes through the influence of four effector modes: a) physiologic, b) self-concept, c) role function, and d) interdependence (Pollock, 1993). The physiologic mode relates to biologic adaptive responses in the process of adaptation. Self-concept, role function, and interdependence are psychosocial modes of adaptation in the Roy Adaptation Model (Frederickson, Jackson, Strauman, & Strauman, 1991). Self-concept mode is an individual's concept of their personal and physical self. Role function relates to the activities associated with various roles in an individual's life. Interdependence mode is the individual's relationships with other people (Bakan & Akyol, 2007). Perception is the mediator/interpreter of physiologic stimuli that connects to cortical awareness of the experience. The linkage of perception to physiologic and psychosocial adaptation is the connection between the regulator and cognator processes (Roy & Roberts, 1981).

The adaptation to chronic illness theory derived from the Roy Adaption Model provides the framework to understand human behavioral responses to chronic illness. Pollock (1993) further described environmental stimuli, cognator/regulator subsystems, and adaptation response of the Roy Adaptation Model in relation to chronic illness (Pollock, 1986; 1993). Environmental

stimuli include: a) chronic illness, b) contextual stimuli, and c) residual stimuli. The definition for chronic illness used in the adaptation to chronic illness theory is taken from the definition by Dimond and Jones (1983). Chronic illness is defined as "a condition of long-term duration, not curable, and/or having some residual features that impose limitations on an individual's functional capabilities" (Pollock, Christian, & Sands, 1990, p. 300). Examples of chronic illness stimuli are: a) type and duration of an illness, and b) symptoms caused by the illness (Whittemore & Roy, 2002). Contextual stimuli are factors that increase, decrease, or alter the environmental stimuli or adaptation process (Roy & Andrews, 1991). Examples of contextual stimuli include: a) demographic characteristics, b) participation in patient education programs and health promotion activities, and c) individual's ability to tolerate stress. Residual stimuli are unknown factors that may influence adaptation (Roy, 1984). Examples of residual stimuli are personal experiences or situations that may influence an individual's ability to adapt to stress.

An individual's perception of the impact of chronic illness can influence adaptation. Perception of illness impact is a key concept of the adaptation to chronic illness theory. Perception of illness impact is defined as the "perceived degree of illness, or functional disability caused by the chronic illness" (Pollock, 1993, p. 88). Perception of illness impact is the link that connects the regulator (physiological) and cognator (psychological) subsystems in the adaptation process (Roy & Andrews, 1991). Adaptation to chronic illness includes both physiological and psychological responses. Physiological adaptation to chronic illness includes the biological responses to the influences of the chronic illness, but is not limited to biological responses. Physiologic adaptation is also associated with subjective report of symptoms related to the chronic illness (Frederickson et al., 1991). Psychological adaptation to chronic illness includes

the categories of: a) intrapsychic function or self-concept, b) role function, and c) social support (Pollock, 1993).

Theoretical Definitions

Adaptation – "an active process whereby the organism adjusts itself to the environment" (Pollock, 1986, p. 91)

Chronic illness – The definition of chronic illness used in the adaptation to chronic illness theory is derived from the definition by Dimond and Jones (1983). Chronic illness is defined as "conditions of long-term duration, not curable, and/or having some residual features that impose limitations on an individual's functional capabilities" (Pollock et al., 1990, p. 300).

Adaptation to chronic illness – "a complex process involving numerous internal and external factors that influence response and subsequent level of adaptation" (Pollock, 1993, p. 86).

Environmental stimuli - In the Roy Adaptation Model (RAM), the person is viewed as an adaptive system in constant interaction with the environment. In the adaptation to chronic illness theory, the environmental stimuli are: a) focal, b) contextual, and c) residual. A focal stimulus is the diagnosis and associated symptoms of a chronic illness condition. Contextual stimuli are the factors that can influence adaptation to the chronic illness, such a demographic characteristics or participation in health-related behaviors. Residual stimuli are unknown factors that could affect adaptive responses, such as personal experiences.

Perception of Illness Impact – A key concept in the adaptation to chronic illness theory defined as the "perceived degree of illness, or functional disability caused by the chronic illness" (Pollock, 1993, p. 88). Perception of illness impact is the link that connects the regulator (physiological) and cognator (psychological) subsystems in the adaptation process (Roy & Andrews, 1991).

Physiologic adaptation – includes both objective measures and subjective measures of adaptive responses (Pollock, 1993). Examples of objective physiologic measures include heart rate and blood pressure. An example of a subjective response of adaptation is the report of presence or absence of symptoms associated with chronic illness.

Psychosocial adaptation – psychological responses categorized into three modes: a) intrapsychic or self-concept, b) role function, and c) social function (Pollock, 1993).

Heart Failure – A clinical condition that "exists when the heart is unable to pump sufficient blood to meet the metabolic needs of the body at normal filling pressures, provided the venous return to the heart is normal" (Hurst, 1990, p. 387). Systolic heart failure is dilation and impairment of the left ventricle that causes reduced cardiac output. In systolic heart failure, the left ventricular ejection fraction is decreased. Diastolic heart failure refers to impaired left ventricular filling due to stiffness of the heart chamber. In diastolic heart failure, left ventricular ejection fraction is preserved (O'Rourke et al., 2009).

New York Heart Association (NYHA) Functional Class – Classification system to describe functional status by severity of symptoms. Class I patients have no symptoms with ordinary physical activity. Class II patients have symptoms with ordinary physical activity and have slight limitation of activity. Class III patients have symptoms with less than ordinary physical activity and have marked limitation of activity. Class IV patients have symptoms at rest or any physical activity (O'Rourke et al., 2009, p. 3)

Physical Activity – "any bodily movement produced by contraction of skeletal muscles that result in a substantial increase over resting energy expenditure" (Thompson, Gordon, & Pescatello, 2010, p. 2).

Exercise –"a type of physical activity consisting of planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness" (Thompson et al., 2010, p. 2).

Exercise intolerance – "reduced ability to perform activities that involve dynamic movement of large skeletal muscles because of symptoms of dyspnea or fatigue" (Pina et al., 2003, p. 1210).

Exercise training can improve exercise endurance and muscle strength (Thompson et al., 2010).

Research Hypothesis

The theoretical hypothesis for this study developed from the adaptation to chronic illness framework was participation in a 12-week home-based combined aerobic and resistance exercise training program would decrease perception of illness impact and increase physiological adaptation and psychosocial adaptation in patients with chronic heart failure.

Operational Definitions

The independent variable in this study was the exercise intervention consisting of a 12-week exercise training program including both aerobic and resistance training exercise. Participants were randomized to either the intervention group or the wait-list control group. The intervention group participated in a low-level intensity walking program with a goal of walking 20 minutes daily for four weeks. After four weeks of low-intensity aerobic training, participants in the intervention group began low-intensity resistance training with 1-pound dumbbells for 20 minutes in addition to the 20-minute daily walking program for the remainder of the study weeks 5-12. Participants were instructed to begin and end each exercise session in weeks 1-12 with 5 to 10 minutes of warm-up and cool-down exercises. Instruction on proper technique for warm-up and cool-down exercise, aerobic exercise, and resistance training exercises were provided in face-to-face contact with the participant after informed consent for study enrollment was

obtained. Participants in the wait-list control group received usual care that included patient education on pharmacologic and nonpharmacologic management of heart failure, but were not given specific instruction for physical exercise. The same exercise instructions were provided to participants in the wait-list control group at the end of the 12-week study. The reader is referred to Chapter 3 for details on exercise description and instruction for this study.

The dependent variables in this study were perception of illness impact, physiologic adaptation, and psychologic adaptation. Perception of the impact of chronic illness has been described as an important influence on the ability of the individual to adapt to chronic illness (Pollock, 1993). The individual's perception of illness has been shown to be more influential than the degree or severity of illness in adaptation to chronic illness (Frederickson et al., 1991). Perception of illness impact was measured by the Illness Perception Questionnaire (IPQ-R). The IPQ-R was developed to measure perception of illness in individuals with chronic illness conditions (Moss-Morris et al., 2002). This study examined the effects of participation in a structured exercise program on perception of illness in patients with chronic heart failure.

The four modes of adaptation consistent with the adaptation to chronic illness theory were measured in this study. Physiological adaptation from the exercise intervention was operationalized by the 6-minute walk test to measure the distance walked in six (6) minutes and total pedometer steps recorded by the Omron HJ-720ITC pedometer. Psychosocial adaptation was measured by the Sickness Illness Profile (SIP). The SIP was developed to measure perception of health status over time across different types of illness with varying levels of severity and has been used to measure the psychosocial modes of intrapsychic function, role function, and social support within the Roy Adaptation Model (Frederickson et al..,1991).

The reader is referred to Chapter 3 for detailed description of the instruments used in this study.

Assumptions

Assumptions of this study based on the theoretical framework include the following:

1. Perception of illness connects the regulator (physiologic) and cognator (psychologic) subsystems in adaptation to chronic illness theory.
2. An individual with a chronic illness is in constant interaction with the environment and perceives stimuli through the cognator and regulator subsystems.
3. Adaptation includes physiologic and psychologic responses.
4. Normal physiologic responses occur with exercise.

Limitations

Study limitations include:

1. Small sample size obtained from one private cardiology practice in the same geographic location in a small city in the Southeastern United States. Patient demographic characteristics for age, gender, educational level, and socioeconomic status may not be generalizable to the larger heart failure patient population.
2. Use of a low-to-moderate intensity home-based exercise program in stable NYHA Functional Class II and III patients may limit generalizability to larger heart failure population with different functional limitations.

Delimitations

Delimitations of this study include convenience sample obtained from English speaking patients age 18 years and older who have been diagnosed with systolic heart failure from a private cardiology office in the Southeastern United States. The study included only participants with NYHA Function Class II or III heart failure.

Significance for Nursing Science

The middle range theory of adaptation to chronic illness theory (Pollock, 1993) derived from the Roy Adaptation Model (Roy, 1984) was the theoretical framework for this study. Adaptation to chronic illness theory provides the framework to understand human behavioral responses to chronic illness. Chronic illness is defined as "a condition of long-term duration, not curable, and/or having some residual features that impose limitations on an individual's functional capabilities" (Pollock et al., 1990, p. 300). An individual's perception of the impact of chronic illness can influence adaptation. Perception of illness impact is a key concept of the adaptation to chronic illness theory and is defined as the "perceived degree of illness, or functional disability caused by the chronic illness" (Pollock, 1993, p. 88). Perception of illness impact is the link that connects the regulator (physiological) and cognator (psychological) subsystems in the adaptation process (Roy & Andrews, 1991).

Use of middle range theory in nursing research allows for further testing of nursing theory to understand and explain phenomena encountered in nursing practice. Middle range nursing theory can be further developed and refined through nursing research to guide nursing practice and advance nursing science for a specific patient population (Whittemore & Roy, 2002). Adaptation in chronic illness is a process that involves both physiologic and psychosocial adaptive responses (Pollock, 1993). Little is known about the effects of a structured exercise

program on adaptation to chronic illness in patients with heart failure. This study will expand nursing knowledge of the effects of exercise on adaptation to chronic illness for heart failure patients.

Chapter Summary

Patients with heart failure must adapt to limitations in physical activity tolerance due to symptoms associated with altered heart pumping function. Limitations in physical activity can result in physical deconditioning and worsening of symptoms. Exercise can increase physical endurance in heart failure patients and improve functional ability. The process of adaptation includes physiologic and psychosocial adaptive responses. The effect of exercise on adaptation to chronic illness in heart failure patients has not been studied.

Chapter Two

Literature Review

A critical review of the literature for this study was done to include research relevant to the adaptation in chronic illness theory as the theoretical framework for the study and empirical research on exercise in heart failure patients. Methodology used for the literature review was an electronic database search of CINAHL, MEDLINE, and PsycINFO databases using the keywords: adaptation, illness, chronic, perception, heart failure, exercise, aerobic, and resistance training. A broad search was conducted to include international publications. Abstracts were reviewed for relevance to this study on exercise in patients with systolic heart failure for research articles, opinion articles, or literature reviews. Articles selected for this literature review were written in English and published in peer reviewed journals. Articles accepted were not limited by publication date. Recent publications were included for current evidence of exercise in heart failure as well as older publications that have made significant contributions to knowledge of exercise in heart failure. This review included quantitative and qualitative research articles. Published research to date has been predominantly quantitative research. A review of the theoretical research has been presented first, followed by the empirical research on exercise in heart failure. A summary of theory-based and empirical research have been presented at the end of each section. An overview of theory-based and empirical research have been presented in the chapter summary.

Theory-Based Research

The theoretical framework used to guide development of this study is the adaptation to chronic illness theory (Pollock, 1993). The adaptation to chronic illness theory is a middle-range theory derived from the Roy Adaptation Model (Roy, 1984). Adaptation is defined as a “process

whereby the organism adjusts itself to the environment" (Pollock, 1986, p. 91). In the Roy Adaptation Model, the individual is an adaptive system with regulator (physiologic) and cognator (psychologic) processes that influence response to environmental stimuli through four effector modes: a) physiologic, b) self-concept, c) role function, and d) interdependence (Pollock, 1993). The Roy Adaptation Model has been used widely in nursing research for various age groups, settings, and health conditions (Meleis, 2007).

The relationship between physiologic and psychosocial adaptation responses based on the Roy Adaptation Model was studied in 45 cancer patients undergoing chemotherapy using a cross-sectional nonexperimental design (Frederickson et al., 1991). Measurement instruments used in that study included: a) APACHE II (Acute Physiology and Chronic Health Evaluator) to measure severity of illness, b) Symptom Distress Scale (SDS) to measure subjective level of pain or discomfort, and c) Sickness Impact Profile (SIP) to measure perception of illness on psychosocial modes of self-concept, role function, and interdependence. Study findings supported the three hypotheses based on the relationships of the Roy Adaptation Model: a) physiologic stimuli are transformed from the regulator process into perceptions that interpret the incoming stimuli for the individual, b) perceptions of physiological stimuli can affect psychosocial domains, and c) adaptive modes are interrelated and any input stimulus in one mode can affect another mode (Frederickson et al.).

Perception of illness involves the individual's interpretation, translation, and understanding of incoming stimuli through cognator (psychosocial) and regulator (physiologic) processes (Frederickson et al., 1991). An individual's perception of their overall health and ability to adapt to chronic illness is influenced by perception of the degree of disability caused by the chronic illness (Pollock et al., 1990). In chronic illness, an individual's experience and

perception of physical symptoms may not correlate with their actual physiologic condition. Perception of illness disability is influential on physiologic adaptation (Frederickson et al., 1991). Perception of illness disability also effects self-concept, role function, and relationships in psychosocial adaptation to chronic illness (Whittemore & Roy, 2002).

Application of the Roy Adaptation Model to develop nursing interventions has been studied in patients with chronic disability. The Roy Adaptation Model was used as the theoretical framework for an intervention study of elderly patients with hearing impairment (Tolson & McIntosh, 1996). In that study, the Roy Adaptation Model was used to develop nursing interventions to assist participants with adaptation to hearing aid use to promote hearing acuity. The nursing intervention program developed from the Roy Adaptation Model was effective in increasing hearing aid use, participant satisfaction, happiness, and sense of well-being at 6 and 12 months post-intervention.

One study has been published to date using the Roy Adaptation Model as the theoretical framework to study the effects of an education, exercise, and social support program developed from the Roy Adaptation model for patients with heart failure (Bakan & Akyol, 2007). The study was a secondary analysis of data collected from a randomized control trial of 43 patients with an experimental group (n = 21) and control group (n = 22). The experimental group received the educational program intervention developed from the Roy Adaptation Model which included patient education on heart failure diagnosis, signs and symptoms, dietary instructions, fluid intake, cholesterol levels, tobacco and alcohol use, importance of recording of daily weights, and types of exercise. Participants were instructed on a walking program and provided a booklet of written information that supported adherence to medications and exercise. No difference was identified at baseline between the experimental and control groups on the following data: a)

physiologic data including body mass index and cholesterol levels, b) Minnesota Living with Heart Failure Questionnaire (MLWHF) scores, c) Interpersonal Support Evaluation List (ISEL) scores used to measure interdependence, and d) distance walked on 6-Minute walking test (6MWT). Statistically significant improvement in scores occurred in the intervention group at three months on: a) distance walked on 6MWT ($p < .05$),b) ISEL-SF ($p < .05$) scores to measure interdependence, c) MLWHF total score ($p < .05$), and d) MLWHF physiologic, emotional, and role performance sub-dimension scores ($p < .05$).

The Roy Adaptation Model has been used to study adaptation in a variety of illness conditions (Maxwell, Givant, & Kowalski, 2001; Young-McCaughan et al., 2003) and in different cultures (Bakan & Akyol, 2007; Burns, 2004; Pollock, 1999). Pollock (1989; 1993) further studied the process of adaptation from the Roy Adaptation Model in patients living with chronic illness. From this work, Pollock derived the adaptation to chronic illness middle range theory from the Roy Adaptation Model. Adaptation to chronic illness is defined as a "complex process that is a response to internal and external factors that influence response and subsequent level of adaptation to the illness" (Pollock, 1986, p. 90). Adaptation to chronic illness is a balance between the demands placed on the individual (external factors) and the ability of the individual to respond to these demands (internal factors) (Pollock et al., 1990). The reader is referred to Chapter One for a more complete description of both the Roy Adaptation Model and the adaptation to chronic illness theory.

Adaptation response in chronic illness is a process involving internal and external factors that influence response to stimuli (Pollock, 1993). Understanding of adaptive responses in chronic illness in response to stressors is taken from behavioral theory (Selye, 1956) and coping theory (Lazurus & Folkman, 1984). The characteristic of hardiness was described by Kobasa

(1979) who showed hardiness to be influential in both physiologic and psychologic adaptation to chronic illness (Pollock, 1993; Pollock et al., 1990). The characteristic of hardiness encompasses the constructs of control, commitment, and challenge. Hardiness as a personality characteristic was identified as a mediating variable in adaptation (Pollock, 1993). Pollock and Duffy (1990) developed the Health-Related Hardiness Scale (HRHS) to measure dimensions of control, commitment, and challenge in adaptative responses. Pollock's research on adaptation to chronic illness included total of 597 participants with one the following four types of chronic illness: a) insulin dependent diabetes mellitus (n=251), b) multiple sclerosis (n=137), c) hypertension (n=113), or d) rheumatoid arthritis (n=96) (Pollock, 1993; Pollock & Duffy, 1990). Other researchers have challenged the utility of hardiness as a characteristic to provide understanding of how individuals respond and adapt to stress. The concept of hardiness has not been clearly defined and there has been disagreement on appropriate measurement tools and research methods to evaluate hardiness (Lambert & Lambert, 1999; Lowe, 1999).

The adaptation to chronic illness theory was used to theoretically frame a study of health-related hardiness and perception of illness impact in patients in a cross-sectional, nonexperimental study in 60 patients with hemophilia (Brooks, 2008). High health-related hardiness was positively associated with greater psychosocial adjustment to illness and higher self-perception of health status. High perception of illness impact was associated with lower self-perception of health status. Perception of illness impact mediated the relationship between health-related hardiness and psychosocial adjustment to illness. That study supported the theoretical concepts and framework of adaptation to chronic illness theory in patients with chronic illness.

Adaptation to chronic illness theory was further developed for patients with diabetes mellitus through concept and theory synthesis (Whittemore & Roy, 2002). This led to the development of the Adapting to Diabetes Mellitus middle range theory. Further development and testing of adaptation in chronic illness theory for specific patient populations has implications for nursing practice. Adaptation to chronic illness theory has been studied in patients with diabetes (Whittemore & Roy), hypertension, multiple sclerosis, rheumatoid arthritis (Pollock, 1993), and hemophilia (Brooks, 2008). No studies using adaptation to chronic illness theory in heart failure patients were found for this literature review.

The majority of studies published on exercise in heart failure patients have been quantitative studies. A few qualitative studies that relate to physical activity in heart failure patients have been published. Thornhill, Lyons, Nouwen, and Lip (2008) conducted a phenomenological study of the lived experience of heart failure patients. A convenience sample of 25 heart failure patients (inpatient = 13, and outpatient = 12) living in the United Kingdom were included in this study. The sample was predominantly male (n = 21), British (n = 22), and over 60 years of age (n = 22). Four main themes were identified from the interviews: a) the diagnostic process (identification of symptoms and seeking medical advice), b) change in lifestyle activities (work and self-identity), c) role of others in adjustment to chronic illness, and d) emotional reactions including positive and negative emotions. Physical limitations, due to illness and change in level of activity, were found to be a major issue for study participants. Restrictions on lifestyle, work, social interaction, and change in self-concept occurred due to physical limitations from chronic symptoms (Thornhill et al.).

Similar themes were identified in a systematic review of published qualitative research since 1980 by Tierney et al. (2011). Twenty qualitative studies on exercise in heart failure were

included in this review. Four major themes were identified: a) changing soma due to aging and symptoms from chronic illness, b) negative emotional response such as frustration and anxiety, c) adjusting to altered status such as lifestyle changes to accommodate level of activity tolerance, and d) interpersonal influences with families, friends, and even pets. Findings from that systematic review of published qualitative studies provide understanding of the physical limitations due to symptoms on lifestyle, emotions, and interactions with others from the patient perspective. The authors proposed that self-efficacy theory could be used in this population to develop strategies to manage symptoms and limitations due to heart failure.

Nursing care for heart failure patients has benefitted from nurse researchers whose works have contributed to the body of nursing knowledge for heart failure patients. Advances in nursing science for heart failure care enables nurses to develop interventions that improve care for heart failure patients and assists them to achieve optimal health and functioning. Patients with heart failure must overcome many challenges in day-to-day aspects of their care (Riegel et al., 2011). Management of heart failure to control symptoms and illness exacerbations is often difficult for patients and caregivers. Patients are typically on multiple medications and must adhere to important lifestyle changes to control symptoms and prevent worsening heart failure. Heart failure patients must learn to recognize symptoms and respond with appropriate actions to relieve or prevent worsening of symptoms. Self-care management refers to the decision-making process and behavioral responses that are necessary to manage illness and control symptoms. Self-care management behaviors include: a) medication adherence, b) symptom monitoring and reporting of symptoms, c) adherence to dietary and fluid restriction, d) avoidance of alcohol, e) weight loss to control or maintain weight, f) daily physical activity, g) prevention measures such

as immunizations, and h) avoidance of nonprescription medications that can exacerbate heart failure symptoms (Riegel et al., 2009).

Self-care management is the active involvement of the patient in their care and requires more than just patient adherence to treatment plan (Lee, Moser, Lennie, & Riegel, 2009). Self-care management can be influenced by factors such as age (Riegel et al., 2010), gender (Riegel, Dickson, Kuhn, Page, & Worrall-Carter, 2010), confidence in self-care ability (Riegel et al., 2011), and presence of multiple comorbidities (Dickson, Buck, & Riegel, 2011). Recognition and actions to address signs and symptoms of worsening heart failure (subjective self-care management) was shown to be associated with 56% reduction in all-cause mortality, hospital admissions, and emergency department visits (objective outcomes) (Lee et al.).

Nurse researchers have contributed to the body of knowledge of exercise in heart failure patients using theories from other disciplines. Self-efficacy theory, derived from Bandura's social cognitive theory, has been used as a framework for exercise studies in nursing research. Pozehl, Duncan, Hertzog, & Norman, (2010) studied a 12-week exercise intervention, Heart Failure Exercise and Training Camp (HEART CAMP), to increase self-efficacy based on social cognitive theory to include: a) enactive mastery of experiences (return demonstration of skills, b) vicarious experience (small group sessions and role modeling), c) verbal persuasion (educational materials and feedback on progress), and d) physiologic and affective responses (symptom recognition and management strategies). The exercise training protocol used combined aerobic and resistance training exercises for a total of 12 weeks. Findings from that study showed a 31% increase in self-efficacy in the intervention group, 21% improvement in symptoms in the intervention group, and improved quality of life in both the intervention group and attention control group (Pozehl et al.).

This study will build on the works of other nurse researchers to add new knowledge to expand what is already known about exercise in heart failure patient to improve patient care and outcomes. The middle-range nursing theory of adaptation to chronic illness (Pollock, 1993) was used as the framework for this study. Adaptation to chronic illness theory has not been tested in heart failure patients. This study will test the adaptation to chronic illness theory in patients with heart failure to further develop this theory for use in research and in practice in this patient population.

Summary of Theory-Based Research

The adaptation to chronic illness theory derived from the Roy Adaptation Model has been tested and supported through research in patients with a variety of chronic illnesses including diabetes mellitus, hypertension, multiple sclerosis, rheumatoid arthritis, and hemophilia. Review of the literature revealed no published studies to date that used adaptation in chronic illness theory as framework for nursing research in patients with heart failure. Further development and testing of this theory for use in research and practice will add to the body of knowledge for nursing care of patients with chronic illness.

Empirical Research

Review of the literature on exercise in heart failure patients will be presented in this section. Research in this area has focused primarily on physiologic responses to exercise in heart failure patients. Few studies have evaluated psychosocial adaptive responses to exercise in heart failure patients. Quality of life has been the usual measure in studies that have evaluated psychosocial response (Tai, Meininger, & Frazier, 2008). Review of the literature of exercise in heart failure and physiologic responses have been presented first in this section, followed by the literature on psychological responses to exercise in heart failure.

Physiologic Adaptation

Exercise is defined as "a type of physical activity consisting of planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness" (Thompson et al., 2010, p. 2). Exercise training in heart failure patients has been shown to be safe and beneficial in heart failure patients to improve: a) exercise capacity, b) exercise duration, c) exercise performance, d) quality of life, and e) physiologic and metabolic responses to exercise (Cahalin et al., 2006). In a position statement on exercise in heart failure patients, The American Heart Association Committee on Exercise, Rehabilitation, and Prevention recommends use of exercise training programs to increase physical activity in heart failure patients (Pina et al., 2003).

