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## The Effect of Supportive Education, as a Tertiary Nursing Intervention, on the Quality of Life of Patients with Heart Failure

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**The Effect of Supportive Education, As A Tertiary  
Nursing Intervention, On The Quality Of Life  
Of Patients with Heart Failure**

**By**

**Julie A. Switek**

**A THESIS**

**Submitted to  
Grand Valley State University  
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## **ABSTRACT**

### **THE EFFECT OF SUPPORTIVE EDUCATION, AS A TERTIARY NURSING INTERVENTION, ON THE QUALITY OF LIFE OF PATIENTS WITH HEART FAILURE**

**By**

**Julie A. Switek**

**Quality of life in patients with heart failure is poor. The purpose of this study was to examine the impact of a supportive educational nursing intervention on quality of life. The quality of life of two groups of patients with heart failure were compared, the control group that received placebo interventions and the experimental group that received a supportive educational intervention. The instrument utilized in this study was the Ferrans and Powers Quality of Life Index: Cardiac Version III. Betty Neuman's systems model was the theoretical framework that guided this research. Independent and paired T-tests were utilized to analyze the data. Findings included a significant increase in the quality of life scores for the supportive educational group occurring at the 6-month time period.**

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## CHAPTER 1

### INTRODUCTION

Heart failure represents a major health problem for the United States. It is the nation's most rapidly growing cardiovascular disorder in the United States and is increasing in incidence, prevalence, and mortality (Funk & Krumholz, 1996). As mortality decreases from coronary artery disease, and more people are saved from premature death, the prevalence of heart failure will continue to increase. According to the American Heart Association Heart and Stroke 2000 Statistical Update, heart failure affects an estimated 4.7 million Americans, with 550,000 new cases occurring annually (American Heart Association, [AHA], 2000). Heart failure is not only a problem in the United States, but is also prevalent in Canada, western Europe, and Japan. Combined with the United States, the estimated number of people with heart failure exceeds ten million (Funk & Krumholz, 1996).

The economic impact of heart failure is staggering. In 1979, there were approximately 337,000 hospital discharges annually from congestive heart failure. Currently there are approximately 978,000 heart failure hospital discharges annually. The cost of heart failure is approximately \$19.4 billion dollars - \$14.3 billion due to hospital nursing home costs, \$1.5 billion in physician costs, \$1.6 billion in drugs and other medical durable costs, and \$2.0 billion in home health care (AHA, 2000). Not only are

costs associated with heart failure high, so are the mortality rates. From 1979 to 1998, congestive heart failure deaths increased 135 percent. The 5-year mortality rate for heart failure is about 50 percent (AHA, 2000). According to the Framingham Study (Ho, Pinsky, Kannel, & Levy, 1993), these mortality rates are four to eight times those of the general population of the same age. Heart failure is associated with a shorter life expectancy than that of many common types of cancer.

Successful management of heart failure is important in the long-term outlook of healthcare. It weighs heavily on society with its high cost for treatment, high mortality, marked disability, and subsequent lack of productivity of people with the disease. Development and assessment of new therapeutic interventions have become a major area of research for heart failure in order to keep patients out of the hospital and to decrease mortality and morbidity.

Heart failure research has focused on understanding the pathophysiology and risk factors associated with heart failure, medical management interventions such as diet and medication use, and surgical management interventions such as transplantation and ventricular assist devices (Dracup et al., 1994; Rector & Cohn, 1992; Rogers et al., 1994). Other research studies have centered on issues related to self-care, home care, symptom management, and interventions to assist in keeping patients out of the hospital (Fonarow et al., 1997; Rich et al., 1995; Shah, Der, Ruggerio, Heidenreich, & Massie, 1998; Stewart et al., 1989).

These rapid advances in the treatment of heart failure during the 1980s and 1990s have been accompanied by a growing interest in health-related quality of life issues. According to Dracup et al. (1994), the impact of heart failure on a patient's life may be

related as much to psychological adaptation to the disease as to impairment in physical functioning. Data from the Studies of Left Ventricular Dysfunction indicate that quality of life is a significant, independent predictor of mortality and heart failure related hospitalizations (Freedland & Carney, 2000).

The Agency for Health Care Policy and Research Clinical Practice Guideline entitled “Heart Failure: Evaluation and Care of Patients with Left-Ventricular Systolic Dysfunction” (1994), recommends that providers assess patients’ health-related quality of life including symptoms, physical functioning, and mental health. This information needs to modify treatment and guide patient and family teaching to facilitate adaptation to heart failure. Nursing can play a major role in implementing these guidelines and strategies that help patients to live with heart failure and improve their quality of life.

Numerous nursing researchers have studied quality of life issues related to heart failure (Dracup, Walden, Stevenson, & Brecht, 1992; Grady, 1993; Grady et al., 1995; Hawthorne & Hixon, 1994; Jaarsma et al., 2000; Martensson, Karlsson, & Fridlund, 1997, 1998; Scott, 2000; Shively, Fox, & Brass-Mynderse, 1996). The majority of these studies examined quality of life measurement instruments and measured quality of life related to symptoms and functional status. A few of these studies implemented strategies in order to improve quality of life.

Grady (1993) examined the definition of quality of life related to patients with heart failure and found that health, physical function, psychological function, and social interactions are the four common dimensions that play a role in these patients’ perceptions of their quality of life. Dracup et al. (1992) designed a study to measure quality of life in patients with advanced heart failure waiting for transplantation.

Martensson et al. (1997, 1998) studied male and female patients with heart failure and how they conceptualized their life situation. Hawthorne and Hixon (1994) examined the effects of a nursing model upon reducing readmission rates and improving quality of care. Jaarsma et al. (2000) studied the effects of a supportive education nursing intervention on self-care abilities, self-care behaviors, and quality of life of patients with advanced heart failure. Scott (2000) studied heart failure patients receiving home inotropic infusions and how the caregiver and patient were affected. Rich et al. (1995) conducted a study utilizing an intervention that consisted of comprehensive education of the patient and family, a prescribed diet, social-service consultation, early discharge planning, review of medications, and intensive follow-up. These studies indicate that health care providers have the ability to recognize the variables that influence quality of life, identify patients at risk for poor quality of life, and assist patients to achieve the highest quality of life possible within the constraints of their disease. Any intervention, no matter how minimal, may have a beneficial effect on patients with heart failure.

#### Problem Statement

Many of the quality of life studies that specifically studied heart failure patients (Dracup et al., 1992; Grady, 1993; Grady et al., 1994; Hawthorne & Hixon, 1994; Scott, 2000) found that these patients described their quality of life as poor. According to Dracup et al. (1992) and Hawthorne and Hixon (1994) interventions to improve quality of life need to be targeted toward reducing depression and hostility, increasing daily activity levels, improving knowledge of heart failure, and learning self-care skills. Resources are spent on technological advances with a goal of prolonging life, decreasing hospitalizations, along with decreasing morbidity and mortality. All of these are

important, but resources also need to be spent not only on increasing life span but on increasing quality of life, which can be affected by a patient's condition or treatment, or both. Research needs to test interventions that focus on increasing quality of life.

Nursing interventions need to be studied as well as medical interventions.

Informing and educating the heart failure patient about heart failure treatment and its consequences was associated with improved quality of life and a higher overall feeling of well-being (Jaarsma et al., 2000). According to Jaarsma et al., this was achieved through increasing self-care abilities and improving self-care behavior by educating the patient with heart failure. The purpose of this study was to examine the impact of a supportive educational nursing intervention on quality of life.

## CHAPTER 2

### CONCEPTUAL FRAMEWORK AND LITERATURE REVIEW

#### Conceptual Framework

The conceptual framework that guides this research is Betty Neuman's systems model. The Neuman systems model is based on two major components – stress and reaction to stress. The Neuman systems model has four important nursing concepts – client/client system, environment, health, and nursing (Neuman & Fawcett, 2002).

#### Client

According to the Neuman systems model, the client is viewed as an open, holistic system, continuously interacting and relating with the environment. The client is composed of physiologic, psychological, sociocultural, developmental, and spiritual variables. These five variables interact and function together in order to protect the client from internal and external stressors. Stressors are defined as “tension-producing stimuli with the potential for causing system instability” (Neuman & Fawcett, 2002, p. 21).

In a healthy person, the five client variables function in harmony and remain stable in relation to stressors. In an ill person, the five client variables become unstable in relation to stressors. The patient with heart failure can illustrate how this instability occurs. Heart failure is a “clinical syndrome or condition characterized by (1) signs and symptoms of intravascular and interstitial volume overload, including shortness of breath, rales, and edema, or (2) manifestations of inadequate perfusion, such as fatigue or poor exercise tolerance” (AHCPR Quick Reference Guide for Clinicians, No. 11, p.1).

Heart failure is a disease state that can prevent the client variables from maintaining stability. Heart failure symptoms such as dyspnea, edema, fatigue, exercise

intolerance, and sleeplessness are examples of physiologic variables that could cause client instability. Fear, anxiety, depression, and memory loss are examples of psychological variables that could cause client instability.

The perception of an illness and how it affects the client's life is influenced by the client's cultural and socioeconomic background, the sociocultural variable. Role loss within the family may occur with heart failure due to the client's inability to continue to work and support the family. Lifestyle changes are very important in decreasing the symptoms of heart failure. Other related social issues such as inadequate finances to purchase medications, lack of transportation to appointments, or lack of a safe place to exercise can also affect the client negatively. Difficulty coping with these issues may cause instability within the client's sociocultural variable.

The client's developmental variable is related to the developmental stage of the client, and how the client reacts to change, or how the client may deal with loss of independence. Heart failure is a disease that mainly affects the older adult. Because the disease can be disabling with multiple lifestyle changes, the client may need assistance with things that they have never needed help with before. The client can lose independence and can feel like a burden on family and friends, therefore causing instability within the developmental variable of the client.

The spiritual variable is the client's spiritual beliefs and influences. With heart failure having a high mortality rate, an important spiritual issue may be the heart failure client's belief regarding death and dying, and end of life issues. If the client has a fear of dying, this could be one way that heart failure can cause instability within the spiritual variable of the client.



## Environment

The environment is defined as all the internal and external factors or influences surrounding the client. According to the Neuman systems model, there are two protective mechanisms that enhance and maintain the integrity of the client within the environment: the normal line of defense and the flexible line of defense (Neuman & Fawcett, 2002). The basic structure or client is the central core of Neuman's model and concentric circles called the lines of defense and lines of resistance surround it (see Figure 1). As the client encounters stress over time, a normal range of responses to the environment develops. These responses represent the normal line of defense, which is the client's current or usual wellness/stability state. The flexible line of defense protects the client from immediate or short-term stressors, therefore protecting the normal line of defense. The flexible line of defense prevents stressors from invading the client system. If the lines of defense are unable to protect the client against a particular stressor, then a reaction occurs. A reaction then presents with client instability.

The patient with heart failure can encounter instability within all five of Neuman's variables. Instability of any of these entire variables can negatively affect the patient. Heart failure can be a stressor and break down the lines of defense. If the patient with heart failure is unable to protect themselves, a reaction can occur. This reaction could manifest itself as a perceived decrease in quality of life. Quality of life can be defined as "a person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her" (Ferrans & Powers, 1992, p. 29).

