USING OASIS DATA TO ASSESS MODERATOR EFFECTS OF PATIENT CHARACTERISTICS ON TELEMONITORING OUTCOMES IN HEART FAILURE PATIENTS

by

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DEDICATION

This dissertation is dedicated to my husband, who never stops believing in me and my two daughters, Lia and Jena, who constantly kept my doctoral study in their prayers.
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ABSTRACT

This study had two purposes: 1) to compare the difference between home health care only and home health care plus telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization; and 2) to explore which patient characteristics might moderate telemonitoring’s impact.

Heart failure has emerged as a major public health burden. Like other chronic conditions, heart failure patients have an important role to play in the day-to-day management of their condition. One of the principal reasons for introducing telemonitoring in home health care was to increase heart failure patients’ capacity to self-manage their conditions at home.

This study used a prospective, non-experimental, comparative, descriptive design. A total of 68 participants were recruited with 34 in each group. Symptom burden and self-care of heart failure were measured on enrollment and 40 days later. Hospitalization was measured as an event that either occurred or did not occur.

Although no between-group differences in symptom burden were found, both groups showed significant decreased symptom burden over the 40-day period. Of the three self-care measures, only self-care maintenance differed significantly between the two groups at the 40-day follow-up ($p < .05$). Only the participant’s functional status had significant moderator effect on the relation between type of service received and self-care maintenance ($p < .05$).

The addition of telemonitoring produced similar outcomes to regular home health care, except for self-care maintenance. Like most prior studies, this study focused on evaluating the overall relationship between telemonitoring and outcomes without concern for the transformation process. Although these evaluations were able to provide an overall assessment of whether or not
the telemonitoring program worked, they cannot identify the underlying mechanisms that generate the effects. Without knowing what made the program work or not work, it is difficult to pinpoint what needs to be done for future improvement. A theory-oriented evaluation will be needed in future research. Theory-oriented evaluations not only allow researchers to clarify the connection between a program’s operation and its effect, but also to specify intermediate effects of a program that might become evident and measurable.
CHAPTER ONE: BACKGROUND AND SIGNIFICANCE

Introduction

The dramatic increase in chronic conditions globally demands creative action (The World Health Organization, 2002). In the United States, about 133 million people currently live with a chronic condition. The number of individuals with chronic conditions will reach 157 million by the year of 2020 as the population continues to age (Partnership for Solutions, 2004). Traditionally, our health care system emphasizes an acute, episodic model of care and tries to “fix” patients when they develop a problem. This model of care no longer meets the needs of many patients, especially those with chronic conditions. Chronic conditions require that patients manage and provide much of their own care; such as taking medication, exercising or learning to identify early warning signs of deteriorating health, as well as collaborating with health care professionals.

One of the principal reasons for introducing telemonitoring in home health care settings is to create a new way to increase the ability of chronically ill patients to self-manage their conditions successfully at home. Telemonitoring uses information and telecommunication technologies to monitor patients’ clinical parameters (e.g., blood pressure, heart rate, oxygen saturation and weight) from a distance and facilitates timely identification of clinical problems so that clinicians can adjust treatments rapidly (Meystre, 2005; Lamothe et al., 2006). Telemonitoring also allows patients to communicate with health care professionals about their conditions more often and without leaving home. For individuals who are living with a chronic condition, frequent communication with health care professionals is vital because their health status can change dramatically from one day to the next (ITTA, 2004). However, the current
shortage of nurses, the increasing number of home health care patients and constraints imposed by health care plans limit the number of home visits nurses can make. Thus, telemonitoring can provide home health care agencies an efficient way to manage their chronically ill patients effectively and to minimize or prevent hospital readmission.

Telemonitoring can increase communication between patients and home health care nurses through daily evaluation of physiological data (Holland et al., 2005). However, not all patients receiving telemonitoring will benefit from telemonitoring (Hopp et al., 2006; Whitten & Mickus, 2007); some may do as well with home health care visits alone. Several studies have addressed the need to identify who benefits most from telemonitoring (Cleland et al., 2005; García-Lizana & Sarría-Santamera, 2007; Lusignan, Wells, Johnson, Meredith & Leatham, 2001; Wakefield, Holman, Scherubel & Kenzle, 2007). Given the ever-growing number of patients affected by chronic conditions and the scarcity of resources, it is important that we find ways to identify which patients will benefit most from the technology. How patient characteristics may influence the effect of telemonitoring has yet to be studied. The current study was designed to investigate which patient characteristics might moderate the effect of telemonitoring.

Home health care nurses routinely collect a significant amount of patient data during patient admissions as part of the Outcomes Assessment and Information Set (OASIS). These data may allow us to identify specific patient characteristics that moderate telemonitoring outcomes and thus predict those for whom the addition of telemonitoring is likely to improve outcomes over home health care alone. This study provides the opportunity to explore the usefulness of OASIS data for guiding nursing interventions.
Background

Chronic Conditions

Chronic conditions are health problems with a long and indefinite duration that require ongoing management (The World Health Organization, 2002). Chronic conditions include chronic illnesses and impairment (Hoffman & Rice, 1996) that are expected to last a year or longer, limit what one can do, and/or may require ongoing medical care (Partnerships for Solutions, 2002). The increased incidence of chronic conditions has become one of the greatest challenges to our current health care systems, which were initially developed in response to the needs of patients with acute, episodic health problems. In acute diseases, treatment is aimed at cure, i.e., returning all systems to normal status; however, with chronic disease, treatment is aimed at helping patients self-manage their conditions (The World Health Organization, 2002). Chronic conditions are individualized in terms of the system affected and types of care required. A chronic condition can appear suddenly or develop gradually, have episodic exacerbations, or remain in remission or asymptomatic for a long period of time (Larsen, 2005). Although chronic conditions are sometimes considered an aspect of aging, they are not confined to the older population. Chronic conditions may produce consequences that are caused by, or follow the course of the condition (O’Halloran, Miller & Britt, 2004). Chronic conditions cannot be completely cured or prevented (O’Halloran, Miller & Britt, 2004; Larsen, 2005). Because there is no cure; controlling, minimizing, or managing negative effects becomes an important goal. Any chronic condition may require significant medical intervention over its course; but the responsibility for managing day-to-day care over the course of the illness falls largely on the patients themselves (Holman & Lorig, 2000; Lorig & Holman, 2003; Curtin et al., 2005).
In 2005, more than 133 million people were living with chronic conditions in the United States. It is estimated that the number of people with chronic conditions will reach 157 million by 2020, exceeding an earlier projection of 134 million (Partnership for Solutions, 2004). Multiple factors have contributed to this growth. Developments and advances in the fields of public health, microbiology and pharmacology have led to a significant decrease in mortality from acute and communicable diseases (Larsen, 2005). Advances in medical services and technologies are expected to extend life expectancy and allow people to live longer with their conditions. Also, the likelihood of having a chronic condition increases as one becomes older. In fact, 82% of Medicare enrollees have one or more chronic conditions (Wolff, Starfield & Anderson, 2002). As the baby boomers age, the number of people living with chronic conditions will grow dramatically.

Chronic conditions now represent the dominant clinical problem in health care and the care of people with chronic conditions consumes a large proportion of health and social care resources. In 2001, people with chronic conditions accounted for 83% of all health care spending, up from 78% in 1998 (Medical Expenditure Panel Survey, 2001). About 98% of home care visits were made to people with chronic conditions, which also accounted for 76% of physician visits and 81% of inpatient stays (Medical Expenditure Panel Survey, 2001). In terms of Medicare expenditures, 99% were for beneficiaries with at least one chronic condition (Wolff, Starfield, & Anderson, 2002; Partnership for Solutions, 2004). Many of these elderly patients were hospitalized at a huge cost because their condition had deteriorated until they were in crisis (Wolff, Starfield, & Anderson, 2002). As the prevalence of chronic conditions increases, so too will the stress on our health care systems.
Heart Failure in Older Adults

Heart failure has emerged as a major public health burden for the U.S. (Goff et al., 2000; Rasmusson, Hall & Renlund, 2006). In 2004, the estimated cost for direct and indirect care of heart failure in the United States was $28.8 billion (American Heart Association, 2005). Heart failure is a progressive chronic condition that is caused by damage to the heart muscle or the mechanisms that control the heart’s flow of blood. There are a number of risk factors for heart failure; however, age is the most significant contributor (Fleishman & Sclar, 2004; Forman & Rich, 2003; Rich, 1997). As one ages, there are significant alterations in cardiovascular structure and function that increase the likelihood of heart failure (Forman & Rich, 2003).

