EFFECTIVENESS OF A NURSE-LED INTERVENTION ON QUALITY OF LIFE AND FUNCTIONAL CAPACITY IN PATIENTS WITH HEART FAILURE

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Heart failure (HF) is a major health issue worldwide, costly in human and economic terms. Patients with HF often report a low quality of life (QOL) and functional capacity. Research has not yet demonstrated the most effective methods for improving QOL and functional capacity for HF patients. The purpose of this quasi-experimental study was to evaluate the effect of a nurse-led intervention on QOL and functional capacity, compared to usual medical management of HF. Framed by a health-related QOL model (Ferrans, Zerwic, Wilbur, & Larson, 2005) and a convenience sampling plan, community-dwelling patients with HF were randomly assigned to an intervention (n = 40) or control (n = 40) group. The intervention group received nurse-led education and telehealth management. The control group received routine medical management. Dependent variables were measured by a 6-minute walk tests and the Quality of Life Index (Ferrans & Powers, 1992). Results provide nurses with new knowledge to guide the education and care of HF patients in ways that elevate QOL and functional capacity and potentially impact the use of health care resources.
Chapter I

Introduction

Heart failure is a chronic, progressive condition in which the heart muscle cannot pump enough blood to the rest of the body. In the United States of America (USA), 5.7 million people have heart failure (HF), afflicting 10 in every 1,000 people over the age of 65 (American Heart Association, 2013). This alarming statistic illustrates why HF is now considered a major public health problem. HF is the primary reason for 12 to 15 million medical office visits and 6.5 million hospital days each year, as well as the major contributing factor in approximately 280,000 deaths in 2008 in the USA (Centers for Disease Control and Prevention, 2012).

HF is viewed by health care experts as an emerging epidemic. Over one-half million new cases of HF are diagnosed each year in the USA. It is the only cardiovascular disorder on the rise. As the elderly population grows and survival rates for people with heart disease grow, this number is expected to increase (Heart Failure Society of America, 2012).

HF imposes a substantial economic burden to patients, families, and society. HF is the most common hospital discharge diagnosis among individuals served by Medicare. More Medicare dollars are spent for the diagnosis and treatment of HF than for any other diagnosis, according to the American Heart Association (AHA) (2013). The estimated direct and indirect cost of HF was $29.6 billion in 2006 (Manning, Wendler, & Baur, 2010). In 2009, the direct and indirect costs in the USA were approximately $37.2 billion.

Direct costs are escalating due to expensive new medications and advanced technology for diagnosis, treatment, and monitoring (Zaya, Phan, & Schwarz, 2011). It is estimated that 75% of the direct costs are due to hospitalizations, for the HF disease process leads to costly and frequent
hospitalizations, with many HF patients experiencing a readmission rate of 13% within 15 days of hospital discharge, a 30 day readmission rate of 25%, and 6 month readmission rate of 50% (Zaya et al.). Frequently, the causes of readmissions are a lack of self-care disease management, lifestyle choices, and medication and/or dietary noncompliance (Kutzleb & Reiner, 2006).

The incidence of HF is more frequent in men than women, and African-Americans are 1.5 times more likely to develop HF than Caucasians. A diagnosis of HF carries a 30% mortality rate within 12 months after the first hospital admission for treatment, according to the Centers for Disease Control and Prevention (CDC) (2013). Approximately half of those diagnosed with HF die within 5 years of initial diagnosis, and only 25% are alive at 10 years after diagnosis (Heart Failure Society of America, 2012).

HF typically is a consequence of coronary artery disease, hypertension, or myocardial infarction. HF can cause breathlessness, effort intolerance, fluid retention, and increased mortality. Patients with HF are likely to experience exacerbations of their symptoms, leading not only to hospital readmissions but to low quality of life (QOL) and decreased functional capacity (Zaya et al., 2011).

It is imperative that HF patients have an understanding of the prevention, diagnosis, and treatment of the disease process. HF patients must have knowledge of the early warning symptoms of exacerbation, medication regimens, weight control, and dietary management. It is with this education that HF patients can manage the disease, monitor their progress, and prevent acute episodes. Educational strategies hold the potential to decrease the overall long term costs of this complex disease and improve QOL and functional capacity (Zaya et al., 2011). Health care payers consider it the responsibility of the health care professional team to instruct HF patients on
all aspects of the disease. When HF patients are well managed, patients experience a better QOL and functional capacity and costs to the health care system decrease.

Patients with HF often report poor health-related QOL (HRQL) due to the debilitating symptom burden of the disease (CDC, 2000; Healthy People, 2011). Researchers have reported that the symptom burden among patients with HF was equivalent to that of patients with advanced pancreatic and lung cancer (World Health Organization, 2007). Therefore, improving HRQL through HF care remains a priority (Bakas et al., 2012).

While some research has been conducted on nurse-led interventions to support self-management of HF, consistent findings across studies have been elusive. More research is needed, particularly on the perceptual outcomes of QOL and functional capacity. Patients’ perceptions are closely related to self-care management, treatment compliance, and overall decision-making regarding the disease process, thus holding the potential to influence the use of health care resources.

**Background and Significance**

According to the World Health Organization (WHO) (2006), health is defined as a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity. Interestingly, this definition has not been amended since 1948. The CDC has taken the WHO health definition and expanded it to include the concept of health-related QOL. The definition of HRQOL has evolved since the 1980s to include physical, mental, emotional, spiritual, and social aspects of health or well-being, as well as perceptions of health risks, functional status, social support, and socioeconomic status (CDC, 2013). HRQOL is a subjective evaluation qualifier of both positive and negative aspects of life. Individuals define HRQOL for themselves.

HF not only consists of the physical disease process; it is a complete clinical syndrome that affects many aspects of life. Mental health, as well as physical health, are greatly affected in HF
patients. Factors that may impact QOL and functional capacity include physical symptoms of HF, psychological difficulties in adjusting to chronic illness, social limitations from symptoms, and the burden of disease management (Demir & Unsar, 2011).

The experience of living with HF has been explored in nursing research. Two primary factors in patients’ descriptions of life with HF include low QOL and diminished functional capacity. Low QOL and diminished functional capacity are often related, as patients report that their level of productivity, ability to perform meaningful activities, social and emotional status, and life satisfaction define their QOL and functional capacity. Frustration, fear, anxiety, depression, and guilt are common symptoms associated with HF (Kutzleb & Reiner, 2006).

Studies have shown that self-care and cognitive deficits can be associated significantly with poor QOL and negative healthcare outcomes among HF patients (Pressler et al., 2010). Patients who display a decreased understanding of medication compliance and self-care activities, such as diet and exercise, also exhibit a decreased QOL and functional capacity. Self-care competence plays a significant role in the overall QOL for patients with HF (Jurgens, 2006). Thorough education regarding the HF disease process, treatment options, dietary restrictions, symptom management, and healthy lifestyle behaviors plays a vital role in decreasing re-admissions and increasing QOL (Britz & Dunn, 2010). Patients have fewer symptoms and an improved functional capacity when they have a sufficient understanding of the disease process and how to manage it.

An important goal in comprehensive HF treatment is to sustain a meticulous program of self-managed care in order to maintain satisfactory QOL. While research has suggested general principles for improving the self-care management and QOL of adults with HF, few studies have explored the process and outcomes of nurse-led interventions. Further studies are needed that compare interventions and measure valued outcomes in this vulnerable population.
Statement of Problem

Patients who have been diagnosed with HF report reduced physical, mental, spiritual, and social health, which lessens QOL and functional capacity. Research has not yet clearly identified the effects of a nurse-led intervention on QOL and functional capacity in community-dwelling adults with HF (Kutzleb & Reiner, 2006).

Purpose of Study

The purpose of this study was to evaluate the impact of a nurse-led intervention on functional capacity and QOL when compared to protocol-driven, medical management care in community-dwelling adults with HF. This is a partial replication of Kutzleb and Reiner’s (2006) study.