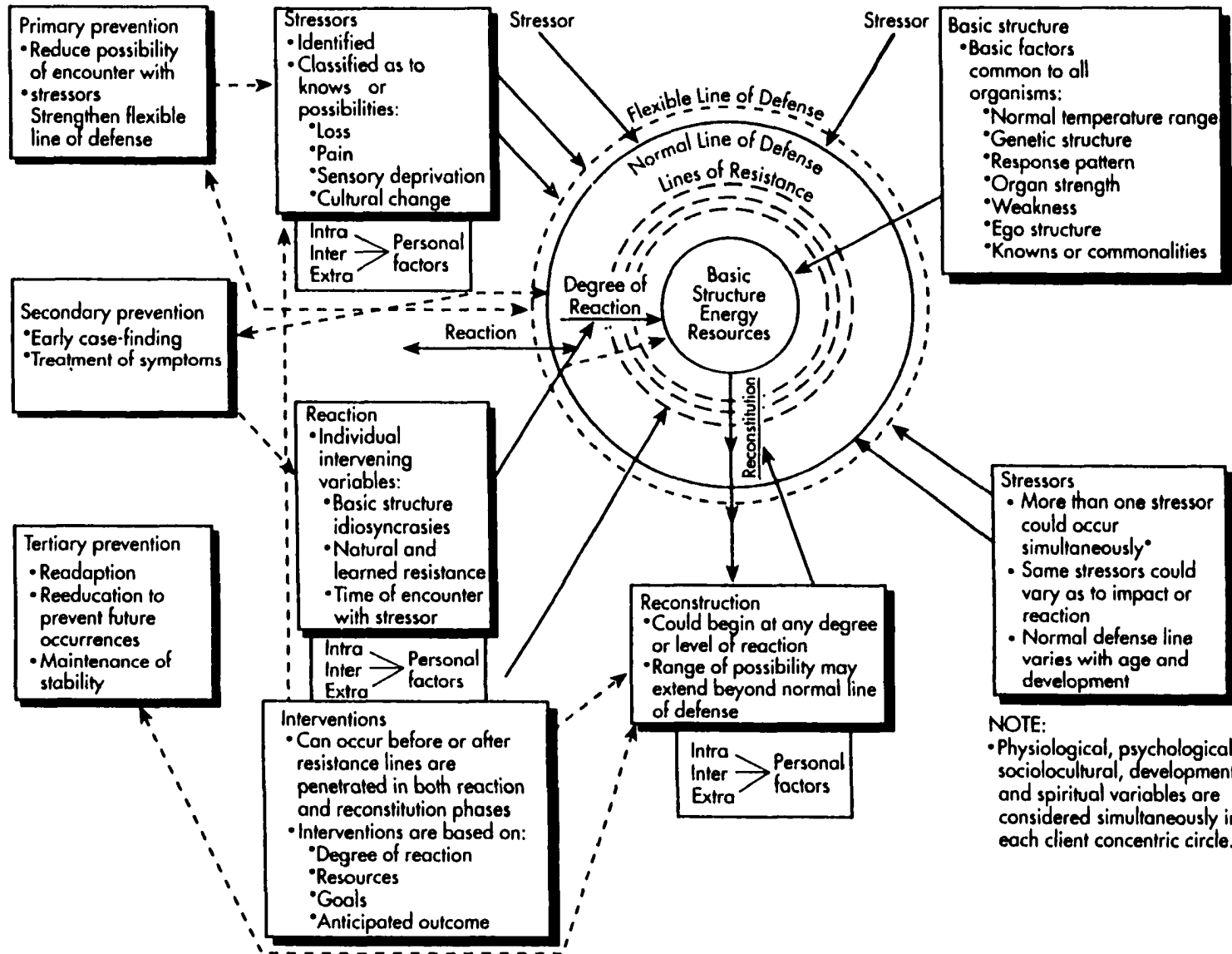


Figure 1. The Neuman Systems Model: Neuman, B. & Fawcett, J. (2002). *The Neuman Systems Model* (4<sup>th</sup> ed.). Upper Saddle River, NJ: Prentice Hall. Reprinted with permission (see Appendix A).

## Health

Health or wellness is defined as the “condition or the degree of system stability, in which all parts or subparts (variables) are in balance or harmony with the whole of the client or client system” (Neuman & Fawcett, 2002, p. 12). Wellness and illness can be placed on opposite ends of a continuum, with health being the best possible wellness state at any given time, the state of optimal well-being. Neuman views health as “a manifestation of living energy available to preserve and enhance system integrity” (p. 23). When the client variables become unstable due to a stressor such as heart failure, the stressor is then able to penetrate the lines of defense and a reaction occurs. When this reaction occurs, it is important for the client to return to an optimal wellness level. Quality of life is one important aspect of optimal wellness for the client with heart failure, particularly with the increasing ability to prolong life due to technological advances. These technologic advances may negatively affect the client’s quality of life.

## Nursing

The main focus of nursing is to keep the client system stable. Nursing is the link between the client, the environment, and health. Nursing actions and/or interventions are instituted in order to retain, attain, or maintain optimal client health. Primary, secondary, and tertiary prevention are nursing interventions to assist in achieving optimal health, according to the Neuman systems model (Neuman & Fawcett, 2002). Interventions are based on possible or actual degree of reaction, resources, goals, and anticipated outcomes. Interventions should be started when a stressor is either suspected or identified. In order for nurses to stabilize the client and assist in reconstitution, primary, secondary, and tertiary interventions are required.

Primary, secondary, and tertiary interventions. Primary prevention is carried out as a stressor or potential stressor is suspected or identified but a reaction has not yet occurred. The primary prevention goal would be to retain heart function and strengthen the flexible line of defense in order to decrease the risk of heart failure and enhance heart function. Since heart failure is an end result of other diseases such as coronary artery disease and hypertension, examples of primary prevention in relation to heart failure would include interventions to prevent these diseases. These interventions include following a low fat diet, daily exercising, and enrolling in a weight loss or smoking cessation program, in order to prevent heart disease.

Secondary prevention involves interventions or treatment after symptoms of stress have occurred. Secondary prevention is the active treatment of actual stressors. Secondary prevention could be hospitalization for treatment of heart failure symptoms. These symptoms may be treated with pharmacological interventions, surgical interventions, or lifestyle changes, such as diet and activity.

Tertiary prevention focuses on readjustment toward optimal client system stability after active treatment or secondary prevention has occurred. Tertiary prevention assists in reconstitution. Reconstitution is the state of adaptation to stressors in the internal and external environment (Neuman & Fawcett, 2002). Tertiary prevention would focus on re-education of the heart failure patient to help prevent recurrence of heart failure symptoms. Tertiary prevention leads back to primary prevention, in that the goal is to again strengthen the lines of defense, so that a reaction does not occur again.

An example of tertiary prevention is the nursing care provided in the home through a home care agency after a heart failure patient is newly diagnosed or after the

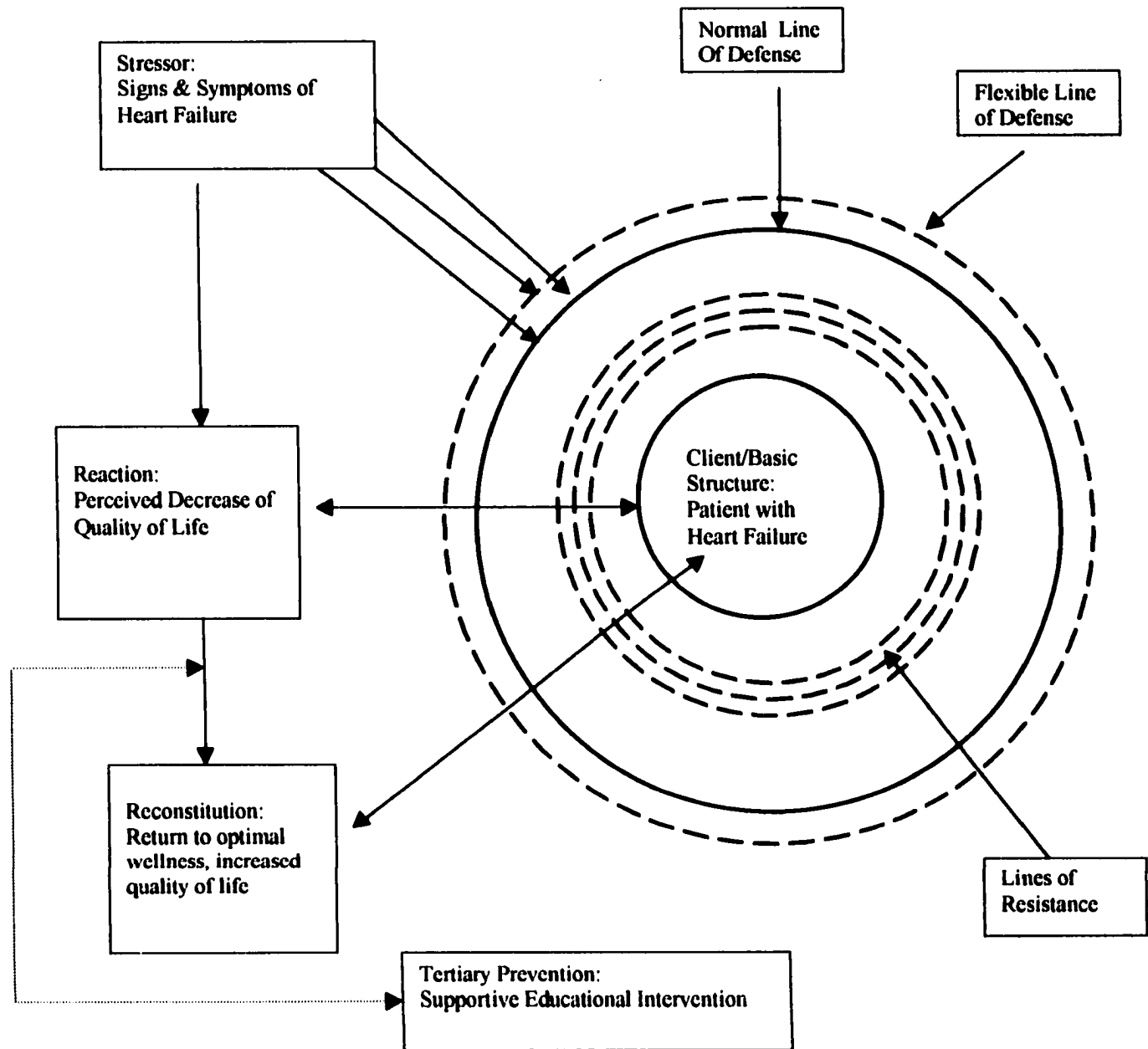
patient has recently been discharged from the hospital. Home care can assist in providing support and education related to the patient's disease state. As the patient's variables start to interact in a more positive manner due to tertiary prevention, the patient becomes more stable. This stability should decrease symptoms and increase the patients' perception of quality of life, thereby allowing reconstitution to occur.

### Variables

Important concepts from Neuman's systems model that relate to the study variables of this research are client, stressor, reaction, tertiary prevention, and reconstitution (see Figure 2). The client is the patient with heart failure with five variables interacting together to maintain stability. As heart failure and its characteristics become a stressor, this causes instability of the five client variables. This stressor, heart failure, breaks down the lines of defense causing a reaction, which is decreased quality of life. When a reaction occurs, nurses need to apply a tertiary prevention intervention, in order to reeducate the patient to prevent future occurrences and to attain optimal wellness. An example of tertiary prevention is a supportive educational intervention in the patient's home. Reconstitution occurs as tertiary prevention reduces further stress reaction by increasing the patient's quality of life.

### Review of Literature

The major concepts of this study are quality of life and heart failure, and how they relate to each other. In the literature, the terms quality of life (QOL) and health related quality of life (HRQOL) are frequently used interchangeably. For the purpose of this research, health-related quality of life and quality of life will be considered the same concept.



**Figure 2. The Concepts of the Neuman Systems Model Related to Quality of Life in the Patient With Heart Failure**

## Quality of Life Research

Quality of life research is not a new research subject. According to Kinney, Burfitt, Stullenbaarger, Rees, and DeBolt (1996), publications with quality of life in their title increased from 200 in 1980, to 2100 in 1994. Testa and Simonson (1996) referenced “quality of life” as the key words in 5 articles from the Medline data base in 1973. In 1994, the same authors were able to reference 1252 articles with the key word “quality of life.”

There are many issues surrounding quality of life research. One of these issues is that there is not a consensus on the conceptualization or the definition of quality of life. Quality of life conceptualizations and definitions are numerous and multidimensional. Another issue is that there is not a consensus on how to measure quality of life. There are multiple instruments that measure different definitions of quality of life. Therefore, these two issues make it difficult to compare results across studies.

Testa and Simonson (1996) conceptualize quality of life and health related quality of life as the physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person’s experiences, beliefs, expectations and perceptions. Keister and Blixen (1998) conceptualize quality of life as an “elusive phenomenon,” encompassing biological, interpersonal, social, economic, and cultural dimensions. Farquhar (1995) developed a taxonomy of quality of life definitions – global definitions, component definitions, focused definitions, and combination definitions. The ability to develop a taxonomy shows the complexity and difficulty in the utilization of the term quality of life.

Ferrans has published multiple articles on quality of life related to chronic illnesses such as cancer, renal failure, and heart failure (1990, 1992). She has also developed the Quality of Life Index instrument. Ferrans groups the definition of “quality of life” into five categories: normal life, happiness/satisfaction, achievement of personal goals, social utility, and natural capacity. Ferrans also lists examples of various dimensions frequently used to measure quality of life. They are health and physical functioning, psychological/spiritual variables, social/economic variables, and family.

The use of multiple measures of quality of life presents with problems. According to Kinney (1995), use of different and multiple instruments do not allow comparison of results across studies and these measures seldom undergo psychometric evaluation. In the measurement of quality of life, researchers use study-specific measures in order to capture the outcomes of the specific study, not allowing for comparison of results. Kinney reviewed 84 descriptive studies and 84 experimental studies in her meta-analysis of quality of life publications and discovered that 75% of the descriptive studies and 71% of the experimental studies failed to address the issues of validity, reliability and sensitivity.

The measurement and evaluation of quality of life has become increasingly important in health care practice, research, and social policies. As advances in care and technology continue, quality of life measurement can assist in decisions about treatment by evaluating the benefits and costs of these new interventions. This is important particularly in a disease such as heart failure, with its high morbidity and mortality, and escalation of new cases. It is apparent that quality of life is an important clinical outcome when measuring health outcomes. The Agency for Health Care Policy and Research



(AHCPR) determined that the number one recommendation related for research of health outcomes is the need to reduce mortality and improve quality of life (Hadorn, Baker, Dracup, & Pitt, 1994). The Heart Failure Guideline Panel, sponsored by the AHCPR, decided that relevant outcomes are those experienced directly by patients, such as mortality and quality of life, and that evaluating changes in only biochemical, physiological, anatomical, or histological outcomes were insufficient (Hadorn et al., 1994).