Nearly 5 million people are currently living with heart failure in this country, of which 75% are 65 or older (American Heart Association, 2005). The prevalence of heart failure has grown by 500 percent over the past 30 years, with approximately 550,000 new cases reported each year (Fleishman & Sclar, 2004). Heart failure is one of the five most common chronic conditions in the Medicare population (Super, 2004) and is the leading diagnostic-related group (DRG) for Medicare hospital admission (American Heart Association, 2005). Heart failure is associated with significant morbidity and mortality (less than 50% survives more than 5 years) (Chriss et al., 2004). Unlike other cardiovascular diseases, heart failure is the end stage of a cardiac disease. Despite recent advances in pharmacological therapy and management of cardiovascular disease, there has been no substantial improvement in incidence or survival of patients with heart failure (Formiga at al., 2003; Kosiborod et al., 2006; Senni et al., 1999). Although only 14% of Medicare beneficiaries have heart failure, they account for 43% of

During the first six months after discharge, approximately one third of heart failure patients are readmitted to the hospital (Hoyt & Bowling, 2001; Proctor et al., 2000; Todero, LaFramboise & Zimmerman, 2002). Hospitalization related to heart failure is frequent, expensive, and possibly preventable in about 40% of the cases (Vinson et al., 1990; Pappas et al., 1997; Michalsen, König & Thimme, 1998; Schwarz & Elman, 2003). In 2003, $4.4 billion was paid to Medicare beneficiaries for heart failure-related hospitalizations (Center for Medicare & Medicaid Services, 2005). Clearly, heart failure places considerable stress on our health care systems, especially with the increasing percentage of elderly in our population.

As in other chronic conditions, heart failure patients have an important role to play in the day-to-day management of their condition (Holman & Lorig, 2004; Lorig & Holman, 2003; Newman, Steed & Mulligan, 2004). Heart failure is a highly debilitating condition that involves a range of symptoms; such as fatigue, shortness of breath and difficulty breathing, swelling of the ankles and lower legs, loss of appetite, abdominal discomfort, and weight gain from fluid retention (Flavel & Stevenson, 2001). Successful self-management of a chronic condition can ameliorate symptoms, prevent complications, delay disease progression and conserve health care resources (Bodenheimer, Wanger & Grumback, 2002; Kane, Priester & Totten, 2005). However, successful management often means dramatic lifestyle changes (Kane, Priester & Totten, 2005). Heart failure is an exceedingly difficult condition to manage (Fleishman & Sclar, 2004). Heart failure patients typically must adhere to a complex medication regime, low sodium diet and restricted fluid intake, and must carefully monitor their symptoms (Jaarsma et al., 1999). The
management of chronic conditions becomes more complex as people age and require more monitoring and guidance for them to remain stable (McMannus, 2004; Shaul, 2000). Most heart failure patients are over 65 years old; and about half have three or more other medical conditions, which only exacerbate the problem of heart failure management (De Geest et al., 2004). Clearly, more effective strategies to increase heart failure patients’ self-management capacity are needed, especially in the older adult population.

Cardiac decompensation is a major problem in managing heart failure at home. Once heart failure patients undergo decompensation, costly hospital admissions may be needed. Usually, decompensation is preceded by changes in vital signs and weight gain that, if detected early, can lead to early interventions that prevent hospital readmission (Benatar et al., 2003; Friedman, 1997). However, recognizing changes in signs and symptoms is difficult for most heart failure patients (Carlson, Riegel & Moser, 2001).

Telemonitoring as a Potential Solution

Today, information and telecommunication technologies are available that allow clinicians to monitor patients remotely in their homes. Daily monitoring of vital signs and other data can lead to nurses’ quicker detection of changes in patients’ conditions (Chaudhry et al., 2007a; Paré, Jaana & Sicotte, 2007; Wootton, Dimmick, & Kvedar, 2006). For patients, the use of telemonitoring allows them, not only to be more closely and effectively supervised, but also to receive prompt feedback from nurses that can enable them and their caregivers to more effectively manage their conditions and take a more active role in their care. (Chaudhry et al., 2007a; Gagnon et al., 2006; Lamothe et al., 2006; Paré, Jaana & Sicotte, 2007; Wootton, Dimmick, & Kvedar, 2006). The World Health Organization (2002) identified two common
problems in providing chronic care at the patient level: 1) the failure to empower patients and 2) the failure to value patient interactions and partnerships. Telemonitoring may provide us a channel to empower patients and promote quality interactions and partnerships.

Telemonitoring is defined as the use of audio, video and other telecommunications and electronic information processing technologies, to monitor patient status at a distance (Institute of Medicine, 1996). One of the common telemonitoring interventions in home health care consists of the transmission of physiological data from a remote location to another location for data interpretation and decision-making by healthcare professionals. Physiological functions are monitored by peripheral devices that collect data and transmit them to the central location through a phone line or wireless media. Data gathered at distant locations are then processed and analyzed, offering accurate information and an automatic alert to the central station. Patients typically use the electronic home monitoring device once a day to collect and report basic physiological data (e.g., weight, blood pressure, heart rate and oxygen saturation) and to answer specific questions about their condition. Home health care nurses use the telemonitoring data to track early warning signs and symptoms. The data not only provide nurses with a real-time picture of their patients' status, but allow them to communicate changes in patient status quicker and more effectively to other care providers, thus improving clinical decision making overall and facilitating timely feedback and treatment modification. Telemonitoring may provide home health nurses with a useful tool to help heart failure patients manage their conditions at home (Chaudhry et al., 2007a; Kleinpell & Avitall, 2005; Louis et al., 2003) and provide greater continuity of care.
Purpose of the Study

This study had two purposes: 1) to compare the difference between home health care only and home health care plus telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization; and 2) to explore which patient characteristics, assessed by nurses during the home health care admission and documented in the OASIS data set, might moderate telemonitoring’s impact on symptom burden, self-care of heart failure and re-hospitalization. The overall goal of this study was to improve the delivery of telemonitoring by identifying which patient characteristics may moderate its efficacy.

Research Questions

This study addressed two research questions:

**Question 1:** Is there a significant difference between home health care only and home health care plus telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization?

**Question 2:** Which patient characteristics, assessed by nurses during home health care admission and documented in the OASIS data set, significantly moderate the outcomes of telemonitoring on heart failure patients’ symptom burden, self-care of heart failure, and re-hospitalization?

Significance to Nursing

It is well known that patients differ in their individual characteristics and in their response to interventions. These differences reflect the uniqueness of the person in terms of physiological and physical functioning, affect, behavior, attitudes, beliefs, values, cognitive processes, cultural norms, and psychosocial functioning (Sidani & Braden, 1998). These differences can also affect
patients’ susceptibility to illness, as well as the nature and extent of the presenting problem and
the nurse’s options for the design and selection of interventions. Given this, it is important to
know which patients presenting with which characteristics respond in what particular way to
telemonitoring. This study examined the degree to which telemonitoring enhanced usual home
health care for heart failure patients and what patient characteristics might moderate its impact
on patient outcomes. Knowing which patient characteristics moderate the effects of
telemonitoring would allow the technology to be more appropriately deployed to maximize its
impact on patient outcomes.

OASIS data are routinely collected during home health care admissions. The data set
contains many patient characteristic variables such as age, financial status, medical diagnosis,
severity of illness, co-morbidity, functional status, psychosocial status, social support and
resources availability. In home health care, the OASIS data set was developed to standardize the
collection of data for outcome monitoring, clinical assessment, care planning and other internal
agency-level applications, as well as for broader evaluation of home health care service
outcomes (Center for Medicare & Medicaid Service, 2006; Health care Financing
Administration, 2000; Shaughbessy, Crisler & Schlenker, 1998). Most OASIS data elements
were developed by a CMS (Center for Medicare & Medicaid Services) funded national research
program, in concert with the Robert Wood Johnson Foundation.

OASIS data have been used to predict clinical outcomes. For example, Rosati and
colleagues (2003) used OASIS data from a home care agency to examine risk factors for re-
hospitalization. Bowles and Cater (2003) also examined re-hospitalization risk factors among
home health patients using OASIS data. Keepnews et al. (2004) suggested that OASIS data could
also be used to analyze patient-level functional outcomes. However, whether we can also use OASIS data to identify how patient characteristics might moderate, the impact of a specialized intervention such as telemonitoring on the outcomes of care has yet to be determined. This study provides an opportunity to examine the usefulness of the OASIS data set, for guiding the successful deployment of telemonitoring technology in the home health care arena.