Theoretical Framework

Health-related QOL is a multidimensional concept that includes biological variables, symptom status, functional status, health perceptions, and overall well-being (Walker & Avant, 2005.) HRQOL is commonly conceived as dynamic and subjective, and the dimensions often include physical, social, psychological, and spiritual factors. Many HRQOL models have been proposed and described in health care literature. The models have been designed for different health and illness conditions, across the lifespan, and among individuals, their families, and communities. However, the specific dimensions across tools are labeled differently by different authors (Haas, 1997). Differing conceptualizations of HRQOL limit the ability to develop a coherent body of evidence to guide further HRQOL research and practice (Bakas et al., 2012).

One commonly used model of HRQOL was proposed by Ferrans, Zerwic, Wilbur, and Larson (2005). It was a revision of Wilson and Cleary’s (1995) HRQOL model. The five major domains of the original model were retained, while definitions were clarified and non-medical factors were removed.
The theoretical work of Ferrans and colleagues (2005; Ferrans & Powers, 1992) formed the framework for this study. In Ferrans and colleagues’ (2005) model, QOL was characterized as a subjective perception reported by an individual. Positive QOL reflected an individual’s life satisfaction, which was perceived when key elements interacted to elicit positively-toned emotions. Key elements of QOL were multi-dimensional and included health, physical ability, psychological state, social involvement, and work or financial stability. In this study, QOL is understood to be HRQOL.

Research Questions

The research questions that guided this study were:

1. Are there differences in functional capacity in two groups of HF patients, one that received a nurse-led intervention and the other group that received traditional protocol-driven medical management of HF?

2. Are there differences in QOL in two groups of HF patients, one that received a nurse-led intervention and the other group that received traditional protocol-driven medical management of HF?

Definition of Terms

Quality of Life

Conceptual definition: QOL is defined by Ferrans and Powers (1992) as an individual’s sense of well-being as it relates to contentment in one’s life.

Operational definition: The QOL Index-Cardiac IV (Ferrans & Powers, 1992) was a 64-item questionnaire that was divided into 2 parts: the first measured life satisfaction, and the second measured the importance of the various aspects of life satisfaction. A total QOL
score was computed, as well as four subscale scores that reflected the psychological/spiritual, social, economic and family domains.

**Functional Capacity**

*Conceptual definition:* An objective measure of tolerance for moderate activity.

*Operational definition:* The distance walked in the 6-minute walk test.

**Nurse-led Intervention**

*Conceptual definition:* The nurse-led intervention that provided education on lifestyle modification, daily weight, medication compliance, and dietary compliance in order to improve QOL and functional capacity. Community-dwelling patients were assessed physiologically and through perceptual surveys and were monitored through telehealth methods, specifically a weekly phone call from a registered nurse (RN) with specialized knowledge of cardiac disease. A close alliance between the patient’s nurse and physician assured that monthly physician appointments were attended and plans of care were tailored and modified when needed. The intervention continued for one year (Kutzleb & Reiner, 2006).

**Protocol-driven Medical Management**

*Conceptual definition:* Patients who were involved in the protocol driven medical management group were given follow-up appointments at the cardiology clinic every 3 months for a year for medical management. At each cardiology visit, a QOL survey and a 6 minute walk test were completed. Patient education information regarding smoking cessation, medication compliance, and diet/nutrition counseling were provided at each visit as determined by the health care provider. Weekly telephone calls were not provided for this group (Kutzleb & Reiner, 2006).
Limitations of the Study

This study is limited by the sampling plan, which called for a convenience sample of willing participants. Patients who had a language barrier or literacy issues were unable to participate in this study. This limitation is significant especially due to the high rates of functional illiteracy in the USA.

A second limitation of the study is that the control group could have received care that varied widely, since the care was not regulated as part of the study design. The education and follow-up care they received depended on the provider assigned to them. Also uncontrolled were sources of education that any participants in the study could access independently, beyond what was provided as part of routine care or the tailored, nurse-led intervention.

Lastly, mortality could have affected the study results, since up to one-third of patients with HF do not live for a year after initial hospitalization. Participants in the study had been hospitalized at least twice prior to enrollment and therefore may not have completed the study due to mortality or inability to complete study instrumentation.

Assumptions of the Study

Four assumptions that undergirded the study were:

1. HF patients prefer a tailored intervention plan and frequent contact with health care providers.
2. HF patients can learn to manage the telemonitoring equipment and have the ability to attend clinic visits.
3. HF patients will respond honestly and introspectively to items on study instrumentation.
4. The QOL Index measured the salient aspects of living with heart failure.
Summary

Heart failure (HF) is a major cause of hospital admission and death in the USA. Patients with HF often report a low quality of life (QOL) and low functional capacity. Research has not yet demonstrated the most effective methods for improving QOL and functional capacity for HF patients. In specific, few studies have compared nurse-led education and monitoring with telehealth to traditional, protocol-driven medical management. The purpose of this study was to evaluate the impact of a nurse-led intervention on functional capacity and QOL when compared to patients who received protocol-driven, medical management care for HF. This was a partial replication of Kutzleb and Reiner’s (2006) study. The intervention tested was telehealth monitoring and education about diet, daily weight management, lifestyle behaviors, and medication compliance in order to improve QOL and functional capacity in patients with HF.
Chapter II

Literature Review

Heart failure is a chronic and complex disease process requiring astute medical and nursing management. Patients living with HF need an understanding of the diagnosis and treatment of the disease process to avoid exacerbations and frequent hospitalizations. Research suggests that nurse-led strategies may elevate patients’ self-care management of HF, optimize functional capacity, and enhance QOL. Low functional capacity and QOL contribute to recurrent hospitalizations, which significantly add to the overall high cost of caring for this population. Further testing of nurse-led strategies is needed to clarify outcomes in diverse samples.

Purpose

The primary aim of this study was to evaluate the impact of a nurse-led intervention focused on telehealth monitoring and education about medication and diet compliance, daily weight, and lifestyle modifications on QOL and functional capacity.

Organization of the Literature

To provide a context for this study, a review of research related to various aspects of HF and the process and outcomes of nurse-led interventions was indicated. Following a description of the theoretical framework for this study, literature is reviewed on QOL of HF patients and caregivers, sleep and QOL in HF patients, home-based and nurse-led interventions for HF patients, physical exercise and QOL in heart failure patients, and prevention of heart failure.

Theoretical Framework

Health-related QOL (HRQOL) is a multidimensional concept that includes biological variables, symptom status, functional status, health perceptions, and overall well-being (Walker
& Avant, 2005.) HRQOL is commonly conceived as dynamic and subjective, and the dimensions often include physical, social, psychological, and spiritual factors. Many HRQOL models have been proposed and described in health care literature. The models have been designed for different health and illness conditions, across the lifespan, and among individuals, their families, and communities. However, the specific dimensions are labeled differently by different authors (Haas, 1997). Differing conceptualizations of HRQOL limit the ability to have a coherent body of evidence to guide further HRQOL research and practice (Bakas et al., 2012).

One commonly used model of HRQOL was proposed by Ferrans et al. (2005). It was a revision of Wilson and Cleary’s (1995) HRQOL model. The five major domains of the original model were retained, while definitions were clarified and non-medical factors were removed.

The theoretical work of Ferrans and colleagues (2005; Ferrans & Powers, 1992) formed the framework for this study. In Ferrans and colleagues’ model, QOL was conceived as a subjective perception reported by an individual. QOL reflected an individual’s life satisfaction, which was perceived when key elements interacted to provide positively toned emotions. Key elements of QOL were multi-dimensional health, physical ability, psychological state, social involvement, and work or financial stability.

QOL in HF patients has been measured using a variety of research tools. The Ferrans and Powers (1992) QOL Index-Cardiac IV tool measured satisfaction with various domains of life and the importance of those aspects. Specific domains included perceived health, functional capacity, psychological/spiritual domain, social/economic domain, and family domain. The QOL Index-Cardiac IV tool is the most recent version of the tool and was designed for broad populations experiencing illness.
Quality of Life for Heart Failure Patients and Caregivers

Perceptions of QOL are individualized, meaning that standard measurement of QOL has been difficult to develop and interpret. Therefore, qualitative methodologies hold promise for explicating key elements of QOL as experienced by patients with HF. In a study by Bosworth et al., 2004), descriptions of perceptions of QOL were explored. The purpose of the study was to collect specific descriptions of QOL from individuals living with HF.