The largest clinical trial to date of exercise in heart failure patients is the HF-ACTION (Heart Failure and A Controlled Trial Investigating Outcomes of Exercise TraiNing) trial (Keteyian et al., 2009; O'Connor et al., 2009). The HF-ACTION trial studied multiple aspects of exercise in patients with New York Heart Association (NYHA) Functional Class II, III, or IV heart failure. A total of 2,331 participants were randomized to either the exercise training group that received 36 supervised exercise training sessions with transition to home-based exercise, or to the usual physical activity control group. Reduction in primary end-point of all-cause mortality or hospitalizations in the exercise training group compared to the usual care group was not significant. There was marginal significance in reduction in all-cause mortality and hospitalizations and cardiovascular and heart failure mortality and hospitalizations when data was adjusted for baseline predictive characteristics for heart failure (O'Connor et al.)

Keteyian et al. evaluated the safety aspects of exercise in 2,037 participants enrolled in the HF-ACTION trial that completed a sign-and-symptom limited graded exercise test at

baseline, 3 , 12, and 24 months, using either a treadmill or cycle ergometer with measurement of expired gases. Graded exercise testing regarding exercise related events were recorded. An event was considered exercise related if it occurred on the same day or on the following day after completion of exercise. No exercise related cardiovascular deaths were reported during the study period. Two exercise related non-fatal cardiovascular events due to sustained ventricular arrhythmias were successfully treated (0.45 events/1,000 tests) (Keteyian et al.). Forman et al. (2009) evaluated cardiopulmonary testing data obtained from symptom-limited graded exercise testing with expired gas analysis in 2,229 of the 2,331 total participants in the HF-ACTION trial. Study findings revealed age to be the most significant independent predictor of exercise capacity and ventilatory efficiency in the heart failure patient population. Although the HF-ACTION trial was a large randomized controlled trial, a limitation of that study is the participants referred by physicians to a large exercise training laboratory may be slightly healthier than the general heart failure patient population which could effect generalizability of study findings.

Research on exercise in heart failure patients has focused on: a) aerobic training, b) resistance training, c) combined aerobic and resistance training, and d) cardiopulmonary respiratory muscle training. Larsen, Aarsland, Kristiansen, Haugland, and Dickstein (2001) studied three different aerobic exercise protocols over 12 weeks in 30 male participants with NYHA Functional Class II – III heart failure with a mean ejection fraction (EF) of 32%. Exercise protocols evaluated were: a) maximal cardiopulmonary exercise test using a braked cycle ergometer, b) submaximal exercise test using the 6-minute walk test, and c) endurance exercise test using a treadmill and protocol selection according to baseline exercise capacity. Study findings showed all three aerobic exercise protocols improved exercise tolerance, but did

not significantly improve peak VO_2 (Larsen et al.). Small sample size and exclusion of female participants limit the generalizability of this study.

Heart rate and blood pressure were measured in response to resistance exercise training using knee flexion and extension exercise (Degache, Roche, Bernard, & Calmels, 2009). Participants completed at 10-minute warm-up on a cycle ergometer prior to the isokinetic exercise. Findings showed both heart rate and blood pressure increased significantly with isokinetic exercise in heart failure patients. A decrease in heart rate between exercises was not observed in this study. That finding has important implications for development of exercise protocols to allow for ample time between exercises in cardiac patients. Limitations of that study include a small sample that was not diverse to gender.

Resistance training alone or resistance training in combination with aerobic exercise in heart failure patients was evaluated in a review by (Cahalin et al., 2006). Thirty studies using either resistance training or resistance training and aerobic exercise protocols were included in this review. Findings showed much variation in protocols in type, length, and duration of exercise. Measurement of skeletal muscle strength and endurance in resistance training protocols was also variable. Similarly, a review of 69 randomized controlled trials from 1966 to 2006 also revealed variation in exercise protocols as well as variation in measurement of physiologic response to exercise. Measurement of physiologic response to exercise reported in the literature include: a) central hemodynamic response, b) peripheral blood flow, c) endothelial function, d) neurohormonal parameters and cytokines, e) skeletal muscle metabolism, and f) quality of life (Tai et al., 2008).

Aerobic training, resistance (strength) training, or combined aerobic and resistance training has been shown to improve peak oxygen consumption (peak VO_2) in heart failure

patients. Strength training can be used to improve muscle mass and muscle strength prior to initiation of aerobic training. Exercise protocols that combine strength and aerobic training may be beneficial to decrease muscle atrophy, improve symptoms, and increase quality of life (Gunn, Smith, McKelvie, & Arthur, 2006). A four-week resistance and aerobic exercise training program was shown to improve physical endurance and quality of life in heart failure patients. Quality of life declined in elderly patients > 70 years of age at 6 months post-intervention (Miche et al., 2009). Endurance training with the use of a cycle ergometer was shown to increase exercise capacity and prevent muscle atrophy common in elderly patients with heart failure (Geilen et al., 2012).

Resistance training alone or in combination with aerobic exercise has been shown to improve muscle strength and endurance (Bartlo, 2007; Mandic et al., 2009). A combined resistance training and aerobic exercise program in the cardiac rehabilitation setting (n=21, 19 males, 2 females) was shown to decrease symptoms of fatigue on the Piper Fatigue Scale and on the Dyspnea Index (Pozehl, Duncan, & Herzog, 2008). A limitation of that study is the use of the Dyspnea Index as this instrument has been studied in COPD patients, but has not been validated in heart failure patients.

Chiappa et al. (2008) studied the effects of inspiratory muscle training using a hand-held breathing device on blood flow in heart failure patients. Findings of that study showed improvement in skeletal muscle blood flow from inspiratory muscle training. Padula, Yeaw, and Mistry (2009) studied the effects of a home-based inspiratory muscle training program using a hand-held breathing device. Study findings revealed improvement in respiratory volume, respiratory rate, and perception of dyspnea.

Witham and McMurdo (2008) studied a community-based group exercise training program in elderly heart failure patients. Elderly patients with multiple comorbidities may often have difficulty attending facility-based exercise programs due to limitations with mobility or transportation. Exercise training done in the home setting would allow elderly patients who do not have access to exercise programs to benefit from exercise training. Resistance training was done using elasticized bands, upper and lower limb exercises, and functional exercises, such as sit-to-stand exercises, similar to activities of daily living were conducted in twice weekly sessions over 12 weeks. Study results showed average improvement in six minute walk test of greater than 19 meters and in overall functional ability for everyday activity (Witham & McCurdo).

Psychosocial Adaptation

Quality of life has been the predominant measure of psychosocial effects on exercise in heart failure patients. Improvement in exercise capacity from exercise training can improve quality of life in heart failure patients. Increased tolerance to physical activity allows individuals to be more independent in daily activities and more active in social interactions to improve quality of life (McConnell, 2005). The influence of self-care on quality of life remains uncertain as some studies have reported improvement in quality of life from self-care interventions and other studies have not (Riegel et al., 2009). Inconclusive effects of exercise training on quality of life was also reported by Tai et al. (2008) in a literature review of 69 published trials from 1966 to October 2006. Inconclusive findings may be due to the various instruments that have been used to measure quality of life in published trials. Also, quality of life is not clearly defined and is different for each individual (Tai et al.).

Summary of Empirical Research

Limitations of research in the area of exercise in heart failure include few randomized controlled trials. The HF-ACTION trial is the largest randomized controlled study of exercise in heart failure patients to date. Sample sizes of published studies have primarily been small nonrandomized samples. Exercise protocols studied to date have been variable in type, duration, frequency, and length. Measurements used in exercise studies have also been variable. Women, older adults, and minorities have been underrepresented in published studies. Research to date has focused primarily on physiologic responses to exercise. Few studies have evaluated the effect of exercise of quality of life in heart failure patients. No studies were found that evaluated the effects of exercise on perception of illness and adaptation to chronic illness.

Chapter Summary

Research studies on exercise in heart failure published to date have focused primarily on physiologic responses to exercise. There have been few studies that have evaluated effect of exercise on quality of life in heart failure patients. The effect of exercise on perception of illness and adaptation to chronic illness in heart failure patients has not been studied. Exercise protocols for heart failure patients used in research trials include aerobic exercise, resistance training, and combined aerobic resistance training protocols. Combined aerobic resistance training exercise protocols have been shown to improve muscle strength and endurance in heart failure patients. Various exercise protocols have been shown to be safe in heart failure patients without an increase in adverse events, worsening heart failure, hospitalizations, or death in large randomized controlled trials. Adaptation to chronic illness theory has been studied in patients with chronic illnesses including diabetes mellitus, hypertension, multiple sclerosis, rheumatoid arthritis, and hemophilia. No studies have been published to date using adaptation to chronic illness theory in

heart failure patients. Thus, a gap in the literature exists in knowledge of effects of exercise on perception of illness in patients with heart failure within the adaptation to chronic illness theory. Research in this area will add to the body of knowledge for care of patients with chronic heart failure.

Chapter Three

Methods

The purpose of this study was to evaluate the effects of a 12-week home-based exercise program on perception of illness and adaptation in heart failure patients. In this chapter, an overview of the research methodology for this study, research design, procedures for the exercise intervention, sampling and recruitment of participants, risks and protection of study participants, method of data collection and analysis, and threats to validity have been presented. I have concluded this chapter with a chapter summary of the research methodology.

Study Design

This study was a true-experimental, quantitative research design. Participants were randomized to an experimental (intervention) group or a wait-list control group. The experimental group received the intervention (12-week home-based combined aerobic and resistance training exercise program) and the wait-list control group received usual care for heart failure patients.

Aims and Hypotheses

The specific aims of this study were to: a) determine effects of 12-week home-based exercise intervention on individual's perception of degree of functional limitation due to heart failure using the Illness Perception Questionnaire-Revised, 2) determine effects of 12-week home-based exercise intervention on physiologic adaptation to chronic heart failure using the 6-minute Walk Test (6MWT), New York Heart Association Functional Class (NYHA FC), total minutes walked, and average weekly pedometer step counts, 3) determine effects of 12-week home-based exercise intervention on psychosocial adaptation to chronic illness using the

Sickness Impact Profile, and 4) compare the number of hospitalizations for participants in the intervention and control groups.

The hypotheses tested in this study were: 1) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have lower perception of illness impact as evidenced by lower scores on the Illness Perception Questionnaire-Revised than the control group at 8 weeks and at 12 weeks. 2) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have improved physiologic adaptation from baseline as evidenced by higher scores on 6MWT, total pedometer step counts, and total minutes walked per week and will have no decline in NYHA Functional Class when compared to the control group at 4 weeks, 8 weeks and at 12 weeks. 3) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have improved psychosocial adaptation as evidenced by lower scores on the Sickness Impact Profile than the control group at 8 weeks and at 12 weeks. 4) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have fewer number of hospitalizations than the control group during the 12-week study.

Variables

The independent variable was the 12-week home-based exercise aerobic and resistance training exercise intervention for participants randomized to the treatment group. Participants in the control group did not receive the 12-week exercise intervention. Dependent variables in the study were perception of illness impact and physiologic and psychosocial adaptation. Perception of illness impact and physiologic and psychosocial adaptation were concepts that were measured within the adaptation to chronic illness theory (Pollock, 1993).

Sample

The sample for this study (n = 71) included male and female participants diagnosed with systolic heart failure confirmed by medical record review. Study participants were English speaking adults, at least 18 years of age or older, and current patients of Wellmont Cardiovascular Associates (CVA) Heart Institute, a private cardiology practice in East Tennessee.

Setting

All study participants were recruited from established patients of Wellmont CVA Heart Institute, a private practice which provides cardiovascular services for individuals residing in Upper East Tennessee and surrounding geographic area including Southwest Virginia, Eastern Kentucky, and Western North Carolina. Wellmont CVA Heart Institute provides care for adults with acute and chronic cardiovascular conditions. Face-to-face sessions at baseline, 4 weeks, 8 weeks, and 12 weeks with the participant and Principal Investigator were conducted at the private cardiology office, The Heart Center, located in Kingsport, TN. The home-based exercise intervention was implemented by the participant in their own home setting.

Inclusion and Exclusion Criteria

Inclusion criteria for enrollment in the study were**:** a) participants must be at least 18 years of age; b) diagnosed with systolic heart failure with an ejection fraction of less than or equal to 40% confirmed by echocardiogram or cardiac magnetic resonance imaging (MRI); c) NYHA Functional Class II (symptoms occur with greater than usual daily activity) or NYHA Functional Class III heart failure (symptoms occur with less than usual daily activity); d) on stable heart failure medication regimen for beta blocker and Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) medications; e) have not required any

adjustment in beta blocker, ACE Inhibitor, or ARB medications in previous 30 days; f) if known coronary artery disease (CAD) and patient stable with no higher than NYHA Functional Class I or II symptoms, and g) have approval from the primary cardiologist for enrollment in the study. Exclusion criteria for the study included: a) NYHA Functional Class I (no symptoms with usual daily activity); b) NYHA Functional Class IV (symptoms are present at rest); c) unstable angina; d) sustained ventricular arrhythmias requiring antiarrhythmic medications; e) 2^{nd} or 3^{rd} degree heart block without an implantable pacemaker device; f) coronary artery disease on cardiac angiogram of > 70% without coronary revascularization procedure and physicially limiting angina; g) atrial arrhythmia with HR >120 bpm; h) stenotic valvular disease with greater than moderate stenosis; i) neurologic or orthopedic condition that limits physical ability to exercise; j) physical condition that limits mobility or range of motion causing inability to complete 6MWT or return demonstration of resistance training exercises during face-to-face session with Principal Investigator; k) cognitive impairment that limits ability to follow instructions, and l) current enrollment in a cardiovascular rehabilitation program (Pina et al. 2003; Thompson, Gordon, & Pescatello, 2010).

Recruitment of Study Participants

Participants who met study inclusion criteria were accessed through physician referral at their regular cardiology follow-up appointments. Flyers for the study with contact information were also posted in the private cardiology office waiting area and exam rooms for patients to review and contact the Principal Investigator if interested in participating in the study (See Appendix A). All potential participants were screened by the Principal Investigator and met inclusion/exclusion criteria for enrollment in the study. All participants who met inclusion criteria had cardiologist approval before enrollment in the exercise study (See Appendix B). No

individual was excluded from participation in the study based on gender, ethnicity, or socioeconomic status.

Instruments

Illness Perception Questionnaire-Revised. The Revised Illness Perception Questionnaire (IPQ-R) was the instrument used to measure the concept of perception of illness impact in this study (Moss-Morris et al., 2002) (See Appendix C). This measurement tool was derived from the Illness Perception Questionnaire (IPQ) developed by Weinman, Petrie, Moss-Morris, and Horne (1996) based on Levanthal's (1984, 1997) Self-Regulatory Model. There are five components of illness representation in the Self-Regulatory Model. The five components of illness representation are: a) identity, b) consequences, c) timeline, d) control/cure, and e) cause. The IPQ-R was developed to address limitations of the original IPQ in measurement and internal consistency of its subscales. The original IPQ also did not include measures of emotional representations and this was added as a revision of the IPQ-R (Moss-Morris et al.).

The identity subscale of the IPQ-R consists of 14 common symptoms experienced in illness. Participants respond in a yes/no format to presence of symptoms and perception of relation of the symptom to their illness. The score of the identity subscale is the sum of the total of yes responses. Internal reliability of the identity subscale in relation to experience of symptoms in perception of illness was demonstrated by a Cronbach's alpha of 0.75.

The illness dimension subscale of the IPQ-R is a 38-item Likert scale measuring perception of impact of the illness in relation to: a) consequences (a=0.84), b) timeline acute/chronic (a=0.89), c) timeline cyclical (a=0.79), d) personal control (a=0.81), e) treatment control (a=0.80), f) illness coherence (a=0.87), and g) emotional representation (a=0.88). The causal subscale is an 18-item Likert scale that measures items related to perception of the cause of illness from: a)

psychological attributions (a=0.86), b) risk factors (a=0.77), c) immunity (a=0.67), and d) accident or chance (a=0.23). Responses to the Likert-type scale in the illness dimension subscale and the causal subscale are scored from 1 ("Strongly Disagree") to 5 ("Strongly Agree"). The score of the illness dimension subscale is calculated as the total sum of the items, adjusting for reverse scoring of selected items, divided by the total number of items. The correlation between the items in the causal subscale is low and each item in this subscale is treated as a separate score (Moss-Morris, 2002). Higher scores are associated with higher perception of illness representation, and lower scores are associated with lower perception illness representation (Weinman et al., 1996; Moss-Morris). The IPQ-R was completed by each study participant in a private office.

6-minute Walk Test. Physiologic adaptation was measured by the 6-minute Walk Test (6MWT). This test has been widely used to measure exercise capacity in heart failure patients (Hwang et al., 2008). In addition, the 6MWT has been used to measure physiologic adaptation in an exercise intervention study based on the RAM theoretical framework, and improvement in distance walked was comparable to improvement in functional performance (Bakan & Akyol, 2007). The 6MWT has been shown to be an appropriate test for submaximal exercise endurance in testing of cardiac and pulmonary patients with correlation of 0.42 to cycle ergometer testing ($p<0.001$). Small treatment effects may be detected with feasible sample sizes (Guyatt et al., 1985). Participants were asked to walk in a corridor that is a wide, long hallway located inside the private cardiology practice. The corridor was marked off in 100 meters in intervals of five meters to measure distance walked in 6 minutes. Each participant was supervised by the Principal Investigator during the 6MWT and was asked to walk as far as they could at their own pace during a timed interval of exactly 6 minutes using a stopwatch. Chairs were provided along

the corridor and participants were instructed they could stop and rest as long or as often as they needed during the six minute interval. The timing on the stopwatch continued without stopping for a full six-minute interval. At the end of the timed six minutes, the total distance in meters was recorded for each individual.

Pedometer Step Counts. Pedometer step counts were used to measure physiologic adaptation. Pedometers have been used to measure steps in various patient populations including heart failure patients (Evangelista et al., 2005). Pedometers have also been used to measure physical activity older adults with multiple chronic illnesses including hypertension, arthritis, cancer, osteoporosis, diabetes, depression, cardiovascular disease, and pulmonary disease (Farmer, Croteau, Richeson, & Jones, 2006). New pedometers utilizing the piezoelectric technology are more accurate than the original pendulum technology pedometers (Jehn, Schmidt-Trucksäss, Schuster, Hanssen, & Kohler, 2010). Piezoelectric accelerometer-based pedometers count steps by analyzing the acceleration versus time curve from a mechanism that produces a deflection with each vertical movement from the hip. The number of steps taken is determined from the count of the number of deflections (Crouter, Schneider, Karabulut, & Bassett, 2003; Tudor-Locke & Lutes, 2009). At slower walking speeds when there is less vertical movement of the hip, pedometers have been shown to be less accurate at step counting (Crouter et al., 2003). Most pedometers are less accurate at walking speeds less than 54 meters/min (2 miles per hour), but are highly accurate at walking speeds of 80 meters/min and above (Crouter et al.)

The Omron HJ 720ITC pedometer utilizes piezoelectric technology and has been studied in patients with chronic heart failure. Jehn et al. (2010) evaluated use of this pedometer in 97 patients with NYHA Functional Class I, II, or III heart failure. All 97 participants completed a 6MWT to measure self-paced walking. A small subgroup of 10 participants with NYHA

Functional Class I heart failure completed treadmill walking to measure controlled walking speeds at 40, 50, 60, 70, and 80 meters/min for 6 minutes. Pedometer accuracy decreased at: a) 60 meters/min for both treadmill walking (mean % error 5.0 ± 4.9, $p = 0.039$) and self-paced walking (mean % error 4.7 ± 1.9, $p < 0.001$); b) 50 meters/min for treadmill walking (mean % error 8.9 ± 9.6, $p = 0.019$) and self-paced walking (mean % error 8.6 ± 5.8, $p = 0.006$), and c) 40 meters/min for treadmill walking (mean % error 28.3 ± 9.0, $p < 0.001$) and self-paced walking (mean % error 25.6 ± 10.8, $p < 0.001$) (Jehn et al.) While the overall correlation between pedometer steps and actual steps recorded by digital hand counter was high ($r = 0.95$, $p < 0.001$), differences in pedometer steps between recorded and actual steps were highest in participants with slower walking speeds who walked < 400 meters distance in the 6MWT. Walking a distance of < 400 meters in the 6-minute Walk Test occurred in NYHA Functional Class III participants with the most severe functional disability. Average distance walked on the 6MWT for each functional class respectively was: a) NYHA Functional Class I (640 meters ± 81.2), b) NYHA Functional Class II (532 ± 70.9), and c) NYHA Functional Class III (378 ± 95.4) (Jehn et al.).

Evangelista et al. (2005) studied use of pedometers as a measure of exercise adherence in 38 patients with NYHA Functional Class II – IV participating in a 12-month home-based walking program. Participants were asked to complete: a) exercise diary to record daily walk times, b) complete a 6MWT at baseline and six months, and c) complete a symptom-limited exercise stress test with measurement of expired gases at baseline and six months. Pedometer scores at baseline and six months were calculated to determine differences in scores at the time intervals. Participants who had > 10% change in scores (n = 20) were identified as adherers (Group 1), and participants who had < 10% change in scores (n = 18) were identified as non-

adherers (Group 2). Then, groups were compared at baseline and 6 months to each other for measurement of: a) ejection fraction, b) VO_2 max, c) 6-minute Walk Test distance in feet, d) pedometer distance in miles/month, and e) exercise diary history of walking in hours/month. Statistically significant differences were found between adherers and non-adherers at 6-months for: a) VO_2 max ($p = 0.011$), b) 6-minute walk distance ($p = 0.022$), c) pedometer distance ($p < 0.011$), and d) exercise diary history ($p < 0.001$). Researchers concluded that pedometers were a valid measure of exercise adherence in chronic heart failure patients in a home-based walking program. Use of exercise diaries in conjunction with pedometers to record amount and type of physical activity was recommended (Evangelista et al.). A limitation of that study was the use of a pedometer that required the participant to reset the device to zero each morning (Sportline Pedometer 330). Use of a pedometer, such as the Omron HJ 720ITC, that requires no action to reset the device facilitates pedometer use and acceptability.

Sickness Impact Profile. The Sickness Impact Profile (SIP) has been used to measure interdependence, role-function, and self-concept as modes of psychosocial adaptation (Frederickson et al., 1991). The SIP is a self-administered questionnaire consisting of 136 weighted items for 12 subscales that measures the impact of the illness on level of dysfunction. Three field studies were conducted during the development of the SIP, the initial pilot study in 1973, and two additional field studies in 1974 and 1976 to test the revised instrument. Validity of the SIP was evaluated throughout the development of this measurement tool. The 1973 pilot study used a panel of 25 expert judges who rated each item on a 15-point scale from minimally to maximally dysfunctional. This process was used to develop the scoring method for the tool. A second, separate group of judges was used to validate the scoring method for each item. From the pilot study, the original SIP was decreased from 312 to 189 items. In a field trial in 1974,the

revised SIP was tested for: a) comprehensive test of reliability of SIP, b) preliminary assessment of validity, c) preliminary testing of method of administration of the instrument, and d) assessment of the revised SIP (Bergner et al., 1981, p. 790). In the 1974 study criterion-related validity was determined by measuring the relationship between the SIP and: a) participant self-assessment of illness and dysfunction, b) clinician assessment of illness and dysfunction, and c) score on another instrument to measure sickness and dysfunction (Activities of Daily Living Index, National Health Interview Survey). A field trial in 1976 was conducted to: a) analyze final content and scoring of the SIP, b) assess discriminant, convergent, and clinical validity of the SIP, and c) compare the reliability and validity of different methods of administration of the tool. Criterion-related validity assesses the relationship of the instrument to an external criterion (Polit & Beck, 2008). Relationship between the concepts of impact of sickness and behavioral dysfunction was evaluated in the field studies of the instrument and was shown to have high correlation.

Construct validity is the consistency of the relationship between the items on the measurement tool and the concepts of the theoretical framework for a study (Waltz, Strickland, & Lenz, 2010). Construct validity of the SIP was determined by hypothesis testing of the relationship of the SIP with: a) self-assessment of dysfunction, b) self-assessment of sickness, c) National Health Interview Survey (NHIS) index, and d) clinician assessment of dysfunction, and e) overall rating of sickness. The hypothesis of higher correlations of SIP to self-assessment of dysfunction (0.69) and self-assessment of sickness (0.63) were supported. Lower correlations were found for SIP to NHIS index (0.55), clinician assessment of dysfunction (0.50), and clinician assessment of sickness (0.40).

Multi-trait multimethod matrix (MTMM) technique was used to assess convergent and discriminant validity. Convergent validity assesses the degree of similarity of measurement of a construct by two different methods. Discriminant validity is the difference of one construct to another (Polit & Beck, 2008). The matrix showed high correlation of scores among the different categories indicating the SIP score is a measurement of the constructs of sickness and dysfunction. Additional multiple regression analysis was done to assess convergent and discriminate validity. Clinical validity was assessed by use of SIP in three different disease categories: a) total hip replacement, b) hyperthyroidism, and c) rheumatoid arthritis. Descriptive validity of the SIP to measure similarities and differences among groups was assessed using pattern and profile analysis and cluster analysis for each disease category. The tool was tested in development among all different types of illness and non-illness and in different settings (inpatient, outpatient, home-care, and walk-in clinic patients). Test-retest reliability of the SIP was shown to be 0.92, with an internal consistency of the instrument of 0.94. Overall reliability of this instrument was good with r = 0.75-0.92 (Frank-Stromberg & Olsen, 2004).