One key challenge of using an existing data set is that variables of interest are often missing due to their not being directly collected or not being collected in a manner acceptable to the researcher (Savik et al., 2005). Investigators are limited to the variables available in the data set and the time intervals at which they were collected. Also, when the data are collected previously by someone unknown to the investigator, investigators have little to no ability to assess the quality or accuracy of the data. Because the data already exist and the person who collected the data may only have minimal research training and a lack of understanding with regard to integrity and reliability issues, reliability can be problematic. Also, because the data set was designed for other purposes; potential threats to validity are unavoidable (Brown & Semradek, 1992; Lange & Jacox, 1993; Magee et al., 2006). As a result, the use of large data sets for research can be challenging. To minimize problems, it is important that investigators exercise care in evaluating, selecting and analyzing these data. Recognizing the potential pitfalls in using large data sets and taking steps to maintain rigor can help to prevent many problems (Lacey & Hughes, 2007; Magee et al., 2006). One of the goals of this study was to explore the usefulness of the OASIS data set in generating new knowledge to guide home health care nurses in incorporating telemonitoring to maximize its impact on patient outcomes.
Definitions of Terms

Chronic Condition

This study adopts the definition of a chronic condition offered by Curtin and Lubkin (1995): “Chronic condition is the irreversible presence, accumulation, or latency of disease states or impairments that involve the total human environment for supportive care and self-care, maintenance of function, and prevention of further disability” (pp.6-7).

Self-management of Chronic Conditions

Self-management of chronic conditions is defined as an individual’s perceived capability to be actively involved in dealing with all that a chronic condition entails: including symptoms, treatment, physical and social consequences, and lifestyle changes, through effective communication and partnership with professionals, to optimize health.

Symptom Burden

Symptom burden is defined as a subjective, multidimensional experience that includes frequency, severity and distress of symptoms and can be quantified using symptom checklists.

Self-care of Heart Failure

Self-care of heart failure is defined as a process of maintaining physiologic stability through health practice and making decision on managing the condition.

Telemonitoring

Telemonitoring is the remote monitoring of patients from a distance. In this study, telemonitoring is limited to telephone contact and remote physiological monitoring. Remote physiological monitoring consists of an electronic device in the patient’s home that collects data on the patient’s condition. Patients typically use the electronic home monitoring device once a
day to collect basic physiological data (weight, blood pressure, heart rate and oxygen saturation) and to answer specific questions about their condition. Clinicians may contact patients via telephone regarding their readings and provide patient education.

**Home Health Care**

Home health care is limited to health care that provides professional nursing services in the home of adult individuals with medical care needs.

**Summary**

Chapter one identified the need for creative action in response to emerging chronic conditions, especially for heart failure among older adults. How chronic conditions impose a burden on society and individuals was discussed. The incidence and economic impact of heart failure in the United States were presented. An introduction to telemonitoring as a potential solution was described. Purposes of this study and related research questions were stated, as well as the study’s significance to nursing. The definitions of related terms were provided.
CHAPTER TWO: LITERATURE REVIEW AND CONCEPTUAL FRAMEWORK

Introduction

This chapter reviews literature denoting why telemonitoring can be effective in managing heart failure and the current state of science in using telemonitoring to manage heart failure management. The gaps identified in the literature review are used to guide the development of a conceptual framework for this study. The chapter begins with the review of self-management of heart failure.

Self-Management of Heart Failure

Heart failure is a common chronic condition among older adults. Because there is no cure for chronic conditions, long-term management over time is essential. Management of most chronic conditions requires that patients take a great deal of responsibility for their own care, including taking medications, making lifestyle changes, monitoring signs and symptoms, and undertaking preventive actions (Newman, Steed & Mulligan, 2004). Self-management is now a common component of health education and patient education programs (Lorig & Holman, 2003). Indeed, the Institute of Medicine report, entitled Crossing the Quality Chasm: a New Health System for the 21st Century, acknowledged self-management training as an important aspect of effective chronic care (IOM, 2001). Research on self-management strategies has grown rapidly over the past 20 years, as chronic conditions have become more prevalent and treatment more dependent on patient self-management (Chodosh et al., 2005). Strategies or programs that enhance self-management in chronic conditions have demonstrated significant improvement in patients’ self-efficacy, symptom management and resulted in better communication with health professionals (Farrell, Wicks & Martin, 2004; Lorig et al., 1999; Wright et al., 2003). When
combined with standard care, strategies to enhance self-management can improve patients’ knowledge, self-management behaviors, self-efficacy and health status (Borlow et al., 2002). Telemonitoring has the potential to be one of these strategies because it allows patients to: communicate information about their health status to clinicians regularly, gain more control over their care, and take a more active role in improving their health (Chaudhry et al., 2007a; van Montfort & van der Helm, 2006).

Self-management is directed at optimizing health, preventing complications, controlling symptoms, using medical resources carefully, gaining a sense of control over-day-to-day life, and enjoying a better quality of life (Curtin & Mapes, 2005; Koch, Jenkin & Kralik, 2004; Schilling, Grey & Knafl, 2002) by actively participating in self-monitoring and decision making (Chodosh et al., 2005; Coleman & Newton, 2005). Self-monitoring, as described by Wilde & Garvin (2007), is the “awareness of symptoms or bodily sensations that is enhanced through periodic measurements, recordings and observations to provide information for improved self-management.” Self-monitoring allows patients to recognize symptoms and common triggers and develop personal responses, thus improving self-management (Wilde & Garvin, 2007). However, recognizing changes in signs and symptoms can be difficult for heart failure patients (Carlson et al., 2001). Failure to recognize early signs and symptoms, especially when the early symptoms are subtle, may delay patients from seeking help until something is seriously wrong. This delay may be minimized by introducing telemonitoring. Telemonitoring allows patients to have their physiological data collected and assessed regularly by their clinicians without leaving their home, thus enabling earlier detection of exacerbations.
Successful self-management of heart failure requires major long-term lifestyle changes, including: modifications in diet and activities, adherence to a complex medication regimen and the need to monitor symptoms (Dracup et al., 1994). The motivation, knowledge and skills required to make these changes are considerable. Indeed, the most common risk factors that predict hospitalization and/or readmission for decompensated heart failure are the lack of knowledge and adherence to self-management for the condition (Bennett et al., 1998; Chin & Goldman, 1997; Happ, Naylor & Roe-Prior, 1997; Michalsen, König & Timme, 1998; Moser, Doering & Chung, 2005; Vinson et al., 1990). However, for patients with heart failure to comply with the prescribed regimen, they need to have a certain level of understanding of their condition and the behaviors required to stay well (Leventhal et al., 2005). In their study, Ni et al. (1999) found that 71% of 113 patients reported receiving educational materials regarding heart failure; and 75% reported receiving verbal advice about heart failure self-management from health care providers. However, when asked how much they knew about heart failure, 38% said “little or nothing” and half said “some”. Only 58% of the patients weighed themselves daily, and approximately 40% of the patients did not know the importance of weighing themselves daily. Although 80% of the patients knew they should follow a sodium restricted diet, only 40% reported always avoiding salty foods. The authors found that adherence to self-care correlated significantly with knowledge scores ($r = .33; p < .001$).

Although patients’ knowledge of heart failure and its treatment enhances medication adherence; it is patients’ abilities to connect particular symptoms of heart failure with specific medications that actually improves adherence (Wu et al., 2008). Inability to integrate knowledge with behavioral outcomes impedes self-management (Riegel & Carlson, 2002). For example,
even though patients know that a low sodium diet is important; they may fail to link excess sodium to weight gain and shortness of breath. Perhaps this is why educational programs may not always influence behavior. Telemonitoring allows clinicians to provide ongoing and repeated patient teaching, based on anticipated and demonstrated need.

Although strategies to enhance self-management in chronic conditions are an essential component of chronic care, they are challenging to implement (Glasgow et al., 2002). Patient characteristics that predict successful outcomes of these strategies remain unknown. Based on data from 53 randomized, controlled trials of self-management interventions for adults with Diabetes Mellitus, hypertension, or osteoarthritis, Chodosh et al. (2005) reported that self-management programs helped reduce hemoglobin A1c and blood pressure levels in diabetes and hypertension, respectively, but could not identify specific program characteristics; such as tailoring, group setting, feedback, psychological emphasis and medical care, that predicted successful outcomes. Variables, especially patient attributes (e.g., social supports, disease severity) that might contribute to the success of a self-management strategy, are rarely reported (Warsi et al., 2004). Noting that self-management strategies may be more effective in specific patient subgroups, the authors concluded that identifying who benefits most from which self-management interventions could lead to a more effective selection of strategies and targeting of resources (Newman et al., 2004; Warsi et al., 2004). The current study aimed to identify who may benefit most from usual home health care plus telemonitoring, over usual home health care alone.
Telemonitoring in Managing Heart Failure

The advancement of information and telecommunication technology can be used to supplement more traditional care for heart failure patients (van Montfort & van der Helm, 2006). Telemonitoring is gaining attention as an effective strategy to enhance the care of heart failure patients. By collecting clinical data without the need for face-to-face contact, telemonitoring provides close and efficient monitoring and support for patients, and enhances communication between patients and clinicians (Chaudhry et al., 2007b). A number of studies have described the utility of telemonitoring for heart failure patients (Artinian et al. 2003; Benatar et al. 2003; Bondmass et al., 1999; Cordisco et al., 1999; Cleland et al. 2005; Goldberg et al., 2003; Heidenreich, Ruggerio & Bassie, 1999; Jerant, Azari & Nesbitt, 2001; Luisignan et al. 2001; Lehmann & Giacini, 2004; McManus, 2004; Whitten & Mickus, 2007). In fact, the use of telemonitoring for cardiac patients has predominantly focused on managing heart failure (Kleinpell, 2007).