In this study, 15 male HF patients from a central database were selected non-randomly. Specific sampling criteria included: a documented diagnosis of HF, ejection fraction (EF) of less than 40% by echocardiogram, support for diagnosis per nuclear cardiology studies or angiography, and a visit to the general medicine clinic of the target facility in 1999. Three focus groups were created, and participants were assigned according to their individual disease stage. Discussions lasting approximately 90 minutes were led by a psychologist, using open-ended communication techniques. Participants were asked about their feelings regarding dealing with chronic illness, then about the meaning and important components of QOL. A grounded theory approach was used to analyze the data. Five broad themes and 30 attributes were identified using a constant comparison analysis and open axial coding techniques (Bosworth et al., 2004).

Five themes emerged through data analysis: coping, social support, role loss, symptoms, and effective responses. Frustration about the loss of ability to participate in previous work and activities had an overall negative impact on QOL. Participants reported emotional strain and feelings of depression, low self-worth, anxiety, fear, and guilt. Symptoms were discussed in great detail with the participants. A common coping strategy with all participants was their level of spirituality, especially those participants who had advanced stage HF. Participants expressed both the positive
and negative aspects of social support by family and friends when coping with HF (Bosworth et al., 2004).

Bosworth and colleagues (2004) determined that many of the identified aspects of QOL were not included in the standard QOL measures used in clinical trials. Examples of the aspects that were not included were: the loss of independence, the unpredictability of the HF disease process, hopelessness, frustration with the changing roles and limitations, tangible and emotional support. The main symptoms of HF were assessed with disease-specific QOL measures, but the main symptoms of cognitive and emotional functioning identified by the focus groups were not thoroughly assessed. “Identifying both deficiencies and strengths of patients presents an opportunity for the clinician to build upon individual resources” (Bosworth et al., p. 89). Future research on how health-related QOL can be thoroughly assessed as a multidimensional experience could enable clinicians to better care for patients and their families.

In another research study on QOL in HF patients, Murray and colleagues (Murray, Kendall, Boyd, Worth, & Benton, 2004) explored the spiritual aspect of QOL. The researchers asserted that health-related QOL included a spiritual dimension. Spiritual needs were often not addressed by health care professionals due to lack of time, vulnerability, or a poor understanding of spirituality. The researchers designed a study to investigate whether chronically ill patients and caregivers experienced significant spiritual needs. The study compared the spiritual concerns of a HF group to a lung cancer group and investigated how spiritual concerns differed over the course of each unique disease process, including how spiritual needs were supported.

The study by Murray et al. (2004) was guided by the following research questions.

1. Do patients with life-threatening illness and their informal caregivers experience significant spiritual needs?
2. How did spiritual concerns vary by type of illness and over the course of each illness?

3. How do patients and their caregivers perceive that they might be helped and supported in addressing spiritual issues?

The study took place at the Royal Infirmary of Edinburgh, the Western General Hospital Edinburgh, St. Johns Hospital, Livingston, and Liberton Hospital in the United Kingdom. The sample consisted of 20 patients with inoperable lung cancer and 20 patients with end-stage HF and informal caregivers for each group. A total of 149 in-depth interviews were completed, which included 56 interviews with caregivers and 93 interviews with patients. In the lung cancer group, 15 of the sample lived with spouses; the average age was 65 years old; and 12 patients had small-cell lung cancer. Of the lung cancer group, 17 were offered chemotherapy or radiotherapy, and 16 received it. At the end of the study, 5 of the 20 patients were alive. The most common cause of HF was ischemic heart disease. In the HF group, the average age was 74 years old, in which 11 patients had a live-in caregiver, and 7 were alive at the end of the study (Murray et al., 2004).

A qualitative approach to data collection through individual interviews was used in order for the researchers to gain an understanding of patients’ perceptions. Open-ended questions and active listening techniques were used in the interviews, which lasted from 40 minutes to over 2 hours. Patients and caregivers were not consistently willing or able to communicate needs, thoughts, and feelings openly. The study design allowed the researcher and participants to develop relationships over the minutes and hours of the interview, which promoted an open discussion of needs (Murray et al., 2004).

Narrative analysis techniques and the qualitative data analysis package NVivo were used to transcribe, analyze, and code the audio-recorded interviews. A multidisciplinary steering group
negotiated themes from the data and identified common themes among the two groups. Based on the data and literature review, a thematic framework was formed (Murray et al., 2004).

Both lung cancer and HF groups experienced spiritual needs; some spiritual needs were common in both groups of patients and their caregivers. There were also some variations in the spiritual needs across disease processes. For both groups, spiritual needs were important early in the disease process and again later in the illness progression. Needs for love, meaning, and purpose in life were expressed by all patients and caregivers. Peace of mind and spiritual well-being were also important in both groups. In the lung cancer group, the feeling of dying was imminent in the beginning of the disease process. In the HF group, isolation, hopelessness and loss of confidence prevailed throughout the illness progression. In both groups, patients and caregivers struggled with self-image, changes in dependence upon others, and changes in relationships. Caregivers struggled with spiritual needs, especially when it involved the stress of assisting a loved one spiritually (Murray et al., 2004).

An additional finding was that professionals did provide spiritual care, but at times patients’ sense of identity or self-worth was felt to be unimportant during care received. Patients may be reluctant to talk about spiritual issues, but will “open up” when addressed with open-ended questions and given adequate time to express hopes and fears with health care professionals (Murray et al., 2004).

The authors concluded that patients who have been diagnosed with a life-threatening illness need spiritual support in order to manage feelings about death and dying. This support is needed long before the terminal stage of illness is reached (Murray et al., 2004). The findings of this study expand what is known about health-related QOL in HF patients and their caregivers.
In another comparative study of QOL in HF patients, Luttik and colleagues (Luttik, Jaarsma, Lesman, Snadermann & Hagedoorn, 2009) explored the QOL of the partners of HF patients as compared to those living with healthy partners. The researchers acknowledged that formal and informal caregivers play an extensive role in caring for patients with HF and that the impact of providing care to a loved one can greatly affect caregivers’ QOL. Little research has explored the QOL for support persons for patients with HF.

Luttik et al. (2009) hypothesized that partners of patients affected with HF would report a lower QOL than those living with a healthy partner and their continuous involvement in chronic care would negatively affect QOL of the caregivers. The role of involvement in care and gender were also variables investigated in this study.

Data were collected between the dates of October, 2002, and February, 2005, using a cross-sectional, comparative design. The convenience sample included 303 partners of HF patients. Questionnaires regarding QOL and general well-being were completed by participants (Luttik et al., 2009).

The overall findings of this study were that the differences in QOL in partners of those with HF and individuals who lived with a healthy partner were minimal. Results showed that gender does play an important role in perceptions of QOL of partners of persons with HF. Females tended to be more involved in the caretaking role than male partners in a reversed role. Female partners performed the caregiving tasks typically associated with pain, vitality, and the social aspects of QOL. The care-giving was not just for the patient but also for a social network of persons connected with the patient with HF. These female, caregiving partners were found to be at risk for low QOL and needed particular attention regarding their psychological well-being (Luttik et al., 2009).
Sleep and Quality of Life in Heart Failure Patients

Studies have indicated that diet and exercise regimens may affect the QOL and functional capacity of HF patients, but there are also lifestyle adjustments that are equally important when caring for persons with this complex disease process. The quality of sleep in HF patients can play a significant role in their QOL and functional capacity. The harmful effects of waking too early, difficulty falling asleep, difficulty staying asleep, and sleeping supine in a bed can cause a great deal of physiological and emotional stress for chronic HF patients (Wang, Lee, Tsay, & Tung, 2010). A study was performed to investigate factors that affect the quality of sleep in patients with HF. The specific aim of the study was to describe demographics, disease characteristics, emotional status, and lifestyle factors that influenced the sleep quality of patients with HF. A predictive correlational design guided the study in a convenience sample of 101 patients who were recruited from a cardiology clinic in Taiwan. Data were collected from September, 2007, to December, 2007.