Participants respond in a yes/no format to each item. The score for each category is calculated by totaling the scaled values of each item within that category. This number is then divided by the maximum total dysfunction score for each category and then multiplied by 100. The total score for the SIP is calculated by adding the scaled valued for each category, dividing by maximum total dysfunction score for the SIP, and then multiplying by 100 for the total score. A higher score indicates a higher level of dysfunction. Due to copyright restrictions, the SIP cannot be reproduced in any form and therefore will not be included with this document. The SIP User Agreement was sent to the Principal Investigator in an email with the SIP questionnaire and

SIP Scoring Instructions attached to the email. This email confirmation of the SIP User Agreement is included at the end of this document (See Appendix D).

Study Procedures

Authorization to access medical record information was requested of all study participants in compliance with Health Insurance Portability and Accountability Act (HIPAA) of 1996. Authorization to access medical record information is contained within the Confidentiality section of the Informed Consent Statement. The participant's signature on the Informed Consent Statement authorized access by the research team to the individual's medical record information. All study participants completed a demographic questionnaire at baseline (See Appendix E). The IPQ-R and the SIP were completed by both the intervention group and the control group at baseline, 8 weeks, and 12 weeks. All participants completed a 6MWT at baseline, 4 weeks, 8 weeks, and 12 weeks . Activity logs were reviewed during the 4 week, 8 week, and 12 week follow-up sessions (See Appendix F). Pedometer data was downloaded at the 4 week, 8 week, and 12 week follow-up sessions. All participants were contacted by telephone every week to obtain pedometer step counts, report of occurrence of symptoms, and daily weights. Once weekly telephone follow-up was implemented to both monitor activity as well as monitor participants for any symptoms indicating a change in health status that would be of concern and need medical evaluation. The researcher recorded data for each participant on the Telephone Follow-Up Data Collection Record (See Appendix G). Participants in the intervention group were encouraged to continue with the daily exercise protocol for the study in the telephone follow-up. Participants in the wait-list control group were not given any specific exercise information or exercise protocols during the weekly telephone follow-up. Participants in the wait-list control did receive the same exercise instruction for the combined aerobic and

resistance training exercise intervention as the intervention group at completion of the 12-week study.

Intervention

This quantitative, randomized controlled study examined the effects of participation in a structured home-based exercise program on perception of illness and adaptation to chronic illness in patients with systolic heart failure. Participants randomized to the intervention group received usual heart failure education plus education on exercise physiology in heart failure, benefits and risks of exercise, and instruction on exercise protocol for the study. Participants in the intervention group were given information on warm-up and cool-down exercises, a walking schedule for aerobic exercise, and use of hand-held one pound dumbbells for resistance training exercises in a face-to-face session with the Principal Investigator at the 4-week follow-up to begin Week 5 of the study (See Appendix H). Enrollment sessions took place in a private room located in a private cardiology office.

Participants in the intervention group were instructed to begin each exercise session with warm-up exercises and end with cool-down exercises comprising five to ten minutes of the exercise session (Williams, 2006). Participants included each of the following exercises performed in a seated position: a) finger-squeezes – flexion and release of fingers on both hands (10 repetitions), b) wrist roll – rotation of each wrist and hand in circular motion (10 repetitions), c) shoulder shrug – raising and lowering of both shoulders (10 repetitions), d) head-to-side neck stretch – movement of head to each side to shoulder and to front (5 seconds on each side and front), e) seated trunk-twist – turning at waist to each side (10 seconds on each side), f) toe points – flexion and extension of each foot (10 repetitions), and g) ankle rolls – rotation of each ankle in circular motion (10 repetitions). Warm-up exercises were continued in a standing position with

the following exercises: a) calf-stretch – back leg straight with front leg bent while holding on back of chair (10 repetitions each leg), b) leg swing while holding to chair – swing leg across front from left to right (10 repetitions) each leg, c) quarter squat – bend at knees and hold position (10 seconds), and d) side-to-side lunge – feet apart at shoulder length alternating knee flexion and extension to move body side-to-side (5 repetitions each side).

For aerobic exercise, participants in the intervention group were instructed to walk short intervals of 3 to 5 minutes with rest periods as needed working toward a goal of 20 minutes daily. Participants were instructed to increase their walking time as tolerated and use the Borg Rating of Perceived Exertion Scale (RPE) based on a scale of 6 (no exertion at all) to 20 (maximal exertion) (Williams, 2004). Cardiac patients have been advised to exercise to a perceived exertion of 11-14 (fairly light to somewhat hard) (Thompson et al., 2010).

Resistance training exercises were performed three times weekly allowing at least 48 hours between resistance training sessions added at Week 5 of the protocol (Thompson et al., 2010). Resistance exercises were performed while seated using 1 lb. dumbbells with the following exercises: a) dumbbell flys – lean forward in chair with back straight and elbows bent, lift weights to side using upper back and shoulder muscles, b) shoulder/chest press – hold weights in front of shoulders and lift weights above head, c) front shoulder raises – hold weight down to side and raise arms straight up in front of body to shoulder level, d) side shoulder raises – hold weights down to side with palms facing body and lift arms out from side to should level, e) curls – elbows slight bent and arms down to side with palms facing up lifting arms to place weight in front of shoulder, f) triceps kickback – leaning forward slightly with back straight with weights held at hip and elbow bent extend elbow with arm straight on each side, and g) leg extension – while seated extend knee to straighten leg (10 repetitions). Resistance exercises

began with 5 repetitions with up-titration to maximum of 10 repetitions (Williams, 2006). Participants were instructed to rest between exercises as often as they needed. Proper breathing techniques during exercise, inhaling with lifting of weights, exhaling with release, and avoidance of breath holding during exercise were demonstrated to patients.

Participants in the intervention group ended each exercise session with cool-down exercises. Cool-down exercises performed in a standing position included: a) foot rocking- rock back and forth from heels to toes (10 repetitions), b) side-to-side lunge- feet apart at shoulder length alternating knee flexion and extension to move body side-to-side (10 repetitions, 5 on each side), c) trunk-twist – twist from side-to-side with elbows and knees slightly bent (10 repetitions, 5 on each side), d) calf-stretch – back leg straight with front leg bent while holding onto back of chair (10 seconds each leg). Cool-down exercises performed in a seated position included: a) toe points – flexion and extension of each foot (10 repetitions), b) seated trunk-twist – turning at waist to each side (10 seconds each side), c) shoulder rolls – rotate shoulder in circular motion (10 repetitions each side), d) head-to-side neck stretch – movement of head to each shoulder and forward to front (5 seconds to each side and front), and e) deep breathing (breaths with deep inhale and slow exhale (4 repetitions). Participants in the intervention group participated in return demonstration of exercises with the Principal Investigator to show understanding of proper exercise technique. Review and return demonstration of resistance training exercises were repeated at the follow-up visits as indicated if patients reported any problems or difficulty with the exercises.

Participants in both the intervention and wait-list control group were given a pedometer to record total number of daily steps. Participants in both the intervention and wait-list control group were given a log to record daily weight, occurrence of symptoms, and total number of

pedometer steps per day. Participants in the wait-list control group received usual care consisting of heart failure education packet on heart failure diagnosis, symptoms of heart failure, and treatment for heart failure including medications, sodium and fluid restrictions, importance of daily weights, and regular physical activity. No specific exercise instructions or exercise plan was provided to the wait-list control group. All participants were given instructions on proper attire for physical activity including proper shoes and non-restrictive clothing, and instructed to keep hydrated with activity.

Data Collection

Baseline data collection included: a) demographic survey that included age, gender, marital status, education, and income; b) medical information related to type of heart failure, length of time since diagnosis, ejection fraction % by echocardiogram, NYHA Functional Class; c) 6MWT, d) IPQ-R, and e) SIP. The 6MWT and NYHA Functional Class were recorded at: a) baseline pre-intervention, b) at 4 weeks, c) at 8 weeks, and d) at 12 weeks. The IPQ-R and SIP surveys were collected at: a) baseline, b) 8 weeks, and c) 12 weeks. Demographic data were obtained at the initial session only. All data files and password protected laptop computer were kept in a secured location accessible only by the Principal Investigator. Guidelines for protection of personal health information were followed in compliance with HIPAA regulations.

Data management plan included review of all data forms by the Principal Investigator for completeness. Each participant was assigned a participant number. Participant number was placed on all data forms and surveys for each participant. All surveys were reviewed by the Principal Investigator after completion to identify any missing data or information. Any missing data were obtained from the study participant during the face-to-face sessions or telephone

follow-up sessions. Data entry was reviewed for accuracy and consistency by the Principal Investigator.

Intervention fidelity was maintained by providing participants with verbal and written instructions on the exercise program. Pictures and diagrams of exercises were included with written instructions to assist with comprehension. All participant instruction was done by the Principal Investigator with time for verbalization of understanding, return demonstration of proper exercise technique, and questions from study participants. The Principal Investigator conducted all follow-up telephone calls. Research assistants were not used in this study.

Threats to study validity included: a) maturation of subjects over time with natural change of their heart failure in response to adherence or non-adherence to usual treatment of their condition, b) mortality or attrition of study participants, and c) testing due to familiarity with use of the same instruments for data collection. Actions taken by the Principal Investigator to limit threats to internal validity included: a) randomization of study participants into experimental and control groups, b) calculation of power analysis for sample size with recruitment of larger sample size to allow for attrition, and c) allowing a length of time between testing when using the same instrument to decrease participant recall of item responses (Creswell, 2009; Polit & Beck, 2008).

Data Analysis

A priori sample size determination power analysis using G*Power Version 3.1.2 (Faul, Erdfelder, Lang, & Buchner, A., 2007) using a one-tailed test, medium effect size (0.30), level of significance $\alpha = 0.05$, and power $(1 - \beta)$ of 0.80 for each hypothesis, revealed a sample size for this study of $n = 64$. Most nursing studies have a modest effect size ranging from 0.20 to 0.40 (Polit & Beck, 2008). In the absence of effect size known from prior relevant research, a modest

effect size of 0.30 was used for sample size determination in this study. A one-tailed test was used for the directional hypotheses (Munro, 2005).

Data were entered into SPSS Version 19.0 for data analysis and reviewed for accuracy. Descriptive statistics were used to describe demographic data characteristics.

Hypothesis Testing

Hypothesis testing was performed for: Hypothesis # 1) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention would have lower perception of illness impact as evidenced by lower scores on the IPQ-R than the control group at 8 weeks and at 12 weeks.; Hypothesis #2) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention would have improved physiologic adaptation from baseline as evidenced by higher scores on 6MWT, total pedometer step counts, and total minutes walked per week and will have no decline in NYHA Functional Class when compared to the control group at 4 weeks, 8 weeks, and at 12 weeks; and Hypothesis # 3) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention would have improved psychosocial adaptation as evidenced by lower scores on the SIP than the control group at 8 weeks and at 12 weeks. Hypothesis testing for hypotheses # 1, 2, and 3 were performed separately using repeated measures ANOVA to analyze the IPQ-R, 6MWT, Total Minutes Walked, and Weekly Average Pedometer Step data collected at baseline (Time 1), 4 weeks (Time 2), 8 weeks (Time 3) and 12 weeks (Time 4). An F statistic was calculated to report differences across time in the data collected at baseline, 4 weeks, 8 weeks, and 12 weeks. Post hoc analysis testing Fisher's exact test was used to analyze group differences. Nonparametric testing was used for Hypothesis #3 due to the non-normal distribution of the SIP. Transformation of this variable to a normal distribution was attempted using usual square root

and logarithm methods (Munro, 2005). However, transformation of this variable did not result in a more normal distribution. This was likely due to a large number of zero values from the NYHA Functional Class II participants from leaving unchecked a large number of questionnaire items to indicate these items did not apply to them. Kruskal-Wallis nonparametric test was selected as this is the nonparametric test similar to a one-way ANOVA (Munro). Testing for Hypothesis #4, Participants in a 12-week home-based combined aerobic and resistance training exercise intervention would have fewer number of hospitalizations than the control group, was done using Fisher's exact test to compare actual numbers of hospitalizations between each treatment group (Munro).

Risks and Protections

Risks to participants during the exercise intervention include worsening of heart failure, cardiac dysrhythmias, and cardiovascular hemodynamic instability. All training exercise sessions at the time of enrollment were conducted in a private cardiology office with emergency resuscitation equipment readily available. The Principal Investigator is a licensed Advanced Practice Nurse in the State of Tennessee and is certified as an Adult Nurse Practitioner by the American Nurses Credentialing Center. The Principal Investigator has extensive experience in caring for patients with cardiovascular disease and is certified in Advanced Cardiac Life Support. Board certified cardiologists were onsite and immediately available to respond to a cardiac emergency.

All participants enrolled in this exercise study had cardiologist's approval prior to enrollment. All participants were required to demonstrate ability to perform a 6MWT prior to being randomized to the intervention or control group. Any participant who could not demonstrate physical ability to perform the 6MWT was not enrolled. Any participant who

experienced symptoms of cardiac instability during the 6MWT was evaluated immediately by the Principal Investigator and a board certified cardiologist available onsite. If further evaluation or treatment was indicated, Emergency Medical Services (EMS) would have been contacted for transport to Wellmont Holston Valley Medical Center Emergency Department. Any participant who experienced cardiac instability such as chest pain, increased dyspnea, palpitations, lightheadedness, or dizziness during the screening 6MWT was not enrolled in the study. One potential study participant did not complete the screening 6MWT due to complaint of chest pain with approximately one minute remaining of the 6MWT. She was evaluated immediately by the primary cardiologist and scheduled for a nuclear stress test to evaluate for cardiac ischemia. The stress test showed evidence of prior known scar, but did not show evidence of cardiac ischemia. She was placed on a medication to treat microvascular cardiac disease and had no further episodes of chest pain. She remained interested in participation in the exercise study and was cleared by her cardiologist to enroll. This participant completed all 12-weeks of the exercise study with no further episodes of chest pain or other cardiac symptoms. One participant became lightheaded and dizzy after completing the 6MWT. He was also evaluated immediately by a cardiologist. There was no EKG evidence of acute or new cardiac findings. Physical exam and vital signs were normal. This participant was a known diabetic and had not eaten prior to his follow-up session. He did not inform the Principal Investigator of this prior to the 6MWT. This participant was reminded to eat prior to subsequent follow-up sessions

All participants were contacted every week during the 12-week study by telephone to monitor progress and obtain daily weight recordings, report of symptom occurrence, and daily pedometer step counts. All participants were instructed about signs and symptoms that must be reported to the Principal Investigator including increased shortness of breath, swelling of

extremities, cough that is worse at night, palpitations, increased fatigue/weakness, lightheadedness, dizziness or chest pain. All participants were instructed to notify the Principal Investigator for signs and symptoms of worsening heart failure or change in cardiac status, and the Principal Investigator would contact the primary cardiologist and arrange for appropriate evaluation as indicated by the clinical situation. Participants were instructed to seek medical attention at their local emergency department without delay for any sudden change or increase in symptoms that would indicate change in cardiac status.

Ethical Considerations

Approval for the study was obtained from the Institutional Review Boards (IRB) of the University of Tennessee and of Wellmont Holston Valley Medical Center (See Appendix I and J). The Principal Investigator was accountable for reporting any study variances to both IRBs (See Appendix K and L). A letter of approval was obtained from the study location where the research was conducted as required by the University of Tennessee IRB (See Appendix M). All study reviews and documentation were done in compliance with each IRB. Informed consent was obtained prior to participant enrollment in the study (See Appendix N). Verbal and written information was provided for the study participant. Time was allowed for participants to ask questions regarding the study. Individuals who agreed to participate signed the statement for informed consent. The original signed informed consent and copy were kept in a secured location with access only by the principal investigator. A copy of the signed Informed Consent was given to the study participant at the time of enrollment. Participants were instructed that participation was voluntary and they could withdraw from the study at any time without threat of alteration in treatment or care. Permission to obtain data from the medical record was obtained

from each participant. Participants were not excluded from the study based on gender, ethnic background, or socioeconomic status.

Confidentially of information and protection of the individual's health record was maintained in compliance with HIPAA regulations. Each participant was assigned a number for identification at the time of enrollment. The list of participant names and corresponding identification number was kept in a locked file cabinet accessible only by the Principal Investigator. All completed questionnaires, demographic sheets, and data entry sheets were kept in a locked file cabinet accessible only by the Principal Investigator. One copy of the Informed Consent was given to each study participant and one copy was kept in a locked cabinet in the office of the dissertation chair, Dr. Ken Phillips. All study forms, questionnaires, and data sheets will be kept for three (3) years and then destroyed. All data entries for data analysis were entered on the Principal Investigator's laptop computer that was kept in a secure location with access only by the Principal Investigator.

Chapter Summary

The purpose of this study was to examine the effects of a structured 12-week home-based exercise program on perception of illness and adaptation in heart failure patients. This study was a quantitative study using an experimental research design with an experimental (treatment) group and control group. The intervention (treatment) was a 12-week home-based exercise program consisting of combination aerobic and resistance training exercises. Participants were recruited from established patients of a private cardiology office in East Tennessee. Participants who met inclusion/exclusion criteria for the study and provided Informed Consent were enrolled in the study. All participants were required to successfully complete a screening 6MWT before randomization into the experimental or control group. The experimental (treatment) group

received the 12-week home-based exercise intervention. The wait-list control group received usual heart failure care during the 12-week study, and then received the same home-based exercise intervention provided to the intervention group during the study. All study participants received a pedometer to record total number of steps per day. All study participants maintained an Activity Log during the 12-week study. All participants were followed once weekly by telephone contact during the study to monitor progress and identify any problems. Study participants attended four (4) face-to-face sessions with the Principal Investigator at the Wellmont CVA Heart Institute over the 12 week study period. Demographic data was collected at baseline. The 6MWT, NYHA Functional Class, pedometer data, and total weekly minutes walked at home were recorded at baseline, 4 weeks, 8 weeks, and 12 weeks. The IPQ-R and SIP were obtained at baseline, 8 weeks, and 12 weeks. Data were entered into SPSS 19.0 by the Principal Investigator. All data entry was reviewed for accuracy and completeness prior to data analysis.

Chapter 4

Results

Study findings are presented in this chapter. First, research hypotheses tested are stated again for the reader. Next, description of the study sample is presented. This followed by description of methods for hypothesis testing and details of data analysis. The chapter concludes with a summary of study findings.

Research Hypotheses

Four hypotheses were tested to examine the effects of a home-based exercise program on perception of illness and adaptation in heart failure patients. The Adaptation to Chronic Illness Theory (Pollock, 1993) was the theoretical framework that guided this study. The hypotheses tested were: a) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have lower perception of illness impact as evidenced by lower scores on the Illness Perception Questionnaire than the control group at 8 weeks and at 12 weeks, b) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have improved physiologic adaptation from baseline as evidenced by higher scores on 6MWT, total pedometer step counts, and total minutes walked per week and will have no decline in NYHA Functional Class when compared to the control group at 4 weeks, 8 weeks and at 12 weeks, c) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have improved psychosocial adaptation as evidenced by lower scores on the Sickness Impact Profile than the control group at 8 weeks and at 12 weeks, and d) Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have fewer number of hospitalizations than the control group during the 12-week study.

Description of Sample

Recruitment was done by physician referral or by participant response to flyers placed in patient examination rooms and in the lobby area in a private cardiology practice. Seventy-one (71) patients met inclusion criteria and were enrolled in the study after obtaining informed consent and successfully completing the screening 6MWT Participants were randomly assigned to either a treatment group (n=36) or a control group (n=35) using a computer-generated table of random numbers from www.stattrek.com.

Four participants (5.60%) did not complete the study. Two participants (2.82%) were removed after enrollment due to a change in health status that no longer met inclusion criteria and prohibited continuation in the exercise study. One participant experienced ventricular tachycardia while walking to his mailbox, and received appropriate shock from his implantable cardioverter defibrillator (ICD) which terminated the arrhythmia. The cardiac arrhythmia occurred with activity but was unrelated to exercise or activity associated with this study. He was evaluated in the cardiology office and underwent cardiac testing to determine the etiology for the cardiac arrhythmia. Findings from the nuclear stress test were abnormal suggestive of cardiac ischemia. Cardiac catheterization revealed multivessel coronary disease appropriate for coronary artery bypass graft surgery. At the time of the presenting arrhythmia, this participant was instructed not to exercise until further evaluation was completed; he was removed from the study. Another participant was removed from the study due to worsening known diabetic retinopathy. Declining visual acuity required evaluation and treatment by an ophthalmologist, but was not related to exercise or physical activity. However, the decline in visual acuity created concern for participant safety during ambulation and he was removed from study participation (See Figure 1).

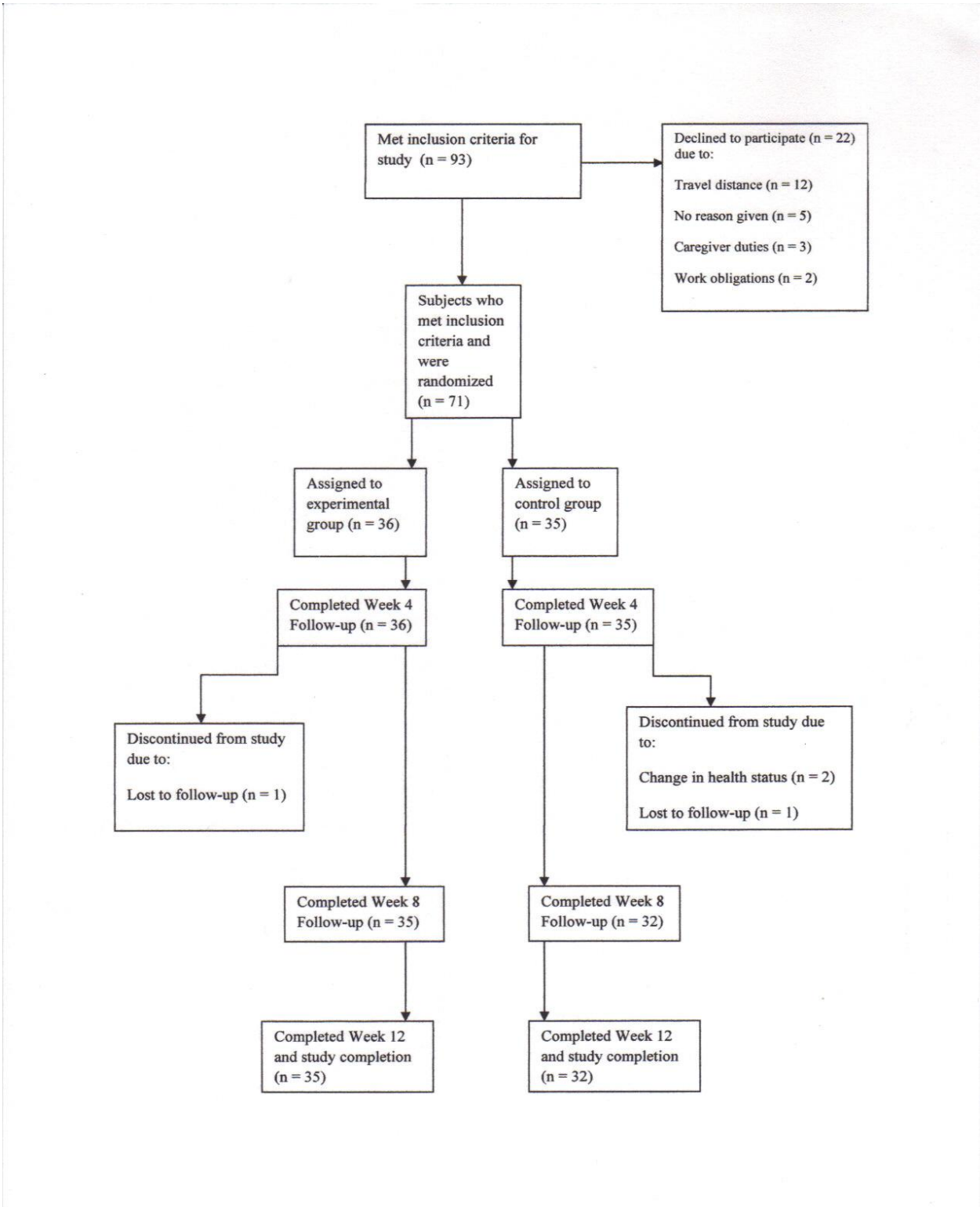

Figure 1. Sampling and Flow of Subjects Through Study

Two participants (2.82%) did not complete the study. Both participants completed four weeks of the study, but afterward could not be contacted by phone and did not return for follow-up. In total, four participants (5.63%) were not included in the final data analysis. Sixty-seven (67) of the total 71 participants (94.40%) who were enrolled completed the study and comprised the final sample.

Demographic data collected included: 1) age, 2) gender, 3) marital status, 4) race, 5) height, 6) weight, 7) body mass index (BMI), 8) heart failure etiology, 9) number of hospitalizations in previous 12 months, 10) ejection fraction, 11) New York Heart Association (NYHA) Functional Class, 12) educational level, 13) number of people living in the home, 14) employment status, and 15) annual income. Eighteen participants (26.90%) did not respond to the question regarding annual income in the demographic data form.