### Descriptive Research Involving Quality of Life and Heart Failure

There are numerous studies with the key words of heart failure and quality of life (Chin & Goldman, 1998; Cline, Willenheimer, Erhardt, Wiklund, & Israelsson, 1999; Dracup, Walden, Stevenson, & Brecht, 1992; Grady, 1993; Jaagosild et al., 1998; Kinney, 1995; Kinney, et al. 1996; Leidy, Rents, & Zycynski, 1999; Moser & Worster, 2000; Muirhead et al., 1992; Riedinger et al., 2001; Shively, Fox, & Brass-Mynderse, 1996; Van Jaarsveld, Sanderman, Miedema, Ranchor, and Kempen, 2001; Walden et al., 1994). Six of these publications analyzed multiple studies of quality of life and heart failure. Ferrans (1992) examined 22 studies on the conceptualization of quality of life in patients with cardiovascular disorders. Grady (1993) likewise examined the definition of quality of life, conceptual frameworks, and commonly used measurement instruments and outcomes in medically and surgically managed patients with heart failure. Kinney et al. (1996) analyzed 84 studies of quality of life in cardiac patients published during the periods of 1987 and 1991. Shively et al. (1996) too reviewed eight studies measuring health-related quality of life in medically managed heart failure patients. Leidy et al. (1999) also examined outcomes of 46 studies that involved randomized, controlled

treatment trials of heart failure. Moser and Worster (2000) reviewed five studies linking psychosocial variables to morbidity and mortality outcomes in patients with heart failure.

After review of these studies, Ferrans (1992), Grady (1993), Kinney et al. (1996), Shively et al. (1996), and Leidy et al. (1999) discovered similar issues and findings within quality of life descriptions and heart failure. All five articles discuss the need for quality of life to be defined and conceptualized as it relates to heart failure, since it has become a common focus of research. Three of the four studies, Kinney et al., Grady, and Leidy et al. found that there were small positive effects of treatment on quality of life, in regards to symptomology, functional ability and overall quality of life. Most of the studies found that the primary domain affected by treatment or symptoms is the performance of activities of daily living (ADLs). The authors of these studies agree that more critical analysis of the approach to research related to quality of life in cardiac patients is needed. Two of the studies, Kinney et al. and Leidy et al., suggest more studies need to be done on family member's perspective or health care provider to supplement the evaluation of quality of life.

Four recent studies (Cline et al., 1999; Dracup et al., 1992; Muirhead et al., 1992; Walden et al., 1994) assessed the heart failure patient's quality of life using various measures and subjects. Dracup et al. measured the quality of life of 134 patients with symptoms of advanced heart failure being evaluated for a possible heart transplant and measured three dimensions of quality of life, which were functional capabilities, symptoms, and psychosocial perceptions. Instruments utilized to measure functional capabilities were the Heart Failure Functional Status Inventory (HFFSI) and the six-minute walk. Instruments utilized to measure psychosocial perceptions were the Multiple

Affect Adjective Checklist (MAACL) and the Psychosocial Adaptation to Illness Scale (PAIS). Instruments utilized to measure symptoms were the New York Heart Association class and the HFFSI. The New York Heart Association (NYHA) functional capacity classification is frequently used when defining severity of heart failure and is shown in Table 1 (Borsody, Courtney, Taylor, & Jairath, 1999).

Table 1

NYHA Functional Classifications

Class	Description
Class I	Patients with cardiac disease but without resulting limitations of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain.
Class II	Patients with cardiac disease resulting in slight limitations of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or anginal pain.
Class III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV	Patients with cardiac disease resulting in inability to carry out any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Muirhead et al. (1992) assessed coping and quality of life in 41 patients with advanced heart failure awaiting heart transplantation. The instruments utilized were the Profile of Mood States (POMS), the Dyadic Adjustment Scale (DAS), a symptom/feeling

checklist, a 44-question quality of life scale, Derogatis' Symptom Checklist-90-Revised (SCL-90-R), and the Folkman and Lazarus' Ways of Coping Checklist.

Walden et al. (1994) assessed the quality of life of 31 patients with heart failure – 12 patients with advanced heart failure stabilized with medical therapy and 19 patients who had undergone heart transplantation. These patients were assessed at two different time frames – at time of heart transplantation evaluation and 41 months later. Quality of life was measured utilizing the Multiple Affect Adjective Checklist (MAACL), the Psychosocial Adjustment to Illness Scale (PAIS), and the Heart Failure Functional Status Inventory (HFFSI).

Cline et al. (1999) assessed quality of life in 191 elderly patients with heart failure. The instruments utilized to measure quality of life were the Nottingham Health Profile (NHP), the Quality of Life Questionnaire in Heart Failure, and the Patient's Global Self- Assessment.

The patients in all four studies (Cline et al., 1999; Dracup et al., 1992; Muirhead et al., 1992; Walden et al., 1994) described their quality of life as compromised, negative, or poor. Dracup et al., Muirhead et al., and Walden et al. also discovered that these patients had varying degrees of anxiety, depression, hostility, and similar symptoms causing major limitations, such as fatigue, shortness of breath, and weakness.

Two of the above studies correlated quality of life and clinical variables (Cline et al., 1999; Dracup et al., 1992). Both studies looked at ejection fractions, age, gender, and marital status and how these variables correlate with quality of life. In the Cline et al. study, three instruments were used to measure quality of life, the Patients' Global Self-Assessment (PGSA), the Nottingham Health Profile (NHP) and the Quality of Life

Questionnaire in Heart Failure (QLQ-HF). There are significant correlations with total quality of life scores using these three measures ( $p < .001$ ). The authors reported a very strong correlation between the QLQ-HF and the PGSA ( $r = 0.80$ ), with moderate correlations between the QLQ-HF and the NHP ( $r = 0.65$ ), and between the PGSA and the NHP ( $r = 0.59$ ).

A relationship between quality of life and the New York Heart Association class (NYHA) was found in the Cline et al. (1999) study utilizing the NHP and the QLQ-HF. According to the results, the higher the NYHA class, the poorer the quality of life (NHP,  $p < 0.001$ ; QLQ-HF,  $p < 0.01$ ).

Dracup et al. (1992) correlated ejection fractions, metabolic equivalents to the task (METs) level and 6-minute walk. The 6-minute walk results significantly correlated with the patients' self-reported MET level ( $r = -0.60$ ,  $p < 0.001$ ) and with the New York Heart Association class ( $r = -0.46$ ,  $p < 0.001$ ).

Cline et al. (1999) also found a significant finding in regard to age. The oldest age group, ages 80-84, reported less interference between their health and their hobbies or interests ( $p < 0.01$ ). Quality of life was poorer in women as compared to men in the total scores of all three instruments utilized: the NHP ( $37.6 \pm 21.0$  vs.  $25.8 \pm 19.7$ ,  $p < 0.001$ ), the QLQ-HF ( $4.7 \pm 0.9$  vs.  $1.0 \pm 1.1$ ,  $p < 0.001$ ), and the Patient's Global Self-Assessment ( $4.5 \pm 1.3$  vs.  $3.8 \pm 1.6$ ,  $p < 0.001$ ).

Riedinger et al. (2001) evaluated gender differences in quality of life and heart failure utilizing secondary data from the Studies of Left Ventricular Dysfunction (SOLVD) trials. The sample compared 691 women with 691 men. The instruments used to assess quality of life were the Ladder of Life, Profile of Mood States Inventory,

Functional Status Questionnaire, Symptoms Scale, and one item from the Medical Outcomes Study – perception of general health. Women had significantly worse quality of life ratings than men for intermediate ADLs ( $30.77 \pm 13.52$  vs.  $37.34 \pm 11.60$ ,  $p < .0001$ ) and social activity ( $77.22 \pm 29.47$  vs.  $86.16 \pm 26.17$ ,  $p < .008$ ) after adjusting for the NYHA classification (Riedinger et al., 2001).

Moser and Worster (2000) suggest that psychosocial factors, particularly lack of social support and depression, are associated with poorer outcomes in cardiac patients. In the limited publications that studied psychosocial variables and quality of life, there is evidence that relates poor quality of life, social isolation, lack of emotional support, anxiety, depression, morbidity, and mortality. Moser and Worster agree that quality of life is a multidimensional concept, but many studies define it as unidimensional, focusing on physical functioning and symptoms, leaving out the psychosocial piece of quality of life.

One limitation of the studies done by Muirhead et al. (1992), Riedinger et al. (2001), and Walden et al. (1994) is that it is difficult to generalize the results. Muirhead et al. had possible bias due to the fact that the patients that underwent transplantation quickly or who were too ill to complete the lengthy questionnaires were not included, and the mean age of 48 seems to be much lower than the mean ages of other studies. Walden et al. had a response rate of 40% to 59% at baseline and at 3½-year follow-up, causing a potential bias due to the small number of patients responding to the questionnaires. Walden et al. also had another potential bias regarding the large number of deaths from heart failure (64%) compared with deaths related to heart transplantation (34%), being that only the survivors completed the questionnaires. Muirhead et al. and Walden et al.

both had small sample sizes. A limitation of a secondary analysis study, such as the study that Riedinger et al. (2001) did is that the research is limited to studying the available data.

### Longitudinal Research Involving Quality of Life and Heart Failure

Two recent studies by Van Jaarsveld et al. (2001) and Jaagosild et al. (1998) studied quality of life over time. Both Van Jaarsveld et al. and Jaagosild et al. were part of larger studies. Van Jaarsveld et al. collected their initial data from a community-based survey, the Groningen Longitudinal Aging Study (GLAS), which was a population-based prospective study. The GLAS had a baseline population comprised of 5,279 subjects. Jaagosild et al. pulled their patient sample from the Study to Understand Prognosis and Preferences for Outcomes and Risks of Treatments (SUPPORT), which was a prospective 5-center study. The SUPPORT study had a baseline population of 9,105 patients.

Van Jaarsveld et al. (2001) studied two patient populations, older adult patients with an acute myocardial infarction or with a diagnosis of heart failure. Premorbid data were collected from the original study. After baseline data were collected (T0), 207 patients with a new episode of an acute myocardial infarction with 292 patients with a new diagnosis of heart failure were followed for 12 months after diagnosis. Changes in quality of life were measured at 6 weeks after diagnosis (T1), at 6 months (T2), and at 12 months (T3). The outcome measures for quality of life were conceptualized as the three domains relating to functioning – physical, psychological, and social. The measurement tool used to assess physical functioning was the Groningen Activity Restriction Scale (GARS). The tool used to assess psychological function, mainly symptoms of depression and anxiety, was the Hospital Anxiety and Depression Scale (HADS). Two subscales

from the Medical Outcomes Study (MOS) Short Form were used to assess social functioning.

In comparing the premorbid quality of life of the reference group, the acute myocardial group, and the heart failure group, the heart failure patients started out with a poorer quality of life, except for anxiety (Van Jaarsveld et al., 2001). Van Jaarsveld et al. discovered a relationship between physical functioning and heart failure. At the 6-week time frame, physical functioning had worsened and remained worse at the 12-month time frame. The changes from premorbid to 6 weeks after diagnosis and the change between time frame 1 and time frame 3 were significant ( $ES = .90, p < .05$ ).

Van Jaarsveld et al. (2001) also discovered that the psychological functioning results in the heart failure patient were significantly lower ( $p < .05$ ). Mean levels of anxiety increased over time and remained elevated at the 12-month time frame. Heart failure patients did not experience depression until 6 and 12 months after diagnosis. Social functioning mean scores increased at each time frame for the heart failure patients, as did role functioning mean scores. These increases in scores showed significant worsening in the quality of life measures in regard to the psychological functioning domains of anxiety ( $ES = .32, p < .05$ ), social functioning ( $ES = .37, p < .05$ ), and role functioning ( $ES = .37, p < .05$ ).

According to Van Jaarsveld et al. (2001) there were limitations to this study. Some of the changes in the quality of life of patients with heart failure could be due to aging and other morbidity causes. Since the responders to the larger GLAS study were younger, more often male, and had better baseline physical functioning and less comorbidity than the non-responders, the effects of heart failure may be larger on the



total population, since the responders seemed to be less limited. Also the study does not include longitudinal data on the reference group, therefore the quality of life changes may not be due to heart failure.

Jaagosild et al. (1998) studied quality of life, resource use and survival of the patient with acute exacerbation of severe heart failure. Out of 9105 patient enrolled in the SUPPORT study, 1390 patients met the inclusion criteria for the Jaagosild study. Jaagosild et al. utilized the following instruments: The Acute Physiology Score component of the Acute Physiology and Chronic Health Evaluation III, measuring the patients' physiologic status; the Glasgow Coma Scale, assessing the patients' neurologic status; the Duke Activity Status Index, measuring the patients' activity status; the Sickness Impact Profile, measuring perceived health status; the Katz Index of Activities of Daily Living, measuring the patients' functional status.