Instrumentation for the study included questionnaires for demographics, disease characteristics, the Perceived Health Scale (Huang, 1993), Physical Activity Scale for the Elderly (PASE) (Washburn, Smith, Jette, & Janney, 1993), lifestyle behaviors, revised Short-Form Geriatric Depression Scale (SF-GDS) (Lesher & Berryhill, 1994), and the Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman, & Kupfer, 1989; Wang et al., 2010). The clinical data pertinent to the disease of HF included ejection fraction, New York Heart Association (NYHA) functional class, number of times hospitalized due to HF, period of time having HF, diagnosis of other chronic illnesses, and the number of medications currently taking. These data were collected from the patients’ records in the cardiology clinic (Wang et al.).

Inclusion criteria for the sample were age 55 years or older, having a diagnosis of HF, and receiving care in the target cardiology clinic in Taiwan. The exclusion criteria included: a
hospitalization with HF within the previous month, having a history of cancer or uremia, or currently living in a long-term care facility. An experienced nurse collected the data by reading each question to participants. Each item of the instrumentation was answered without assistance, and the participants were not allowed to take the questionnaires home (Wang et al., 2010).

To measure patients’ perceptions of their health, the study used the Perceived Health Scale (Huang, 1993). The scale measured 3 items, specifically perceptions of overall health, current health compared to that in the previous year, and current health compared to that of others that were the same age. A 5-point Likert scale ranging from 1 (very bad) to 5 (very good) was used for all the items. The total point range was 3 to 15, with higher scores indicating a more positive perception of participants’ view of their own health (Wang et al., 2010).

Using the PASE (Washburn et al., 1993), physical activity was evaluated with 12 items that measured three activity levels experienced during the past week. The three activity levels included leisure activities (six items), household activities (five items), and occupational activities (one item). Frequency and duration of each leisure activity was measured by a 4-point Likert scale. Some items, such as household activities and occupational activities, required yes/no responses. The higher the score, the greater the activity level, with the scores ranging from 0 to 360. When used with community-dwelling older adults, the PASE demonstrated acceptable test-retest reliability, with a coefficient of 0.75 (CI = 0.69 - 0.80) (Wang et al., 2010).

Through a revised version of the SF-GDS (Lesher & Berryhill, 1994), the study by Wang et al. (2010) measured depressed mood. Using a scale of 15 yes/no items, the study assigned a 1 to each yes answer and a 2 to each no answer. A possible total score of 15 was used, in which the higher score was representative of greater depression.
The Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989) was used to measure sleep quality. The PSQI scale measured seven dimensions of sleep characteristics including: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medication, and daytime functioning. The scale included 19 items with a possible score of 0 to 21. A higher score was indicative of poor quality of sleep (Wang et al., 2010).

Participant characteristics were described using percentages, means, and standard deviations. One-way analysis of variance (ANOVA) and independent t-tests were used to study the associations among demographics, lifestyle behaviors, and sleep quality. Pearson r correlations explored relationships among the study variables of health, physical activity levels, depressed mood, and sleep quality, all of which were measured at the interval level of data. To reveal the significant predictive factors of sleep quality, multiple regressions were computed (Wang et al., 2010). The majority of the participants were male (77.2%) and married (76.2%), with a mean age of 74 (SD = 9.4) years and a body mass index (BMI) of 24.3 (SD = 3.7). Most took a daytime nap (74.3%) and exercised regularly (67.3%); most did not smoke (94.1%), or drink tea (60.4%), coffee (87.1%), or alcohol (82.2%). Walking was reported most frequently as a preferred exercise activity (91.1%). The mean daily activity level measured with the PASE was 72.5 (SD = 58.4) (Wang et al., 2010).

The mean number of months since diagnosis of HF was 36.8 (SD = 31.3), and participants had a mean of 1.2 (SD = 1.4) hospitalizations due to HF in the past year. The mean ejection fraction was 37.0 (SD = 8.6), with a comorbidity mean of 3.8 other diseases (SD = 1.6). Hypertension was the most common comorbid condition (66.3%); two others that were listed frequently were hyperlipidemia (56.4%), and coronary heart disease (57.4%). Patients were prescribed a mean of 6.70 (SD = 206) medications (Wang et al., 2010).
As measured by the Pittsburgh Sleep Quality Index (Buysse et al., 1989), mean scores of participants was 10.8, a mid-range score. 81% of the participants gave an account of poor sleep quality, and 31% were unhappy with the quality of their sleep. According to the correlational analyses, 31% of the variance in sleep quality was explained by perceived health, number of comorbidities, gender, and depression score ($F = 12.2, p < 0.001$). Sleep quality was negatively associated with self-perceived health ($r = -0.451, p < 0.001$) and BMI ($r = -0.199, p < 0.046$). Patients with better sleep quality had better perceived health and higher BMI scores (Wang et al., 2010).

It can be concluded that sleep problems are a common occurrence in HF patients. Sleep problems may have a negative impact on the functional ability and QOL in HF patients. Chronic HF patients need to be instructed on proper sleep hygiene in order to adhere to disease-management regimens and experience enhanced QOL from leisure time activities and overall emotional health (Wang et al., 2010).

**Home-based and Nurse-led Interventions for Patients with Heart Failure**

A major role in the care of HF patients involves health promotion and teaching along with a comprehensive follow-up program for patients. HF patients are frequently admitted to the hospital, with the causes of the admissions being a lack of self-care disease management, lifestyle behaviors, medication and/or diet noncompliance. Patients with HF utilize emergency and inpatient hospital services frequently, placing a financial burden on the healthcare system. Many insurers and healthcare systems have adopted disease management strategies, such as telemonitoring, in order to provide care sooner to help prevent acute exacerbations of HF. The purpose of a recent research study was to determine if the use of telemonitoring devices impacted selected outcomes for Medicare patients diagnosed with HF (Tompkins & Orwat, 2010).
The study took place in Phoenix, Arizona and consisted of recruited patients from the CIGNA Healthcare for Seniors, an insurance plan. CIGNA patients who had one or more diagnoses of HF using International Classification of Diseases, 9th Revision diagnostic codes in CIGNAS claims data medical records were recruited for this study. Patients were taken from the CIGNA’s Medical Group (CMG), which was a large medical practice group practice owned and operated by CIGNA Healthcare of Arizona. There was a total of 390 participants who met the inclusion criteria and agreed to participate. The inclusion criteria were CIGNA HealthCare for Seniors insurance participants who were age 65 or older and enrolled in the CIGNA Seniors plan for at least 6 months prior to the study. The exclusion criteria were a diagnosis of severe dementia, late-stage cancer, end-stage kidney disease, enrollment in a hospice program, the inability to speak English, the inability or unwillingness to complete the informed consent form, and the intention to leave the health plan, or travel extensively in the next 6 months (Tompkins & Orwat, 2010).

The participants were either assigned to a telemonitoring group or a standard care group. Monitoring devices were installed in the homes of the subjects assigned to the telemonitoring group. The monitors were used in the homes for up to 6 months. Data collection occurred from April, 2007, through November 30, 2007. Participants were followed for an average of 175.5 days. The control subjects were followed longer than the intervention subjects, 178.1 days, compared to 172.9 days respectively. The original protocol was 180 days, but due to the occurrence of mortality, hospice, or withdrawal from the program, the length of time was shortened. Many of the participants were retired and were not year-round Arizona residents. The study also had a lower than expected recruitment; one of the reasons may have been because of the exclusion criteria (Tompkins & Orwat, 2010).
During this study period, the monitors provided a daily process of vital sign collection, including weight, blood pressure, heart rate, and blood oxygen levels. A pre-determined set of questions was prompted by the monitors. Questions such as blood glucose levels were included if the participants were diabetic. Participants and families were made aware that monitors sent information to the central nursing station every morning. The software color coded each patient’s results for the day, which were reviewed for intervention by the CMG registered nurse if necessary. Red or yellow alerts were transmitted, and the CMG registered nurse would determine the need to call the patient or recommend further interventions, such as a physician visit (Tompkins & Orwat, 2010).