Participants ranged in age from 49-90 years of age (Mean = 67.61, SD = 9.56). There were 46 males (68.70%) and 21 females (31.30%). Fifty-three (79.10%) participants were married; seven (7) participants were divorced (10.40%); six participants were widows or widowers (9.00%); and one participant was single (1.50%). There were 65 participants (97.00%) who self-identified as Caucasian, and two participants self-identified as African American (3.00%). Forty-seven participants (70.10%) had ischemic cardiomyopathy as the etiology of their heart failure, and 20 participants (29.90%) had non-ischemic cardiomyopathy as the heart failure etiology. At enrollment, 36 participants (53.70%) were classified as NYHA Functional Class II, and 31 participants (46.30%) were classified as NYHA Functional Class III. Education level among participants included 13 participants (19.40%) with less than high school education; 25 participants (37.30%) with high school education; 14 participants (20.90%) with some college education; 10 participants (14.90%) with college education; and five (5) participants (7.50%)

with Master's or higher education. Forty-five (45) participants were retired (67.20%); 11 participants were actively employed (16.40%); six participants (9.00%) were on disability; and five participants (7.50%) were unemployed. Number of people living in the home ranged from 1 to 7 (Median = 2.26, SD = 1.07). Time since diagnosis ranged from 4 months to 172 months (Mean = 46.21, SD = 42.35). Independent samples t-test and Chi-squared test showed no significant difference between control and intervention group for any demographic data (See Tables 1 and 2).

Table 1. *Study Sample Demographics - Independent Samples t-test*

Variable	Group	N	Mean	Std. Deviation	Std. Error Mean	Sig.
Age	Control	32	68.63	10.23	1.81	.411
	Intervention	35	66.69	8.96	1.51	
Weight	Control	32	190.03	43.92	7.76	.497
	Intervention	35	197.37	43.87	7.42	
BMI	Control	32	29.64	6.18	1.09	.733
	Intervention	35	30.13	5.69	.96	
Time Since Diagnosis	Control	32	49.13	45.80	8.10	.594
	Intervention	35	43.54	39.42	6.66	
Ejection Fraction	Control	32	27.34	7.83	1.38	.320
	Intervention	35	29.34	8.44	1.43	
Annual Income	Control	23	31126.09	18539.20	3865.69	.091
	Intervention	26	40749.04	20269.37	3975.15	

Table 2. *Study Sample Demographics - Chi Square Analysis*

Category	Characteristic	Intervention	Control	Chi Square
Gender	Male	23	23	.587
	Female	12	9	
Marital status	Single	1	0	.245
	Married	29	24	
	Divorced	4	3	
	Widow/widower	1	5	
Race	Caucasian	34	31	.949
	African American	1	1	
HF Etiology	Ischemic	25	22	.811
	Nonischemic	10	10	
NYHA FC	NYHA FC II	18	18	.156
	NYHA FC III	17	14	
Education	No high school	4	9	.364
	High school grad	13	12	
	Some college	8	6	
	College degree	6	4	
	Master's or higher	4	1	
Number of people in home	1	5	4	.618
	2	23	20	
	3	3	4	
	4	2	3	
	5	2	0	
	6	0	0	
	7	0	1	
Employment	Unemployed	3	2	.981
	Employed	6	5	
	Retired	23	22	
	Disabled	3	3	

Hypothesis Testing

The adaptation to chronic illness theory guided this study (Pollock, 1993). Within this theoretical framework, perception of illness impact is the concept that connects to cognator (psychological) and regular (physiological) subsystems in adaptation.

The four hypotheses tested are presented in this section in numerical order.

Hypothesis #1

The first hypothesis tested was: Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have lower perception of illness impact as evidenced by lower scores on the Illness Perception Questionnaire-Revised than the control group at 8 weeks and at 12 weeks. Perception of illness impact is the individual's interpretation of the degree of disability due to their chronic illness (Pollock, 1993). Findings for each of the eight subscales and the causal dimension are presented.

The IPQ-R Identity Subscale evaluates the participant's interpretation of number and type of symptoms experienced selected from a list of 14 different symptoms (Moss-Morris et al., 2002). Lower scores are desired and indicate fewer symptoms the participant experiences and perceives related to their illness. Repeated measures ANOVA and multivariate analysis were used to test for differences at baseline (Time 1), 8 weeks (Time 2), and 12 weeks (Time 3) between the intervention and control group. There was significance (Wilks' Lambda = .920; $F_{2, 62} = 2.704$; $p = 0.04$, partial $\eta^2 = .08$) for the interaction of time and intervention. Mean scores on the IPQ-R Identity Subscale for NYHA Functional Class III participants in the intervention group (T1 = 5.18, T2 = 3.65, T3 = 4.11) decreased from Time 1 to Time 3 (See Table 3).

Table 3. *Mean Scores IPQ-R Identity Subscale*

Group	Heart Failure Classification	Time			95% Confidence Interval	
			Mean	Std. Error	Lower Bound	Upper Bound
Control	NYHA FC II	1	3.06	.60	1.85	4.26
		2	3.61	.66	2.29	4.93
		3	3.67	.64	2.40	4.94
	NYHA FC III	1	4.07	.69	2.70	5.44
		2	5.14	.75	3.645	6.64
		3	4.86	.72	3.42	6.30
Intervention	NYHA FC II	1	4.11	.60	2.90	5.32
		2	4.56	.66	3.24	5.88
		3	4.11	.64	2.84	5.38
	NYHA FC III	1	5.18	.62	3.93	6.42
		2	3.65	.68	2.29	5.01
		3	4.12	.65	2.81	5.42

Mean scores for NYHA Functional Class III in the control group and for NYHA Functional Class II in either control or intervention group did not decrease over time. There was slight increase in mean scores for NYHA Functional Class II and NYHA Functional Class III in the control group from Time 1 to Time 3. Mean scores for NYHA Functional Class II in the intervention group increased slightly from Time 1 to Time 2, then returned to baseline at Time 3. Decrease in mean scores for NYHA Functional Class III participants in the intervention group revealed this group reported one less symptom by the end of the study than all other groups and functional class (See Figures 2 and 3).

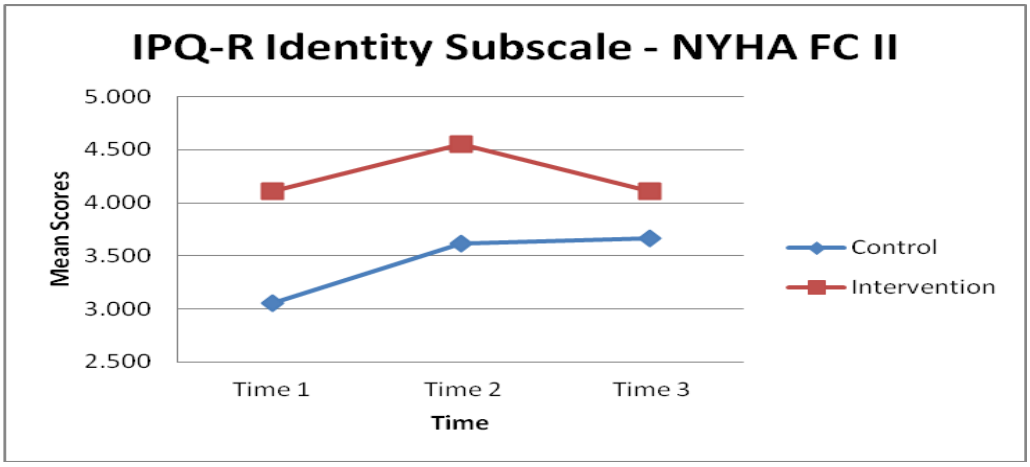

Figure 2. Mean Scores IPQ-R Identity Subscale - NYHA FC II

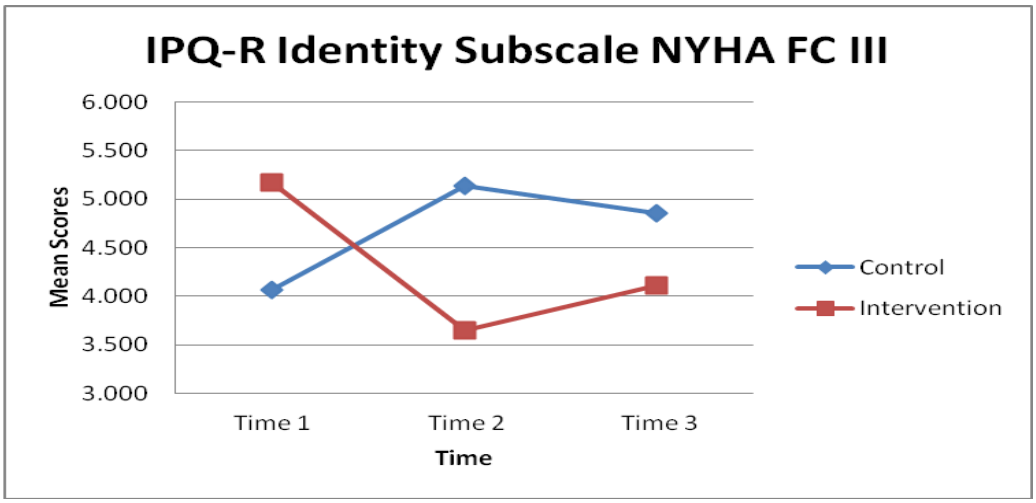

Figure 3. Mean Scores IPQ-R Identity Subscale NYHA FC III

The IPQ-R Timeline Acute/Chronic Subscale measures the perception that the conditions related to the chronic illness will be short or long term. Lower scores are desired on this subscale. Analysis of the IPQ-R Timeline Acute/Chronic subscale revealed no significant difference by treatment and functional class over time (Wilks' Lambda = .96; $F_{2, 62} = 1.38$; $p = .13$). There was significant difference of between subjects effects for functional class for

participants in the intervention group (p =.02). Mean scores on the IPQ-R Timeline Acute/Chronic Subscale for the NYHA Functional Class III decreased over time in the intervention group (T1 = 24.05, T2 = 23.35, T3 = 23.41) (See Table 4). In contrast, mean scores on the IPQ-R Timeline Acute/Chronic Subscale for NYHA Functional Class II in the intervention group (T1 = 23.72, T2 = 24.94, T3 = 25.39) increased over time, as did mean scores for NYHA Functional Class II (T1 = 20.72, T2 = 19.89, T3 = 21.44) and NYHA Functional Class III (T1 = 23.5, T2 = 24.5, T = 23.42) in the control group (See Figures 4 and 5). Lower scores in the NYHA Functional Class III participants in the intervention group indicate this group perceived their illness condition could improve with fewer long term effects.

Table 4. *Mean Scores IPQ-R Timeline Acute/Chronic Subscale*

Group	Heart Failure Classification	Time	Mean	Std. Error	95% Confidence Interval	
					Lower Bound	Upper Bound
Control	NYHA FC II	1	20.72	1.22	18.28	23.16
		2	19.89	1.06	17.77	22.01
		3	21.44	1.15	19.14	23.75
	NYHA FC III	1	23.50	1.39	20.73	26.27
		2	24.50	1.20	22.10	26.90
		3	23.43	1.31	20.82	26.04
Intervention	NYHA FC II	1	23.72	1.22	21.28	26.16
		2	24.94	1.06	22.83	27.06
		3	25.39	1.15	23.09	27.69
	NYHA FC III	1	24.06	1.26	21.55	26.57
		2	23.35	1.09	21.18	25.53
		3	23.41	1.19	21.04	25.78

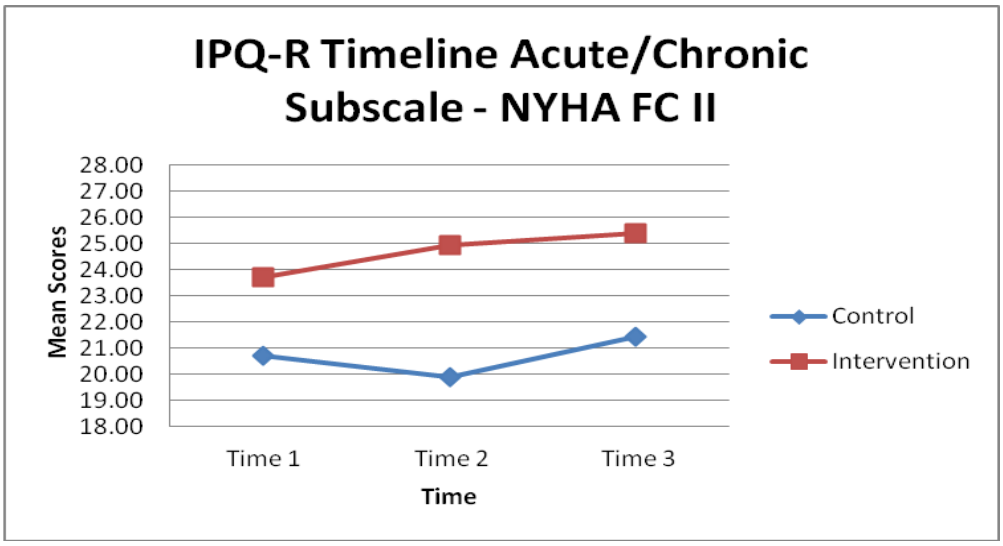

Figure 4. Mean Scores IPQ-R Timeline Acute/Chronic Subscale - NYHA FC II

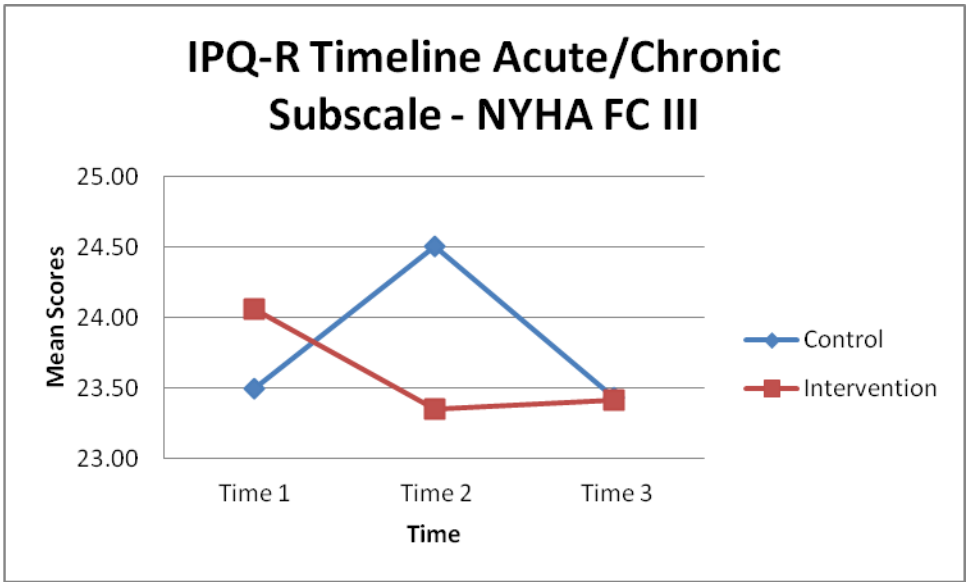

Figure 5. Mean Scores IPQ-R Timeline Acute/Chronic Subscale - NYHA FC III

The IPQ-R Consequence Subscale measures perception of negative effects or outcomes related to chronic illness. Lower scores indicate less perception of negative consequences related

to the illness. For the IPQ-R Consequence Subscale, there was significance (Wilks' Lambda = .92; $F_{2, 62} = 2.821$; $p = .03$; partial $\eta^2 = .08$) for effects of interaction of time, intervention, and functional class. NYHA Functional Class III participants in the intervention group had a decrease in mean scores on the IPQ-R Consequence Subscale from Time 1, Time 2, to Time 3 (T1 = 23.71, T2 = 23.30, T3 = 21.88). Mean scores on the IPQ-R Consequence Subscale for NYHA Functional Class III in the control group showed no significant change (T1 = 21.28, T2 = 23.00, T3 = 21.64) (See Table 5). Mean scores on the IPQ-R Consequence Subscale for NYHA Functional Class II participants were constant across time in the control group (T1 = 20.28, T2 = 20.33, T3 = 20.33) and intervention group (T1 = 21.22, T2 = 22.56, T3 = 22.11) (See Figure 6 and 7). These scores indicate the NYHA Functional Class III participants in the intervention group perceived fewer negative consequences related to their chronic illness over time.

Table 5. *Mean Scores IPQ-R Consequence Subscale*

Group	Heart Failure Classification	Time			95% Confidence Interval	
			Mean	Std. Error	Lower Bound	Upper Bound
Control	NYHA FC II	1	20.28	.88	18.51	22.05
		2	20.33	.91	18.52	22.15
		3	20.33	.91	18.53	22.14
	NYHA FC III	1	21.29	1.03	19.28	23.29
		2	23.00	1.03	20.94	25.06
		3	21.64	1.03	19.59	23.69
Intervention	NYHA FC II	1	21.22	.88	19.46	22.99
		2	22.56	.91	20.74	24.37
		3	22.11	.91	20.30	23.92
	NYHA FC III	1	23.71	.91	21.88	25.53
		2	23.30	.93	21.43	25.16
		3	21.88	.93	20.02	23.74

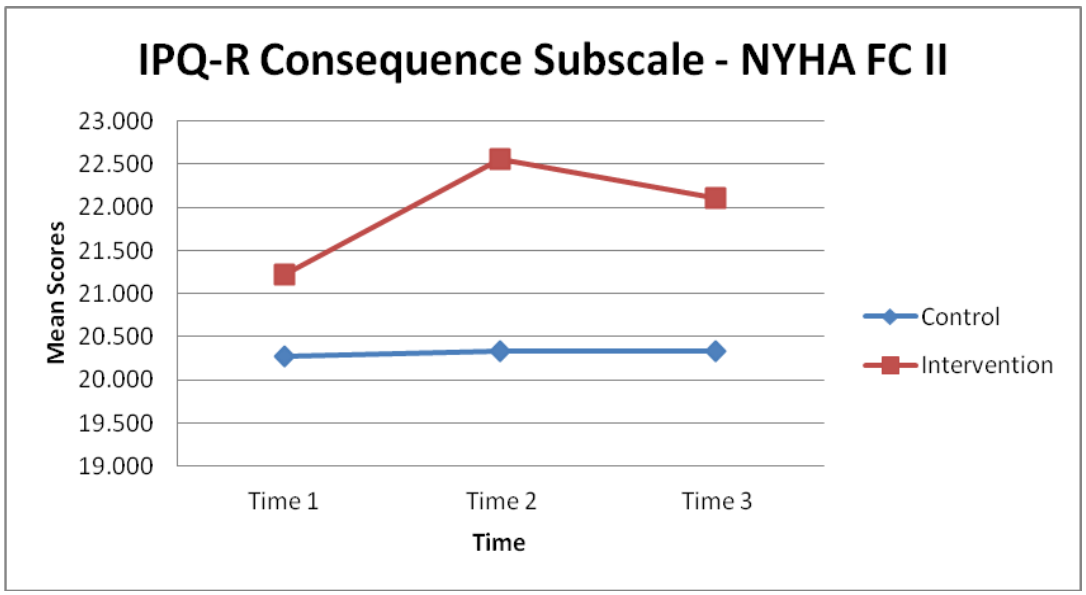

Figure 6. Mean Scores IPQ-R Consequence Subscale - NYHA FC II

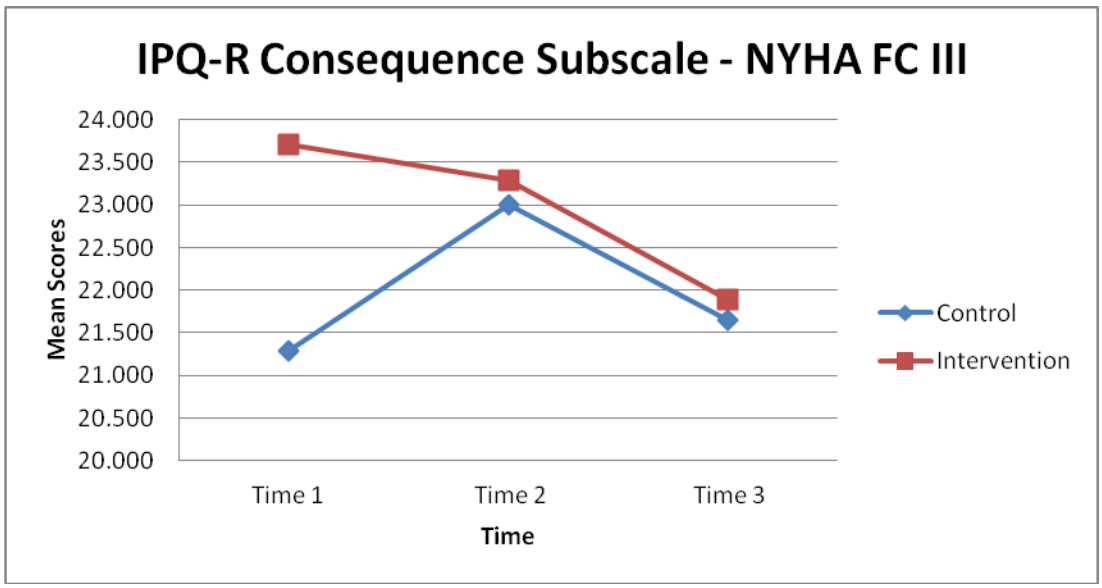

Figure 7. Mean Scores IPQ-R Consequence Subscale - NYHA FC III

An individual's perception of level of personal control they have over their illness is measured on the IPQ-R Personal Control Subscale. A higher score on this subscale is desired and indicates the individual perceives their own actions can help control their illness. Analysis of

the IPQ-R Personal Control Subscale revealed significance (Wilks' Lambda = .93; $F_{2, 62}$ = 2.45; p = .05) for the interaction of time and intervention. There was no statistical significance of interaction of time, intervention, and functional class (Wilks' Lambda, .96; $F_{2, 62}$ = 1.39; p = .13). Tests for between-subjects effects revealed significance for functional class (p = .05) (See Table 6). Mean scores on the IPQ-R Personal Control Subscale for NYHA Functional Class III decreased slightly from Time 1 to Time 2, then increased from Time 2 to Time 3 (T1 = 22.76, T2 = 22.18, T3 = 23.65) (See Figures 8 and 9). Scores for NYHA FC III in the control group decreased over time (T1 = 22.14, T2 = 21.79, T3 = 21.07).

Table 6. *Mean Scores IPQ-R Personal Control Subscale*

Group	Heart Failure Classification	Time			95% Confidence Interval	
			Mean	Std. Error	Lower Bound	Upper Bound
Control	NYHA FC II	1	23.00	.72	21.55	24.44
		2	23.39	.79	21.82	24.96
		3	23.61	.61	22.39	24.83
	NYHA FC III	1	22.14	.82	20.51	23.78
		2	21.79	.89	20.00	23.57
		3	21.07	.69	19.69	22.46
Intervention	NYHA FC II	1	23.67	.73	22.22	25.11
		2	22.17	.79	20.60	23.74
		3	23.50	.61	22.28	24.72
	NYHA FC III	1	22.77	.74	21.28	24.25
		2	22.18	.81	20.56	23.79
		3	23.65	.63	22.39	24.90

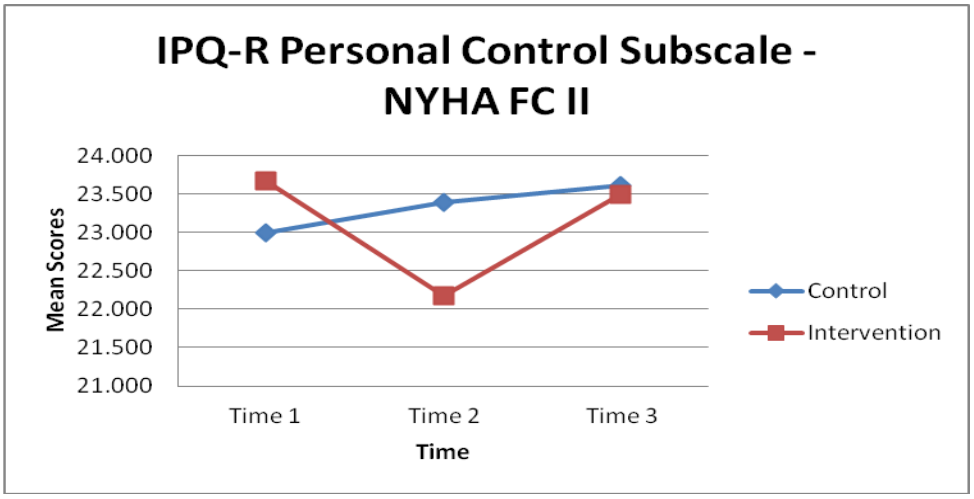

Figure 8. Mean Scores IPQ-R Personal Control Subscale - NYHA FC II

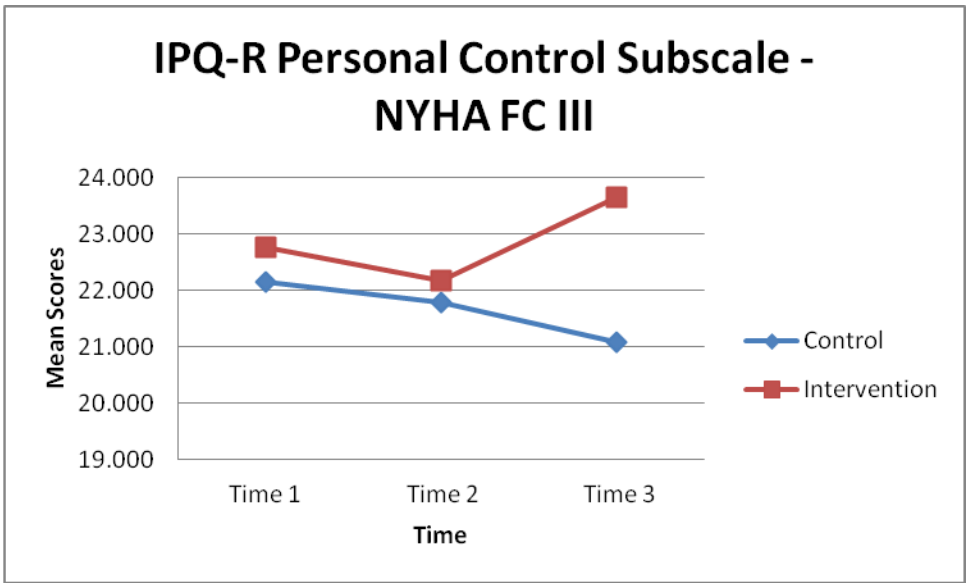

Figure 9. Mean Scores IPQ-R Personal Control Subscale - NYHA FC III

The IPQ-R Treatment Control Subscale measures perception of effectiveness and benefits of treatment for the illness. Higher scores are desired and indicate perception that the treatment can control the illness. There was no significance found on the IPQ-R Treatment Control

Subscale analysis for time, intervention, and functional class interaction (Wilks' Lambda = .98; $F_{2, 62} = .76$, $p = .236$). There was statistical significance of between subjects effects ($F_{2,62} = 7.97$; $p = .003$) between NYHA Functional Class II and NYHA Functional Class III on the IPQ-R Treatment Control Subscale. Data analysis separated by functional class revealed mean scores on the IPQ-R Treatment Control Subscale for interaction of time and functional class for NYHA Functional Class II (T1 = 17.36, T2 = 17.61, T3 = 18.03) increased over time (See Table 7). In contrast, mean scores on the IPQ-R Treatment Control Subscale for interaction of time and functional class decreased over time for NYHA Functional Class III participants overall (T1 = 16.33, T2 = 16.35, T3 = 15.81) (See Figure 10). On the IPQ-R Treatment Control Subscale, NYHA Functional Class II participants had higher scores overall than NYHA Functional Class III participants. These scores indicate the NYHA Functional Class II participants had increased perception that treatment can improve their chronic condition.