Jaagosild et al. also assessed health perception with the use of two general health status scales. One of the scales involved having the patient rate their overall QOL as excellent, very good, good, fair, or poor. The other health status scale involved having the patient rate their current state of health on a scale from 0 (death) to 100 (excellent health). Health utility was measured by the time-tradeoff technique. The time frames of data collection were at admission into the study (hospitalization with acute exacerbation of heart failure), at 60 days after admission and then at 180 days after admission.

The two purposes of the Jaagosild et al. (1998) study were to determine mortality and quality of life outcomes over time. Ninety three percent of the patients survived their hospital stay, 90.3% survived to 30 days post hospitalization, 83.8% survived to 60 days post hospitalization, 72.9% survived 180 days, and 61.5% survived at 1 year. Where the

patients returned after the acute episode of heart failure, 92.6% returned home, 3.1% were discharged to a nursing home, 0.5% to a hospice program, 2.3% to a rehabilitation hospital, and 1.6% to another acute care hospital. Overall quality of life was rated as excellent, very good, or good in 35.7% of patients at admission, 49.3% at 60 days ( $p < .001$ ), and 58.2% at 180 days ( $p < .001$ ).

Both Jaagoslid et al. (1998) and Van Jaarsveld et al. (2001) found statistically significant results related to the change of quality of life over time, but the results were different. The quality of life for the patients in the Jaagoslid et al. study improved ( $p < .001$ ), whereas the quality of life for the patients in the Van Jaarsveld et al. study worsened. Variables that may have made the difference in the two studies were that the demographics of the heart failure study populations were slightly different. More men participated in the Jaagoslid et al. study (62%) when compared to the Van Jaarsveld et al. study (41%). The mean age of patients in the Van Jaarsveld et al. study was 75 versus mean age of 68 in the Jaagoslid et al. study.

Another difference in the two studies (Jaagoslid et al., 1998; Van Jaarsveld et al., 2001) is how the patients were enrolled in the study in relation to the diagnosis of heart failure and the length of time that the data was collected. Data collection for Van Jaarsveld et al. began prior to diagnosis of heart failure and then continued until 12 months after diagnosis. The period between the baseline measurement and diagnoses of heart failure ranged from 1 month to 58 months, averaging 26 months for the heart failure patient. Data collection for Jaagoslid et al. began at admission to the hospital with an acute exacerbation of heart failure, at 60 days post admission, and at 180 days post admission. The measurement period for the Jaagoslid et al. study was 6 months. Since

the Van Jaarsveld et al. study was over a much longer time frame than the Jaagoslid et al. study, this could account for the different results.

Chin and Goldman (1998) examined gender differences in the processes of care and quality of life of patients with heart failure from the time of admission to the hospital until 1 year after discharge. There were 435 patients admitted to the study and the time frames involved were at admission to the hospital with heart failure, two months after discharge and then one year after discharge. The instrument used to measure quality of life was the MOS Short Form-36. In relation to mortality, 77% of the patients survived past the first year, and the rates were similar for both genders. Chin and Goldman's mortality findings are slightly higher than the Jaagoslid et al. (1998) findings.

Chin and Goldman's research was consistent with most of the studies related to low quality of life baseline scores, but women had lower scores than men for vitality, physical function, and their physical component summary scores (PCS) were also lower ( $p \leq 0.05$ ). The Dracup et al. (1992) study did not find any gender differences in quality of life scores, but the sample was only 17% female, whereas Chin and Goldman's sample was 50% women. At the 2-month time frame, women continued to have lower scores than men for health perception, vitality, physical function, social function, and PCS ( $p \leq 0.05$ ). Women continued to have lower scores at the 1-year time frame in all domains measured except role mental function and mental component scale (MCS).

According to Chin and Goldman, limitations of this study were that the findings may not be generalizable because it was done at one urban academic medical center and that they may not have adjusted for all confounding factors across gender, despite their use of multivariate regression techniques and stratification.

Known limitations with longitudinal studies utilizing surveys are missing data and non-response. Even though most researchers do careful non-response analyses, response bias is always a factor. Polit and Hungler (1999) state that the most serious problem with longitudinal studies is attrition, the loss of participants at different points in the study.

#### Correlational Research Involving Quality of Life and Heart Failure

Konstam et al. (1996) examined the relationship of quality of life to mortality in the heart failure patient. This was a substudy of The Studies of Left Ventricular Dysfunction (SOLVD). SOLVD had a study population of 6,797 subjects from 23 centers. These patients were randomized to receive double-blind enalapril or placebo to evaluate the effects on patients with heart failure.

The quality of life assessment utilized by Kostam et al. (1996) was a self-report questionnaire selected from a battery of instruments, with demonstrated validity and reliability. The questionnaire assessed physical functioning, emotional distress, social health, intimacy, life satisfaction, perceived health and productivity. The study found that quality of life significantly influenced the relative risk of mortality. Utilizing a multivariate model, independent predictors of mortality are heart failure symptoms ( $p < 0.025$ ), activities of daily living ( $p < 0.000$ ), and general health ( $p < 0.000$ ). Needed refinement of the quality of life questionnaire and the degree of missing quality of life data during follow-up are limitations of this study.

Grady et al. (1995) studied 359 patients with advanced heart failure who were awaiting heart transplantation. Grady et al. examined life satisfaction, correlation of life satisfaction, and predictors of quality of life utilizing eight instruments. The Quality of Life Index by Ferrans and Powers was used to determine life satisfaction. The top five

items that the patients were most satisfied with were health care, emotional support from others, children, family's health, relationship with spouse or partner, with mean scores ranging from 5.02 to 5.62. The top five items that the patients were least satisfied with were current health status, ability to travel, energy for daily activities, ability to do things around the house, sex life, with mean scores ranging from 2.40 to 3.74.

Grady et al. (1995) also found a significant correlation of overall life satisfaction to demographic, physiologic, and psychosocial variables. Life satisfaction was correlated with older age ( $r = 0.13$ ,  $p = 0.008$ ) and lower New York Heart Association functional classification, ( $r = -0.16$ ,  $p = 0.001$ ). These were the same results that Dracup et al. (1992) and Cline et al. (1999) found. Fewer daily medications were also significantly correlated ( $r = -0.16$ ,  $p = 0.001$ ) to life satisfaction. Overall life satisfaction was significantly related to less overall symptom distress ( $r = -0.44$ ,  $p \leq 0.001$ ), moderately correlated with less stress overall ( $r = -0.49$ ,  $p \leq 0.0001$ ), and coping ( $r = 0.31$ ,  $p \leq 0.0001$ ).

Grady et al. (1995) found significant predictors of higher quality of life in the study population. By performing stepwise multiple regression, utilizing overall life satisfaction as the dependent variable and 19 independent variables, 11 of the 19 variables were significant predictors of overall life satisfaction ( $p \leq 0.0001$ ). Symptom distress was the highest variable ( $r = -0.44$ ,  $F = 84.75$ ), which accounted for 19% of the variance.

Friedman and Griffin (2001) found that physical symptoms and physical functioning correlated with depression, one of the frequently studied psychosocial variables related to quality of life. The sample group for this study was 170 patients with

heart failure. Data were collected per interview at two different time frames, the time of hospitalization and 4-6 weeks after discharge. The instruments utilized were a 13-item symptom checklist generated from the list of heart failure symptoms contained in the Agency for Health Care Policy Research 1994 publication, a 10-item physical functioning scale from the MOS Short Form Health Survey, the 10-item depression CES-D scale Short Form, medical history, and sociodemographic data. Physical symptoms ( $r = 0.48$ ) and physical functioning ( $r = -0.32$ ) were moderately correlated with depression, and physical symptoms contributed to 13% of the variance in depression and physical functioning contributing only 2%.

Mayou, Blackwood, Bryant, and Garnham (1991) studied the relationship between exercise capacity, symptoms, and quality of life. The study sample consisted of 123 patients, classified as New York Heart Association Class II or III, with a median age of 60 years old. The instruments utilized for measuring quality of life were a 5-point Likert scale of “best to worse” on 11 variable symptoms, the Profile of Moods State and interview ratings from a questionnaire developed and shown to be reliable in previous cardiac research, and patient diaries.

Mayou et al.'s (1991) top three physical symptoms from the 5-point Likert scale measurement were tiredness, breathlessness, and chest pain. Tiredness and breathlessness are similar to findings from other studies, such as Dracup et al.(1992), Walden et al. (1994), Muirhead et al. (1992), and Friedman and Griffin (2001). Mayou et al. also examined associations between exercise capacity and quality of life symptom measurement and quality of life interview. Statistically significant differences were present associating poor exercise capacity with more symptoms and limitations. Those

that did the least well on the treadmill suffered more tiredness ( $p < 0.005$ ), and difficulty sleeping ( $p < 0.005$ ), inability to walk quickly ( $p < 0.001$ ), and were unable to perform daily tasks quickly ( $p < 0.01$ ). The patients that did poorly on the treadmill also reported limitations with leisure ( $p < 0.05$ ) and sex ( $p < 0.05$ ).

Mayou et al. (1991) also examined the relationship between changes in exercise capacity and quality of life. Over a three-month period, regression analysis showed significant positive relationships between Likert symptom scores and ability to walk and perform daily tasks ( $F=31.77$ ,  $p < 0.001$ ).

### Therapeutic Treatment Research Involving Quality of Life and Heart Failure

Leidy, Rents, and Zycynski (1999) evaluated quality of life outcomes in patients with heart failure in randomized controlled trials. Pharmacological and non-pharmacological treatments were reviewed. Forty-one studies were actually reviewed, with 30 of the 41 studies evaluating a pharmaceutical agent, and the remaining 11 evaluating the impact of physical exercise, nasal continuous positive airway pressure treatment during sleep, nurse-managed care and primary care on quality of life. The overall reviews of these studies showed that both treatment types have a positive impact on quality of life. The pharmacological treatments improved overall quality of life, with the domains of symptoms and physical activity being the most sensitive. The non-pharmacological treatments suggested that they improve quality of life, but were more elusive.

Pharmacological treatments and interventions. Rogers et al. (1994) were investigators for The Study of Left Ventricular Dysfunction (SOLVD). This study assessed the quality of life of patients with left ventricular dysfunction for 2 years after

randomization to enalapril, an angiotensin-converting enzyme inhibitor, or placebo. The main aim of the SOLVD study was to compare the effect of enalapril and placebo on mortality, with a subsequent study on the effects of treatment on quality of life. The study population consisted of 5,025 patients randomized into either the treatment group or the placebo group. All patients completed a questionnaire at randomization, at 6 weeks, at 1 year and at 2 years of follow-up. The questionnaire contained 14 scales, excerpted from previously validated instruments addressing 7 components of quality of life: physical functioning, emotional distress, social health, intimacy, life satisfaction, perceived health, and productivity of job performance.

Quality of life scores were significantly better with enalapril group in two consecutive follow-up intervals, six weeks (TF2) and 1 year (TF3) in two areas, social functioning and dyspnea. The enalapril group had improved dyspnea at 6 weeks ( $p = 0.002$ ), with a mean of 2.03 as compared to the placebo group with 2.28, and at 1 year ( $p = 0.0003$ ), with a mean of 2.09 as compared to the placebo group with 2.29. The enalapril group also had improved social functioning at 6 weeks, with a mean of 1.48 as compared to the placebo group with 1.57 ( $p = 0.0003$ ), and at 1 year with a mean of 1.45 as compared to the placebo group with 1.54 ( $p = 0.02$ ). The main limitation with this study is the significant extent of missing data during follow-up. The missing data were related to non-survivors and failure to complete the survey.

Rector and Cohn (1992) enrolled 198 patients with a diagnosis of heart failure in order to determine the reliability and validity of the Minnesota Living with Heart Failure (LHFE) questionnaire. Rector and Cohn's study involved a randomized, double-blind, placebo-controlled, 3 month trial of pimobendan, which is an investigational medication



with inotropic and vasodilator effects. The oral pimobendan was administered at 3 different doses – 2.5mg, 5.0mg, and 10mg daily. The LihFE questionnaire, an exercise test, and patient ratings of dyspnea and fatigue measured the patient's quality of life. The questionnaire was administered at baseline, and at 4, 8, and 12 weeks after randomization.

The results of this study showed significant improvement in the total quality of life score with the 5mg pimobendan dose as compared with the placebo (CI = 0, 18;  $p = 0.01$ ) and with the physical dimension (CI = 0, 8;  $p = 0.01$ ). There were also weakly related changes in the total ( $r = 0.33$ ;  $p < 0.01$ ) and physical ( $r = 0.35$ ;  $p < 0.01$ ) quality of life scores to exercise times, which corresponded with changes in patients' ratings of dyspnea and fatigue.

Non-pharmacological treatments and interventions. Four recent publications studied the use of non-pharmacological interventions on functional status and quality of life, which are frequently studied together as variables (Belardinelli, Georgiou, Cianci, & Purcaro, 1999; Fonarow et al., 1997; Kostis, Rosen, Cosgrove, Shindler, & Wilson, 1994; Oka et al., 2000). All four of the studies incorporated some type of exercise training within their studies. The results in the studies by Fonarow et al., Kostis et al. and Belardinelli et al. showed that exercise training had a positive effect on quality of life. Kostis et al. also examined mood changes with positive results.