The intervention achieved statistical significance for two utilization measures. There was a higher rate of urgent care visits among the telemonitored group (p < .05). The lower average of hospital stays for the telemonitored group was found to be marginally significant (p < 0.1). Higher utilization rates for all types of services were seen for elderly patients and also including comorbid diabetes or COPD patients (p < .05). Females had more physician ambulatory visits and urgent care visits (p < .05). There was a significant difference seen in almost all types of services in the clinic setting (p < .05). Prescription costs were greater for the telemonitored group and also for elderly females that had other disease processes such as diabetes or COPD (p < .01) (Tompkins & Orwat, 2010).

It can be concluded that patients assigned to telemonitoring had a tendency for lower costs and a lower total number of hospital days. Telemonitoring appeared to aid in the ambulatory management of HF patients. No study results were reported for QOL or functional capacity. It was suggested that further studies be done to determine the cost effectiveness of telemonitoring interventions and the effects on QOL (Tompkins & Orwat, 2010).
In another study of home-based interventions in patients with HF, Servantes and colleagues (Sevrantes et al., 2011) examined the effects of home-based exercise training on functional capacity, QOL, strength and endurance of lower limbs, and sleep for patients with chronic HF and sleep apnea. Servantes et al. provided in-depth background for the study, noting that QOL in HF was an important indicator of the effective management of this delicate patient population. Chronic HF patients experience progressive intolerance to exercise and dyspnea with physical exertion. The effects of reduced blood supply to the skeletal musculature can cause peripheral limitations. Evidence suggests that there are structural and biochemical changes that occur as a result of reduced skeletal muscle perfusion. This results in impaired strength and endurance during exercise and holds the potential to reduce QOL.

Servantes et al. (2011) noted that, in addition to intolerance to physical activity, another correlate of HF is sleep apnea. The incidence of sleep apnea occurs in 45-82% of chronic HF patients. Clinicians have expressed an increased interest in the pathological similarities between sleep apnea and chronic HF and the effect of exercise training on mortality and morbidity.

Treatments aimed specifically at improving muscle and respiratory function may improve QOL and functional capacity for chronic HF patients. Since long-term supervised rehabilitation programs are often not available for HF patients, home-based exercise programs are more accessible and acceptable. However, research has not yet clarified the outcomes of home-based exercise programs in patients with HF and sleep apnea (Servantes et al., 2011).

The study was grounded by two research questions.

1. Does a home-based exercise training program in patients with chronic HF and sleep apnea increase muscle strength and endurance?
2. Does a home-based exercise program in patient with chronic HF and sleep apnea improve QOL and functional capacity (Servantes et al., 2011)?

Considered for inclusion in the sample of this study were persons who had a diagnosis of HF based on the presence of signs and symptoms, such as fluid retention, shortness of breath and activity intolerance, along with objective evidence of cardiac systolic HF. Participants received care from the medical center in Sao Paulo Federal University in Brazil between March, 2007, and November, 2008. Specific inclusion criteria included: New York Heart Association Class II-III, ejection fraction less than 40%, age range 30-70 years, clinically stable for three months, peak VO2 less than 20ml/kg/min, receiving β-blocker therapy, documented sleep apnea, and the ability to participate and understand in an home exercise training program without supervision. Exclusion criteria included: New York Heart Association Class IV, history of myocardial infarction, or revascularization within the past four months, unstable angina, history of symptomatic ventricular arrhythmias, obstructive aortic, or mitral valvular disease, hypertropic cardiomyopathy, hypotension, pulmonary arterial pressure greater than 50mmHg, COPD, vascular leg blockage, musculoskeletal disease, or emotional and psychological disorders that would prevent the patient from understanding exercise directions without supervision (Servantes et al., 2011).

This prospective randomized controlled trial consisted of three randomized groups. During the trial, all patients were advised to remain on their medication regimens and were evaluated at baseline and after three months. The sample consisted of a total of 50 chronic HF patients with sleep apnea. The groups were labeled Group 1 (aerobic training, n = 18), Group 2 (aerobic with strength training, n = 18), and Group 3 (untrained, n = 14). The recruitment began in March, 2007, and ended in November, 2008, with data collection lasting 3 months (Servantes et al., 2011).
After providing baseline data, Groups 1 and 2 began home-based exercise for three months and then underwent three supervised exercise sessions. Patients’ progress was reviewed monthly and also tracked through weekly follow-up phone calls from the HF clinic. In order to make sure that Group 3 remained untrained, they were evaluated and interviewed weekly by the HF clinic staff (Servantes et al., 2011).

Cardiopulmonary exercise testing, isokinetic strength and endurance testing and polysomnography were evaluated in all participants at baseline and after three months of exercise. In addition, all participants completed the Minnesota Living with HF Questionnaire (MLHFQ) (Pina et al., 2003) at baseline and after three months. The patients in Groups 1 and 2 received weekly telephone calls to monitor and assess program adherence and provide support. They were also reviewed monthly by a physiotherapist and a cardiologist to evaluate and adjust exercise intensity. The patients in the untrained Group 3 were followed weekly at a specialist HF medical center from Sao Paulo Federal University, Brazil. In a weekly interview, their physical activity status was evaluated (Servantes et al., 2011).

Outcome measures included a symptom-limited treadmill test, which included a respiratory gas exchange analysis and metabolic measurements. Patients’ heart rate and rhythm were monitored by 12-lead electrocardiograms during the treadmill tests. Blood pressure readings were obtained at rest and at the end of each stage using mercury sphygmomanometers. Using a 15-point self-report exertion intensity scale, peak effort was recorded at intervals during the test. The patients were encouraged to exercise until exhaustion, and gas exchange data were collected in 30-second periods. Peak oxygen consumption (Peak VO2) was calculated as the highest 30-second time. Using the V-slope method, the VO2 was calculated. Using the linear regression technique, the slope-related ventilation to carbon dioxide production (VE/VCO2 slope) was computed. This slope did not
include the nonlinear part of the data after the onset of ventilator compensation for metabolic acidosis (Servantes et al., 2011).

In order to measure strength and endurance of the knee extensors and flexors, an isokinetic dynamometer was used. The dynamometer modified the speed and the angle of movements. The test protocol consisted of a 5-minute warm-up, three repetitions at 60 seconds, and 10 repetitions at 180 seconds, with a resting phase of three minutes. Using the MLHFQ (Pina et al., 2003), QOL was measured as disease-specific health-related QOL. The MLHFQ tapped patients’ perception of the effects of chronic HF on ability to perform daily activities. The MLHFQ consisted of 21 items that measured physical, socioeconomic, and psychological impairments related to chronic HF. The higher the MLHFQ score, the lower the perception of QOL (Servantes et al., 2011).

Using a digital system with 17 channels, overnight polysomnography was performed on HF patients. The test included the electroencephalogram, electrooculogram, electromyogram, and electrocardiograms. All polysomnograms were performed by experienced sleep technicians and reviewed by a sleep medicine physician. Sleep efficiency was documented in real sleep time (Servantes et al., 2011).

The outcome measures for functional capacity demonstrated that exercise can improve functional capacity. In groups 1 and 2, peak VO2 and VO2 AT increased significantly $(p < 0.001)$, and VE/VCO2 slope deceased significantly $(p < 0.001)$ (Servantes et al., 2011).

The outcome measures for muscle strength and muscle endurance indicated a significant improvement after home-based rehabilitation in Groups 1 and 2 $(p < 0.001)$. But in Group 3, either there was no change or a small amount of deterioration was found in muscle strength. All the tests performed were two-sided, and a p value of less than 0.05 was considered statistically significant. It
was concluded that home-based training maintained or improved patients’ current muscle strength (Servantes et al., 2011).

The total MLHFQ scores decreased significantly, indicating that the QOL significantly improved in Groups 1 and 2 (Group 1 = -48.8%; Group 2 = -44.4%). It was determined that regular physical activity proposed by the home rehabilitation programs to increase physical conditioning was associated with improved QOL. There was not a significant change in the MLHFQ in Group 3 (Servantes et al., 2011).