Table 7. *Mean Scores for IPQ-R Treatment Control Subscale*

Heart Failure Classification	Time			95% Confidence Interval	
		Mean	Std. Error	Lower Bound	Upper Bound
NYHA FC II	1	17.36	.46	16.45	18.27
	2	17.61	.52	16.57	18.66
	3	18.03	.42	17.19	18.87
NYHA FC III	1	16.33	.49	15.34	17.32
	2	16.35	.57	15.22	17.48
	3	15.81	.45	14.90	16.72

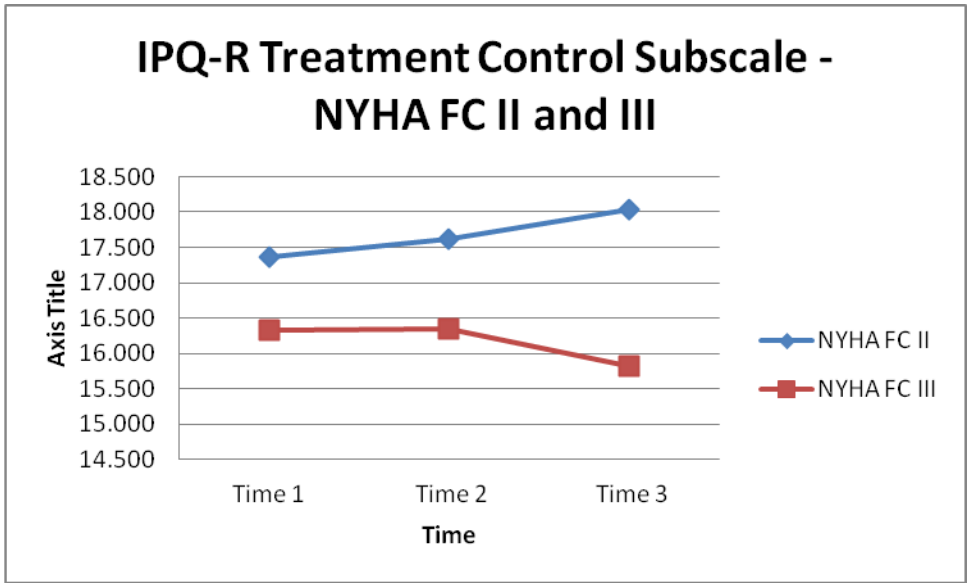

Figure 10. IPQ-R Treatment Control Subscale - NYHA FC II and III

Understanding of one's illness is measured by the IPQ-R Illness Coherence subscale. Higher scores are desired and indicate a higher level of understanding of the illness. Analysis of the IPQ-R Illness Coherence subscale showed significance of time and functional class interaction (Wilks' Lambda = .90; $F_{2, 62} = 3.32$; $p = .02$). The effect of interaction of time, intervention, and functional class was not statistically significant (Wilks' Lambda = .29; $F_{2, 62} = .285$; $p = .38$). When functional class was viewed as separate data, the difference for NYHA Functional Class II was statistically significant (Wilks' Lambda = .78; $F_{2, 34} = 4.867$; $p = .007$) as mean scores on the IPQ-R Illness Coherence Subscale increased over time (T1 = 16.89, T2 = 17.83, T3 = 18.14) as shown in Table 8.

Table 8. *Mean Scores for IPQ-R Illness Coherence Subscale*

Heart Failure Classification	Time			95% Confidence Interval	
		Mean	Std. Error	Lower Bound	Upper Bound
NYHA FC II	1	16.89	.53	15.81	17.97
	2	17.83	.62	16.58	19.09
	3	18.14	.51	17.10	19.18
NYHA FC III	1	18.35	.66	17.02	19.69
	2	17.26	.63	15.97	18.55
	3	17.74	.55	16.62	18.87

There was no statistical significance for change in NYHA Functional Class III (Wilks' Lambda = .93; $F_{2, 29} = 1.17$; $p = .322$) for mean scores on the IPQ-R Illness Coherence Subscale (T1 = 18.36, T2 = 17.26, T3 = 17.74). Pairwise comparison analysis showed significance in the increase of scores between Time 1 and Time 3 ($p = .012$) for NYHA Functional Class II (See Table 9). NYHA Functional Class II had higher scores than NYHA Functional Class III on the IPQ-R Illness Coherence subscale, which indicates the NYHA Functional Class II participants had increased understanding of their chronic illness over time (See Figure 11).

Table 9. *Pairwise Comparison IPQ-R Illness Coherence Mean Scores*

Heart Failure Classification	Time	Interval	Mean Difference	Std. Error	Sig.[a]	95% Confidence Interval for Difference[a] Lower Bound	Upper Bound
NYHA FC II	1	2	-.94	.57	.330	-2.39	.50
		3	-1.25*	.41	.012	-2.27	-.23
	2	1	.94	.58	.330	-.50	2.39
		3	-.31	.41	1.000	-1.35	.74
	3	1	1.25*	.41	.012	.23	2.27
		2	.31	.41	1.000	-.74	1.35
NYHA FC III	1	2	1.10	.70	.389	-.69	2.88
		3	.61	.68	1.000	-1.12	2.34
	2	1	-1.10	.70	.389	-2.88	.69
		3	-.48	.60	1.000	-2.02	1.05
	3	1	-.61	.68	1.000	-2.34	1.12
		2	.48	.60	1.000	-1.05	2.02

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

*. The mean difference is significant at the .05 level.

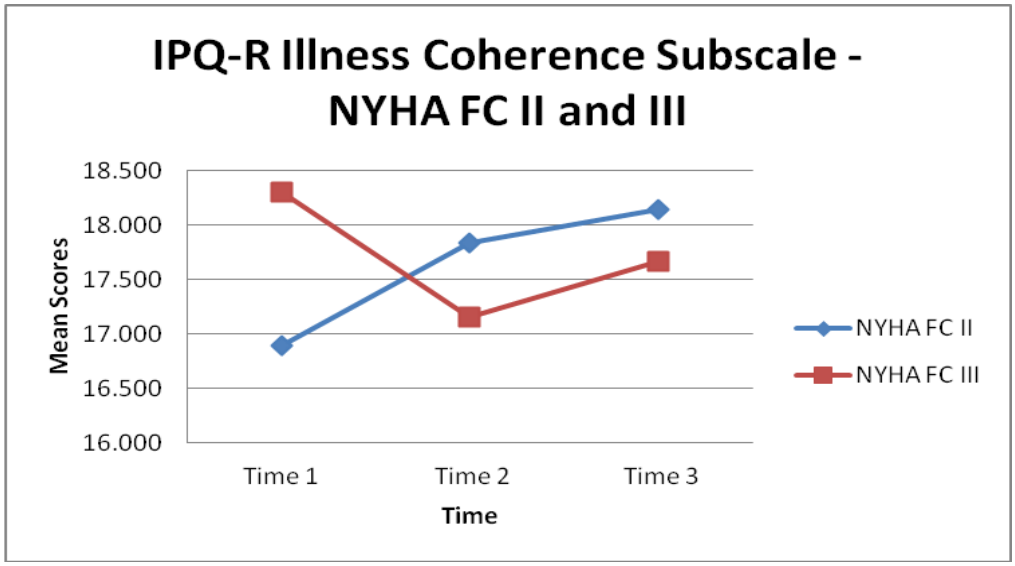

Figure 11. IPQ-R Illness Coherence Subscale - NYHA FC II and III

The IPQ-R Timeline Cyclical subscale measures perception of variation of symptoms and conditions related to illness. A lower score is desired and indicates less perception of variation of the illness. Mauchly's test of sphericity was not met for IPQ-R Timeline Cyclical subscale ($p < .001$) for assumption of compound symmetry. Tests of within-subjects effects showed no effect of interaction of time, intervention, or functional class on IPQ-R Timeline Cyclical subscale (Greenhouse-Geisser Mean Square = 2.61; $df = 1.62$; $F_{2,62} = .427$; $p = .31$) (See Figures 12 and 13). There was no difference between treatment groups or functional class in perception of cyclical changes in their condition (See Table 10).

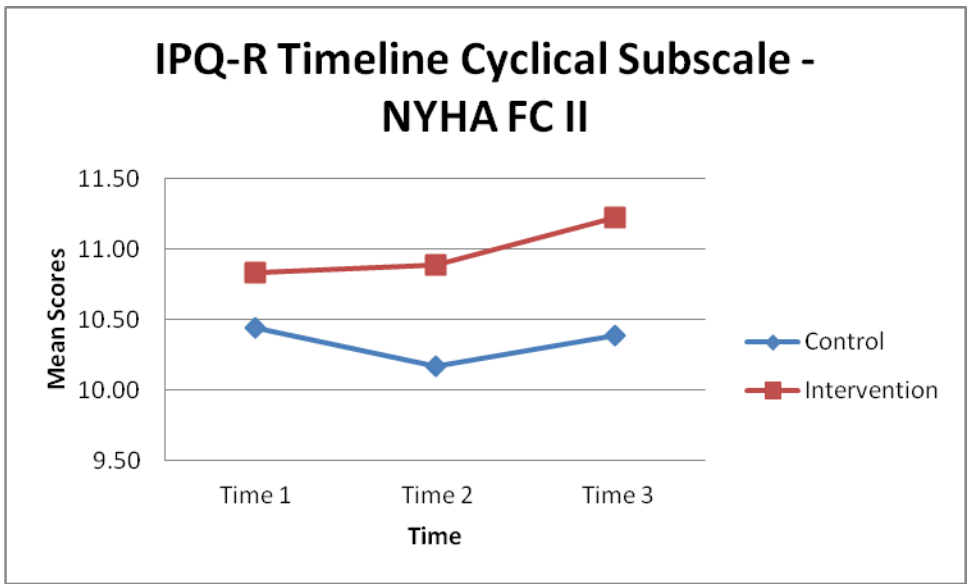

Figure 12. IPQ-R Timeline Cyclical Subscale - NYHA FC II

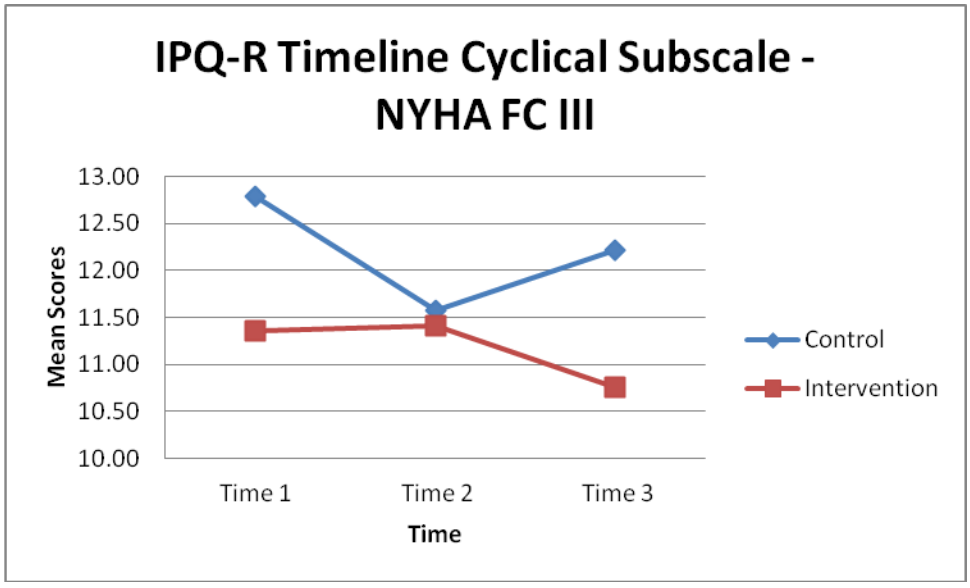

Figure 13. IPQ-R Timeline Cyclical Subscale - NYHA FC III

Table 10. *Mean Scores Timeline Cyclical Subscales*

Group	Heart Failure Classification	Time	Mean	Std. Error	95% Confidence Interval	
					Lower Bound	Upper Bound
Control	NYHA FC II	1	10.44	.83	8.79	12.10
		2	10.17	.71	8.75	11.58
		3	10.39	.75	8.89	11.88
	NYHA FC	1	12.79	.94	10.91	14.66
	III	2	11.57	.80	9.97	13.18
		3	12.21	.85	10.52	13.91
Intervention	NYHA FC II	1	10.83	.83	9.18	12.49
		2	10.89	.71	9.47	12.31
		3	11.22	.75	9.73	12.72
	NYHA FC	1	11.35	.85	9.65	13.05
	III	2	11.41	.73	9.95	12.87
		3	10.76	.77	9.23	12.30

The IPQ-R Emotional Representations Subscale measures perception of emotional responses to the illness. A lower score is desired and indicates less perception of negative emotions related to the illness. Analysis of the IPQ-R Emotional Representation Subscale revealed interaction of time, intervention, and functional class. Assumption of compound symmetry was not met by Mauchly's Test of Sphericity ($p = .008$). Tests of within subjects effects revealed significance for time, intervention, and functional class (Greenhouse-Geisser Mean Square = 26.49, $df = 1.75$, $F = 4.56$, $p = .008$, partial $\eta^2 = .07$) (See Figure 14 and 15).

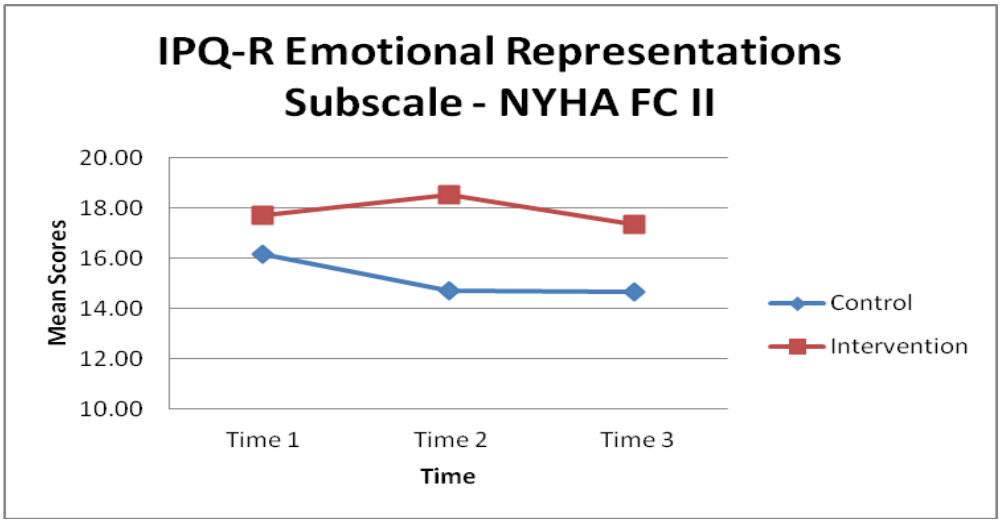

Figure 14. Mean Scores IPQ-R Emotional Representations - NYHA FC II

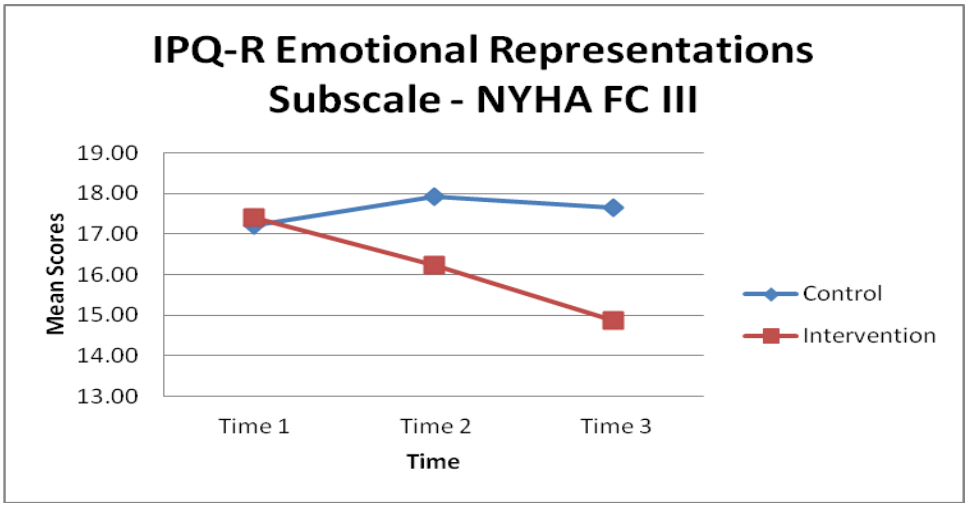

Figure 15. Mean Scores IPQ-R Emotional Representations- NYHA FC III

Tests of between subjects on the effects revealed significance by intervention and functional class (p = .03, partial n^2 = .06). Mean scores on the IPQ-R Emotional Representations

Subscale for NYHA Functional Class III participants in the intervention group decreased over time (T1 - 17.41, T2 – 16.24, T3 – 14.88) (See Table 11).

Table 11. *Mean Scores Emotional Representations Subscale*

Group	Heart Failure Classification	Time	Mean	Std. Error	95% Confidence Interval	
					Lower Bound	Upper Bound
Control	NYHA FC II	1	16.17	1.11	13.95	18.38
		2	14.72	1.04	12.65	16.80
		3	14.67	1.09	12.50	16.84
	NYHA FC III	1	17.21	1.26	14.70	19.73
		2	17.93	1.18	15.57	20.28
		3	17.64	1.23	15.18	20.11
Intervention	NYHA FC II	1	17.72	1.11	15.51	19.94
		2	18.50	1.04	16.42	20.58
		3	17.33	1.09	15.16	19.51
	NYHA FC III	1	17.41	1.14	15.13	19.69
		2	16.24	1.07	14.10	18.37
		3	14.88	1.12	12.65	17.12

Difference in mean scores on the IPQ-R Emotional Representations Subscale from Time 1 to Time 3 was 2.53 for NYHA Functional Class III in the intervention group. Mean scores on the IPQ-R Emotional Representation Subscale for NYHA Functional Class II participants in the control group decreased over time (T1 – 16.17, T2 – 14.72, T3 – 14.67). Difference in mean scores from Time 1 to Time 3 for NYHA Functional Class II participants was not as large at 1.51.

The IPQ-R Causal Dimension is not used as a subscale (Moss-Morris et al., 2002). On the IPQ-R Causal Dimension, participants respond to a list of possible causes for their illness on a Likert-type scale from 1 (strongly disagree) to 5 (strongly agree), and then rank in order the three most important causes of their illness. The three most important causes of heart failure ranked in order by study participants regardless of treatment group or functional class at Time 1, Time 2, and Time 3 were: a) family history (30.86%), b) stress (14.4%), and c) diet (10.43%). Participant views and rankings of the three most important causes of their heart failure were unchanged over time.

Hypothesis #2

Repeated measures ANOVA and multivariate testing were used to test the second hypothesis for this study as follows: Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have improved physiologic adaptation from baseline as evidenced by higher scores on 6MWT, total pedometer step counts, and total minutes walked per week and will have no decline in NYHA Functional Class when compared to the control group at 4 weeks, 8 weeks and at 12 weeks. This section will describe the results of testing for the 6MWT, change in NYHA Functional Class during the study period, Total Minutes Walked, and Average Daily Pedometer Steps.

Analysis of the 6MWT showed significance for increase in distance walked for both groups over time (Wilks' Lambda = .52; $F_{3, 61} = 18.81$; $p = < .001$). There was significant effect of time by intervention (Wilks' Lambda = .90; $F_{3,61} = 2.37$, $p = .04$). There was no significance of interaction of time and functional class (Wilks' Lambda = .98; $F_{3,61} = .37$; $p = .39$). Interaction of time, intervention and functional class was not significant (Wilks' Lambda = .97;

$F_{3,61} = .61$; $p = .31$). Tests of between subjects effects indicated participants in the intervention group improved more than the control group ($F_{3,61} = 3.87$; $p = .03$) (See Figure 16).

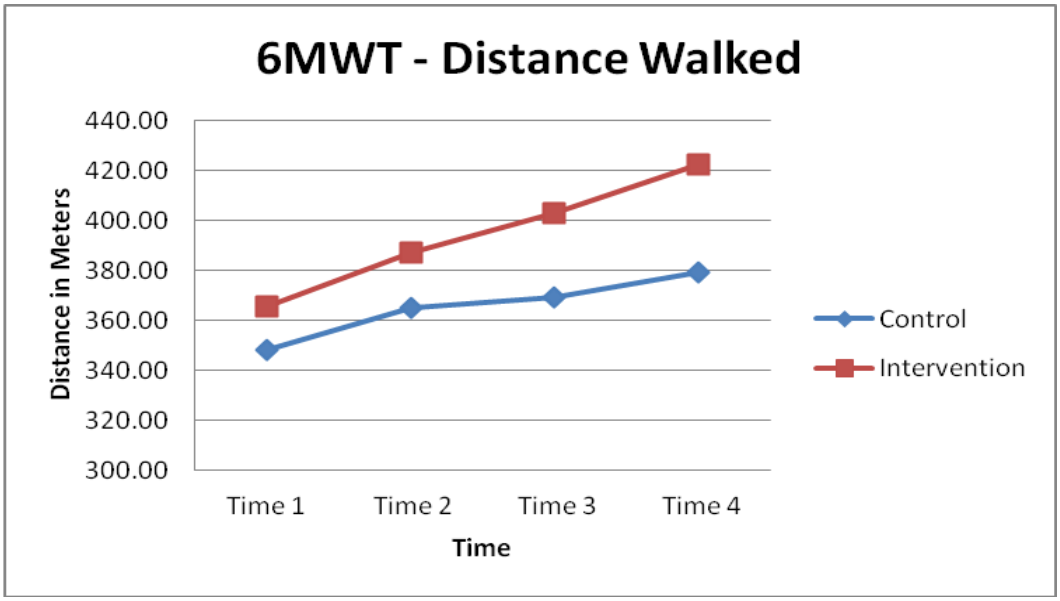

Figure 16. 6-Minute Walk Test Distance Walked by Treatment Group

Pairwise comparison between 6MWT means for both treatment groups showed marginal increase of 19 meters from Time 1 to Time 2 ($p = .055$). The most significant increase was a mean of 28.80 meters from measure at Time 1 to Time 3 ($p = .001$). There was less increase in distance walked (mean 14.36 meters) in 6MWT from Time 3 to Time 4, but the increase remained statistically significant ($p = .011$) (See Tables 12 and 13).

Table 12. 6-Minute Walk Test Overall Mean Scores

Time			95% Confidence Interval	
	Mean	Std. Error	Lower Bound	Upper Bound
1	353.44	9.96	333.53	373.35
2	372.44	9.59	353.28	391.61
3	382.26	9.64	362.99	401.54
4	396.62	9.29	378.05	415.20

Table 13. *6-Minute Walk Test Pairwise Comparisons*

Time	Interval				95% Confidence Interval for Difference[a]	
		Mean Difference	Std. Error	Sig.[a]	Lower Bound	Upper Bound
1	2	-19.04	7.06	.055	-38.25	.24
	3	-28.83*	7.34	.001	-48.83	-8.82
	4	-43.18*	6.38	.000	-60.57	-25.80
2	1	19.04	7.06	.055	-.24	38.25
	3	-9.82	5.70	.540	-25.35	5.71
	4	-24.18*	5.13	.000	-38.15	-10.22
3	1	28.82*	7.34	.001	8.82	48.83
	2	9.82	5.70	.540	-5.71	25.35
	4	-14.36*	4.40	.011	-26.34	-2.38
4	1	43.18*	6.38	.000	25.80	60.57
	2	24.18*	5.13	.000	10.22	38.15
	3	14.36*	4.40	.011	2.38	26.34

Based on estimated marginal means

a. Adjustment for multiple comparisons: Bonferroni.

*. The mean difference is significant at the .05 level.