Fonarow et al. (1997) developed a comprehensive heart failure management program that included medical and non-medical treatments and then assessed the impact of this program on hospital costs, hospital readmission rates, and functional status. The program included changes in the patient's medical regimen after right heart

catheterization and pulmonary pressure monitoring. The changes in the patient's medical regimen consisted of a 98% increase in angiotensin-converting enzyme inhibitor dose and a flexible diuretic regimen. The non-medical part of the program included comprehensive patient education. This education was taught by a heart failure clinical nurse specialist, either in group and/or individual sessions. The educational content included information about diet, progressive exercise, and self-monitoring. Two hundred and fourteen heart failure patients being evaluated for transplantation participated in the study over a three-year period. The New York Heart Association classification and peak oxygen consumption testing assessed functional status.

Fonarow et al.'s (1997) study results showed a significant improvement in functional status six months after the program was initiated. At six months, 179 patients had not received a transplant, who were classified as a New York Heart Association functional class of III or IV at the start of the study. At six months, 49% of these patients increased to a New York Heart Association functional class of I or II ( $p < 0.001$ ). There were 35 additional patients that were dying or had received a transplant. When these patients were included with the 179 other patients, as a functional class IV, the improvement remained significant ( $p < 0.01$ ). Peak oxygen consumption could be measured in 72% of the study sample and a significant increase was present (15.2 vs. 11.0 ml/kg per min.,  $p < 0.001$ ).

The study by Kostis et al. (1994) also resulted in non-pharmacological therapy in improving functional status, along with emotional status improvement in the heart failure patient. Kostis et al. compared a multimodal non-pharmacological intervention, consisting of an intensive life-style modification program, to digoxin and placebo in 20

patients with mild heart failure, with a New York Heart Association class of II (n=19) or III (n=1). The non-pharmacological program included structured exercise, dietary modifications, and cognitive-behavioral therapy for a 12-week period. The patients were randomly assigned to one of the three treatment groups and were monitored over a 12-week period. Measurement instruments included the following: selected physical symptoms such as dyspnea, fatigue, evidence of rales, edema, third heart sound, neck vein distention, hepatomegaly; modified Naughton protocol treadmill exercise testing; echocardiography; 6-minute walk test; the Anxiety Disorders Interview Schedule-Revised and the Beck Depression Inventory; the Hamilton Scales.

At baseline, there were no significant differences among the three groups that Kostis et al. (1994) compared. There were significant improvements within the non-pharmacological therapy group as compared to the digoxin and placebo groups. One significant improvement was exercise tolerance on the treadmill test ( $p < 0.05$ ) when comparing the nonpharmacologic group ( $182 \pm 139$ ) to the digoxin group ( $51 \pm 50$ ). There was also significant improvement with weight loss ( $p < 0.05$ ) when comparing the nonpharmacologic group ( $-4.37 \pm 4.50$  kg) to the digoxin group ( $0.32 \pm 1.76$  kg).

Both the digoxin and the placebo groups deteriorated in the mood change variables as compared to the nonpharmacologic group. Anxiety scores improved significantly ( $p < 0.05$ ) in the nonpharmacologic group ( $5.0 \pm 5.0$ ) as compared to the placebo group ( $3.0 \pm 6.8$ ) and the digoxin group ( $-5.2 \pm 5.4$ ). Depression scores also improved significantly ( $p < 0.05$ ) in the nonpharmacologic group ( $5.0 \pm 5.0$ ) as compared to the placebo group ( $1.0 \pm 4.9$ ) and the digoxin group ( $-6.6 \pm 10.1$ ). The digoxin group did have significant improvement ( $p < 0.05$ ) in ejection fraction ( $4.4 \pm 6.5$ ) when

compared to the placebo group ( $-1.2 \pm 3.9$ ) and non-pharmacological group ( $-3.2 \pm 3.9$ ) without improvement in the quality of life measures.

Belardinelli et al. (1999) also studied how exercise training affects functional status and quality of life in the heart failure patient. Belardinelli et al. took 99 patients with heart failure and randomized them into two groups. One group participated in an exercise program two times a week for one year, while the other group did not exercise. Functional status was measured with a cardiopulmonary exercise test and thallium scintigraphy, and was measured at baseline, 2 months, and 14 months. Quality of life was assessed utilizing the Minnesota Living With Heart Failure Questionnaire at 2, 14, and 26 months. The only significant changes for functional status or quality of life were within the exercise group. Functional status improved at 2 months ( $p < 0.001$ ) and did not change at any other points in time. Quality of life score improved significantly in the exercise group ( $r = 0.80$ ,  $p < 0.001$ ) after 2 months and remained stable throughout the rest of the exercise program and follow-up.

Oka et al. (2000) examined the efficacy of a home-based exercise program on heart failure in relation to the patient's symptoms, dyspnea and fatigue, and also on the quality of life domains of emotional function and mastery. Forty heart failure patients with a New York Heart Association class of II or III were the study population. The patients were randomly placed in two groups. One group received three months of usual care, and the other group received home-based walking and resistance exercise training. Exercise capacity was measured by a treadmill exercise test using a modified Naughton protocol to determine peak oxygen uptake as did Kostis et al. (1994). The symptoms of

dyspnea and fatigue, along with quality of life, were measured with the Chronic Heart Failure questionnaire. These variables were measured at baseline and at 3 months.

Oka et al.'s (2000) study results observed no differences in sample characteristics between the two groups and no significant differences in exercise capacity between the two groups. These findings are inconsistent with Kostis et al. (1994), Fonarow et al. (1997), and Belardinelli et al. (1999) who all found significant changes in relation to exercise capacity. Oka et al. did find significant results with the exercise group, which were improved fatigue ( $F(1,74) = 6.66; p < 0.02$ ), and improved emotional function ( $F(1,220) = 7.93; p < 0.01$ ).

Rich et al. (1995) conducted an experimental study on 282 heart failure patients to assess the effects of a nurse-directed intervention on hospital readmission rates, quality of life, and costs of care. The patients were randomized into a control group and experimental group. The control group received conventional care and the experimental group received an intervention that consisted of comprehensive education of the patient and family, a prescribed diet, social-service consultation and planning for an early discharge, a review of medications, and intensive follow-up. Quality of life was measured utilizing the Chronic Heart Failure Questionnaire and the time frames assessed were at baseline and at 3 months. Out of the 282 patients that participated in the study, 126 had the quality of life questionnaires administered to them. There were 59 patients in the control group with 67 patients in the experimental group.

According to the results of Rich et al.'s (1995) study, quality of life significantly improved more in the experimental group than the control group ( $22.1 \pm 20.8$  vs.  $11.3 \pm 16.4, p < 0.001$ ), even though quality of life scores improved over time in both groups.

The experimental group also had a significant increase over the control group in three subscales of the quality of life questionnaire: dyspnea ( $6.8 \pm 7.9$  vs.  $3.8 \pm 5.4$ ,  $p < 0.01$ ), fatigue ( $5.4 \pm 5.5$  vs.  $2.7 \pm 6.1$ ,  $p < 0.01$ ), and emotional function ( $5.6 \pm 7.1$  vs.  $1.9 \pm 5.2$ ,  $p < 0.001$ ).

Jaarsma et al. (2000) conducted an experimental study on 179 patients with advanced heart failure, New York Heart Association classification III and IV, to determine the effects of a supportive educational nursing intervention on self-care abilities, self-care behavior, and quality of life. Functional capabilities, symptoms, and psychosocial adjustment to illness were the three dimensions of quality of life that were examined. Functional capabilities were measured utilizing the Heart Failure Functional Status Inventory. A questionnaire assessed symptoms asking about their occurrence, severity, and distress. The Psychosocial Adjustment to Illness Scale was used to measure psychosocial adjustment to illness. Cantril's Ladder was used to measure overall well being of the patients. Assessment and reassessment occurred at enrollment, and at 1, 3, and 9 months after discharge from the hospital. The experimental group received systematic education and support by a nurse in the hospital and at home. The control group received routine care.

Jaarsma et al. (2000) results showed a significant decrease in the average number of symptoms at the 3-month timeframe for both groups ( $p < .001$ ), from 3.9 at baseline to an average of 1.9 symptoms in the control group and 2.2 symptoms in the intervention group. Both groups also showed a significant decrease in average symptom severity after discharge ( $p < .001$ ) and a decrease in average symptom distress ( $p < .001$ ).

The five studies involving non-pharmacologic treatments did have some limitations. Limitations of Rich et al. (1995) and Kostis et al. (1994) are the inability to generalize results and the brief duration of both studies. A limitation of Fonarow et al. (1997) is also the inability to generalize results and that the data collection was done in retrospect before referral. Another limitation of both Rich et al. and Fonarow et al. is the inability to distinguish or attribute the quality of life changes to the study variables. Small sample size was a limitation in both Kostis et al. and Oka et al. (2000). Jaarsma et al. (2000) stated that a limitation of the study was that the quality of life instrument might not have been sensitive to change over time.

### Summary

Heart failure is a debilitating and costly disease, and its incidence continues to rise. Much research has been done related to heart failure and how to manage the disease. Much research has been done on heart failure and quality of life, but a majority of this research has been descriptive and exploratory. Numerous studies define the heart failure patient's quality of life as poor. Research studies reflect that the patient's symptoms and functional status are two reasons for a poor quality of life, therefore the focus of many studies has been on decreasing symptoms or increasing functional status. The few studies that have shown an improvement in quality of life have involved treatment that included an exercise program and an educational nursing component. Future studies need to focus on how to improve quality of life in the patient with heart failure.. One way to do this may be through nursing education programs provided to patients with heart failure that have shown to be effective in increasing the quality of life of heart failure patients.

Another issue surrounding quality of life research and the heart failure patient is the need to define quality of life. Currently, quality of life is defined differently from study to study. There are many different domains of quality of life. The frequently used domains include physiological, psychological, or psychosocial. Current studies have researched one domain or all domains, utilizing a multitude of instruments. Some of these instruments are disease specific while some are not. Future studies need to focus on defining quality of life in a similar fashion from study to study. More studies need to be done utilizing an instrument that measures quality of life and is specific to heart failure.

#### Research Question

Does a tertiary nursing intervention, supportive education, increase quality of life in patients with heart failure?

#### Study Hypothesis

Quality of life scores for patients with heart failure that receive a supportive educational nursing intervention will be higher than those patients receiving placebo nursing interventions.

#### Definitions of Terms

**Heart failure:** “A clinical syndrome or condition characterized by (1) signs and symptoms of intravascular and interstitial volume overload, including shortness of breath, rales, and edema or (2) manifestations of inadequate tissue perfusion, such as fatigue or poor exercise tolerance” (AHCPR Quick Reference Guide for Clinicians, No. 11, p.1).

**Quality of Life:** “A person’s sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her” (Ferrans & Powers, 1992, p. 29).



**Placebo nursing interventions:** Nursing interventions for health promotion that include topics such as immunizations for adults, decreasing risks for falls, general nutrition, normal aging, general health maintenance, and insomnia.

**Supportive educational nursing intervention:** Nursing interventions that not only include the placebo nursing interventions, but also nursing actions that guide, support and teach the client in providing self-management for the health-deviation of heart failure.

## CHAPTER 3

### METHODOLOGY

#### Design

This study is a secondary analysis of a primary study conducted by Kay Setter-Kline, RN, PhD, Professor at Grand Valley State University in Allendale, Michigan. The primary study utilized a blind, experimental design, comparing three different nursing approaches with home care patients having a primary diagnosis of congestive heart failure. The three nursing approaches were supportive-education, mutual goal setting, and a placebo intervention. The subjects were randomly assigned to receive one of these three nursing approaches. All subjects received nursing care routinely provided by the home care agencies.

The long-term goal of the primary study was to develop a program of research that would explain the relationship between nursing care and cardiovascular disease outcomes, particularly heart failure. The outcomes the study were (a) increasing self-management of heart failure as measured by the Self-Management Tool, (b) increasing the quality of life for persons with heart failure as measured by the Ferrans and Powers Quality of Life Index, (c) reducing hospital readmission rates, and (d) decreasing length of stay if admitted to the hospital.

According to Polit and Hungler (1995), the controlled experiment is considered the “ideal of science” and a double blind experiment, such as the primary study, has greater power because it can control for experimental disadvantages. The advantage of a true experiment is that a causal relationship between the independent and dependent variable may be inferred with confidence. One disadvantage of a true experiment is that

experiments seem artificial because of the requirement for randomization and equal treatment within groups. Another disadvantage of a true experiment is the Hawthorne effect, a placebo effect due to the subject behaving differently because of participation in the study.

The data for this secondary analysis used two of the groups that were randomly assigned from the primary study; the placebo group that received placebo nursing interventions and the experimental group that received the supportive educational nursing intervention. The quality of life of the two groups were compared in this secondary analysis. There are advantages and disadvantages with secondary analysis. The advantage of secondary analysis is that it is efficient and economical. Data collection can be very expensive and time-consuming and secondary analysis bypasses this part of the research process. The disadvantage of secondary analysis is that the investigator does not play a role in the data collection, therefore the data set may not be exactly as the researcher would have collected it (Polit & Hungler, 1995).