The quality of sleep in Groups 1 and 2 improved in home-based rehabilitation (p < .05). In Group 1, there was a decrease in hypopnea levels, and in Group 2 there was a significant decrease in the number of apnea and hypopnea events (p < .05). The mean oxygen saturation at sleep for all three groups showed no significant differences after three months. There was an increase in sleep efficiency and a decrease in the number of nocturnal arousals in Groups 1 and 2. The findings demonstrated the importance of exercise for sleep quality in Groups 1 and 2. However, Group 3, which was untrained, showed a significant increase in the number of nocturnal awakenings and no increase in sleep efficiency after three months (Servantes et al., 2011).

The gold standard measure for aerobic capacity is peak VO2 readings through cardiopulmonary exercise measurements. In this study, Group 1 and Group 2 demonstrated improvement in peak VO2. The untrained patients in Group 3 had a significant decrease in peak VO2 and VO2 AT, with no significant changes observed in VE/VCO2 slope after three months. Study findings suggest that the VE/VCO2 slope is more powerful to predict mortality that peak VO2 alone. The association between carbon dioxide and ventilation production during incremental exercise is atypical in chronic HF, and an abnormally high VE/VCO2 slope (typically > 34) is indicative of a greater risk of a cardiovascular event. This variable significantly decreased to normal
rates only in the trained Group 1 and Group 2 after the introduction of home-based exercise programs (Servantes et al., 2011).

It was demonstrated in this study that home-based exercise training programs for chronic HF patients provided a cost effective and therapeutic strategy that was efficient and beneficial. The home groups displayed high rates of participation and exercise adherence to the program. The only major limitation in the study was the exclusion of many typical HF patients. The majority of the patients that were seen by the specialist at the HF clinic were not eligible for the study (84.7%). Chronic HF patients can have many co-morbidities, such as uncontrolled arrhythmias, pulmonary embolism, pulmonary hypertension, renal insufficiency, and decompensated diabetes, which excluded them from the study (Servantes et al., 2012).

This study concluded that HF patients can benefit greatly from home-based exercise training, which results in an increase in muscle strength, endurance, and can improve the QOL and functional capacity. Home-based exercise programs are easily reproducible and beneficial to HF patients. Physical limitations can affect the QOL in HF patients, which can make it difficult for all HF patients to participate in home-based exercise training without supervision (Servantes et al., 2011).

In another intervention study in the care of HF patients, Kutzleb and Reiner (2006) noted that educating patients about HF and monitoring patients’ progress were critical in promoting QOL, supporting functional capacity, and decreasing chances of post discharge readmissions to hospitals. Kutzleb and Reiner argued that patients and caregivers must be informed about best practices and current treatments in HF and that more research was needed to explore the process and outcomes of nurse-directed self-care management programs for HF patients.

Kutzleb and Reiner (2006) proposed a research study aimed at two purposes. The first purpose was to evaluate the effects of nurse-directed patient education in HF patients.
education focused on daily weights, lifestyle modification, medication and diet compliance in order to improve functional capacity and QOL in HF patients. The second purpose was to explore how well patients understood the information about the HF disease process, QOL, and functional capacity.

The study was framed by the following research questions.

1. Is there a difference in functional capacity and QOL in two groups of HF patients, one that was treated by nurse practitioners in a comprehensive self-care program and one group that received the traditional protocol driven medical management?

2. To what extent did the self-care nurse-directed patient education program influence the functional capacity and QOL of participants (Kutzleb & Reiner, 2006)?

Considered for inclusion in the study were all patients who were referred to either a community-based hospital medical clinic or an inner city medical center for evaluation of HF symptoms and who were 18 - 75 years of age and lived in an eastern United States metropolitan area. Of the 65 eligible patients, 23 consented to participate in the study. Data were collected over a 12 month period of time, using a quasi-experimental, multicenter research design. The study compared a nurse-directed care group, who received education and a weekly telephone conference with a nurse, to a medical management team group whose care was guided by protocol and guidelines through routine outpatient visits. The nurse-directed (NC) group was managed by a cardiac nurse specialist and a cardiologist. HF patients in the medically managed routine care (RC) group were managed by a cardiologist along with cardiac fellows. Referrals for both group came from a cardiology clinic. Both sites had a similar patient population mix and comparable medical management, in which cardiac protocols were closely followed (Kutzleb & Reiner, 2006).
All patients had evidence of left ventricular systolic dysfunction or diastolic dysfunction with a confirmed diagnosis of HF based on echocardiography. Patients excluded from the study were illiterate in English, had a HF diagnosis secondary to another chronic comorbidity such as myocardial infarction, or had an illness such as cancer, which could possibly compromise survival over the duration of the study. The total population baseline characteristics included age, marital status, gender, average ejection fraction percentage, New York Heart Association (NYHA) classification, etiology, risk factors, and medications. The severity of symptoms fit into four categories according to NYHA functional classifications: class I, no cardiac symptoms, unlimited activity, class II, ordinary activity causes fatigue, dyspnea, or palpitations, class III, no symptoms at rest, but marked limitation of activity and symptoms with less than usual activity, class IV, symptoms may occur at rest, and any physical activity causes symptoms. Patients were interviewed in order to determine their symptoms and hospitalization history regarding HF. They were placed into one of the four (NYHA) classifications for the study according to their symptomology and history (Kutzleb & Reiner, 2006).

The instrument used to measure QOL (QOL) was developed by Ferrans and Powers (1992). The QOL instrument provided a high level of validity, reliability, and sensitivity based on Cronbachs alphas, which ranged from .84 to .98 in 26 studies (Kutzleb & Reiner, 2006). The QOL instrument consisted of two parts, one of which measured satisfaction with different aspects of life, and the other of which measured the importance of those aspects.

Overall QOL scores were calculated in four domains: health and functioning, psychological/spiritual, social/economic, and family. Possible scores ranged from 0 to 30. A 6 minute walk test was used to objectively measure functional capacity in the study groups. The participants walked an appropriate distance according to their limitations at a brisk pace, which
included an allotted rest time. This measure was difficult to standardize, in regards to step length and pace. All of the walking tests had the same researcher, used the same physical area, and received the same directions in order to keep the objective conditions consistent (Kutzleb & Reiner, 2006).

Thirteen patients from the nurse-directed group (NC) and 10 patients from the routine care group (RC) participated out of 65 eligible participants. There were more women (65%), than men (35%) in the study, with the mean age of the participants being 58 years old. The average ejection fraction was 47%. Gender, race, or group membership did not affect the study variables. The average number of medications that each participant was taking was six, which was consistent with this complicated disease process. Eighty percent of the RC group did not follow a low sodium diet, or were never placed on a low sodium diet. Compliance with medications was low in the RC group. In the NC group, two patients participated in a prescribed exercise program through cardiac rehabilitation. Weekly exercise programs were participated in by 84% of the NC group and 40% of the RC group. In the RC group, 60% of patients managed their disease process by limiting their activities and resting often. During the study, there were no hospital readmissions, deaths, or patients who were non-compliant to follow-up care (Kutzleb & Reiner, 2006).

Results of the study revealed a significant relationship between functional capacity and QOL (p < .05). When comparing scores on the dependent variables between the groups, there was a significant improvement over the 9-month intervention in the NC group for QOL (F = 13.569, p < 0.0001), health and function (F = 3.995, p < 0.003), social and economic (F = 14.109, p < 0.0001), and family functioning (F = 2.384, p < 0.05). The data analysis also indicated that there was no statistical significance between the NC group and the RC group regarding functional capacity. QOL scores at 9 months improved more from the beginning of the study for patients in the NC group than
In the RC group. There was significantly more improvement in QOL in the treatment group, although both groups showed improvement. QOL scores in all four subscales improved in both groups, with the domain of health and function being the most significant. The RC group had a 25% improvement compared to a 62% in the NC group in the domain of health and function ($F = 3.995$, $p < 0.003$). In both groups, functional capacity improved, but the NC group had a more improvement than the RC group (73% increase versus 9% increase) over the 9-month study period. Therefore, the results signified that there was a relationship between QOL and functional capacity and that nurse-directed care was effective in improving QOL (Kutzleb & Reiner, 2006).