There was a mean increase in distance walked of 43.18 meters for all participants from Time 1 to Time 4 which was significant ($p < .001$). Independent samples t-test was carried out to evaluate group differences for change in 6MWT between the groups. For the intervention group, there was a mean increase in distance walked of 56.71 meters (SD = 41.54). For the control group, there was a mean increase in distance walked of 31.13 meters (SD = 61.21). Levene's Test for equality of error variances was significant ($p = .011$) indicating there was some variation of homogeneity of the groups (Munro, 2005). Independent samples t-test of the 6MWT change with equal variances not assumed indicated possible significant change in the intervention group ($p = .052$).

To determine change in NYHA Functional Class over time, Chi-Square analysis was used to determine differences between intervention and control groups for functional class at Time 1 and Time 4. Chi-Square analysis and Fisher's exact test for NYHA Functional Class II showed no significant difference ($\chi^2 = .364$; Fisher's exact test = .50; $p = .55$) between intervention and control groups for improvement in functional class over time. Findings revealed two NYHA Functional Class II participants (11.10%) in the control group had improvement in functional class. There was one NYHA Functional Class II participant (5.60%) in the intervention group that demonstrated improvement in functional class (See Table 14).

Table 14. *Change in Functional Class- NYHA Functional Class II*

			Change in Functional Class		
			No change	Improved	Total
Group	Control	Count	16	2	18
		% Change Within Control	88.90%	11.10%	100.00%
		% Within Total	48.50%	66.70%	50.00%
	Intervention	Count	17	1	18
		% Change Within Intervention	94.40%	5.60%	100.00%
		% Within Total	51.50%	33.30%	50.00%
Total		Count	33	3	36
		% Change NYHA FC II	91.70%	8.30%	100.00%
		% Total NYHA FC II	100.00%	100.00%	100.00%

a. NYHA FC = NYHA FC II

There was statistical significance difference for NYHA Functional Class III participants in the intervention group for improvement in functional class over time ($\chi^2 = 4.64$; Fisher's exact test = .038; $p = .031$). There were seven NYHA Functional Class III participants (41.20%) in the intervention group that demonstrated improvement in functional class to a higher level NYHA functional classification. In the control group, there was one NYHA Functional Class III participant (7.10%) that showed improvement in functional class (See Table 15). NYHA Functional Class III participants in the intervention group had greater improvement in functional class than did NYHA Functional Class III participants in the control group.

Table 15. *Change in Functional Class NYHA Functional Class III*

			Change in Functional Class		
			No change	Improved	Total
Group	Control	Count	13	1	14
		% Change Within Control	92.90%	7.10%	100.00%
		% within Total	56.50%	12.50%	45.2%
	Intervention	Count	10	7	17
		% Change Within Intervention	58.80%	41.20%	100.00%
		% within Total	43.50%	87.50%	54.80%
Total		Count	23	8	31
		% Change NYHA FC III	74.20%	25.80%	100.00%
		% Total NYHA FC III	100.00%	100.00%	100.00%

a. NYHA FC = NYHA FC III

Repeated measures ANOVA and multivariate analysis were used to analyze the Total Minutes Walked for both groups (See Table 16). Analysis revealed both groups improved over time (Wilks' Lambda = .63; $F_{3, 61} = 11.86$; $p < .001$) with no significance by intervention (Wilks' Lambda = .97; $F_{3, 61} = .54$; $p = .33$) or by functional class (Wilks' Lambda = .92; $F_{3, 61} = 1.86$; $p = .07$) (See Figure 17). Pairwise comparison showed no significant change for either group from Time 1 to Time 2 ($p = .11$). There was significant increase in Total Minutes Walked for both groups from Time 1 to Time 3 ($p < .001$) and from Time 2 to Time 3 ($p = .004$). There was no significant increase in Total Minutes Walked from Time 3 to Time 4 ($p = .67$) (See Table 17). Difference in mean scores showed patients were walking an average of 21 minutes more at Time 2, an average of 58 minutes more at Time 3, and an average of 71 minutes more at Time 4 when compared to baseline (Time 1).

Table 16. *Total Minutes Walked Weekly Average*

Time				
			95% Confidence Interval	
	Mean	Std. Error	Lower Bound	Upper Bound
1	83.83	13.06	57.73	109.93
2	104.95	14.99	74.99	134.91
3	141.94	16.34	109.28	174.59
4	155.72	17.82	120.12	191.32

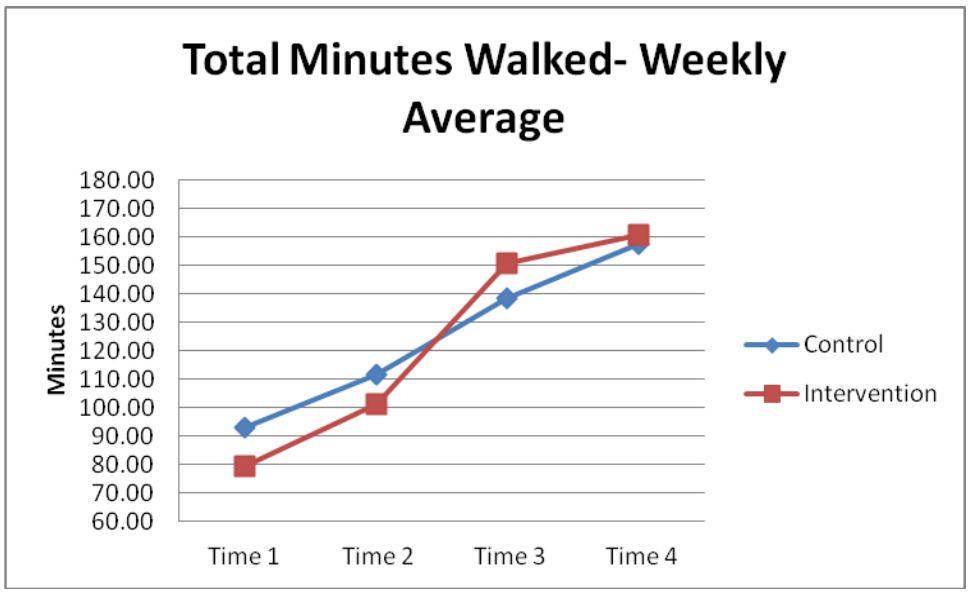

Figure 17. Total Minutes Walked by Treatment Group

Table 17. *Pairwise Comparisons Total Minutes Weekly Average*

Time	Interval				95% Confidence Interval for Difference[a]	
		Mean Difference	Std. Error	Sig.	Lower Bound	Upper Bound
1	2	-21.12	8.75	.112	-44.96	2.72
	3	-58.11*	11.91	.000	-90.54	-25.67
	4	-71.89*	12.60	.000	-106.23	-37.56
2	1	21.12	8.75	.112	-2.72	44.96
	3	-36.99*	10.21	.004	-64.80	-9.17
	4	-50.77*	9.51	.000	-76.67	-24.87
3	1	58.11*	11.91	.000	25.67	90.54
	2	36.99*	10.21	.004	9.17	64.80
	4	-13.79	8.54	.669	-37.05	9.48
4	1	71.89*	12.60	.000	37.56	106.23
	2	50.77*	9.51	.000	24.87	76.67
	3	13.79	8.54	.669	-9.48	37.05

To analyze the pedometer steps data, the EM (Estimation Maximization) function in SPSS was utilized to estimate any missing days of pedometer data (5.00%). Participants were given the pedometer with instruction for proper use and wear. Participants were instructed to begin pedometer wear in the morning and wear until bedtime. Participants were instructed to avoid getting the pedometer wet and not to wear the pedometer while showering or bathing. A valid day of pedometer wear was at least 10 hours confirmed by analysis of the Omron Pedometer software program. If a participant did not have at least 10 hours of pedometer wear, or if the pedometer was not worn on a given day, this was considered a missing value for that day. Missing value data in SPSS Version 19.0 were calculated using the EM function. This function was used to estimate missing values for each 7-day week, except for Week 1 and Week

12. A 6-day week was used to estimate missing data for these weeks because Day 1 (the first day of pedometer wear) and Day 84 (the final day of pedometer wear) were typically not valid 10-hour pedometer wear days. Participants received and turned in pedometers on Day 1 and Day 84 and did not wear the pedometer a minimum of 10 hours. Missing values were estimated for any missing days and average daily steps for each week were calculated.

Repeated measures ANOVA and multivariate analysis were used to determine effect of time, intervention, and functional class. There was significance of the effect of time (Wilks' Lambda = .62; $F_{3, 61} = 12.46$; $p < .0005$, partial $\eta^2 = .38$) as both groups improved over time. Effects of interaction of time and intervention (Wilks' Lambda = .99; $F_{3, 61} = .08$; $p = .97$), interaction of time and functional class (Wilks' Lambda = .92; $F_{3, 61} = 1.78$; $p = .16$) were not significant. Interaction of time, intervention, and functional class (Wilks' Lambda = .90; $F_{3, 61} = 2.18$; $p = .05$) was significant. Tests of between subjects effects revealed significance by intervention ($F = 4.26$, $p = .02$) and functional class ($F = 12.22$, $p = .0005$, partial $\eta^2 = .06$) (See Figure 18 and Figure 19). The intervention group improved more than the control group. Within the intervention group, NYHA Functional Class III participants increased more than the NYHA Functional Class II participants. Description of weekly step averages overall for NYHA Functional Class II participants in the intervention group showed increase in steps from Time 1 to Time 3 with decrease in weekly step average at Time 4. Weekly step average for NYHA Functional Class III participants in the intervention group increased from Time 1 to Time 4 with no decline in weekly step average at Time 1, Time 2, Time 3, and Time 4 (See Table 18). There was no significant increase in weekly step averages for Time 3 to Time 4 for both NYHA Functional Class II and III participants in the control group, and for NYHA Functional Class II in the intervention group.

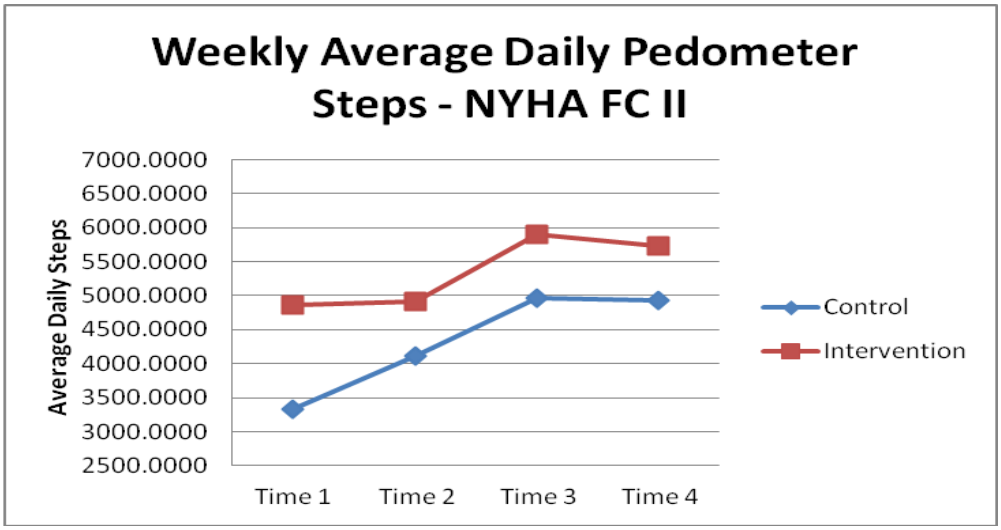

Figure 18. Weekly Step Averages - NYHA FC II

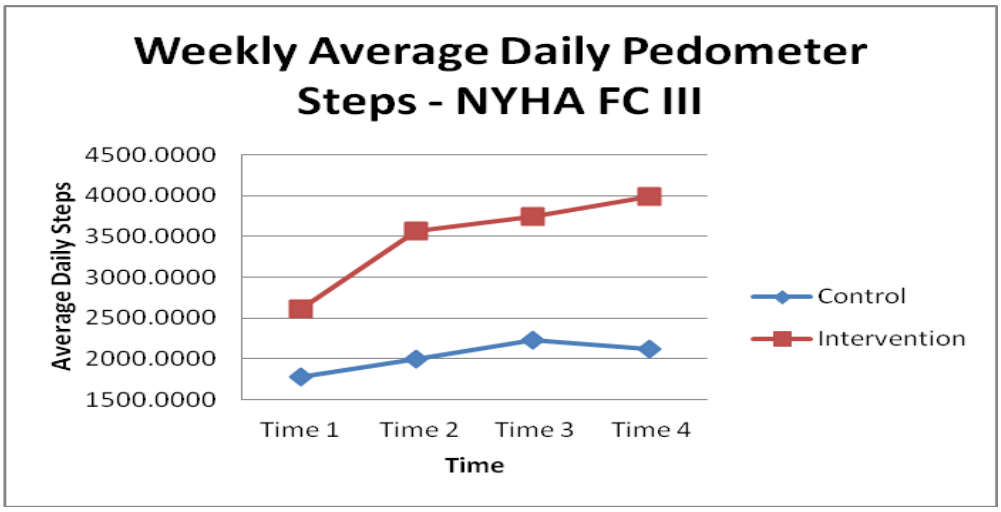

Figure 19. Weekly Step Averages - NYHA FC III

Table 18. *Weekly Step Averages by Functional Class*

Group	Variable	Mean	95% Confidence Interval		SD	Minimum	Maximum
			Lower Bound	Upper Bound			
NYHA FC 2	Week 1 Step Average	4094.83	3257.75	4931.91	2473.99	768.12	12480.00
	Week 4 Step Average	4508.32	3680.77	5335.87	2445.83	662.86	10991.43
	Week 8 Step Average	5437.65	4420.78	6454.52	3005.36	997.57	12003.14
	Week 12 Step Average	5332.48	4399.81	6265.16	2756.53	1359.33	12125.67
NYHA FC 3	Week 1 Step Average	2234.27	1652.00	2816.54	1587.42	420.50	8264.83
	Week 4 Step Average	2857.18	1778.08	3936.28	2941.91	730.57	14243.29
	Week 8 Step Average	3060.10	2064.92	4055.29	2713.13	573.12	12914.57
	Week 12 Step Average	3143.21	2123.42	4162.99	2780.21	704.30	12840.83

Hypothesis #3

Due to non-normal distribution of the variable, nonparametric tests were used to test Hypothesis #3: Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have improved psychosocial adaptation as evidenced by lower scores on the SIP than the control group at 8 weeks and at 12 weeks This section will present findings for analysis of the SIP used to measure adaptation to chronic illness.

The SIP Total Score variable had non-normal distribution for Time 1 (skewness = 1.06, kurtosis = .68), Time 2 (skewness = 1.20, kurtosis = 1.29), and Time 3 (skewness = 1.48, kurtosis = 2.04). For normal distribution, the skewness value should be between $^{-}1$ and $^{+}1$. A large positive number for the kurtosis value indicates a peaked distribution that is leptokurtic (Munro, 2005). The Kruskal-Wallis test, the nonparametric test analog of one-way analysis of variance, was selected to analyze the SIP Total Score data. The data were analyzed by treatment group. Findings revealed for SIP Total Score at Time 1 (χ^2 (1) = .38, p = .54, control mean rank

= 32.47, intervention mean rank = 35.40), Time 2 (χ^2 (1) = .04, p = .85, control mean rank 33.52, intervention mean rank = 34.44), and Time 3 (χ^2 (1) = .63, p = .43, control mean score = 35.97, intervention mean rank = 32.20) (See Table 19 and Table 20). Mean scores for the SIP Total Score decreased overall (Mean Score T1 = 9.8064, SD = 7.94, Mean Score T2 = 8.31, SD = 7.25, Mean Score T3 = 7.98, SD = 8.11). These findings indicate that mean scores decreased for both treatment groups over time, which indicates both groups had improvement in adaptive responses. However, the difference between groups was not significant.

Table 19. *SIP Total Score Kruskal-Wallis Test*

SIP Total Score	Group	N	Mean Rank
Time 1	Control group	32	32.47
	Intervention group	35	35.40
	Total	67	
Time 2	Control group	32	33.52
	Intervention group	35	34.44
	Total	67	
Time 3	Control group	32	35.97
	Intervention group	35	32.20
	Total	67	

Table 20. *SIP Total Score Kruskal-Wallis Test Statistics*

	Time 1	Time 2	Time 3
Chi-Square	.378	.038	.626
df	1	1	1
Asymptotic Sig.	.538	.846	.429

a. Kruskal-Wallis Test

b. Grouping Variable: Intervention

The SIP Physical Dimension was analyzed by the Kruskal-Wallis test due to non-normal distribution. Findings revealed for SIP Physical Dimension were Time 1 (χ^2 (1) = .001, p = .97, control mean rank = 33.91, intervention mean rank = 34.09), Time 2 (χ^2 (1) = .007, p = .93, control mean rank = 33.80, intervention mean rank = 34.19) and Time 3 (χ^2 (1) = .369, p = .54, control mean rank = 35.48, intervention mean rank = 32.64) as shown in Table 21 and Table 22. Mean Scores for SIP Physical Dimension decreased slightly over time (Mean score T1 = 6.07, SD = 6.39, Mean score T2 = 5.44, SD = 6.48, Mean Score T3 = 5.80, SD = 7.14), which indicates slight improvement in physical adaptive responses. The difference between the intervention and control groups was not significant.

Table 21. *SIP Physical Dimension Kruskal-Wallis Test*

SIP Physical Dimension	Group	N	Mean Rank
Time 1	Control	32	33.91
	Intervention	35	34.09
	Total	67	
Time 2	Control	32	33.80
	Intervention	35	34.19
	Total	67	
Time 3	Control	32	35.48
	Intervention	35	32.64
	Total	67	

Table 22. *SIP Physical Dimension Kruskal-Wallis Test Statistics*

SIP Physical Dimension	Time 1	Time 2	Time 3
Chi-Square	.001	.007	.369
df	1	1	1
Asymptotic. Sig.	.970	.934	.544

a. Kruskal-Wallis Test

b. Grouping Variable: Intervention

Analysis of the SIP Psychosocial Dimension scores by Kruskal-Wallis testing revealed Time 1 (χ^2 (1) = .00, p = 1.0, control mean rank = 34.00, intervention mean rank = 34.00) Time 2 (χ^2 (1) = .00, p = .99, control mean rank = 33.97, intervention mean rank = 34.03), and Time 3 (χ^2 (1) = .25, p = .62, control mean rank = 35.20, intervention mean rank = 32.90) as shown in Table 23 and 24. Mean score for SIP Psychosocial Dimension decreased overall (Mean score T1= 7.22, SD = 9.45, Mean Score T2 = 6.82, SD = 8.68, Mean Score T3 = 5.60, SD = 9.32) but

this change was not significant. These results show improvement in psychosocial adaptive responses in both the intervention and control group, but the differences between the groups was not significant.

Table 23. *SIP Psychosocial Dimension Kruskal-Wallis Test*

SIP Psychosocial Dimension	Group	N	Mean Rank
Time 1	Control	32	34.00
	Intervention	35	34.00
	Total	67	
Time 2	Control	32	33.97
	Intervention	35	34.03
	Total	67	
Time 3	Control	32	35.20
	Intervention	35	32.90
	Total	67	

Table 24. *SIP Psychosocial Kruskal-Walllis Test Statistics*

	Time 1	Time 2	Time 3
Chi-Square	.000	.000	.252
df	1	1	1
Asymptotic Sig.	1.000	.990	.616

a. Kruskal Wallis Test

b. Grouping Variable: Intervention

Hypothesis #4

The fourth hypothesis to be tested in this study was: Participants in a 12-week home-based combined aerobic and resistance training exercise intervention will have fewer number of hospitalizations than the control group during the 12-week study. This section will describe results of testing of this hypothesis.

Nonparametric testing was selected to test this hypothesis. At baseline, there were 22 participants (68.60%) in the control group who had no hospitalizations in the previous 12 months, and 18 participants (51.40%) in the intervention group who had no hospitalizations in the previous 12 months. There were 10 participants (31.30%) in the control group who had experienced one or more hospitalizations in the previous 12 months, and 17 participants (48.50%) in the intervention groups of had experienced one or more hospitalizations in the previous 12 months (See Tables 25 and 26).

Table 25. *Hospitalizations in Previous 12 Months Prior to Enrollment*

			Hospitalized Past Year		
			No	Yes	Total
Group	Control	Count	22	10	32
		% Within Control	68.80%	31.30%	100.00%
		% Within Total	55.00%	37.00%	47.80%
	Intervention	Count	18	17	35
		% Within Intervention	51.40%	48.60%	100.00%
		% Within Total	45.00%	63.00%	52.20%
Total		Count	40	27	67
		% Hospitalized Previous 12 months	59.70%	40.30%	100.00%
		% Total	100.00%	100.00%	100.00%

Table 26. *Hospitalizations During Study Enrollment*

			Hospitalized During Study		
			No	Yes	Total
Group	Control	Count	28	4	32
		% Within Control	87.50%	12.50%	100.00%
		% Within Total	45.20%	80.00%	47.80%
	Intervention	Count	34	1	35
		% Within Intervention	97.10%	2.90%	100.00%
		% Within Total	54.80%	20.00%	52.20%
Total		Count	62	5	67
		% Hospitalized During Study	92.50%	7.50%	100.00%
		% Total	100.00%	100.00%	100.00%

At completion of the 12-week study, the control group had four participants (12.50%) who had been hospitalized, and the intervention group had one participant (2.90%) hospitalized during the 12-week study. Pearson's Chi-Square test was used to determine difference between the groups. There was no significant difference between intervention and control group ($\chi 2 = .13$; Fisher's exact test = .15) for number of hospitalizations at the end of the 12-week study.

Chapter Summary

Findings were obtained through parametric and nonparametric statistical analysis. Analysis of responses on the IPQ-R surveys at Time 1, Time 2, and Time 3 was done to measure the concept of perception of illness impact within the adaptation to chronic illness theoretical framework. Overall, significant findings from the final analysis showed NYHA Functional Class III participants in the intervention group had improved scores on the IPQ-R Identity Scale, Timeline Acute/Chronic, Consequences, Personal Control, and Emotional Representations

subscales. NYHA Functional Class II participants had improved scores overall regardless of treatment group on the Treatment Control and Illness Coherence subscales.

The 6MWT, NYHA Functional Class, Total Minutes Walked, and Weekly Average Steps were measures used for physiological adaptive responses. Both the intervention and control groups demonstrated improvement in distance walked on the 6MWT. The intervention group showed a greater increase in distance walked than the control group. NYHA Functional Class II participants showed no significance for improvement in functional class. NYHA Functional Class III participants in the intervention group showed improvement in functional class that was significant. Both the intervention and control groups had an increase in Total Minutes Walked that was significant. There was an increase in Weekly Average Steps for both the intervention and control groups, with the intervention group showing a greater increase over time than the control group.

The SIP was used to measure adaptive responses, physiological and psychosocial, within the adaptation to chronic illness theoretical framework. Mean scores for the SIP Total Score and SIP Psychosocial Dimension decreased over time for both treatment groups. Mean scores for the SIP Physical Dimension also decreased slightly over time. The differences between treatment groups for each measurement were not significant.

The number of hospitalizations during enrollment in the study was determined for each treatment group. There were four participants in the control group that were hospitalized during study enrollment. The intervention group had fewer hospitalizations with one participant hospitalized during the study. The difference between the intervention and control group for number of participants hospitalized while enrolled was not significant.

A review of the results of testing for each of the four hypotheses has been presented. Study findings will be discussed in detail in Chapter 5.

Chapter 5

Discussion

This randomized controlled trial examined the effectiveness of a home-based combined aerobic and resistance training exercise program for heart failure patients based on the adaptation to chronic illness theoretical framework. Sample demographics and participant attrition are discussed followed by a review of study findings. Implications of this study for the theoretical framework, clinical practice, and future research are discussed. The chapter ends with a summary of the study and findings.

Demographic Characteristics

Comparison of demographic characteristics for the control and intervention groups showed no significant difference between the two groups at baseline. Study participants were predominantly male (68.70%), Caucasian (97.00%), with high school education or higher (80.70%). Mean age for the study population was 67.61 years. There was no significant difference between the control and intervention group at baseline on classification of heart failure functional class or etiology of heart failure. Females and minorities were underrepresented in this study. Minorities were also underrepresented with 3% of participants self-identified as African American. This percentage is slightly under the reported census data for population of African Americans (4.1%) in the geographic region where this study took place (United States Census Bureau, 2012). Underrepresentation of females and minorities in the sample is a limitation of this study and limits generalizability of findings to women, non-white ethnicity, and younger patients with heart failure.

Average length of time since heart failure diagnosis was 49.13 months (SD = 45.79) in the control group and 43.54 months (SD = 39.42) months in the intervention group. There was a

wide variation in length of time since heart failure diagnosis, which is a limitation of this study. This limits generalizability of study findings to individuals with a recent diagnosis of heart failure. Further research is indicated to evaluate effects of exercise in patients who have been recently diagnosed with heart failure.

Sixty-seven (94.4%) of the 71 participants enrolled completed the 12-week study and were included in final data analysis. Attrition occurred due to non-exercise related change in health status or participant drop-out from the study. Two participants (2.82%) were removed due to change in health status that no longer met inclusion criteria. Two participants (2.82%) dropped out of the study. It is not known why the two participants dropped out of the study. These participants attended the follow-up session at Week 4, but did not return for follow-up sessions at Week 8 and Week 12. They could not be reached by phone after Week 4. One of the participants who dropped out was in the control group, and one was in the intervention group. Both of the participants removed from the study due to health reasons were in the control group.