### Sample

Subjects were selected for the primary study from two non-profit western Michigan home care agencies from two different cities. A convenience sample was utilized that met the following criteria: (a) a primary diagnosis of heart failure, (b) over the age of 18, (c) able to understand and speak English, and (d) agreement to participate in the study. The goal of the primary study was to enroll 62 subjects for each of the three nursing intervention groups, for a total of 186. This number of subjects would achieve an estimated power of 80%. The primary study also tried to equalize the groups according to the two sites, which would place 31 subjects in each group, at each site. Fifty-eight

subjects were included in this secondary analysis with 31 subjects in the placebo group and 27 subjects in the supportive educational group.

### Characteristics of Sample Subjects

The demographic data included in this secondary analysis follows: (a) age; (b) gender; (c) marital status broken down into 2 categories, never married or married, which included divorce and widow/widower; (d) employment status, employed or unemployed, (e) highest level of education, (f) insurance provider, (g) health care provider treating the heart failure, (h) annual income in dollars, and (i) length of diagnosis of heart failure. The mean age of the subjects in the placebo group was 76 (SD =9.97) with a range of 56 to 94 years. The mean age of the subjects of the supportive educational group was 75 (SD = 13.54) with a range of 42 to 94 years. Both the supportive educational and placebo group had a higher percentage of females than males within the sample, with 51.9% of the supportive educational and 61.3% of the placebo group being female (see Table 2).

One subject from the supportive educational group and one subject from the placebo group had never been married. The rest of the subjects in both groups are currently married, divorced, or widowed. Almost half of the subjects from the supportive educational group (n=13) and half from the placebo group (n=15) were still married. The other 48% of the subjects from the educational group were either divorced (n=2) or widowed (n=13). Forty-eight percent of the placebo group were widowed (n=13) and none were divorced. Only one subject from the placebo group was employed and worked approximately two hours per week.

Table 2

Characteristics of Subjects

	<u>Placebo Group</u>		<u>Supportive Educational Group</u>	
	(n=31)		(n=27)	
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
<b>Gender</b>				
Male	12	38.7	13	48.1
Female	19	61.3	14	51.9
<b>Marital status</b>				
Married	15	48.4	13	48.1
Unmarried	16	51.6	14	51.8
<b>Highest level of education</b>				
1-7 years	3	9.7	1	3.7
8-10 years	5	16.1	4	14.8
11-12 years	19	61.3	13	48.1
> 12 years	4	12.9	9	33.3
<b>Annual income in dollars</b>				
< 10,000	9	29.0	5	19.2
10-20,000	9	29.0	12	46.2
20-30,000	11	35.5	8	30.8
30-40,000	2	6.5	1	3.8

Table 2 also shows the highest level of education of the subjects in both the placebo and supportive educational intervention groups. Sixty-one percent of the subjects in the placebo group attended the 11<sup>th</sup> or 12<sup>th</sup> grade, with 13% having some type of college education. The percent of subjects in the supportive educational group that attended at least the 11<sup>th</sup> or 12<sup>th</sup> grade is 48%, with 33% having some type of post secondary education. The main insurance provider for the subjects in both the placebo and the supportive educational groups was Medicare. Ninety percent of placebo group (n=28) and 85% of the supportive educational group (n=23) had Medicare.

Sixty-seven percent of the subjects in the placebo group and 85.2 % in the supportive educational group had a cardiologist caring for their heart failure. The other subjects had various other health care providers for their heart failure (see Table 3). The length of time since diagnosis of heart failure was similar between the two groups. Thirty-two percent of the subjects in the placebo group had heart failure for < 1 year (n=10) and thirty-two percent had heart failure for > 5 years (n=10). The majority of the subjects in the supportive educational group had heart failure for > 5 years (n = 8), which was 29.6% (see Table 4).

**Table 3**

**Health Care Providers**

	<u>Placebo Group</u>		<u>Supportive Educational Group</u>	
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
Family practice physician	08	25.8	3	11.1
Cardiologist	21	67.7	23	85.2
Internist	10	32.3	8	29.6
Nurse practitioner	3	9.7	1	3.7
Physician assistant	0	0.0	0	0.0
Other	3	9.7	3	11.1

**Table 4**

**Length of Time Diagnosed With Heart Failure**

	<u>Placebo Group</u>		<u>Supportive Educational Group</u>	
	<u>n</u>	<u>%</u>	<u>n</u>	<u>%</u>
< 1 year	10	32.3	7	25.9
1-2 years	5	16.1	5	18.5
3-5 years	6	19.4	7	25.9
> 5 years	10	32.3	8	29.6

## Instruments

The primary study utilized two instruments, the Self-Management Tool adapted from the Chronic Disease Self-Management Study Measures by Lorig et al. (1996) and the Ferrans and Powers Quality of Life Index: Cardiac Version-III (QLI) (Ferrans & Powers, 1985, 1992). For the purpose of this secondary analysis focusing on the quality of life of the patient with heart failure, the QLI is the instrument that was used. The QLI is a 72-item scale consisting of two parts. Part one measures “how satisfied” the subject is with various aspects of their lives. Responses range on 6-point Likert scale from (1) very dissatisfied to (6) very satisfied. Part two measures the “importance” of various aspects of their life, with responses ranging from (1) very unimportant to (6) very important. Internal consistency with cardiac subjects has been reported from .86 to .96 (Biley & Ferrans, 1993). Content validity is supported by Ferrans and Powers (1985) and by the study done by Oleson (1990). Contrasted groups (Ferrans & Ferrell, 1990; Ferrans & Powers, 1992) also supported construct validity.

Reliability of the Ferrans and Powers Quality of Life Index: Cardiac Version-III (QLI) was calculated for this secondary analysis. According to Polit and Hungler (1995), a reliability coefficient of .70 or greater is considered sufficient to make group comparisons. The Cronbach alpha for all 72 items of the QLI and the overall sample (n=55) was .88. The reliability of each subscale of the QLI was also calculated (see Table 5). The four subscales of the QLI are health and functioning, social and economic, psychological/spiritual, and family. Two of the QLI subscales' Cronbach alphas fell below .70, social and economic and family. The small sample size, the number of items in the subscale, and the instrument itself may be reasons for the lower coefficients.



Table 5

Reliability Coefficients of the QLI Subscales

<u>QLI Subscales</u>	<u># of Items</u>	<u>Reliability Coefficient</u>
Health & functioning	32	.85
Social & economic	18	.67
Psychological/spiritual	14	.82
Family	8	.65

Procedure

Approval for the primary study was obtained through the Grand Valley State University's Human Research Review Committee in order to protect the patients' rights. Recruitment of subjects for the primary study consisted of selecting cases from a list of clients admitted to the two home care agencies with a primary diagnosis of congestive heart failure (ICD-9 code of 428). Patients that met the inclusion criteria were then approached by the home care agency manager and introduced to the study utilizing a script (see Appendix B). If the patient was interested in participating in the study, the data collector, a graduate nursing student, made arrangements to visit the patient, explain the study, obtain informed consent (see Appendix C), and collect the baseline data utilizing a demographic data tool (see Appendix D). Once the data collector obtained the baseline data, Dr. Setter-Kline, the primary investigator, randomly assigned the patients to one of the three treatment groups utilizing a table of random numbers.

A nursing intervention provider visited each patient once a week for a total of eight weeks. Each treatment group had a separate nursing provider. During the visits, the nursing provider administered one of the treatments. All groups received routine home care interventions that consisted of health maintenance topics. Data collection occurred initially, and again at 3, 6, 9, and 12 months using the data collection instruments. The initial data and the data obtained at the 6-month time frame was the data utilized for this secondary analysis.

The data were coded using a numerical coding system in order to identify the patients and to protect their confidentiality. There were no physical risks to the patient during the data collection or intervention sessions, except possible fatigue. The nursing provider assessed this on an individual basis during the sessions. If signs of fatigue occurred, the session was terminated.

Approval to conduct this secondary analysis was obtained from Grand Valley State University's Human Research Review Committee (see Appendix E). Permission was obtained to use the data for this secondary study from Dr. Setter-Kline, the principal investigator of the primary study (see Appendix F).

## CHAPTER 4

### RESULTS

The purpose of this study was to determine if a tertiary nursing intervention, supportive education, had an effect on the quality of life of patients with heart failure. The research question for this study was, “Does a tertiary nursing intervention, supportive education, increase quality of life in patients with heart failure?” The hypothesis in this study was as follows: Quality of life scores for patients with heart failure that receive a supportive educational nursing intervention will be higher than those patients receiving routine nursing interventions.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS). In order to test the hypothesis for this study, analysis of covariance (ANCOVA) was considered. The ANCOVA would control for pre-test differences between the two study groups. Due to the small sample size of this secondary analysis the use of the ANCOVA was prohibited. Instead, independent and paired t-tests were performed. The independent t-test compared differences between groups and the paired t-test compared changes within a group. The level of significance was established at  $p < .05$ .

#### Overall Quality of Life Scores

The QLI scores are determined by weighting satisfaction with the importance of each identified item of the QLI scale. These scores range from 0 to 30, with 0 being the lowest QOL score and 30 being the highest. The QLI scores of heart failure patients were measured at baseline and at the 6-month time frames in the two groups being studied, the placebo and supportive educational groups.

The baseline QOL scores for the placebo group (n = 31) ranged from 10.07 to 28.25, with a mean of 20.71 (SD = 5.04). Eighty-four percent of subjects in the placebo group had scores greater than 15, which was the midpoint in the scale. At the 6-month time frame, the QOL scores (n = 24) ranged from 9.30 to 27.47, with a mean of 20.77 (SD = 4.97). Ninety-two percent of the subjects in the 6-month time frame had QOL scores greater than 15.

At baseline, the QOL scores for the supportive educational group (n = 27) ranged from 13.04 to 26.99, with a mean of 20.87 (SD = 3.75). Ninety-three percent had scores greater than 15. The range of the QOL scores for this group (n = 17) at the 6-month time frame is 13.51 to 28.82, with a mean of 23.41 (SD = 4.47) and 89% of the subjects had a score greater than 15. Table 6 summarizes these results.

#### Hypotheses

“Quality of life scores for patients with heart failure that receive a supportive educational nursing intervention will be higher than those patients receiving a placebo nursing intervention” was the hypotheses that was tested. The data analysis indicated a slight improvement in the mean QOL scores over time for both groups, with the supportive educational group having a greater increase. The expectation would be that an increase in QOL scores would be an increase in QOL. There was a .16 increase of the mean QOL scores for the placebo group from baseline to 6 months, and a 2.64 increase for the supportive educational group. In order to determine the statistical significance of this increase and test the hypothesis, an independent t-test was done which tests for the statistical significance of differences between two group means.

Table 6

Quality of Life Scores

	<u>n</u>	<u>Range</u>	<u>Mean</u>	<u>SD</u>
<b>Placebo</b>				
Baseline time frame	31	10.07-28.25	20.72	5.04
6-month time frame	24	9.30-27.47	20.77	4.97
<b>Supportive Educational</b>				
Baseline time frame	27	13.04-26.99	20.87	3.75
6-month time frame	17	13.51-28.82	23.41	4.47

As shown in Table 7, the difference in the mean QOL scores between the two groups was not significant. Therefore the research hypotheses was not supported.

Table 7

Difference Between QOL Scores At Baseline and Six Months

Timeframe	t	df	p
Baseline	-0.13	55	.897
6-month	-1.74	39	.089

A paired sample t-test was done on both the placebo and the supportive educational group in order to determine if the changes in the QOL mean scores within

each group were significant. The overall QOL scores and QOL subscale scores were both analyzed. The QOL subscales are health and functioning, social and economic, psychological/spiritual, and family.

The paired sample t-test did not show any significant difference in the change in the overall QOL scores for the placebo group (n=24), however it did show a significant decrease in the social and economic subscale score ( $t = 2.77$ ;  $df = 23$ ;  $p = .011$ ) in this group. The supportive educational group (n=17) had a significant increase in the overall QOL scores ( $t = -2.90$ ;  $df = 16$ ;  $p = 0.01$ ), along with the health and functioning subscale scores ( $t = -3.27$ ;  $df = 16$ ;  $p = .005$ ). Table 8 shows the significant results from the paired t-test analysis.

Table 8

Paired t-test Analysis

QOL Subscale	Mean Baseline Score (SD)	Mean 6-Month Score (SD)	t	df	p
Placebo					
S & E	22.63 (5.11)	20.92 (5.55)	2.77	23	.011
Supportive Educational					
Overall QOL	21.52 (3.68)	23.41 (4.47)	-2.90	16	.01
H & F	18.72 (5.18)	21.52 (6.40)	-3.27	16	.005

Note: S&E = social and economic subscale; H&F = health and functioning subscale

## CHAPTER 5

### DISCUSSION AND IMPLICATIONS

#### Discussion

The purpose of this secondary analysis was to examine the effect of a supportive educational nursing intervention on quality of life (QOL) in patients with heart failure. The hypothesis, “Quality of life scores for patients with heart failure that receive a supportive educational nursing intervention will be higher than those patients receiving placebo nursing interventions,” was not supported. While the supportive educational group did increase QOL scores from baseline to the 6-month time frame, the change in scores was not statistically significant.