Based on the findings, a nurse-directed, focused intervention does have a significant influence on improving QOL. Symptom monitoring and disease self-management were significantly improved with nurse-directed oversight and patient education. Further study is needed in other samples and with a continued focus on improving functional capacity (Kutzleb & Reiner, 2006).

**Physical Exercise and Quality of Life in Patients with Heart Failure**

In another study that featured exercise activity as an intervention for HF, Bocalini and colleagues (Bocalini, Santos, & Serra, 2008) explored the effect of physical activity on functional capacity and QOL in adults with HF. The authors suggested that, although a number of drugs have been developed in order to control symptoms and hemodynamic disorders in HF, a more therapeutic approach, such as physical exercise, may be equally beneficial. It has been traditionally understood that exercise promotes physical stress, which could impair the cardiac function in HF patients. The question remains unanswered as to whether or not patients with HF can exercise safely and experience the benefits of improved functional capacity and QOL, as a non-pharmaceutical therapy.

Bocalini et al.’s (2008) study included 56 subjects, who had the following inclusion criteria: ejection fraction less than 45% by echocardiography, symptoms of NYHA functional class II and III,
had received established pharmacological therapy for at least 4 weeks, and had been diagnosed with compensated HF more than 2 months prior to the study. Of the 56 recruited patients, 7 declined to participate, 16 presented with one or more exclusion criteria, and 33 were randomly divided into 2 distinct groups: Untrained (S) (n = 25) or Trained (T) (n = 28). All patients maintained pharmacological therapy including individual dietary management (Bocalini et al., 2008).

**Prevention of Heart Failure**

HF often results from coronary heart disease (CHD) that is not prevented or treated promptly, resulting in a weakened heart muscle. Sufficient evidence exists in health care science to prevent or detect CHD early and prevent HF. According to Kiessling, Lewitt, and Henriksson (2011), there is a gap between what is known about CHD and what health care providers deliver as evidence-based practice. The gap contributes to mortality and morbidities, such as HF. Kiessling and colleagues (2011) proposed a research study to determine differences in mortality rates in two groups of CHD patients, one that received traditional care and the other with newly-designed interventional care.

The sample for the study consisted of patients in Stockholm, Sweden, who were younger than 70 years of age with a diagnosis of CHD, according to the International Classification of Diseases, Ninth Revision. A registry from a local hospital in the region was used in which patients who were treated for CHD from the time period August 1, 1993 to July 31, 1994. Patients required a diagnosis of angina pectoris based on coronary angiography, clinical assessment, or stress test, or a diagnosis of myocardial infarction based on World Health Organization criteria in order to be considered for this study. Recruitment of patients took place between October 1994 and February, 1995. In a primary care setting, a total of 323 patients were identified; of those, 79% participated in the study. The patients were divided into two groups, an intervention and a control group. The intervention group consisted of patients treated by a general practitioner, and the control group
consisted of patients treated by specialists. For two years, general practitioners who were participating in care of the intervention group received case-based training that applied the most current evidence to practice. A particular emphasis was on new evidence-based guidelines regarding intensified lipid-lowering recommendations for patients with CHD. Patients in the control group, or traditional care group, received the physicians’ usual standard of care for that time. There were a total of 255 patients included in the longitudinal study (Kiessling et al., 2011).

A primary report on lipid levels was done after two years, and a second report on lipid levels was done after 10 years. Repeated questionnaires, clinical examinations, and blood sampling were completed by an independent organization at baseline and during 2 years of the study. Through the Swedish Cause of Death Register by use of National Registry Numbers, the patients’ data were analyzed from each patient’s inclusion date through 2006, after 10 years in the study. Data collected included gender, hypertension, age, smoking, and diabetes. Using the Kaplan-Meier method, cumulative incidence and 95% confidence intervals were calculated (Kiessling et al., 2011).

Intention-to-treat and Cox proportional hazards regression analysis were used to compare the study groups. The findings at the 10-year mark included that 22% of the patients in the intervention group had died, which was significantly fewer than the patients in the intervention group 44% (p < .02). It was determined that the difference was due to reduced cardiovascular mortality in the intervention group (p < .01). Additionally, a mortality rate of 23% was seen in patients that were treated by a specialist, which was comparable to the 22% mortality rate in the intervention group (Kiessling et al., 2011).

The researchers concluded that, by using case-based training to implement evidence based care in general practice, there was decreased mortality at 10 years in patients with
The authors recommended that the effects of case-based training be tested in other areas of clinical practice (Kiessling et al., 2011).

**Summary**

A review of the literature presented significant published studies on various aspects of maintaining QOL and increasing functional capacity in HF patients. Bosworth et al. (2004) determined the importance of understanding the many components of QOL in HF patients so that health care professionals can support QOL during the course of this chronic disease. Murray et al. (2004) discussed the importance of spiritual care throughout the entire disease process, beginning with diagnosis and ending with death. Also emphasized in the study was the importance of having a strong support network before the terminal stage of the illness is reached.

Luttik et al. (2009) concluded that QOL not only affects the HF patient, but it also can have a drastic effect on the caregivers of HF patients. Nurse-led interventions can provide family and caregiver support during the course of this complex, chronic, and debilitating disease.

One factor contributing to QOL in HF patients is sleep quality. Wang et al. (2010) concluded that there are many factors that influence sleep quality in HF patients. HF patients have difficulty falling asleep and maintaining sleep, usually due to their inability to lie supine. The sleep problems can have a negative effect subsequently on functional capacity.

Research has included studies that test interventions that could improve the experience of living with HF. Tompkins and Orwat (2010) concluded that telemonitoring of HF patients has been shown to reduce hospital days and decrease total costs. Telemonitoring facilitates better communication management and monitors daily weights, vital signs, and lifestyle of HF patients. Servantes et al. (2011) determined that home-based exercise programs were safe and did improve exercise performance, functional capacity, QOL, and muscle strength. Although the self-monitored
nature of home-based exercise programs is difficult to monitor, they demonstrate improvement in exercise performance in HF patients without documented safety risks. Bocalini et al. (2008) also concluded that guided and monitored physical exercise was safe and beneficial for HF patients and had the potential to improve functional capacity and QOL. In addition to exercise, research suggests that a major element of a HF treatment plan should include management of activities of daily living, maintaining independence, and developing psychosocial well-being. Kutzleb and Reiner (2006) concluded that a nurse-directed approach to care could improve patient knowledge of self-management of HF and therefore QOL and functional capacity.

Kiessling et al. (2011) concluded that implementing evidence-based practice in primary care can be beneficial in decreasing the severity of CHD, a primary antecedent to HF. Effective strategies for continued comprehensive care need to be implemented in order to provide thorough medical management.

One key theme of the literature review was that HF patients have considerable educational needs, especially for education on lifestyle modifications, daily weight management, and diet and medication compliance. Research has suggested that nurse-led comprehensive care can increase QOL and functional capacity in HF patients, thus impacting use of resources as well as mortality. Further research is needed to evaluate nurse-led interventions to manage HF.
Chapter III

Methodology and Procedures

Heart failure is a major public health problem, a key contributing cause in approximately 280,000 deaths per year, and a primary factor in escalating health care costs in the United States (Centers for Disease Control and Prevention, 2012). HF is viewed by health care experts as an emerging epidemic. Over one-half million new cases of HF are diagnosed each year in the United States. It is the only cardiovascular disorder on the rise. As the elderly population grows and survival rates for people with heart disease grow, this number is expected to increase (HF Society of America, 2012).

While some research has been conducted on nurse-led interventions to support self-management of HF, consistent findings across studies have been elusive. More research is needed, particularly on the perceptual outcomes of QOL and functional capacity. Patients’ perceptions are closely related to self-care management, treatment compliance, and overall decision-making regarding the disease process.

This chapter contains a description of the methods and procedures for a study that is a partial replication of Kutzleb and Reiner’s (2006) research study. The aim of the work is to contribute to nursing knowledge about the nurse-led management and support of health care regimens for patients with HF.