Overall, attrition rate was low at 5.60%, which is well under the 20% attrition rate that has been reported for other home-based exercise intervention studies (Covera-Tindel, Doering, Gomez, & Dracup, 2004; Padula, Yeaw, & Mistry, 2009). This low attrition rate may have been due to the multiple face-to-face sessions and weekly telephone contact by the Principal Investigator which kept participants engaged in the study. Hwang et al. (2008) reported adherence to home-based exercise programs is facilitated by telephone follow-up and support, use of pedometers, and regular face-to-face sessions with the health care provider. The low attrition rate (5.60%) is a strength of this study.

Hypothesis #1

It was hypothesized that participants in a home-based exercise program of combined aerobic exercise and resistance training would have lower perception of illness impact than participants in the control group who received usual heart failure care. Perception of illness impact is a concept based on the adaptation to chronic illness theory (Pollock, 1993) and is the individual's perception of their degree of disability related to chronic illness. The IPQ-R measures the concept of perception of illness. Only one of the eight subscales, the IPQ-R Timeline Cyclical Subscale, showed no change in scores by time, intervention, or functional class. The IPQ-R Timeline Cyclical Subscale measures the individual's perception of changes in their symptoms and condition over time. A 12-week study may have not been long enough to experience any variations in their symptoms or condition, such as an illness exacerbation or worsening of symptoms.

On two of the IPQ-R subscales, Timeline Acute/Chronic and Emotional Representations, NYHA Functional Class III participants in the intervention group had better scores than the control group. On the IPQ-R Identity Subscale, NYHA Functional Class III participants in the intervention group reported one less symptom at Time 3 (12 weeks). Improved scores on these three subscales indicates NYHA Functional Class III participants in the intervention group: a) had fewer emotions, such as anxiety, frustration, or anger about their heart failure; b) identified fewer symptoms associated with heart failure over the 12-week study period; and c) had less perception of acute and chronic nature of their condition that would not improve.

There were two subscales of the IPQ-R, Treatment Control and Illness Coherence Subscales, on which NYHA Functional Class II scored better than NYHA Functional Class III. The IPQ-R Treatment Control Subscale measures the individual's perception of how effective

their treatment is for their chronic illness. Level of understanding of one's illness is measured by the IPQ-R Illness Coherence Subscale. A higher score on each of these subscales is desired and indicates a higher level of understanding of the individual's condition and treatment for the condition. Scores for NYHA Functional Class II participants increased over time regardless of treatment group. Participation in an exercise program may have promoted more active involvement in their health and increased understanding of their illness condition for NYHA Functional Class II participants.

In four of the eight subscales of the IPQ-R (IPQ-Identity, IPQ-R Timeline A/C, IPQ-R Consequences, and IPQ-R Emotional Representations), NYHA Functional Class III participants in the intervention group had lower scores than participants in the control group with a significant finding. Lower scores on the subscales are desired and indicate less perception of negative emotions, consequences, and fewer symptoms associated with chronic illness. For the IPQ-R Personal Control Subscale, a higher score is desired and indicates that an individual perceives higher sense of control over his/her chronic illness. Scores for NYHA Functional Class III participants on the IPQ-R Personal Control Subscale in the intervention group improved over time. In all, NYHA Functional Class III participants in the intervention group scored better on five of the eight subscales of the IPQ-R indicating a lower perception of illness impact when compared to NYHA Functional Class II participants in the control group.

On two of the IPQ-R subscales, IPQ-R Treatment Control and IPQ-R Illness Coherence, NYHA Functional Class II participants scored better than NYHA FC III participants regardless of treatment group. This finding suggests that overall NYHA Functional Class II participants had higher degree of control in their treatment and understanding of their illness than did NYHA

Functional Class III participants. There was no effect of the exercise intervention on perception of variation in illness condition and symptoms by treatment group.

Data analysis revealed that Hypothesis #1 was not supported for all participants in the intervention group. However, there was a trend toward significance that NYHA Functional Class III participants who received the combined aerobic and resistance training exercise intervention had lower perception of illness impact evidenced by improvement in scores in five of eight subscales of the IPQ-R. Improvement in scores for NYHA Functional Class II participants regardless of treatment group occurred on two subscales related to personal influence on their chronic condition. These findings suggest that NYHA Functional Class III participants in the combined aerobic and resistance training exercise intervention had decreased perception of level of disability due to their chronic heart failure. The finding that NYHA Functional Class II participants had better scores for two subscales related to perception of level of personal influence or control, rather than subscales associated with symptoms or negative outcomes, suggests that participants at a higher level of functional ability in an exercise program may gain more sense of personal influence and control of their chronic condition.

Prior works to test adaptation in chronic illness theory in different patient populations showed perception of illness impact to be related to both physiologic and psychosocial adaptation. The adaptation to chronic illness theory has been shown to describe adaptation to chronic illness in other chronic conditions, such as diabetes mellitus, rheumatoid arthritis, multiple sclerosis, and hypertension (Pollock, 1993; Whittemore & Roy, 2002). Similar to other individuals with chronic illness, heart failure patients face daily challenges for monitoring and management of their condition. How they interpret and respond to these daily challenges is important for maintenance of their heart failure. Perception of illness impact is the individual's

interpretation of the level of disability related to the chronic illness condition. Adaptation to chronic illness theory was an appropriate theoretical framework for this study to examine effects of an exercise intervention on perception of illness and adaptation in chronic heart failure. In this study, NYHA Functional Class III participants in the intervention group had lower perception of illness impact as evidenced by IPQ-R scores. Lower perception of illness impact indicates perception of a lesser degree of disability related to their chronic heart failure condition.

Hypothesis #2

The second hypothesis tested was participants in a 12-week home-based combined aerobic and resistance training exercise program would have improved physiologic adaptation based on adaptation to chronic illness theory (Pollock, 1993). Adaptation to chronic illness theory describes adaptation as a process that is both physiological and psychological. Physiological adaptation in this study was measured by: a) 6MWT at baseline (Time 1), 4 weeks (Time 2), 8 weeks (Time 3), and 12 weeks (Time 4); b) NYHA Functional Class at baseline (Time 1) and 12 weeks (Time 4); c) Total Minutes Walked each week recorded Weeks 1-12 with comparison of Week 1, Week 4, Week 8, and Week 12; and d) Average Daily Pedometer Steps with comparison of weekly average steps of Week 1, Week 4, Week 8, and Week 12. This hypothesis was partially supported as the intervention group improved more than the control group on distance walked on the 6MWT and average daily pedometer steps. Both treatment groups improved on total weekly minutes walked. There was no decline in NYHA Functional Class in either treatment group. NYHA Functional Class III participants in the intervention group had greater improvement in functional class than did NYHA Functional Class III participants in the control group.

For the 6MWT, there was an increase in distance walked in both treatment groups regardless of functional class. The intervention group increased by a mean of 56.70 meters and the control group increased by a mean of 31.13 meters, a difference of 25.57 meters between the groups. Participants in the intervention group who received the combined aerobic and resistance training program walked further distance than the control group by the end of the study. This finding suggests that resistance training may increase strength and endurance for other types of physical activity, such as walking, in heart failure patients. In one meta-analysis comparing the effects of home-based exercise intervention studies, distance walked on the 6MWT increased by an average of 41 meters more than with usual activity (Chien, Lee, Wu, Chen, & Wu, 2008). Gianuzzi, Temporelli, Corra, and Tavazzi (2003) reported distance walked on the 6MWT increased by 20% over baseline in participants who completed a homebound walking and calisthenics program combined with supervised bicycle ergometry three to five times weekly in heart failure patients. Physiologic adaptation that occurs in response to combined aerobic and resistance training exercise includes reversal of endothelial dysfunction and vasoconstriction of the peripheral skeletal muscle. Resistance training improves muscle strength and endurance as well as improves tolerance to activities of daily living (Keteyian, 20110).

Classification of NYHA Functional Class was recorded at Time 1, Time 2, Time 3, and Time 4. No participants in either group experienced decline in NYHA Functional Class in this study. Analysis of change in NYHA Functional Class was determined by analysis of classification at baseline (Time 1) and 12 weeks (Time 4). There was no significant change in functional class for NYHA Functional Class II. NYHA Functional Class II participants in both treatment groups demonstrated improvement in functional class, 11.10% in the treatment group and 5.60% in the control group. For the NYHA Functional Class III participants in the

intervention group, 41.20% demonstrated improvement in functional class by the end of the study. In the control group, 7.10% of NYHA Functional Class III improved in functional class. Improvement in NYHA Functional Class means that patients were less short of breath at a higher level of activity by the end of the study. While there was some improvement by both NYHA Functional Class II and NYHA Functional Class III in both treatment groups, NYHA Functional Class III participants in the intervention group demonstrated the most improvement in functional class.

Findings from this study suggest that a combined aerobic and resistance training exercise program may contribute to improved functional capacity with less shortness of breath with activity in heart failure patients. Coyne and Allen (1998) reported cardiac function and functional status are related. NYHA functional class is a method used to categorize levels of function based on report of symptoms and activity limitations. Improvement in functional capacity to a higher level indicates fewer symptoms associated with activity. The trend for more improvement in NYHA Functional Class III participants is consistent with findings from other research that reported more improvement following an exercise intervention in patients with lower level of exercise capacity at baseline (Hwang et al., 2008).

Participants increased overall in weekly Total Minutes Walked by the end of the study regardless of treatment group or functional class. There was a significant increase in Total Minutes Walked from Time 1 to Time 3. There was no significant increase in Total Minutes Walked from Time 3 to Time 4. It is not clear why this occurred. This finding could indicate that individuals were less motivated toward the end of the 12-week study to increase their current level of activity. The combined aerobic and resistance training exercise protocol did not change from Week 5 to Week 12. This finding suggests that a change in the exercise protocol during

Week 8 to Week 12 may have been beneficial for the intervention group. The control group also had no significant increase in Total Minutes Walked from Week 8 to Week 12. The control group did not receive any specific instructions on a walking program and did not receive any resistance training.

Analysis of average daily pedometer steps taken each week showed both intervention and control groups increased average daily steps over the 12-week study. When data were analyzed by treatment group, the intervention group improved more than the control group. NYHA Functional Class III participants in the intervention group improved more than NYHA Functional Class II participants in this group. Overall, NYHA Functional Class III had continued increase in average daily pedometer steps over the course of the study regardless of treatment group. NYHA Functional Class II participants increased average daily steps from Time 1 to Time 3, and then showed a decline in average daily steps from Time 3 to Time 4.

Little has been published on expected number steps per day specific to individuals with heart failure. In a meta-analysis of expected steps per day in special populations, mean steps per day for coronary heart disease and related disorders was 2,840 daily steps (Tudor-Locke et al., 2011). Another meta-analysis reviewed studies regarding steps/day in individuals living with chronic illness conditions including heart and vascular disease, chronic obstructive lung disease, diabetes, breast cancer, neuromuscular disease, arthritis, and disability. There was one study included in this meta-analysis that evaluated steps/day in chronic heart failure patients with reported mean of 4324.40 steps/day in this patient population (Tudor-Locke, Washington, & Hart, 2009). Mean weekly average steps/day for NYHA Functional Class II participants in this study was 5332.48 steps at Week 12, an increase of 1237.17 average daily steps from baseline (4094.83 steps/day). Mean weekly average for NYHA Functional Class III was 3143.21 steps at

Week 12, an increase of 908.94 average daily steps from baseline (2234.27 steps/day). Pedometers have been reported to be effective as short term motivational tools to increase walking to achieve step goals. Daily step goals have been shown to be more effective than a goal of increasing activity in minutes per day in healthy people (Mutrie & Lowry, 2011).

There was some decline in Total Minutes Walked from Time 3 to Time 4 for both treatment groups. A decline in Weekly Average Steps occurred for the NYHA Functional Class II participants from Time 3 to Time 4. It is unclear why this decline occurred from Time 3 to Time 4 measurements. This finding could indicate participants became bored with the exercise intervention, or no longer felt challenged by the protocol that was used at that time. This finding has implications for future research using this protocol for evaluation of an increase in exercise at Week 8 of the program. Covera-Tindel et al. (2004) recommended use of tailored exercise prescription based on individual needs to improve exercise adherence.

Hypothesis #3

The third hypothesis test in this study was that participants in the combined aerobic and resistance training exercise program would have improved psychosocial adaptation to chronic illness based on adaptation to chronic illness theory (Pollock, 1993). This theory describes adaptation as a process that has both physiological and psychosocial components. The Sickness Impact Profile (SIP) was used to measure psychosocial adaptation at baseline (Time 1), 8 weeks (Time 2), and 12 weeks (Time 3). This hypothesis was not supported as both treatment groups showed improved psychosocial adaptation evidenced by lower scores on the SIP over time.

Nonparametric tests were used to test this hypothesis due to the non-normal distribution of the variable. The Kruskal-Wallis test is a nonparametric test that is analogous to a one-way ANOVA, but is less robust and does not provide analysis of interaction of effects for between

subjects or within subjects groups (Munro, 2005). Analysis of the SIP Total Score revealed mean scores decreased over time for all study participants regardless of treatment group or functional class. Lower total scores on the SIP indicate improved adaptation to illness. This finding indicates that participation in an exercise program improves physiologic and psychosocial adaptation to chronic illness in heart failure patients.

Mean scores for the SIP Psychosocial Dimension of the SIP decreased slightly over time overall, but there was no significant difference between treatment groups. Likewise, mean scores for the Physical Dimension of the SIP decreased slightly over time with no significant difference between treatment groups. The trend of lower mean scores over time for the SIP Total Score, SIP Psychosocial Dimension, and SIP Physiologic Dimension overall suggests study participants had improved psychosocial adaptation and physiologic adaptation regardless of treatment group.

Review of individual scores to determine why the SIP variables were not normally distributed revealed scores were much lower for NYHA Functional Class II participants. Many of the NYHA Functional Class II participants had a score of zero (0.00) on various subscales of the SIP, resulting in very low scores on the SIP Total Score, SIP Physical Dimension, and SIP Psychosocial Dimension. These findings suggest the SIP questionnaire may not be sensitive enough to detect change in responses in NYHA Functional Class II heart failure patients who are at a higher functional level and are already more physically active. The SIP did appear to be an appropriate measurement tool for NYHA Functional Class III heart failure patients.

Adaptation to chronic illness involves both internal and external processes which influence physiologic adaptive responses and psychosocial adaptive responses (Whittemore & Roy, 2002). Physiologic adaptation involves not just biologic measurements, such as heart rate and blood pressure, but is also related to symptoms and response to these symptoms

(Frederickson, Jackson, Stauman, & Stauman, 1991). In further testing of adaptation to chronic illness theory as a middle range theory for patients with diabetes, Whittemore and Roy suggested: a) physiologic adaptive responses be redefined as responses or behaviors to stabilize and prevent complications from illness, and b) psychosocial adaptive responses are combined and involve integration of self-concept, role function, and interdependence into self-management roles. Riegel et al. (2011) defined self-care as a choice of behaviors to maintain physiologic stability. Self-care management in heart failure patients has been associated with fewer hospitalizations, fewer emergency room visits, and lower cardiac event risk (Lee, Moser, Lennie, & Riegel, 2009). Regular physical activity to maintain optimal health is an important aspect of self-care for heart failure patients.

Hypothesis #4

The fourth hypothesis tested was participants in the combined aerobic and resistance training intervention would have fewer hospitalizations than the control group during the 12-week study. Four participants (12.50%) in the control group were hospitalized, and one participant in the intervention group (2.90%) was hospitalized during the 12-week study. The intervention group had fewer hospitalizations with only one participant hospitalized during the study compared to four participants in the control group. This finding is consistent with multiple studies that also reported fewer hospitalizations for participants in exercise intervention programs (Gianuzzi et al., 2003; Chien et al., 2008; and Keteyian et al., 2009). This hypothesis was supported as the intervention group had fewer hospitalizations than the control group.

None of the hospitalizations in this study were exercise or study related. The four hospitalizations in the control group were all-cause and not related to worsening heart failure. Reasons for hospitalizations in the control group were: a) coronary artery disease requiring

cardiac surgery, b) cholelithiasis with laproscopic cholecystectomy, c) atrial fibrillation to obtain rate control, and d) electrolyte imbalance and dehydration from gastrointestinal viral illness. Reason for hospitalization in the intervention group was for decompensated heart failure due to dietary noncompliance during an out of town trip.

None of the hospitalizations required length of stay longer than typical length of stay for condition. With the exception of the participant who required cardiac surgery, none of the other four participants who were hospitalized were removed from the study. All four of these participants wanted to remain enrolled in the study and continue exercising.

Implications for Theoretical Framework

Findings generated from this study have important implications for further testing of the theoretical framework for the study, the adaptation to chronic illness theory (Pollock, 1993). Study findings support the usefulness of adaptation to chronic illness theory in patients with chronic heart failure. Participants in a home-based combined aerobic and resistance training intervention had improvement in perception of illness impact and physiologic and psychosocial adaptive responses. There was a trend that NYHA Functional Class III participants improved more than NYHA Functional Class II participants in the study. This finding has important implications for further testing and development of adaptation in chronic illness theory in heart failure patients with different levels of functional capacity.

Perception of illness impact was measured in this study by the IPQ-R. Findings suggest the IPQ-R is an appropriate measurement tool for use in the heart failure patient population. This tool was utilized in this study without any changes to the list of symptoms in the IPQ-R Identity subscale. The developers of the IPQ-R survey recommend using symptoms specific to the diagnosis of the patient population being tested (Moss-Morris et al., 2002). This approach

was not selected for this first-time use of the IPQ-R by this researcher. Frequency of patient selection of symptoms on the IPQ-R for this can aid with selection of symptoms for further use and development of this tool for use in heart failure patients.

The SIP has been used in multiple studies using the RAM theory (Frederickson et al., 1991). Adaptation to chronic illness theory is a middle range theory derived from the RAM. Scores for the SIP for NYHA Functional Class III participants were normally distributed and use of this measurement tool is appropriate for this patient population. Scores for the SIP for NYHA Functional Class II participants were not normally distributed with many participants having a score of zero on multiple subscales. This finding suggests the SIP is not sensitive enough to detect changes in adaptive responses in individuals who are more active and have a higher level of functional capacity.

Implications for Clinical Practice

Findings from this study suggest exercise is beneficial for heart failure patients. NYHA Functional Class III participants in the intervention group had less perception of disability related to their chronic heart failure and improved physiologic and psychosocial adaptive responses. Traditionally, heart failure patients have not been encouraged to participate in exercise programs. Multiple studies have shown that exercise is beneficial for heart failure patients with no increase in hospitalizations or adverse events (Gianuzzi et al., 2003; Chien et al., 2008; and Keteyian et al., 2009). In this study, no hospitalizations or adverse events occurred from participation in the exercise intervention.

NYHA Functional Class III participants in the intervention group showed more improvement in function to a higher level NYHA classification than did other study participants. Further research is indicated to evaluate combined aerobic and resistance training exercise

protocols for NYHA Functional Class II patients as this group is at a higher level of functional capacity at baseline and could benefit from a higher level intensity exercise program. This study did not include NYHA Functional Class I or NYHA Functional Class IV patients. Further research is needed to evaluate exercise in this patient population. Findings from randomized-controlled trials are important for clinical nursing practice to provide evidence-based nursing care and interventions for individuals with chronic heart failure.

Implications for Future Research

Findings from this study support benefits of exercise for patients with systolic heart failure. Participants in both treatment groups increased in Total Minutes Walked and Weekly Average Steps over the 12-week study. Participants reported they liked using the Omron HJ-720ITC pedometer because it was simple to use, lightweight, and did not require any re-setting by the participant. Use of the pedometer was an effective way to monitor daily steps and document adherence to the protocol. Further research is necessary to identify daily step goals appropriate for NYHA Functional Class II and NYHA Functional Class III heart failure patients. This is important information for health care professionals who care for heart failure patients to provide steps goals that will promote a level of increased physical activity that is safe for this patient population.

Further research is needed to evaluate exercise with increasing levels of intensity over a longer study period to identify exercise protocols based on functional capacity in heart failure patients. NYHA Functional Class II participants in the intervention group in this study did not show as much improvement as did NYHA Functional Class III participants. This was likely due to the low-intensity exercise program not increasing muscle strength or endurance for NYHA Functional Class II participants already at a higher level of physical function. Additionally, only

participants diagnosed with systolic heart failure were included in this study. This study did not include participants diagnosed with diastolic heart failure. This limits generalizability of study findings to only patients with systolic heart failure. Further research is indicated in this area to evaluate combined aerobic and resistance training exercise interventions for patients with diastolic heart failure.

Conclusions

In conclusion, this study examined the effects of a home-based combined aerobic and resistance training exercise intervention on perception of illness impact and physiologic and psychosocial adaptation to chronic illness. Results showed participants who received the exercise intervention had lower perception of illness impact and improved physiologic and psychosocial adaptation. NYHA Functional Class III participants in the intervention group showed the greatest improvement from the exercise intervention, and demonstrated improvement in NYHA functional classification that was significant. Both the intervention group and the control group demonstrated an increased level of physical activity and improved psychosocial adaptation. The use of pedometers was appropriate in this patient population to record daily steps taken and monitor adherence to the exercise program. Use of pedometers in future research on exercise in heart failure patients is warranted. Findings from this study demonstrate a combined aerobic and resistance training exercise intervention is safe for NYHA Functional Class II and NYHA Functional Class III patients and improves physiological and psychosocial adaptation. Future research is needed to examine effects of exercise in patients with NYHA Functional Class I and NYHA Functional Class IV heart failure and in patients with diastolic heart failure. Further research on exercise in heart failure patients will add to what is known about the effects of exercise in this patient population and provide health care professionals

caring for heart failure patients with information that is evidence-based for use in clinical practice.

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Appendices

Volunteers Wanted for

Exercise in Heart Failure Research Study

You are invited to participate in a research study

Purpose of the Study:

The purpose of the study is to evaluate the effects of a home-based exercise program in patients with heart failure.

Who is Eligible?

1. You are at least 18 years of age.
2. You have been diagnosed with heart failure and have an ejection fraction (EF) of 40% or less.
3. You have some shortness of breath with physical activity. .
4. You have not had any changes in your heart failure medications within the past 30 days.

What will you have to do to be in the study?

1. Participate in a 12-week exercise program.
2. Perform the simple exercises in the convenience of your own home.
3. Attend only three (4) sessions during the 12 weeks to meet privately with the Principal Investigator. You will complete a 6-minute Walk Test and study questionnaires during these sessions. Completion of study questionnaires will take approximately 30 minutes of your time.
4. Wear a pedometer to record the number of steps you take every day.
5. Perform low-intensity physical exercise such as walking.
6. Speak with the Principal Investigator once a week by telephone to monitor your progress and your condition.

You will NOT be asked to:

1. Have any lab work drawn for this research study.
2. Perform any high-intensity physical activity such as running.
3. Take any experimental medications for this study.

Benefits of the Study:

You may increase your physical activity as a participant in this study. Information obtained from this study will increase knowledge of effects of exercise in patients who have heart failure to help health care professionals provide care for these patients.

Compensation:

Participants will receive a $25 WalMart gift card for appreciation of participation in the study when the study is completed.

Contact Information:

If you are interested in participating in this study, please contact the Principal Investigator, Robin Harris MSN, ANP-BC by phone at 423-230-5673, or by e-mail at: rharri24@utk.edu

Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients
Physician Approval for Participant Enrollment

Patient Name _____

DOB _____

(Patient Name)_____ meets inclusion/exclusion criteria as outlined below and may be enrolled in the Effects of a Home-based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients research study.
MD Signature _____ Date _____

Inclusion/Exclusion Criteria:

Inclusion criteria for enrollment in the study are: a) participants must be at least 18 years of age, able to read and speak English; b) diagnosed with systolic heart failure with an Ejection Fraction of less than or equal to 40% confirmed by echocardiogram or cardiac MRI; c) New York Heart Association (NYHA) Functional Class II (symptoms occur with greater than usual daily activity) or NYHA Functional Class III heart failure (symptoms occur with less than usual daily activity); d) on stable heart failure medication regimen for beta blocker and ACE Inhibitor or ARB medications; e) have not required any adjustment in beta blocker, ACE Inhibitor or ARB medications in the previous 30 days; f) if known CAD and patient is stable with no higher than NYHA Functional Class I or II symptoms; and g) have approval from the primary cardiologist for enrollment in the study.

Exclusion criteria for the study includes: a) NYHA Functional Class I (no symptoms with usual daily activity); b) NYHA Functional Class IV (symptoms are present at rest); c) unstable angina; d) sustained ventricular arrhythmias requiring antiarrhythmic medications; e) 2^{nd} or 3^{rd} degree heart block without an implantable pacemaker device; f) coronary artery disease on cardiac angiogram of > 70% without coronary revascularization procedure and physically limiting angina; g) atrial arrhythmia with HR >120 bpm; h) stenotic valvular disease of greater than moderate stenosis; i) neurologic or orthopedic condition that limits physical ability to exercise; j) physical condition that limits mobility or range of motion causing inability to complete 6-Minute Walk Test or return demonstration or resistance training exercises during face-to-face session with the Principal Investigator; k) cognitive impairment that limits ability to follow instructions; and l) current enrollment in a cardiovascular rehabilitation program (Pina et al. 2003; Thompson, Gordon, & Pescatello, 2010).

ILLNESS PERCEPTION QUESTIONNAIRE (IPQ-R)

Name..... *Date*.....

YOUR VIEWS ABOUT YOUR ILLNESS

Listed below are a number of symptoms that you may or may not have experienced since your illness. Please indicate by circling *Yes* or *No*, whether you have experienced any of these symptoms since your illness, and whether you believe that these symptoms are related to your illness.