According to Polit and Hungler (1995), it can be very difficult to figure out why a hypothesis is not supported. One possible reason the hypothesis was not supported in this secondary analysis may be due to the loss of subjects or attrition. There are many reasons why subjects are unable to continue the study. The patients that left the study could have had the poorer QOL, and would have had the most potential to increase their QOL. If this was a correct assumption, then the patients that remained may have had a good QOL and did not really have a need to increase their QOL.

The small sample size is another possible reason the hypothesis was not supported. The sample size was small at the initial collection of data and decreased significantly at the 6-month time frame. Since it appears that the overall QOL score for the supportive educational group had increased more than the placebo group scores, a larger sample size may have been able to show statistical significance in regards to the hypothesis.

The time frames in which the data were collected could have had an effect on the hypothesis. Data were available for 3 months, 9 months, and 12 months, along with the 6-month data. The 6-month time frame was chosen in order to give the subjects time after the intervention occurred to adjust to the life style changes and incorporate the education and support that they received. If the 3 month data had been used, the attrition rate may not have been as high and the post-intervention sample may have been larger.

The ability to measure QOL may be a reason that the hypothesis was not supported. The reliability and validity of the Ferrans and Powers Quality of Life Index: Cardiac Version III (QLI III) has been widely validated over the recent years. However, quality of life is subjective and the QLI-III measures QOL in objective terms. The QLI-III measures scores on a scale of 0-30. It is unclear which score determines a poor QOL or a good QOL? Someone may have a score near 30 and perceive that their QOL is very poor, or someone may have a score of 10 and perceive that their QOL is good. Therefore, measures for subjective data are required.

Other reasons for the hypothesis not to be supported could be the potential bias of the nurse providers. Did the nurse providers carry out the interventions exactly the same with each patient? The interactions that the nurse providers had with each patient could produce bias, therefore skewing the results.

Fatigue was an area of concern during the primary study when the data were collected and fatigue could have been a factor in the results obtained. Since the visits from the graduate student nurse provider was in addition to their routinely scheduled home visit, the nurse provider needed to assess the patient for signs of fatigue. Did the nurse provider have experience in assessing for signs of fatigue and was it actually



assessed during the intervention? If the nurse provider did not do a good job at assessing for fatigue during the data collection or treatment administration, this could have affected the results. Hawthorne and Hixon (1994) who also utilized the QLI-III in measuring QOL, found indications during their study that this instrument may have caused fatigue, especially in the second portion of the tool.

There is limited research evaluating the effects of nursing interventions on QOL in the patient with heart failure. In a meta-analysis that Kinney et al. (1996) completed on this subject, one intervention study out of 67 was a nursing intervention, with 48 of the other intervention studies being pharmacological. Out of 46 studies that Leidy, Rentz, and Zyczynski (1999) reviewed evaluating QOL outcomes in patients with heart failure, only two involved nursing interventions.

Jaarsma et al. (2000) demonstrated similar results in a study conducted with patients with advanced heart failure that received a supportive educational nursing intervention. Both of the groups in the Jaarsma's et al. study, the control group that received routine nursing care and the experimental group that received supportive education, did show improvement in the QOL dimensions after the baseline measurement but with no differences between the two groups at subsequent follow-up times.

Two other nurse intervention studies demonstrated results that were more conclusive than this secondary analysis. Rich et al.'s (1995) study demonstrated that a nurse-directed, multidisciplinary treatment strategy could improve the heart failure patient's quality of life. Both groups did improve their QOL over time, as in the Jaarsma et al. (2000) study, but there was significantly more improvement in the group that received the nurse-directed intervention.

Hawthorne and Hixon (1994) examined the effects of a nurse monitored, symptom management program on hospital readmission rates and QOL in patients with chronic heart failure. Quality of life did not improve until the patients were stratified by activity levels and the higher activity group had a statistically significant increase in QOL scores.

The study done by Kostis et al. (1994) compared three treatments – placebo, digoxin, and a multimodal nonpharmacologic intervention. Though this study was not categorized as a nursing intervention study, the nonpharmacologic intervention consisting of exercise training, cognitive therapy and dietary intervention is similar to the nursing interventions discussed in the literature. The Kostis et al. study evaluated if any of the three treatments improved functional and emotional status, two dimensions of QOL, and concluded that the nonpharmacologic intervention did improve functional status and mood state.

Neuman's systems model has assisted in guiding this research. According to Neuman (2002), the major concern for nursing is to keep the client system stable through accuracy in assessing the effects of stressors. Nursing must also assist in client adjustments that are required for an optimal wellness level, meaning the best possible state achievable at a given point in time. Nursing actions are initiated to retain, attain, and maintain optimal client health or wellness. The three preventions as interventions, primary, secondary, and tertiary prevention, assist in keeping the client stable. The type of intervention needed depends on the degree to which stressors have penetrated the client's lines of resistance. Tertiary interventions return the client to wellness, or reconstitution, following treatment after some degree of stability has occurred.

Quality of life can be viewed on a continuum as the Neuman Systems Model views health and wellness. The dimensions of QOL are similar to the variables in the Neuman model, acting in balance and harmony to maintain stability. The patient's perception of quality of life, or placement on the continuum, is dependent on the degree of stability and assessment of which stressors are affecting this stability. For example, the patient newly diagnosed with heart failure has stress in learning how to adjust to this disease process, including symptoms, treatment, and life style changes. This stress causes a reaction manifested by a decrease in QOL. Nursing needs to assist in bringing the patient to a perception of optimal quality of life through a tertiary intervention, such as a supportive educational intervention. According to Neuman (2002), tertiary interventions support internal and external resources in order to bring the patient back to reconstitution.

The research question for this secondary analysis was “ Does a supportive educational nursing intervention increase quality of life in patients with heart failure?” Even though the findings did not support the hypothesis, the findings did substantiate that a supportive educational nursing intervention does increase QOL in patients with heart failure. The overall QOL scores did increase in both the placebo and supportive educational group, but the increase was only statistically significant in the supportive educational group, not the placebo group. These findings along with the findings from previous research (Hawthorne & Hixon, 1994; Jaarsma et al., 2000; Kostis et al., 1994; Rich et al., 1995) suggest the importance of education, support, and intense follow-up in increasing QOL in patients with heart failure.

The supportive educational group's overall QOL scores and all four subscales of the QLI-III increased from baseline to 6-months. The increase in the overall QOL score and the health and functioning subscale were statistically significant in this group. The placebo group's overall QOL scores and two of the subscales, health and functioning and psychological/spiritual, also increased but were not statistically significant. The placebo group did have a statistically significant decrease in the QOL subscale of social and economic.

In two longitudinal studies that measured QOL over time, these findings were supported in one and not in the other. The SUPPORT study (Jaagslid et al., 1998), discovered that QOL improved over time without any intervention. The GLAS study (VanJaarsveld et al., 2001) discovered that QOL decreased over time without any intervention. The findings of the SUPPORT study would make the researcher question if the increased QOL were due to the supportive educational intervention or to the passage of time. On the other hand, the findings of the GLAS study would suggest that the supportive educational intervention was the reason for the increase in QOL.

Findings from Grady et al., (1995), Friedman and Griffin, (2001), and Mayou et al., (1991) support the significant increases in the supportive educational group. All three of these studies correlated symptom distress and physical functioning with QOL. Therefore, if an intervention provided the education and support to decrease symptoms and increase physical functioning, QOL may be improved as it was in the supportive educational group.

Another reason for the significant results could be related to attrition or bias. The patients that dropped out of the study could have been the sicker patients, or the patients

with the poorer quality of life. This would leave patients that may have been more able to increase their QOL significantly.

Although not analyzed in this secondary analysis, gender makeup of the placebo group could have affected the overall QOL results and the significant decrease in the social and economic subscale of the placebo group. The supportive educational group was composed of 48% females, while the placebo group was composed of 61% females. According to three recent studies (Chin & Goldman, 1998; Cline et al, 1999; Reidinger et al., 2001), it was found that women with heart failure had a lower QOL than men with heart failure. Since the placebo group had a higher percentage of women than the supportive educational group, this may be why the increase in the overall QOL scores for the placebo group was not statistically significant. Gender differences may also help to explain the decrease in the social and economic subscale of the placebo group. Riedinger et al. also discovered that social scores were significantly worse in women than in men. Bennett, Baker, and Huster (1998) conducted a study on QOL and women with heart and significantly correlated low social support with physical symptom impact.

Many research studies done on patients with heart failure classify the patients into a severity rating, such as the NYHA functional classification (Cline et al., 1999; Dracup, Walden, Stevenson, & Brecht, 1992; Fonarow et al., 1997; Grady, et al., 1995; Hawthorne & Hixon, 1994; Jaarsma et al., 2000; Kostis et al., 1994; Mayou et al., 1991; Oka et al., 2000; Shah et al., 1998; Walden et al., 1994). In the studies done by Cline et al., Grady et al., and Dracup et al., it was discovered that the higher the NYHA classification, the poorer the QOL. Severity of disease may be an explanation for poorer QOL and could have assisted in explaining why the hypothesis was not supported. The

makeup of the two groups in regard to severity of disease may have been unequal, therefore affecting the results of this secondary analysis.

### Limitations

A limitation of doing a longitudinal study is the loss of subjects or attrition. Loss of subjects occurred between the baseline collection of data and the 6-month time frame in both the supportive educational and the placebo group. The placebo group lost seven subjects, which was approximately 23% of the subjects included in the sample when the initial data were collected. The supportive educational group lost 10 subjects, which is more than one third of the initial subjects. According to Polit and Hungler (1995), attrition can introduce bias by changing the composition of the initial sample, particularly if more are lost from one group than the other and attrition rates exceed 20%.

Because of attrition, the sample size became smaller at the 6-month time frame. The supportive educational group had 17 and the placebo group had 24 subjects at the 6-month time frame. According to Polit and Hungler (1995), the larger the sample, the more representative of the population it is likely to be. Small sample sizes also run the risks of a large standard error. A large standard error could result in the rejection of a hypothesis, even when the hypothesis may be correct.

Another limitation that could not be controlled is maturation. Physical growth, emotional maturity, and fatigue are examples of maturation (Polit & Hungler, 1995). Worsening or improvement of symptoms can occur due to the subject or the disease process. This can affect quality of life either in a positive or negative manner. The increase in QOL scores for the supportive educational group may be due to this maturation process and not due to the intervention.

Testing effect is another limitation of this study. Sensitization could have occurred after the questionnaire was completed initially. In the primary study, the subjects were tested at baseline, 3, 6, 9, and 12 months. This secondary analysis only utilized two timeframes, the baseline and 6 months. At the 6-month time frame, the subjects had already completed the QLI-III twice.

There are limitations associated with secondary analysis. The main limitation is that the researcher is limited to studying the available data and variables contained in the primary study. The researcher may find that other data may be helpful to answer the research question or support a hypothesis.

#### Implications for Nursing

As heart failure mortality improves through advances in medical and surgical management, people will live longer with a very disabling disease process. Reducing mortality and improving QOL are observable outcomes that the AHCPR has determined to be of primary importance when discussing treatment effectiveness (Hadorn et al., 1994). Outcomes such as decreasing mortality and increasing QOL do not necessarily go together. Decreasing mortality does not necessarily increase QOL. Decreasing heart failure mortality may mean having to live with a complex disease that requires dramatic lifestyle changes. Increasing or maintaining QOL may mean learning how to deal with a complex disease and the lifestyle changes that accompany it.

Nurses have a great opportunity to affect patient outcomes and validate the science and art of nursing. Nursing is the discipline highly qualified to assess, educate, support, and care for patients with heart failure and assist in bringing them to the highest level of quality of life possible. Nurses need to continue to treat patients in a wholistic

manner, caring for all aspects of the patient with heart failure, including the physiological, psychological, social, economic, developmental and spiritual variables.

Although the hypothesis of this secondary analysis was not supported, there was evidence that a supportive educational nursing intervention did increase quality of life in patients with heart failure. Since it was difficult to compare this study with other studies due to variations in measurement instruments and data collection time frames, further studies need to utilize the same data collection time frames and QOL measurement tools. Nurse scientists need to continue to study the issues that surround the patient with heart failure and quality of life. It is important to continue to research the effects of nursing interventions on quality of life, especially in chronic diseases such as heart failure, cancer, diabetes, and chronic obstructive pulmonary disease. Nurse scientists also need to mentor and motivate others to participate in the research process.

Nurse educators can assist in improving heart failure patient outcomes by insuring nursing school curricula address quality of life issues from the patient, family, and care giver perspectives. Students need to be prepared to assist and care for patients with chronic diseases, such as heart failure. Quality of life issues will increase as technology increases and is a very important part of caring for a patient with a chronic illness. Nursing curricula need to stress the importance of nursing research, assist in understanding the research process, and demonstrate to students how to incorporate research into their practice.