Purpose

The purpose of this study was to evaluate the impact of a nurse-led intervention on functional capacity and QOL when compared to protocol-driven, medical management care in
community-dwelling adults with HF. This is a partial replication of Kutzleb and Reiner’s (2006) study.

**Research Questions**

The study was guided by the following research questions.

1. Are there differences in functional capacity in two groups of HF patients, one that received a nurse-led intervention and the other group that received traditional protocol-driven medical management of HF?

2. Are there differences in QOL in two groups of HF patients, one that received a nurse-led intervention and the other group that received traditional protocol-driven medical management of HF?

**Population, Sample and Setting**

Patients considered for inclusion in this study were ages 18 to 75 years old, male or female, and referred to two target outpatient clinics for a primary diagnosis of HF. Further inclusion criteria were that the patients had a HF diagnosis based on echocardiography, an ejection fraction of less than 40%, and had been hospitalized twice in the past year for a primary diagnosis of HF.

One site for the study (Site One) was a community-based HF clinic managed by a cardiologist and a cardiac nurse specialist, located in a middle income suburban neighborhood in the Midwestern United States. A second site (Site Two) was in the same city in a mid-to lower income inner city medical center clinic near a university hospital where patients were managed by a cardiologist and cardiac fellows. Referrals to both clinics came from local cardiologists. Both sites had similar patient population mixes and physicians with similar approaches to medical management. Exclusion criteria included all patients who did not speak or read English; patients with a recent history of myocardial infarction; patient with a history of unstable angina;
patients for whom HF was not thought to be the primary diagnosis; and patients who had multiple chronic comorbidities that might make it difficult to finish the one-year study.

Target sample size was determined by power analysis to be 30 per group. To allow for attrition, 40 participants per group were recruited.

**Protection of Human Subjects During Research**

The study protocol was approved by the Ball State University Institutional Review Board and also by the review boards of the facilities where data were collected. Patients were informed about the study during a clinical visit by clinic personnel who were not affiliated with the study. Patients were told how to provide contact information if they wished to receive information about the study. Patients who provided contact information were contacted by the principal investigator by phone or mail. If, after receiving information about the study, the patient wished to participate, an appointment was set to meet with the principal investigator in the patient’s home or during a clinic visit. The patient had an opportunity to ask questions and then signed an informed consent. The principal investigator verified that the patient met the inclusion criteria for the study by review of medical records. The principal investigator then set an appointment with participants for verification assessment at one of the two participating clinics, during which an electrocardiogram and 6-minute walk test were completed. Then participants completed the study questionnaires and returned them to a drop box in the clinic area. Study instrumentation was coded with a number assigned to the participant so that data could be matched over time. Data were confidential but not anonymous.

A code sheet of patient names and assigned identification numbers were kept in a locked drawer in the locked office of the principal investigator at the university hospital affiliated with one of the study sites. Informed consents were kept in a locked drawer separate from the code
list. In a third locked drawer, completed instrumentation was stored. Data were entered into a password protected computer to which only the principal investigator has access. At the conclusion of the study, all paper work and computer files were deleted or destroyed. All Health Insurance Portability and Accountability Act (HIPAA) confidentiality guidelines were followed.

**Procedures**

After signing consents and being enrolled in the study, participants were randomly assigned to the routine care (RC) or nurse-led care (NC) groups in order to ensure an ethical and similar patient group mix. The nurse-led group attended the clinic at Site One. The RC group attended the clinic at Site Two.

The NC group received a tailored educational plan from the nurse during the initial visit. The education consisted of basic information on the disease process, key principles of self-management, prompts regarding upcoming clinic visits, and information on telemonitoring of vital signs, daily weight, medication compliance, and self-report of symptoms. Education delivery was tailored for the participant’s educational level and preferred method of receiving information as visual or auditory. NC participants received weekly phone calls from the cardiac specialist nurses in the clinic at the first site. NC participants attended a clinic visit once a month, or more often as needed. At the third month visit and the ninth month visit, participants completed the 6-minute walk tests and completed the questionnaires on QOL and functional capacity. NC participants were given the option of contacting the clinic nurse during or after clinic hours for questions related to seeking immediate help for exacerbating symptoms. At each clinic visit, medical records were reviewed for recent hospitalizations.

The RC group received education that was deemed usual by the health care providers at the second clinic site. The RC group did not receive telemonitoring, weekly phone calls, or
prompts about office visits. RC participants received appointment times to come to the clinic every three month or more often as needed. At the third month visit and the ninth month visit, RC participants completed the 6-minute walk test and the questionnaires on QOL and functional capacity. At each clinic visit, medical records were reviewed for recent hospitalizations.

Data collection and provision of the intervention ceased after one year. Participants were notified and given an opportunity to receive information about the results of the study.

**Methods and Measurement**

The QOL instrument used in this study was the QLI (Ferrans & Powers, 1992), which was developed in order to provide an objective measure of life satisfaction. This instrument offered a high level of validity, reliability, and sensitivity. The QLI had four subscales determined in samples of ill patients. They included life satisfaction, self-esteem, health and functioning, and socioeconomic status. The QLI consisted of a 64-item questionnaire, which was divided into two segments in order to measure satisfaction with a variety of areas of life and the importance of the same areas to the subject.

A 6-point Likert type scale was the response option for each section. For example, in Part One, satisfaction with an aspect of life was reported by the participant as very satisfied (6) to very unsatisfied (1). In Part Two, importance of an aspect of life was reported as very important (6) to very unimportant (1). The scores were calculated as total subscale scores (Ferrans & Powers, 1992).

In order to measure functional capacity, a 6-minute walk test was completed by every patient (Hwang, Chien, & Wu, 2010). Each patient was instructed to walk a brisk pace as far as possible for the 6 minute time period and to rest if necessary. Standardized directions, consistent
research staff, and the same physical walking space were used for the testing (Kutzleb & Reiner, 2006).

Descriptive data for participants were collected, including age, gender, ethnicity, co-morbidities, and medications. Additionally, at each clinic visit descriptive data about any hospitalizations since the last clinic visit were collected from medical records. Also at each visit vital signs and weight were measured and medication lists were reconciled for any changes. A record was kept of attendance at clinic visits.

**Research Design**

A quasi-experimental design guided the study in order to address the two research questions and compare the nurse-directed care (NC) group with the routine medical care (RC) group. The sample was a convenience sample of willing participants who were assigned randomly to groups. Threats to contamination of groups was avoided by conducting the NC intervention only at one clinic site and maintaining clinical visits for the RC group at a separate site.

**Data Analysis**

Data were entered into a database by the principal investigator and analyzed by SPSS. First descriptive statistics were computed for demographic variables and the two groups were compared for baseline differences through statistics appropriate for the level of data (Grove, Burns, & Gray, 2013). Zero order correlations between QOL and functional capacity were computed by pearson r. Then groups were compared through analysis of variance and analysis of covariance to evaluate differences between groups over time. Multiple regression analyses were conducted to identify predictors of QOL and functional capacity. In addition, predictors of mortality were examined, even though not defined as an outcome of the study. Independent
variables included group assignment, demographic variables, attendance at clinic visits, and number of hospitalization. Significance was set at p < .05.

**Summary**

The purpose of this study was to determine the effect of a nurse-led intervention on QOL and functional capacity in a convenience sample of HF patients. Participants included in patients’ assigned randomly to one of two groups. The intervention group received nurse-led care (NC). The control group received routine medical care (RC). The quasi-experimental design called for data collection over a 12 month period.

Instrumentation for the study included the QLI (Ferrans & Powers, 1992) to measure patient’s life satisfaction in multiple areas of life. A 6-minute walk test measured functional capacity. Data were analyzed for relationships and differences between groups through computations appropriate for the level of data.

This study adds to nursing and medical knowledge about HF patients’ perceptions related to living with the disease and outcomes that can be expected from nurse-led interventions that educate, support, and monitor patients through a tailored approach. Future research can take from this study core elements of a nurse-led intervention and reliable and valid outcome measures for further testing, as the discipline of nursing builds a science of chronic disease management impacted by research evidence.
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