Telemonitoring includes a variety of information and telecommunication technologies. Studies that focused on telemonitoring for managing heart failure have included technologies such as reporting weight, vital signs and symptoms into a computerized voice answering system, real-time videoconferences and automated data collection and transmission. Most of these studies demonstrated some benefits, including reduction in hospital readmissions, emergency room visits and cost of care (Benatar et al., 2003; Bondmass et al., 1999; Cleland et al., 2005; Cordisco et al., 1999; Heidenreich et al., 1999; Jerant, Azari, & Nesbitt, 2001; McManus, 2004; Schofield et al., 2005); improvement in quality of life (Artinian et al., 2003; Bondmass et al., 1999); reduction in mortality (Cleland et al., 2005; Goldberg et al., 2003) and morbidity
(Morguet et al., 2008) rates; and improved compliance with medication and/or self-care behaviors (Artinian et al., 2003; Lusignan et al., 2001). Although these studies show promising results, less than half of used a randomized, controlled design. In addition, sample sizes were small, ranging from 20 to 92 participants, except for four studies that involved more than one hundred participants (Benatar et al., 2003; Clemand et al., 2005; Goldberg et al., 2003; Morguet et al., 2008). Although telemonitoring was found to be promising, more evidence is needed to establish its benefits, as well as the form of telemonitoring that may provide the most promising results.

Recently, more organized, large scale, randomized control trials involving multiple sites have been conducted in the United States and Europe (Dansky, Vasey & Bowles, 2008; Dar et al., 2009; Mortara et al., 2009; Wakefield, Holman, Scherubel & Kienzle, 2008). Dar et al. (2009) found significantly fewer unplanned hospitalizations for heart failure and a reduction in clinic and emergency room visits in the telemonitoring group; however, they found no significant difference in the mean direct health service costs (Dar et al., 2009). Although all four studies identified some benefit of telemonitoring in managing heart failure, in no study was the effect statistically significant.

Telemonitoring has also been used by the Veterans Affairs (VA) health care system to care for patients with a variety of chronic conditions, including heart failure; and the results have been promising (Cherry et al., 2003; Chumbler et al., 2005a, b; Meyer, Kobb & Ryan, 2002; Schofield et al., 2005). The VA system uses telemonitoring to enhance the effectiveness and efficiency of their care-coordinated programs. At least one study has been dedicated to the management of heart failure among older adult veterans (Schofield et al. 2005). Patients with
difficult-to-manage or newly diagnosed systolic heart failure were recruited to a care-coordinated, nurse-directed home telehealth management program. An in-home telemonitoring device, capable of reporting patient symptoms and vital signs to the nurse care coordinator via a secure Internet site, was provided to the patient on enrollment. A heart failure disease-specific dialog was written for the in-home device, providing the patient with daily reminders regarding appropriate heart failure self-management. Patients also received daily heart failure specific education via the nurse coordinator throughout their care. Seventy-three patients completed the study, with an attrition rate of 20%. After six months, significant improvement was found in blood pressure, weight and shortness of breath ratings. Compared to the previous year, the total number of inpatient hospital days was reduced, with only 31% of hospitalizations related to heart failure while in the program, demonstrating that telemonitoring can improve the home management of heart failure.

There have been at least four systematic reviews of home telemonitoring in the past six years (Chaudhry et al., 2007a; Kleinpell & Avitall, 2005; Louis et al., 2003; Parè, Jaana & Sicotte, 2007). Three focused on the application of telemonitoring for managing heart failure. Louis et al. (2003) reviewed 18 observational studies and six randomized control trials between 1996 and 2003 involving telemonitoring and heart failure, concluding that telemonitoring might have an important role in delivering effective health care for patients with heart failure, but more evidence of its efficacy was needed. Kleinpell and Avitall (2005) evaluated 12 research-based studies on a variety of telemonitoring interventions and telemanagement in heart failure. The authors concluded that the use of telemonitoring can be beneficial, but urged caution in generalizing the results because of the small sample sizes, non-randomized study designs, high
attrition rates, and lack of controls for confounding study variables. Chaudhry et al. (2007a) reviewed nine studies and suggested that telemonitoring is an effective strategy for disease management in high-risk heart failure patients. Based on their review of 65 empirical studies using telemonitoring to monitor chronic illness; such as pulmonary conditions, diabetes, cardiac diseases and hypertension, Paré et al. (2007) suggested that home telemonitoring can empower patients, positively influence their attitudes and behaviors and potentially improve their conditions, but additional studies were needed to strengthen the evidence.

Taken together, this evidence suggests that telemonitoring may provide home health care agencies with a valuable tool to care for heart failure patients at home and provide greater continuity of care. However, the relatively high attrition rates and inconclusive results of systematic reviews suggest that telemonitoring may not be appropriate for all heart failure patients. In fact, several researchers have argued that it is critical to consider patient characteristics when evaluating the beneficial outcomes of an intervention (Brown, 2002; Lauver et al., 2002; Sidani, Epstein & Moritz, 2003). Brown (2002) suggested that investigators consider the possibility of variation in effectiveness due to individual characteristics early in a program of research because it may help to explain why an intervention results in a small overall effect or insignificant group difference. Further, the results may lead researchers to include those characteristics in subsequent research designs. This study was designed to explore the moderator effect of patient characteristics on telemonitoring and patient outcomes.

Conceptualizing a Moderator Framework

The most common research questions in nursing pertain to the direct association between two constructs: “Does variable X predict or cause variable Y?” Frazier et al. (2004) pointed out
that, although such questions represent a fundamental starting point for research, they only provide a detailed and informative account of the phenomenon. To advance the science, research and practice of the discipline, it is important to move beyond these basic questions – and ask “why” and “how” it happens and “when” and “for whom” it happens (Frazier et al., 2004). This study not only examined the association between telemonitoring and patient outcome, but also the conditions that specified the association, i.e. “for whom” or “when” this association would be stronger or weaker.

Moderators are used to address the conditions that specify an association; for example, “when” or “for whom” a variable most strongly (or weakly) predicts or causes an outcome variable. Moderator variables magnify, attenuate or reverse the relation between a predictor and an outcome (Baron & Kenny, 1989; Frazier, Barron & Tix, 2004; Hoyle & Robinson, 2004). Moderator effects are often considered when there are unexpectedly weak or inconsistent relations from one study to another or from one population to another (Ferketch & Verran, 1999). A moderator effect implies that the relation between an independent variable and a dependent variable changes as a function of the moderator variable (Baron & Kenny, 1986).

Assessing a moderator effect involves evaluating the effect of an independent variable on a dependent variable at different levels of the moderator. Examples in the nursing literature include: Mishel et al.’s (2003) study of moderators in uncertainty management intervention for men with localized prostate cancer and Spitzer et al.’s (1995) study on the moderating effect of demographic variables on coping effectiveness. Although there may be no documented association between the independent variable and dependent variable, it is possible to find a moderator effect (Baron & Kenny, 1986; Hoyle & Robinson, 2004). For example, Riegel et al
(2000) did not find a main effect of a multidisciplinary disease management intervention on the outcomes of heart failure patients; however, there was a significant benefit for SAS (Specific Activity Scale) class II patients. Usually, moderators are fixed characteristics of the individuals or groups being studied, or features of the immediate context. Moderators can be qualitative or quantitative, and do not need to be associated with either the independent or dependent variable (Baron & Kenny, 1986; Hoyle & Robinson, 2004). However, a priori rationale should guide the selection of moderator variables (Aguinis, 2004). In sum, the study of moderator effect provides information on the boundary conditions for the relationship of interest and is important for theory development and clinical practice (Aguinis, 2004).