	I have experienced this symptom *since my illness*			This symptom is *related to my illness*	
Pain	**Yes**	**No**	_____	**Yes**	**No**
Sore Throat	**Yes**	**No**	_____	**Yes**	**No**
Nausea	**Yes**	**No**	_____	**Yes**	**No**
Breathlessness	**Yes**	**No**	_____	**Yes**	**No**
Weight Loss	**Yes**	**No**	_____	**Yes**	**No**
Fatigue	**Yes**	**No**	_____	**Yes**	**No**
Stiff Joints	**Yes**	**No**	_____	**Yes**	**No**
Sore Eyes	**Yes**	**No**	_____	**Yes**	**No**
Wheeziness	**Yes**	**No**	_____	**Yes**	**No**
Headaches	**Yes**	**No**	_____	**Yes**	**No**
Upset Stomach	**Yes**	**No**	_____	**Yes**	**No**
Sleep Difficulties	**Yes**	**No**	_____	**Yes**	**No**
Dizziness	**Yes**	**No**	_____	**Yes**	**No**
Loss of Strength	**Yes**	**No**	_____	**Yes**	**No**

We are interested in your own personal views of how you now see your current illness.

Please indicate how much you agree or disagree with the following statements about your illness by ticking the appropriate box.

	VIEWS ABOUT YOUR ILLNESS	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP1	My illness will last a short time					
IP2	My illness is likely to be permanent rather than temporary					
IP3	My illness will last for a long time					
IP4	This illness will pass quickly					
IP5	I expect to have this illness for the rest of my life					
IP6	My illness is a serious condition					

	VIEWS ABOUT YOUR ILLNESS	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP7	My illness has major consequences on my life					
IP8	My illness does not have much effect on my life					
IP9	My illness strongly affects the way others see me					
IP10	My illness has serious financial consequences					
IP11	My illness causes difficulties for those who are close to me					
IP12	There is a lot which I can do to control my symptoms					
IP13	What I do can determine whether my illness gets better or worse					
IP14	The course of my illness depends on me					
IP15	Nothing I do will affect my illness					
IP16	I have the power to influence my illness					
IP17	My actions will have no affect on the outcome of my illness					
IP18	My illness will improve in time					
IP19	There is very little that can be done to improve my illness					
IP20	My treatment will be effective in curing my illness					
IP21	The negative effects of my illness can be prevented (avoided) by my treatment					
IP22	My treatment can control my illness					
IP23	There is nothing which can help my condition					
IP24	The symptoms of my condition are puzzling to me					
IP25	My illness is a mystery to me					
IP26	I don't understand my illness					
IP27	My illness doesn't make any sense to me					
IP28	I have a clear picture or understanding of my condition					
IP29	The symptoms of my illness change a great deal from day to day					
IP30	My symptoms come and go in cycles					
IP31	My illness is very unpredictable					
IP32	I go through cycles in which my illness gets better and worse.					
IP33	I get depressed when I think about my illness					
IP34	When I think about my illness I get upset					
IP35	My illness makes me feel angry					
IP36	My illness does not worry me					
IP37	Having this illness makes me feel anxious					
IP38	My illness makes me feel afraid					

CAUSES OF MY ILLNESS

We are interested in what <u>you</u> consider may have been the cause of your illness. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your illness rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your illness. Please indicate how much you agree or disagree that they were causes for you by ticking the appropriate box.

	POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
C1	Stress or worry					
C2	Hereditary - it runs in my family					
C3	A Germ or virus					
C4	Diet or eating habits					
C5	Chance or bad luck					
C6	Poor medical care in my past					
C7	Pollution in the environment					
C8	My own behaviour					
C9	My mental attitude e.g. thinking about life negatively					
C10	Family problems or worries caused my illness					
C11	Overwork					
C12	My emotional state e.g. feeling down, lonely, anxious, empty					
C13	Ageing					
C14	Alcohol					
C15	Smoking					
C16	Accident or injury					
C17	My personality					
C18	Altered immunity					

In the table below, please list in rank-order the three most important factors that you now believe caused <u>YOUR illness.</u> You may use any of the items from the box above, or you may have additional ideas of your own.

The most important causes for me:-

1. _____
2. _____
3. _____

RE: 23613 - Sickness Impact Profile

Sihame Chaffai [schaffai@mapigroup.com]
Sent: Friday, September 23, 2011 12:52 PM
To: Harris, Robin Faust
Cc: Phillips, Ken
Importance: High
Attachments:SIPIN2-P-USA.doc (89 KB) ; SIPSE2-P-USA.doc (66 KB) ; scoring_sip_1.0_v1.0.pdf (308 KB)

Dear Robin,

Thank you very much for the scanned copy of your User Agreement, I safely received it. Please make sure to send the original copy via regular mail as soon as possible.

You will consequently find attached to this email the SIP versions you requested. I am also attaching the Scoring Manual for this Questionnaire.

I would be most grateful if you could please kindly confirm safe reception. Many anticipated thanks.

Please do not hesitate to get back to me should you have any question or need anything else.

Kind regards,
Sihame

Sihame CHAFFAI
Project Assistant - PRO Information Support
Not in the office on Wednesdays.

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Before printing, think about ENVIRONMENTAL responsibility

De : Harris, Robin Faust [mailto:rharri24@utk.edu]
Envoyé : mardi 20 septembre 2011 18:53
À : Sihame Chaffai
Cc : Phillips, Ken
Objet : RE: 23616 - Sickness Impact Profile
Importance : Haute

Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients

Demographic Data Sheet

Initials _____

Participant # _____

Age _____ Gender _____ Marital Status _____

Race _____

Height _____ Weight _____ BMI _____

Etiology of Heart Failure _____ Number of hospitalizations in past year_____

Ejection Fraction _____ NYHA Functional Class _____

Educational Level _____ Number of people living in home _____

Employment Status _____ Annual Income _____

Current medications:

Effects of a Home-based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients

Patient Activity Log

Week 1		Weight	Pedometer Steps	Symptoms	Activity	Minutes
	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 2	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week3	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 4	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 5	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 6	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					

Week 7		Weight	Pedometer Steps	Symptoms	Activity	Minutes
	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 8	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 9	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 10	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 11	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					
Week 12	Sunday					
	Monday					
	Tuesday					
	Wednesday					
	Thursday					
	Friday					
	Saturday					

Appendix G

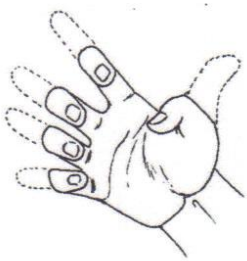
Weekly Telephone Follow-up Contact

Participant #_____ Initials_____

Week	Weights	Symptoms	Pedometer Steps	# of days walked	# of minutes	# days RT exercise
Week 1						
Week 2						
Week 3						
Week 4						
Week 5						
Week 6						
Week 7						
Week 8						
Week 9						
Week 10						
Week 11						
Week 12						

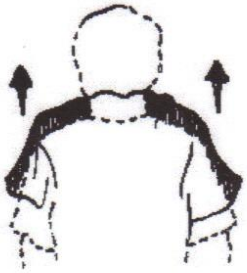
Warm-up Exercises – Seated Position

a) **Finger-Squeezes** – flexion and release of fingers on both hands (10 repetitions),



b) **Wrist Roll** – rotation of each wrist and hand in circular motion (10 repetitions),

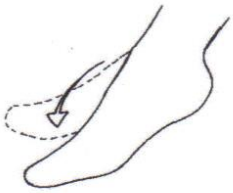
c) **Shoulder Shrug** – raising and lowering of both shoulders (10 repetitions),



d) **Head-to-side Neck Stretch** – movement of head to each side to shoulder and to front (5 seconds on each side and front)

e) **Seated Trunk-Twist** – turning at waist to each side (10 seconds on each side),

f) **Toe Points** – flexion and extension of each foot (10 repetitions)

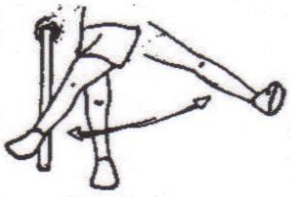


g) **Ankle Rolls** – rotation of each ankle in circular motion (10 repetitions)

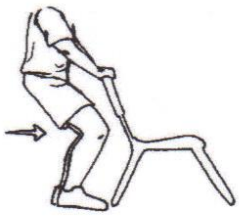
Warm-up Exercises – Standing Position

a) **Calf-Stretch** – back leg straight with front leg bent while holding on back of chair (10 repetitions each leg)

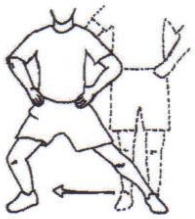
b) **Leg Swing** - while holding to chair, swing leg across front from left to right (10 repetitions each leg)



c) **Quarter Squat** – bend at knees and hold position (10 seconds)



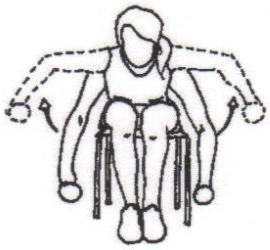
d) **Side-to-side Lunge** – feet apart at shoulder length alternating knee flexion and extension to move body side-to-side (5 repetitions each side)



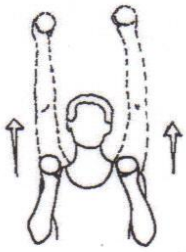
Resistance Exercises

Begin resistance exercises with 5 repetitions and increase to maximum of 10 repetitions. You may rest between exercises as often as you need.

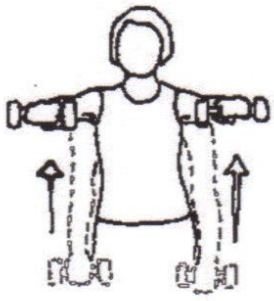
a) **Dumbbell Flys** – lean slightly forward in chair with back straight and elbows bent, lift weights to side using upper back and shoulder muscles



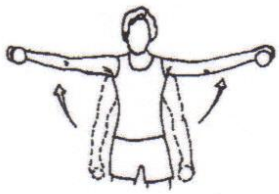
b) **Shoulder/Chest Press** – hold weights in front of shoulders and lift weights above head



c) **Front Shoulder Raises** – hold weight down to side and raise arms straight up in front of body to shoulder level

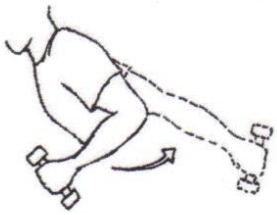


d) **Side Shoulder Raises** – hold weights down to side with palms facing body and lift arms out from side to shoulder level

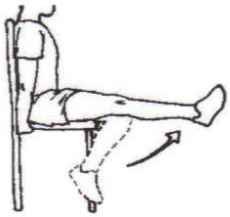


e) **Biceps Curls** – elbows slight bent and arms down to side with palms facing up lifting arms to place weight in front of shoulder

f) **Triceps Kickback** – leaning forward slightly with back straight with weights held at hip and elbow bent extend elbow with arm straight on each side

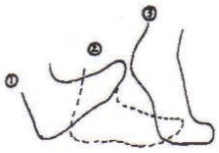


g) **Leg Extension** – while seated extend knee to straighten leg

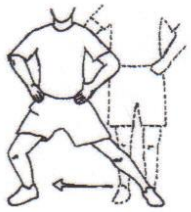


Cool Down Exercises – Standing Position

a) **Foot Rocking**- rock back and forth from heels to toes (10 repetitions),



b) **Side-to-side Lunge**- feet apart at shoulder length alternating knee flexion and extension to move body side-to-side (10 repetitions, 5 on each side)

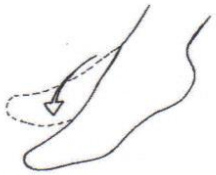


c) **Trunk-Twist** – twist from side-to-side with elbows and knees slightly bent (10 repetitions, 5 on each side)

d) **Calf-Stretch** – back leg straight with front leg bent while holding onto back of chair (10 seconds each leg)

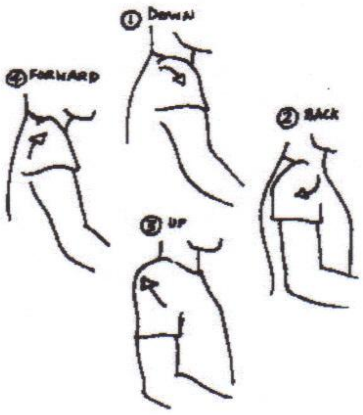
Cool-Down Exercises – Seated Position

a) **Toe Points** – flexion and extension of each foot (10 repetitions)



b) **Seated Trunk-Twist** – turning at waist to each side (10 seconds each side)

c) **Shoulder Rolls** – rotate shoulder in circular motion (10 repetitions each side),



d) **Head-to-side Neck Stretch** – movement of head to each shoulder and forward to front (5 seconds to each side and front)

d) **Deep Breathing** - (Take a deep breath in and exhale slowly) (4 repetitions)

You have completed this exercise session.

THE UNIVERSITY of TENNESSEE KNOXVILLE

DATE: October 24, 2011

Institutional Review Board
Office of Research
1534 White Avenue
Knoxville, TN 37996-1529
Phone: 865.974.3466
Fax: 865.974.7400

IRB #: 8667 B

TITLE: Effects of Exercise on Perception of Illness and Adaptation in Heart Failure Patients

Harris, Robin	Phillips, Ken
Nursing	Nursing
224 Ramey Road	1200 Volunteer Blvd.
Bristol, TN 37620	Campus - 4180

The points of clarification you submitted to this office regarding the above-captioned project, satisfied the concerns of the reviewers and the IRB thus, your project has been granted approval.

Approval is for a period ending one year from the date of this letter. Please make timely submission of renewal or prompt notification of project termination (see item #3 below).

Responsibilities of the investigator during the conduct of this project include the following:

1. To obtain prior approval from the Committee before instituting any changes in the project.
2. To retain signed consent forms from subjects for at least three years following completion of the project.
3. To submit a Form D to report changes in the project or to report termination at 12-month or less intervals.

The Committee wishes you every success in your research endeavor. This office will send you a renewal notice on the anniversary of your approval date.

Sincerely,

Brenda Lawson

Brenda Lawson
Compliances

Enclosure

DEC 2 2011

FORM D

Status for Changes and/or Project Termination for Form B Approved Research Involving Human Subjects

Research Compliance Services
Office of Research
The University of Tennessee, Knoxville
1534 White Avenue
Knoxville, TN 37996-1529

1. IRB No.: 8667 B
2. Principal Investigator: Robin Harris, PhD Student

   Department: College of Nursing
3. Mailing Address: 224 Ramey Road

   City: Bristol State: TN Zip: 37620
4. Project Title: Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients

PLEASE CHECK THE APPROPRIATE BOX(S) BELOW (see instructions on next page):

5. ☒ Change of Project Title
6. ☐ Change of Principal or Co-Principal Investigator(s), Other Collaborators, Student Advisor
7. ☒ Change(s) to Project Which Affect Participation of Human Subjects
8. ☒ Change(s) to Informed Consent Forms and/or Assent Form(s)
9. ☐ Additional Locations for Conducting Project
10. ☐ Adverse Events
11. ☐ Project Completed -- Please Close the IRB Files.

12. SIGNATURES

Principal Investigator: Robin Harris **Date:** 11-29-2011

Student Advisor: Kenneth N. Pursley **Date:** 11-30-2011

Departmental Review*: Kenneth N. Pursley **Date:** 11-30-2011
***(if required)**

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Rev. 01-19-2005

Holston Valley Medical Center
A Member of Wellmont Health System

130 West Ravine Road
Kingsport, TN 37660
423.224.4000
www.wellmont.org

DATE:	November 8, 2011
TO:	Robin Harris, MSN, ANP-BC
FROM:	Wellmont Holston Valley Medical Center Institutional Review Board FWA#: 00004221; IRB #: 00003204
STUDY TITLE:	[281684-1] Effects of Exercise on Perception of Illness and Adaptation in Heart Failure Patients
IRB REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	November 8, 2011
EXPIRATION DATE:	November 6, 2012
REVIEW TYPE:	Full Committee Review
REVIEW CATEGORY:	Expedited review category # *N/A Full Board Review*

Thank you for your submission of New Project materials for this research study. The Wellmont Holston Valley Medical Center Institutional Review Board has APPROVED your submission. No board member who is employed by *Wellmont CVA Heart Institute* participated in the vote. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Full Committee Review based on the applicable federal regulation. It is noted that this is part of a PhD dissertation program and that the University of Tennessee Institutional Review Board is the IRB of record. Per policy all submissions made to the IRB of record should be copied to the local IRB, and any correspondence from that governing IRB should be forwarded to this office. This project is being conducted under the University of Tennessee's Federal Wide Assurance number.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

Generated on IRBNet

If you have any questions, please contact Tammy Dicken at 423-224-3313 or tammy.dicken@wellmont.org. Please include your study title and reference number in all correspondence with this office.

cc:

Generated on IRBNet

Holston Valley Medical Center
A Member of Wellmont Health System

130 West Ravine Road
Kingsport, TN 37660
423.224.4000
www.wellmont.org

DATE: January 11, 2012

TO: Robin Harris, MSN, ANP-BC
FROM: Wellmont Holston Valley Medical Center Institutional Review Board
FWA#: 00004221; IRB #: 00003204

STUDY TITLE: [281684-2] Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients
IRB REFERENCE #:
SUBMISSION TYPE: Amendment/Modification

ACTION: ACKNOWLEDGED
EFFECTIVE DATE: January 10, 2012

Thank you for submitting the Amendment/Modification materials for the above research study. The Wellmont Holston Valley Medical Center Institutional Review Board has ACKNOWLEDGED your submission. No further action on submission 281684-2 is required at this time.

The following items are acknowledged in this submission:

- Amendment/Modification - Form D_Consent form revision approved by UT's IRB_7Dec11 (UPDATED: 12/21/2011)

Because the UT IRB is the IRB of record for this study, and we are providing courtesy oversight only this item was reviewed as a non voting item. Thank you for keeping us apprised of the events related to your project. We wish you much success with your endeavors!

If you have any questions, please contact Tammy Dicken at 423-224-3313 or tammy.dicken@wellmont.org. Please include your study title and reference number in all correspondence with this office.

Generated on IRBNet

KINGSPORT
The Heart Center
2050 MeadowView Parkway
Kingsport, TN 37660
Ph: (423) 230-5000
OR 1-800-322-4124
Fax: (423) 230-5010

BRISTOL
Bristol Regional Medical Center
One Medical Park Blvd
STE 458-W
Bristol, TN 37620
Ph: (423) 844-4975
OR 1-800-741-6129
Fax: (423) 844-4987

NORTON
295 Wharton Lane
Norton, VA 24273
Ph: (276) 679-6493
Fax: (276) 679-9498

Wellmont CVA Heart Institute

www.mycva.com

ABINGDON
24530 Falcon Place Blvd.
Suite 101
Abingdon, VA 24211
Ph: (276) 739-0067
Fax: (276) 739-0069

JOHNSON CITY
Lifestyle Center
316 Marketplace Blvd.
Suite 20
Johnson City, TN 37604
Ph: (423) 232-0500
Fax: (423) 230-5176

GREENEVILLE
438 East Vann Rd,Suite 201
Greeneville, TN 37743
Ph: (423) 278-1825
Fax: (423) 278-1805

August 05, 2011

Facilities for Your Research : "Effects of a Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients"

I understand that you will be serving as the principle investigator for this research.

In my role as President of the Wellmont CVA Heart Institute, you have permission to enroll patients from our facility into your research study. I am honored to grant this request on behalf of our institute and appreciate all of your efforts to ensure the safety and quality care that our patients deserve.

Please let me know if you need additional information, and congratulations on your work.

Sincerely yours,

Gerald G. Blackwell, MD, FACC

GGB/sc D:08/05/11 T: 08/05/11

Appendix H

Informed Consent Form

INFORMED CONSENT STATEMENT

Effects of Home-Based Exercise Program on Perception of Illness and Adaptation in Heart Failure Patients

Principal Investigator: Robin Harris MSN, ANP-BC

Site: Wellmont Cardiovascular Associates (CVA) Heart Institute, The Heart Center
2050 Meadowview Parkway
Kingsport, TN 37660
Telephone: 423-230-5673 or 423-230-5666 (Monday through Friday, 8 AM – 5PM)
423-224-4000 (Through the hospital paging operator nights, weekends, & holidays).

INTRODUCTION

You are invited to participate in a research study on exercise in heart failure patients. The purpose of this study is to evaluate the effects of exercise in patients who have been diagnosed with heart failure.

INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

You decide if you want to be in the study. You may stop the study at any time. If you decide you want to be in the study, you will be asked to sign forms to give your permission to be in the study. You will be randomly assigned into one of two groups for this exercise study. At the first session with the Principal Investigator, you will receive patient education on heart failure that includes information about this diagnosis and what you can to do take care of yourself to prevent your heart failure symptoms from becoming worse. You will be given exercise instruction and begin the exercise intervention based on the study group you have been assigned to. You will be asked to wear a pedometer, a device that can count the number of steps you take each day. An activity log sheet will be given to you to record your total number of steps per day from the pedometer, your daily weight, and any symptoms you may have had during the day. Additional information that will be collected at the first session and recorded include your age, gender, ethnic background, educational level, income, marital status, number of people living in the home, number of hospitalizations you have had for heart failure in the previous 12 months, and list of medications you take every day. You will be asked to attend four (4) one hour face-to-face sessions with the Principal Investigator to collect data at the time of enrollment in the study (baseline), at 4 weeks after enrollment in the study, 8 weeks after enrollment in the study, and again at 12 weeks after enrollment. Face-to-face sessions with the Principal Investigator will be held at Wellmont CVA Heart Institute, The Heart Center, 2050 Meadowview Parkway, Kingsport, TN, 37660. At each face-to-face session you will be asked to complete a 6-minute

_____Participant Initials

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Walk Test and study questionnaires. Follow-up telephone interviews will be conducted each week by the Principal Investigator to monitor your progress and condition during the 12-week study.

RISKS

You could develop symptoms during or after exercise from increased heart muscle activity such as: 1) chest pain, 2) increased shortness of breath, 3) feeling dizzy or lightheaded, 4) feeling a fast or skipping heart beat, or 5) increased swelling in feet, legs, or abdomen. Appropriate medical care and follow-up will not be delayed to any participant in this study who has symptoms with exercise and needs medical evaluation. Privacy and confidentiality of private health information will be maintained in compliance with HIPAA regulations.

BENEFITS

You may increase your physical activity as a participant in this study. Information obtained from this study will increase knowledge of effects of exercise in patients who have heart failure to help health care professionals provide care for these patients.

ALTERNATIVE TREATMENT

If you decide not to participate in this study, your care will not be affected. Medical management of symptoms and clinical conditions will continue. Referral to cardiac exercise rehabilitation programs is available. The Principal Investigator will discuss these with you.

COMPENSATION

You will receive a $25 Wal-Mart gift card in appreciation of your participation in this study at the time of study completion.

CONFIDENTIALITY

The information in the study records will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could connect you to the study. Only the Principal Investigator will have access to any of your data that could identify you as an individual involved in this research study.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "protected health information" or PHI). PHI collected in this study may include information about your health and your cardiac history including your diagnosis and diagnostic studies to confirm the diagnosis as well as basic demographic information. By signing this consent form, you are authorizing the research team at the University of Tennessee to have access to your PHI collected in this study obtained through

_____Participant Initials

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electronic medical record through Wellmont Holston Valley Medical Center and to receive your PHI from your physician(s) at Wellmont Cardiology Services/Wellmont CVA Heart Institute. In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including researchers at Wellmont Holston Valley Medical Center. The Institutional Review Board (IRB) at the University of Tennessee may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. You PHI will be used only for the research purposes described in this consent form. Your PHI will be used until the study is completed.

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study.

EMERGENCY MEDICAL TREATMENT

The University of Tennessee does not "automatically" reimburse subjects for medical claims or other compensation. If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge (Robin Harris MSN, ANP-BC phone# 423-230-5673). Neither Wellmont CVA Heart Institute, the Principal Investigator, or the University of Tennessee have arranged to pay for costs of injuries or the expenses of treatment of injuries resulting from your participation in the research study. You understand that financial compensation for lost wages, disability, discomfort, or similar damages from injuries that result from your participation in the research study is typically not available.

CONTACT INFORMATION

If you have questions at any time about the study or the procedures, or you experience adverse effects as a result of participating in this study, you may contact the researcher, Robin Harris MSN, ANP-BC, at The Heart Center, 2050 Meadowview Parkway, Kingsport, TN 37660, at phone # 423-230-5666, or by e-mail at rharri24@utk.edu. If you have questions about your rights as a participant, contact the IRB Administrator at the University of Tennessee Office of Research at (865) 974-3466 or blawson@utk.edu

PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty.
_____Participant Initials

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If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study, data gathered to that point will be retained for analysis to the extent necessary for completing the research.

_____Participant Initials

CONSENT

I have read this consent and authorization form (or it has been read to me). All my questions about the study and my part in it have been answered.

I authorize the use and disclosure of my health information to the parties listed in the confidentiality section of this consent for the purposes described.

I have received a copy of this form. I agree to participate in this study.

By signing this consent form, I have not given up any of my legal rights.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

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Vitae

Robin F. Harris was born and raised in Kingsport, TN. She attended East Tennessee State University, where she received her Bachelor of Science in Nursing degree. She attended the University of Virginia and completed a Master's of Science in Nursing degree. She received a Post-Master's Certificate in Adult Health Nursing from the University of Tennessee, Knoxville. She holds national certification as a Clinical Nurse Specialist and Nurse Practitioner in Adult Health Nursing. Currently, Robin is a PhD candidate at the University of Tennessee, Knoxville and will complete degree requirements in 2012. She has worked with patients with cardiovascular disease for many years and has special interest in care of patients with heart failure.