Nurse administrators can also play a role in improving outcomes in the heart failure patient. They need to base nursing policies and procedures on evidence-based practice and outcomes. In order to decrease the cost of heart failure and improve QOL



outcomes in patients, nurse administrators need to implement strategies that keep heart failure patients out of the hospital and out of the emergency rooms. Strategies that decrease symptoms and increase functional capabilities are some of the same strategies that increase QOL. They need to search for opportunities for research within their administrative area and support staff research initiatives. Administrators need to be willing to allow nurse scientists to conduct research studies in their practice settings.

Advance practice nurses can have an impact on improving quality of life for patients with heart failure. Advance practice nurses are familiar with research and utilize evidence-based nursing approaches in their practice. With shorter lengths of stays in the hospitals, patients need to be well educated on how to care for themselves. The advanced practice nurse that practices in the hospital setting is able to provide nursing interventions that prepare the patients to be discharged home. The advanced practice nurse that practices in the tertiary care setting, such as a clinic or office, can continue to provide nursing interventions in order to maximize the patient's functioning and QOL.

#### Recommendations

Heart failure is a debilitating and costly disease, which is increasing in incidence and prevalence. Heart failure not only affects patients, it affects families, and society.

Research conducted on the heart failure population and QOL has shown that patients with heart failure have a poor quality of life (Cline et al., 1999; Dracup et al., 1992; Muirhead et al., 1992; Reidinger et al., 2001; VanJaarseld et al., 2001; Walden et al, 1994). Recent research studies have focused on medical or surgical strategies to decrease heart failure mortality and morbidity, and increase QOL. Investigations need to continue in order to identify variables that affect quality of life, either positively or negatively.

It would be interesting to continue the primary study or replicate it, in order to obtain a larger sample and to examine if the hypothesis for this secondary analysis would be supported. Future research is needed on nursing interventions that improve quality of life in the heart failure patient, and decrease hospital readmission and decrease physician or emergency room visits. Specifically, interventions that take place in the home or within nurse based clinics would be very beneficial because more care is being done on an outpatient basis. More research also needs to be done on evaluating the cost-effectiveness of nurse-directed care at home or in clinic settings.

Quality of life needs to be defined. Each study seems to have a slightly different variation of the definition. Some definitions discuss one dimension of QOL and some discuss multiple dimensions. The same issue arises with QOL instruments. Some instruments measure just one dimension of QOL and others measure multiple dimensions. This makes it difficult to compare and contrast study results. Consistent instruments that measure QOL the same way need to be used in future studies. These instruments need to be valid and reliable.

Quality of life needs to be examined from the patients' perspective. Quality of life is very subjective and the research continues to try and measure it with objective tools. In order to fully understand quality of life, we need to listen to what the patient is telling us. Examination of the patients' perception of QOL needs to be attained through avenues such as interviews. The common themes of these interviews can then assist in development of quantitative or qualitative studies that truly affect QOL outcomes from the patients' perspective.

## Summary

Heart failure and its treatment are very complex, with numerous physical and psychological components. Successful management of heart failure requires lifestyle modifications, education, and counseling. Many studies have demonstrated that symptom distress, physical and psychological, is one large reason for a poor QOL (Dracup et al., 1992; Friedman and Griffin, 2001; Grady et al., 1995; Mayou et al., 1991; Muirhead et al., 1992; Walden et al., 1994). An assumption can be made that by gaining a better understanding of heart failure and its treatment, patients will be better able to care for themselves, which in turn decreases symptom distress. If symptom distress decreases, QOL may increase. Any nursing intervention that provides the necessary education and support to decrease severity of symptoms and level of distress could then increase QOL.

The purpose of this secondary analysis was to determine if a supportive educational nursing intervention increased quality life in patients with heart failure. Even though the hypothesis was not supported, there tended to be an increased QOL for patients who received the supportive educational approach at the 6-month time period. These findings seem to validate the importance of a comprehensive educational and supportive program for patients with heart failure and nursing is the discipline that has the knowledge and expertise to deliver such a program. There is much research supporting the hypothesis that QOL is poor in the patient with heart failure. Missing is the effect that nursing interventions can have on increasing QOL. This study is one attempt to explain the effect that nursing approaches may have on QOL. Quality of life is a very important clinical outcome and nursing research needs to be conducted to determine ways to improve it.

## APPENDIX A

# P E A R S O N E D U C A T I O N

One Lake Street  
Upper Saddle River, New Jersey 07458  
(201) 236-3281 Phone  
(201) 236-3290 Fax  
michelle.johnson@pearsoned.com

Michelle Johnson  
Permissions Administrator  
Legal Division 2C37

January 11, 2002

Julie Switek  
125 Elm St.  
Hopkins, MI 49328

Dear Ms. Switek:

You have our permission to use figure 1-3 from our text, ***THE NEUMAN SYSTEMS MODEL 4/e by Neuman/Fawcett***, in your Master's of Science thesis for Grand Valley State University.

Your thesis is on the effects of a supportive educative nursing intervention on the heart failure patient's quality of live.

You may credit our material as follows-

***Neuman/Fawcett, THE NEUMAN SYSTEMS MODEL, 4/E, ©2001. Reprinted by permission of Pearson Education, Inc., Upper Saddle River, New Jersey.***

Sincerely,

  
Michelle Johnson  
Permissions Administrator

**Julie Switek**  
125 Elm St.  
Hopkins, Mi.  
49328

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Phone: 616-341-8976  
E-mail address: jswitek@accn.org  
Fax: 616-341-8249

January 14, 2002

Betty Neuman, PhD, RN, FAAN  
PO Box 77  
Watertown, Ohio 45715

Dear Dr Neuman,

I am a Master of Science in Nursing student at Grand Valley State University. As a requirement for graduation, I am doing a thesis on the effect of a supportive educative nursing intervention on the quality of life of heart failure patients. I am using the Neuman Systems Model for the theoretical framework. I would like permission to reproduce the diagram of your model from the book: The Neuman Systems Model, 4th edition, by Betty Neuman and Jacqueline Fawcett. The diagram in question is Figure 1-3, on page 13. I have already received permission from Pearson Education, Inc.

If you have any questions or concerns, please feel free to contact me.

Sincerely,



Julie Switek

*The above permission request  
is granted. Betty Neuman 1/16/01.  
Kindly send abstract when available.*

## **APPENDIX B**

## Script to Obtain Consent

My name is \_\_\_\_\_. I am a registered nurse. I am taking classes at Grand Valley State University to obtain a Masters Degree in Nursing. I have been given permission by your home health care agency to come here today with your home health care nurse to determine if you are willing to let me explain a nursing research study that is being conducted with people like yourself who have been diagnosed with congestive heart failure and are receiving home care.

After your nurse has finished providing your care today may I stay a few minutes to explain the nursing research study we are doing? (If verbal permission is granted, proceed with explanation of study and obtaining informed consent after the home care nurse has left).

### Explanation of Study

As nurses we are concerned with how people adjust to the medical diagnosis of heart failure. We want to find nursing approaches that will help you learn how to self-manage your heart failure. We believe that when you can self-manage your heart failure you will live a better life.

The study will consist of five (5) interviews of approximately 45 minutes duration for the purpose of obtaining information about your health failure. You will be given \$10 at the completion of each of these five interviews as compensation for your time. The interviews will be spaced three months apart, starting this week. If you agree to participate you will be placed in one of three groups.

Each group will receive a different approach to managing health. Each of the nursing approaches will be provided in addition to the regular care you receive from your home care nurse at no extra cost. Another graduate nursing student who will call you to make an appointment to come to your home will provide each nursing approach to you in weekly 30-minute visits. If you participate in the study, I will give you the names of the students who call you. There will be a total of eight weekly visits. Each visit will provide you with information about managing your health. All visits will be scheduled at your convenience, similar to your current home care visits. You will not be given compensation for these eight visits.

Your participation in this study will in no way affect the regular care you receive from the home care agency, and it may help you improve your self-management of heart failure symptoms. The results of this nursing study may help nurses determine better ways to help other people with heart failure to improve their lives.

Because this is a nursing research study, I will maintain the confidentiality of the information obtained during the interview. Your name will not be identified with any of the information I collect. When reporting the results of the study only groups results will be shared; no names of individuals will be published. The nurses providing you home care will not be told that you are participating in the study.



## APPENDIX C

**Informed Consent**

- I \_\_\_\_\_ agree to participate in the nursing research study for persons with heart failure who are receiving home care. I understand that as a participant in this study: I will be interviewed for five (5) times for approximately 45 minutes each time, once within this week and again at 3, 6, 9, and 12 months. I will be compensated \$10 at the completion of each interview.
- I will receive information about managing my heart and that this information will be delivered by a registered nurse who is a graduate student at Grand Valley State University.
- I will receive this information once a week over the next eight weeks and that each visit will last approximately 30 minutes. I will not be compensated for receiving this information.
- I will be able to withdraw from the study at any time by notifying Dr. Kay Setter-Kline, the principle investigator at 616-895-3517, and that my withdraw will in no way affect the care I receive from the home care nurse.
- I will not be identified by name with any of the information obtained and that sharing of information obtained in this study will be in the form of group summaries of all participants.
- There is no identified risk from participating in this study and I may benefit from receiving information about ways to manage health.
- If in the process of gathering information any symptoms are identified that might need attention the nurse gathering the information will refer me to either the home health care agency or my health care provider.
- I also give permission for review of my health records to verify my health care status. If I have any questions about the research I may contact the Primary Investigator, Dr. Kay Setter Kline at 616-895-3517 or the Chair of Research Review Committee, Paul Huizenga at 616-895-2472 at Grand Valley State University.

\_\_\_\_\_  
Signed

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

The names of the students who are participating in this study are:

\_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_,  
and \_\_\_\_\_.

## APPENDIX D

**DEMOGRAPHIC DATA**  
(To be collected at time of initial interview)

Record Number: \_\_\_\_\_  
Subject Number: \_\_\_\_\_

1. Age \_\_\_\_\_
  
2. Marital Status  
 Never Married  
 Married  
 Divorced  
 Widow/Widower
  
3. Employment Status  
 Employed ( \_\_\_\_\_ hours per week)  
 Unemployed
  
4. Highest Level of Education  
 1<sup>st</sup> – 7<sup>th</sup> grade  
 8<sup>th</sup> – 10<sup>th</sup> grade  
 11<sup>th</sup> – 12<sup>th</sup> grade  
 Associate's Degree  
 Bachelor's Degree  
 Master's Degree  
 Doctoral Degree
  
5. Insurance Provider  
 Private Insurance (Name of Company) \_\_\_\_\_  
 HMO (Name of Group) \_\_\_\_\_  
 Medicare  
 Medicaid  
 Supplemental Insurance (Name of Company) \_\_\_\_\_  
 PPO (Preferred Provider Organization) \_\_\_\_\_  
 Other \_\_\_\_\_
  
6. Health Care Provider  
 Family Practice Physician  
 Cardiologist  
 Internist  
 Nurse Practitioner  
 Physician Assistant  
 Other \_\_\_\_\_

7. Annual Income in Dollars:

- less than \$10,000
- \$10,001 - \$20,000
- \$20,001 - \$30,000
- \$30,001 - \$40,000
- \$40,001 - \$50,000
- over \$50,000

8. How long have you had heart failure?

- less than 1 year
- 1 - 2 years
- 3 - 5 years
- more than 5 years.

9. List current medical diagnoses. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## APPENDIX E



GRAND VALLEY  
STATE UNIVERSITY

1 CAMPUS DRIVE • ALLENDALE, MICHIGAN 49401-9403 • 616/895-6611

November 21, 2002

Julie Switek  
125 Elm St.  
Hopkins, MI 49328

RE: Proposal #03-112-H

Dear Julie:

Your proposed project entitled **Providing a Tertiary Nursing Intervention: Does It Affect the Quality of Life in Patients With Heart Failure** has been reviewed. It is exempt from the regulations by section 46.101 of the Federal Register 46(16):8336, January 26, 1981.

Sincerely,

A black rectangular box redacting the signature of Paul Huizenga.

Paul Huizenga, Chair  
Human Research Review Committee

## APPENDIX F





GRAND VALLEY  
STATE UNIVERSITY

1 CAMPUS DRIVE • ALLENDALE, MICHIGAN 49401-9403 • 616/895-6611

January 12, 1999

Kay Setter Kline  
222 HRY  
Kirkhof School of Nursing

Dear Kay:

The Human Research Review Committee of Grand Valley State University is charged to examine proposals with respect to protection of human subjects. The Committee has considered your proposal, "*Home Care Outcomes for Heart Failure: A Test of Two Nursing Interventions*", and is satisfied that you have complied with the intent of the regulations published in the Federal Register 46 (16): 8386-8392, January 26, 1981.

Sincerely,



Paul Huizenga, Chair  
Human Research Review Committee

*Julie Smith has  
my permission to use  
data from the primary study  
for her thesis.  
Kay Setter Kline  
10-31-02*

## **LIST OF REFERENCES**

## LIST OF REFERENCES

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