In this study, patient characteristics were expected to have a moderator effect on the relationship between telemonitoring and patient outcomes. Identifying which patient characteristics have a moderator effect allows for a more precise description of the relationship between telemonitoring and outcomes and further clarifies for whom telemonitoring will have the greatest effect. Figure 1 shows the moderator conceptual framework for this study. In this framework, the effect of the independent variable (type of service received) on the dependent variable (symptom burden, self-care of heart failure and re-hospitalization) depends on the value or level of the moderator (patient characteristics).
In this study, the independent variable was type of service the heart failure home health care patient received; home health care only (HHC only) vs. home health care plus telemonitoring (HHC plus TM). In home health care, each patient was assigned to one of the nurse case managers. The nurse case manager visited the patient one to three times per week, depending on the patient’s medical needs. Each in-home visit lasted approximately 30 to 45 minutes. In general, nursing activities during each in-home visit included, but were not limited to, vital sign measurement, physical assessment, medication and diet instruction, and patient/caregiver education. In the home health care plus telemonitoring condition, each patient not only received the usual home health care, but also received daily telemonitoring.
Outcome Variables

In this study, outcome measures included symptom burden, self-care of heart failure, and re-hospitalization because successful management of chronic conditions, such as heart failure, has been found to improve these outcomes (Chodosh et al., 2005; Clark, Janz & Dodge, 1997).

Symptom Burden

Symptoms are the subjective evidence of illness or disease. Usually, the presence of symptoms is why people seek health care (Research Center for Symptom Management, [http://nurseweb.ucsf.edu/www/crsm.htm](http://nurseweb.ucsf.edu/www/crsm.htm)). Symptom burden is dynamic, multidimensional, quantifiable, physiologic and subjective (Gapstur, 2007). If symptom burden is high, an individual’s activities may be disrupted and their quality of life adversely affected (Zambroski et al., 2005). Heart failure patients encounter a variety of physical or psychological symptoms that may negatively affect their quality of life, such as fatigue, dyspnea, edema, anxiety and depression (Bennett et al., 2000; Friedman, 1997; Jaarsma et al., 2000). For heart failure patients, symptoms can signal suboptimal self-management, disease progression or the need for additional medical care. In one study of 51 patients with heart failure, a majority placed greater importance on improved symptoms than longer survival (Stanek et al., 2000). Thus, managing patients’ symptoms and minimizing their burden are keys to delivering quality care. In this study, symptom burden was defined as a subjective, multidimensional experience that includes frequency, severity and distress of symptoms and can be quantified using a symptom checklist. The Memorial Symptom Assessment Scale – Heart Failure (MSAS – HF), as modified by Zambroski et al. (2005) from the original Memorial Symptom Assessment Scale, was used to measure symptom burden.
Self-care of Heart Failure

Developing effective self-care skills is essential and crucial for heart failure patients to maintain stability. Self-care involves a process of maintaining health through positive health practices and managing one’s illness (Riegel, Carlson & Glaser, 2000). Self-care of heart failure includes both self-care maintenance and heart failure management (Riegel et al., 2004). In self-care maintenance, the focus is on symptom monitoring and treatment adherence; while in heart failure management, the main task is to respond to symptoms through an active, deliberate decision-making process (Riegel et al., 2004). Poor self-care has been identified as a major contributor to the poor outcomes associated with heart failure (Jaarsma et al., 1999; Krumholz et al., 2002). Indeed, self-care of heart failure can be difficult for elderly patients because of age-related changes, such as hearing loss, vision impairment, co-morbidities and limited functional status (Carlson, Riegel & Moser, 2001). The Self-Care of Heart Failure Index (SCHFI), which consists of 15 items divided into 3 subscales (self-care maintenance, heart failure management and self-confidence), was used to measure self-care of heart failure. The SCHFI is a revised version of the Self-Care of Heart Failure Scale. Both versions were developed by Riegel and her colleagues and have been validated through psychometric testing (Riegel et al., 2004).

Re-hospitalization

Telemonitoring allows clinicians to detect subtle changes in a patient’s condition that may signal deterioration of health status. Early detection, in turn, can facilitate early and effective interventions that prevent unnecessary re-hospitalizations. In this study, only the occurrence of re-hospitalization was measured; i.e. the participant was or was not re-hospitalized.
**Moderator Variables**

Characteristics that define subgroups may be tested for a moderator effect. Moderator variables should be determined based on theory and/or empirical evidence (Aguinis, 2004; Mishel et al., 2003; Wu & Zumbo, 2007). In this study, patient characteristics were expected to moderate the effect of telemonitoring on patient outcomes. Although numerous patient characteristics potentially could influence outcomes, only five patient characteristics, identified in the literature as relevant to the management of chronic conditions and recorded in the OASIS data set, were assessed. Moderator variables obtained from the OASIS data set were collected during the home health care admission. Using the OASIS data minimized participant burden and improved the likelihood of being able to easily translate findings into practice; because OASIS data are collected routinely.

*Number of Chronic Conditions and their Severity*

When patients have several co-morbidities, self-care becomes increasingly complex (Chriss et al., 2004; De Geest et al., 2004; Riegel & Carlson, 2002). Co-morbidities are common among older adults and often contribute to heart failure destabilization (Forman & Rich, 2003). In one study, the average heart failure patient had six co-morbid conditions and took seven medications (Naylor et al., 2004). In another study, 80% had four or more co-morbidities that might have hampered their ability to carry out prescribed interventions (van del Wel et al., 2007). In this study, the number of chronic conditions and the severity score for all chronic conditions, as reported on the OASIS data set during admission to home health care, were tested as moderators.
Functional Status

The impact of a chronic condition on health is substantial and involves all aspects of functioning: physical, role and social (Stewart et al. 1989). Functional status is defined by Leidy (1994) as “one’s ability to perform those activities people do in the normal course of their lives to meet basic needs, fulfill usual roles and maintain their health and well-being.” A common challenge experienced by heart failure patients is physical limitations (Riegel & Carlson, 2002). Due to dyspnea and fatigue, activities associated with mobility during everyday life may be restricted in people with heart failure (van den Berg-Emons et al. 2001). However, physical limitations do not necessarily hinder one’s self-care behavior. Schnell-Hoehn et al. (2009) did not find a significant correlation between physical limitations and self-care behaviors in their study and suggested that people learn to cope with their limitations to care for themselves. Functional status in this study was measured by the number of daily living activities a patient needed help, which recorded in the OASIS data set.

Presence of Anxiety

Anxiety is a future-oriented, negative affective state resulting from perception of threat and a perceived inability to predict, control, or obtain desired results in given situations (Barlow, 1988). The prevalence rates of anxiety in chronic outpatient heart failure patients have been reported to range from 18.4% (Haworth et al., 2005) to 45% (Friedmann et al., 2006). In their study, Katon et al (2007) found that patients with anxiety and chronic medical conditions reported significantly more medical symptoms. In another study, participants with a high level of anxiety practiced fewer health maintenance behaviors than those with positive well-being (Schnell-Hoehn, Naimark & Tate, 2009).
Living Arrangement

Caregiver support helps patients to carry out interventions as prescribed. Studies on the management of heart failure have shown that social support has a positive impact on self-care (Dickson et al., 2006; Happ, Naylor & Roe-Prior, 1997). D’Alto et al. (2003) and Schnell et al. (2006) reported that heart failure patients felt they could care for themselves more effectively with family support. Other studies have reported that social support affects heart failure hospital readmission rates (Krumholz et al., 1998), mortality (Chin & Goldman, 1997; Krumholz et al., 1998; Murberg & Bru, 2001) and quality of life (Bennett et al., 2001; Gott et al., 2006). Heart failure patients living alone may not get the support they need to manage their conditions. A recent study showed that patients who lived with a spouse practiced more self-care than those living alone or with other family (Schnell-Hoehn, Naumark & Tate, 2009).

Summary

Telemonitoring has the potential to improve the management of heart failure and has demonstrated promising results in pilot studies. Examining moderator effects may provide unique, new and valuable information to guide future telemonitoring designs. By exploring moderator effects of patient characteristics on telemonitoring and patient outcomes, we may be able to identify which patients will be most responsive to telemonitoring and which patients might do better with another, more appropriate intervention.
CHAPTER THREE: METHODS

Introduction

The purposes of this study were: 1) to compare the difference between home health care only and home health care plus telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization; and 2) to explore which patient characteristics might moderate the effect of telemonitoring on symptom burden, self-care of heart failure and re-hospitalization. Two research questions were addressed:

1) Is there a significant difference between home health care only and home health care plus telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization?

2) Which patient characteristics significantly moderate the outcomes of telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization?

Chapter 3 presents the methods used to answer these two questions. The research design, setting and sample are described. Procedures for recruiting participants and protecting the rights of human subjects are reported. Instruments used in this study and their reliability are discussed. Last, information regarding the data management and data analysis plan to address each research questions is presented.

Design

This study used a prospective, non-experimental, comparative, descriptive design. The design of this study featured a repeated measurement of outcome variables (symptom burden and
self-care of heart failure) at two points in time and the use of a comparison group. Figure 2 shows the design of this study.

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Non-randomized   O₁  HHC only   O₂
Non-randomized   O₁  HHC plus TM  O₂
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*Note: O₁: Baseline observation; O₂: 40-day follow-up.*

Figure 2. Diagram of the Research Design

There is not much that one can conclude from a one-point in time study of a single group. It is better to have a comparison group and better yet to have measurements before and after the treatment to detect any change. If a comparison group, which does not receive treatment, is added, threats to validity can be reduced. If the groups are not equivalent, there is a possibility of selection bias. A within-subject repeated measures design allows each subject to serve as his or her own control; thus, the error variance is decreased (Munro, 2004). In this study, a reference group and repeated measurements were used to minimize bias.

Participants in the home health care plus telemonitoring group were recruited from a telemonitoring program in the recruitment site. The telemonitoring program was part of the home health care agency’s strategy to manage their chronically ill patients and was not limited to heart failure patients. However, more than one third of the patients being monitored had a primary diagnosis of heart failure. The home health care agency’s criteria for enrolling patients into the telemonitoring program included those who had a higher risk for re-hospitalization based on the nursing assessment during admission or who had a history of multiple re-hospitalizations during the past 12 months. Also patients needed to be capable of following simple commands to operate equipment or have a caregiver able to assist them. A physician’s order for telemonitoring was
needed prior to entering the telemonitoring program. Patients could refuse to be monitored even though there was a physician’s order and an identified need. The home health care agency owned the telemonitoring units and provides them to their patients free of charge. No third party insurance was billed for the service.

Participants in the home health care agency’s telemonitoring program received a telemonitoring unit (HomMed Genesis or Sentry, Honeywell, Brookfield, WI) to which peripheral devices (scale, sphygmomanometer and oxymeter) were connected. The telemonitoring unit was installed at the patient’s home by a registered nurse who was a trained installer. During the installation, patients and/or their primary caregiver were instructed on how to perform the test and were asked to perform a return demonstration. Each telemonitoring unit provided the patient with prompts at each step of the reporting process. On a daily basis, participants or their primary caregiver were responsible for taking and sending the required measures at a pre-set reporting time. When the report time arrived, the telemonitoring unit prompted the patient, “Good morning, it is time to check your vital sign, please step on the scale”. The prompt repeated every five minutes until someone stepped on the scale. If nobody stepped on the scale after 30 minutes, a “no transmission” signal was sent to the central station at the home health care agency. Data collected from the telemonitoring unit in the participant’s home were transmitted via telephone line (HomMed Genesis) or wireless connection (HomMed Sentry) to the central station at the home health care agency. Figure 3 shows the HomMed telemonitoring Genesis and Sentry units.
1. HomMed Genesis Telemonitoring Unit

2. HomMed Sentry Telemonitoring Unit

Figure 3. HomMed Telemonitoring Genesis and Sentry Units

Transmitted patient data were observed by the central station RN at a computer in the home health care agency. The central station RN also responded to alerts. The alert limit was set based on the patient’s baseline vital signs reported by the case manager or as requested by the patient’s physician. The central station RN used professional judgment and agency protocols to guide their responses to alerts. For example, the agency protocol indicated that whenever a patient had greater than a two pound weight gain in a day and complained of increasing shortness of breath, an in-home visit was warranted. Other non-urgent complaints or alerts were reported to the patient’s case manager directly.
In this study, a home health care only group served as a comparison (or reference) group. Participants in the home health care only group were recruited from patients who met the inclusion criteria for, but did not enroll in, the telemonitoring program. In the home health care only group, patients were visited by their case managers one to three times per week, depending on their medical needs. In general, nursing activities during each in-home visit included, but were not limited to, vital sign monitoring, physical assessment, medication and diet instructions and patient education. The teaching and instructions were guided by a heart failure clinical pathway at the home health care agency.

In this study, the home health care agency used telemonitoring to augment, not substitute for, the in-home nursing visits. Patients enrolled in the telemonitoring program received the same amount of in-home nursing visits as the home health care only group. Although patients in the telemonitoring program had their vital signs taken daily, their need for medication and diet instructions, patient education and monitoring for adherence were the same as, or even greater than, the home health care only group due to their high risk of re-hospitalization.

Setting

The setting for this study was a Medicare certified home health care agency in a Midwestern state. The home health care agency was affiliated with a non-profit community hospital. The home health care agency started its home health care program in 1984. The home health care program provided a wide range of services to patients 18 years or older; including skilled nursing visits, physical therapy, occupational therapy, speech therapy, social service, nutritional counseling and a nursing aide service. In addition to the home health care program, the home health care agency also ran a hospice program and a private duty program. Participants
for this study were recruited only from the home health care program and not the other programs. In 2008, the average daily patient census for the home health care program was between 600 and 700. In the winter months (between October and March), the daily census tended to be higher. In September 2005, the home health care agency established a telemonitoring program to serve their home health care patients. The telemonitoring program provided daily remote physiological monitoring to a variety of patients at no cost to the patient. On average, 60-70 patients were monitored each day. These patients had a variety of diagnoses; such as heart failure, chronic obstructive pulmonary disease, hypertension and other cardiac and respiratory disorders. In 2006, 252 patients enrolled in the telemonitoring program and the vast majority expressed a high degree of satisfaction with the technology. The compliance rate was over 90%.

Sample

The sample consisted of home health care patients who were 50 and older with a primary diagnosis of heart failure that was classified as NYHA (New York Heart Association) Class II, III, or IV by their case managers. Table 1 shows the NYHA classification system. In this study, an internal comparison group was used as a reference to ascertain whether telemonitoring changed outcomes. Internal comparison groups were drawn from the same pool of participants, as they were presumed to have more in common than external comparison groups (Shadish, Cook & Campbell, 2002).
Table 1: The New York Heart Association Classification System for Heart Failure

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</td>
</tr>
<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.</td>
</tr>
<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</td>
</tr>
</tbody>
</table>

Patients in the telemonitoring program at the home health care agency were recruited to form the home health care plus telemonitoring group. Patients who refused the telemonitoring service, or whose physician did not think they needed such service, or who were assessed as doing just fine with home health care only were recruited to form the home health care only group.

Patients from the home health care agency who met the inclusion criteria for the study were invited to participate in the study. Inclusion criteria for the study were:

- Age 50 or older;
- Newly admitted to the home health care agency, within 10 days of the first in-home visit;
- Admitted to home health care service having a primary or secondary diagnosis of heart failure;
- Classified as NYHA Class II, III or IV by their case managers;
- Capable of giving informed consent; and
- Capable of speaking and understanding English.
A power analysis was performed prior to the study to determine adequate sample size. The power of a statistical test is the probability that statistically significant results is yielded and depends on four parameters: the significance criterion, the reliability of the results, the sample size and the effect size (Cohen, 1988). Most research on telemonitoring has been pilot studies and their effect sizes have rarely been reported. Thus, it is difficult to estimate the effect size of telemonitoring on heart failure outcomes. Based on the reports that about 40% of the hospitalizations related to heart failure could possibly be prevented (Michalsen, König & Thimme, 1998; Pappas et al., 1997; Schwarz & Elman, 2003; Vinson et al., 1990), the effect size was set at \( r = .30 \), a medium effect size (Cohen, 1988). For the analysis of variance with a power of .80, an alpha of 0.5 and a medium effect size of .30, a sample size of 44 patients per group was needed (Cohen, 1988). For the moderated multiple regression (MMR), the approximate sample sizes needed for achieving the power of .80 for alpha = .05 with one product term and a medium effect size .30 was 57 participants per group (Jaccard, Turrisi & Wan, 1990). The MMR required a higher number of participants (n = 114). With a 10% attrition rate during the 40-day study, recruitment of 126 participants was required. Although efforts were made to increase subject recruitment, the targeted sample size was not met by the end of the first year. A final sample of 68 participants (60% of the targeted sample size) was recruited and completed the study.

Recruitment Procedure

IRB approval from the University of Arizona was obtained prior to recruitment (Appendix A). The home health care agency, which served as a recruitment site, did not have an IRB. However, the study proposal was submitted to the nursing education department and the
risk management department for review. Data collection took place over 13 months, from August, 2008 to September, 2009.

Potential participants were referred by their case managers. A luncheon meeting was held to introduce the study to the case managers, with a question and answer session at the end of the meeting. An informational packet including inclusion criteria, recruitment flyers and contact phone numbers was distributed to case managers during the meeting. Case managers were asked to refer any newly admitted home health care patients who met the inclusion criteria to the principal investigator within 10 days of their admissions. Case managers who did not attend the meeting were contacted individually; when they were in the home health care office. The principal investigator was at the home health care agency weekly to respond to any concerns, answer questions and update staff on study progress.

After receiving a referral from a case manager that indicated the patient was interested in participation in the study and agreed to be contacted, the principal investigator scheduled an in-home visit directly with the potential participant. After describing the study, the principal investigator invited the patient to participate in the study. Informed consent was obtained from each participant prior to data collection. The principal investigator then asked the participant to complete a pretest questionnaire that measured symptom burden and self-care of heart failure. Participants completed the questionnaire in pencil and paper format or had the questions read to them and their responses recorded by the investigator. Participants were followed for 40-days, because the average length of stay for heart failure patients in home health care was about 41 days (Chetney, 2003). A second in-home visit was scheduled at the end of the 40th day during which the same questionnaire was administered as a post-test.
Data related to the five patient characteristics, described in the conceptual framework, were obtained from the OASIS data set in the participant’s home health care medical record. Rehospitalization information was also obtained from each participant’s home health care medical record.

**Recruitment Challenges**

Subject recruitment in home health care settings has always been challenging. Miller et al. (2003) described the recruitment of participants to research studies in home health care settings as being persistently difficult, irrespective of study design, type of intervention, or service provided. Difficulties in recruiting subjects in home health care research include, non-dedicated recruiters, the restructuring of the health care context, gatekeepers, participant feelings about the home as a research setting, and concerns about being overwhelmed (Miller, McKeever & Coyte, 2003; Duffy & Hoskins, 2008). Steps were taken to manage these concerns and facilitate the recruitment process.

Because the investigator needed to access potential participants through case managers, efforts to enlist the ongoing attention and support of case managers were needed. A handwritten note and a chocolate bar were given to case managers after each referral. The investigator also established rapport with admission coordinators, who helped to identify potential participants. A clear scripted recruitment flyer and a handwritten note asking for assistance were then left in the case manager’s mailbox and asked for assistance. A friendly reminder was left in the case manager’s voice mail if the investigator did not hear from the case manager after five days. The principal investigator was very cautious not to overwhelm the case manager and paid close attention to their workloads.
Challenges in recruiting elderly adults are widely acknowledged (Bowsher et al., 1993; Harris & Dyson, 2001; Hawranik & Pangman, 2002; Jacelon, 2007). Some of the reasons for difficult recruitment of this group include: being too overwhelmed by their medical conditions, family members who did not want them to enroll, suspicion of research studies because of feelings of vulnerability or previous experience, impaired vision and hearing, and reduced mobility and energy (Bowsher et al., 1992; Duffy & Hoskins, 2008; Harris & Dyson, 2001). The recruitment process may be even harder for heart failure patients, given the highly symptomatic condition of heart failure, some patients may be too fatigued to take part in a research study (Pressler et al. 2008). Steps were taken to overcome the challenge in this study included:

- Awareness of any sensory impairment;
- Finding the optimal time to call and to see the participant;
- Sensitivity to signs that it may not be a good time to talk;
- Involving family members if participants choose to;
- Established good rapport; when the participant appeared to be more relax, the study was explained;
- Explanation were made succinct and easy to understand; and
- A hand-written note was sent between the two visits to show appreciation.

Instruments

A questionnaire was used to collect outcome data (Appendix B). The two scales used in the questionnaire were the Memorial Symptom Assessment Scale – Heart Failure (Zambroski et al., 2005) and the Self-care of Heart Failure Index (Riegel et al., 2004). The questionnaire was
administered during the initial in-home visit and the 40-day follow-up visit. The following section describes the two instruments and their reliability and validity.

*Mortuary Symptom Assessment Scale – Heart Failure*

Symptom burden was measured using the Memorial Symptom Assessment Scale – Heart Failure (MSAS – HF). This scale was developed by Zambroski et al. (2005) by modifying the Memorial Symptom Assessment Scale (MSAS), which was originally developed for cancer patients (Portenoy et al., 1994), but was later shown to be appropriate for assessing symptoms in other populations as well (Peterson & Bredow, 2004). In the MSAS – HF, cancer-specific symptoms were replaced by cardiac-specific symptoms, such as weight gain, chest pain, palpitations and waking up breathless at night. The MSAS – HF measures 32 symptoms via three subscales (physical, psychological and heart failure symptoms). The reliability estimate for the sum of symptoms presented was 0.92. The reliability estimates for the three subscales: physical, psychological and heart failure symptoms, were 0.83, 0.87, and 0.73 respectively (Zambroski et al., 2005). Participants were asked to rate symptoms experienced during the previous 7 days. If a symptom was present, they were asked to report its frequency and severity using a response scales varying from 1 to 4. Their distress due to the symptom was reported using a scale from 0 to 4. Higher numbers indicate greater frequency, severity or distress. Figure 4 shows part of the MSAS – HF used in the questionnaire.
**Instructions:** We have listed 26 symptoms below. Read each one carefully. If you **HAVE HAD** the symptom during this past week, make an “X” in the box marked “**YES**”. Let us know how **OFTEN** you had it, how **SEVERE** it was usually and how much it **DISTRESSED** or **BOTHERED** you by circling the appropriate number.

<table>
<thead>
<tr>
<th>DURING THE PAST WEEK</th>
<th>IF YES How OFTEN did you have it?</th>
<th>IF YES How SEVERE was it usually?</th>
<th>IF YES How much did it DISTRESS or BOTHER you?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Lack of energy</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Feeling drowsy</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Figure 4. *Example of the Memorial Symptom Assessment Scale – Heart Failure (MSAS – HF)*

*Used in the Study*

Two scores were calculated and used in the statistical tests. The number of symptoms presented was the sum of the symptoms that were checked “**YES**”. The symptom burden for each symptom was determined by calculating the mean of the frequency, severity and distress scores. The total symptom burden score was calculated as the sum of the symptom burden for each symptom presented. Because distress was measured on a 5-point response scale (0 to 4), distress scores were converted to values roughly similar to the frequency and severity, as in the original scale recommended by Portenoy et al. (1994). For example, “not at all” was scored as 0.8, “a little bit” was 1.6, “somewhat” was 2.4, “quite a bit” was 3.2 and “very much” was 4.0.
Reliability is the ability of a scale to produce consistent results when the same construct is measured under the same conditions (Field, 2005). In this study, the reliability of the MSAS – HF was examined. For the sum of symptoms presented at the initial visit and the 40-day follow-up visit, the Cronbach’s alphas were 0.72 and 0.71 respectively.

*Self-care of Heart Failure Index*

Self-care of heart failure was measured using the Self-care of Heart Failure Index (SCHFI). The SCHFI was developed by Riegel (2004) and her colleagues from the Self-management of Heart Failure Scale (Riegel, Carlson & Glaser, 2000) and has undergone psychometric testing using data from 760 heart failure patients. Reliability of the SCHFI was determined to be adequate, with a coefficient alpha of 0.76. Construct validity was supported by confirmatory factor analysis, known-groups technique and subscale-to-subscale correlations (Riegel et al., 2004).

The SCHFI is comprised of 15 items, divided into three subscales: self-care maintenance, heart failure management and self-confidence. Self-care maintenance involves symptom monitoring and treatment adherence; and heart failure management is a decision-making process in response to symptoms (Riegel et al., 2004). In the SCHFI, each item uses a 4-point response scale, which allows for the assessment of progress, with higher numbers indicating better self-care. Five items measure self-care maintenance, six items measure heart failure management and four items measure self-confidence. In this study, the three subscale scores were used separately in the analysis, because not all participants had a heart failure management score at the 40-day follow-up. At the 40-day follow-up interview, if the participant did not experience heart failure symptoms (shortness of breath or swollen arms/legs) during the month prior to the visit, the six
heart failure management items were not assessed. In this study, the reliability of the SCHFI was examined using the full scale. Cronbach’s alpha was 0.76 for the data collected at the initial visit and 0.77 for data collected at the 40-day follow-up visit.

*Outcomes Assessment and Information Set*

In this study, the Outcomes Assessment and Information Set (OASIS) was used to collect patient characteristics data. OASIS was developed to standardize the collection of data for outcome monitoring, clinical assessment, care planning and other internal-level applications, as well as for broader evaluation of home health care service outcomes (Center for Medicare & Medicaid Service, 2006; Health Care Financing Administration, 2000; Shaughbessy, Crisler & Schlenker, 1998). Most of OASIS elements were developed by the Center for Medicare & Medicaid funded national research program and co-funded by the Robert Wood Johnson Foundation. In 1999, all home health care agencies receiving Medicare and Medicaid reimbursements were required to use OASIS as a data collection tool. OASIS consists of 106 items. The data set contains many patient characteristic variables; such as age, financial status, medical diagnosis, severity of illness, co-morbidity, functional status, psychosocial status, social support, living arrangement and resources availability. OASIS data are completed on admission, discharge, and transfer of service, as well as every 60 days.

Madigan and Fortinsky (2004) studied the inter-rater reliability of OASIS items and judged 23 of the 25 items studied to be reliable, based on weighted kappa values ≥ 0.60. However, in another study, the reliability of many OASIS items was considerably lower (Kinatukura, Rosati & Huang, 2005). Although the psychometric properties of OASIS data have yet to be firmly established, the use of these data sets for research can potentially save resources
(Lange & Jacox, 1993; Moriatry et al., 1999; Smaldone & Connor, 2003), provide evidence to support future studies and minimize participant burden. The OASIS data set has been routinely used for the past ten years, making clinicians more experienced in the collection of OASIS data; thus, improving its reliability.

In this study, 19 OASIS indicators of health, emotional status, functional status and living arrangement were used to measure patient characteristics. The number of chronic conditions included both primary and other diagnoses. A total severity score was obtained for each participant by adding the severity ratings for all chronic diagnoses listed in OASIS. There are 13 functional items in OASIS. Each functional item was re-coded as 0 or 1, with 0 indicating the ability to perform the activity independently and 1 indicating that the patient needed help to some degree. Functional status was measured as the total number of daily living activities for which the patient needed help. The living arrangement item was recorded to form a dichotomous variable (living alone vs. living with someone). The presence of anxiety item was also recoded to from a dichotomous variable (the presence of anxiety vs. no anxiety was observed or reported). Appendix C shows the 19 OASIS items and their exact wording.

Data Management and Analysis Plan

Data Management

Study participants were assigned identification numbers that appeared on all questionnaires. Names of study participants, their date of birth, address, social security number and medical record number did not appear on any data collection forms. All signed consent forms were kept in a locked cabinet. After the data collection was completed, all consent forms were filed with the University of Arizona College of Nursing. The master study list that matched
participant’s name with study identification numbers was password-protected and only available to the principal investigator. The master list was destroyed after the data collection was completed. The completed questionnaires were stored in a locked file cabinet. Questionnaires will be retained for five years and will then be shredded.

All data were entered into two computer databases, the Statistical Package for the Social Sciences (SPSS) 16.0 and Microsoft Excel 2007. Both databases were password-protected. The data were entered in the same order in which the questionnaires were administered and in the same order that the items were presented within the questionnaire. All data were crosschecked between the two databases by exporting the data from SPSS database to Microsoft Excel and comparing them column by column to assure data entry was accurate. In addition, fourteen participants’ raw data (20%) were screened and compared to the data files in the computer by the principal investigator. Statistical tests were performed on each variable to examine the distribution, the central tendency, and the dispersion and to identify outliers. If data violated normal distribution assumptions, a decision was made whether to perform transformation.

Data Transformation

In this study, the moderator effect was assessed by a multiple regression framework; except for living alone and the presence of anxiety, which were dichotomous variables. The moderator effect of the dichotomous variables was assessed using analysis of variance (ANOVA). In a regression equation containing interactions (or product terms), it is important to center or standardize predictor and moderator variables that are measured on a continuous scale (Frazier, Barron & Tix, 2004; Jaccard & Turrsi, 2003; West, Aiken & Krull, 1996). Centering simply involves converting each continuous variable to deviation score form by making the
mean of the variable equal to 0 while preserving the units of the scale (West, Aiken & Krull, 1996). The following equation is used to calculate centered $X$:

$$X = X_{\text{raw}} - \text{Mean (} X \text{)}$$

Centering does not alter the significance of the interaction, nor does it alter the values of the simple slope (Holmbeck, 2002). According to Jaccard & Turrisi (2003), when a variable, $X$, is involved in a product term, the coefficient associated with it alone is conditional to the other variable being zero (i.e., the third variable, $Z$ is 0). Thus, the meaning of the value 0 on each continuous variable must be considered. Centering the continuous variables allow for the interpretation of effects as a meaningful value of the continuous variable (i.e., the mean, which has a value of 0 with centered variables). For example, if the number of chronic conditions has been centered, then the effect of telemonitoring can be interpreted as the amount of benefit a patient at the mean number of chronic conditions could expect from telemonitoring. In contrast, if the number of chronic conditions had not been centered, then the effect of telemonitoring will predict only how much benefit patients with zero chronic conditions could expect from telemonitoring, which is unlikely to be useful. Centering the continuous variables can also greatly lessen the problem of multicollinearity of the higher order terms in the multiple regression due to scaling. In this study, the moderated multiple regression (MMR) was used to assess the moderator effect of patient characteristics on the relationship between the type of service received and the patient outcomes. All continuous moderators were centered prior to data analysis.
Data Analysis Plan

Participant Characteristics

Descriptive statistics were computed for all variables. For categorical variables, frequencies and percentage were computed and for continuous variables, means, standard deviations, skewness and kurtosis were computed. Exploratory analyses, such as boxplots, histogram and scatterplot, were used to evaluate distribution and, heterogeneity of variances and to assess for outliers. A Kolmogorov-Smirnov test was used to examine the assumption of normal distribution for continuous variables.

Comparability of the Two Groups

The comparability of the two groups was assessed using chi-square analysis for discrete variables; such as gender, living alone, NYHF classification, oxygen use, dyspnea and the presence of anxiety. ANOVA was used for continuous variables; such as age, number of chronic conditions and their severity score, and number of daily living activities needing help. The significance level was set at $p < .05$ for all statistical tests. Variables that differed significantly across groups were considered for use as covariates in subsequent analyses.

Comparison of Baseline Measurements

The one-way ANOVA was used to compare group differences on the outcome measurements collected at the initial interview (baseline). The outcome measures in the analysis included: number of symptoms presented, total symptom burden score, self-care maintenance score, heart failure management score and self-confidence score. Homogeneity of variance was tested using Levene’s test. A significance level was set at $p < .05$ for all analyses.
Within-Group Differences

When using comparison groups, it is important to not only know the differences between the groups, but also the differences within the group. The paired t-test was used to compare the within group difference between the initial interview and the 40-day follow-up measurement on each outcome score. A significance level was set at $p < .05$.

Assessing the Effects of Telemonitoring

An ANOVA and the chi-square statistic were used to answer research question #1: Was there a significant difference between HHC only and HHC plus TM on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization? The ANOVA was used to assess the effects of telemonitoring on patients’ symptom burden and self-care of heart failure. The chi-square test was used to examine the effects of telemonitoring on re-hospitalization, which was a dichotomous variable. The independent variable was the type of service received by the participant (i.e., home health care only vs. home health care plus telemonitoring). The dependent variables were the 40-day follow-up measures of: number of symptoms presented, total symptom burden score, self-care maintenance score, heart failure management score and self-confidence score. Any study participant characteristics differing significantly across groups were entered as independent variables to assess the interaction effect. Baseline measures (at the initial interview) of the dependent variables differing significantly between the two groups were included as covariates.

Assessing Moderator Effects

In this study, the number of chronic conditions reported in the OASIS data set, their severity score, the total number of daily living activities needing help, living alone and the
presence of anxiety during home health care admission were conceptualized as having a moderator effect on the relationship between the type of service received and the outcome measures. Type of service received was conceptualized as a predictor variable. There were five continuous outcomes: the number of symptoms presented at 40-day follow-up, the total symptom burden score at 40-day follow-up, the self-care maintenance score at 40-day follow-up, the heart failure management score at 40-day follow-up and the self-confidence score at 40-day follow-up. Re-hospitalization was the only dichotomous outcome variable.

ANOVA is a common technique to assess for a moderator effect because it supports the interpretation of the effects (both main and interaction effects), graphical presentation of the results, and post hoc evaluation of significant interactions through tests of simple effects (West, Aikeb & Krull, 1996). ANOVA is useful when predictors are categorical variables. Although one can create a categorical variable from a continuous variable, it will lower the power of statistical tests and can introduce false effects (Cohen, 1983; Jaccard & Turrisi, 2003). Instead of ANOVA, any combination of continuous and categorical predictors can be analyzed using moderated multiple regression (Baron & Kenny, 1986). In this study, three of the moderators were continuous (number of chronic conditions, severity score for all chronic conditions and number of daily living activities needing help), and two were categorical (living alone and presence of anxiety). The independent variable, type of service received, was dichotomous. A moderated multiple regression (MMR) approach was used when the moderator variable was continuous. In MMR, a product term was created by multiplying the independent variable and the moderator variable. By including the product term in the moderated multiple regression equation, the
The moderated multiple regression includes the first-order effect as well as a higher order effect. In structuring the MMR equation involving product term, all variables contained in the product term(s) must be included in the equation (West, Aiken & Krull, 1996):

\[ Y = b_0 + b_1X + b_2Z + b_3XZ + e \]

Where \( Y \) is the outcome variable, \( b_1 \) is the coefficient of the predictor \( X \), \( b_2 \) is the coefficient of the moderator \( Z \), \( b_3 \) is the coefficient of the product term \( XZ \), and \( e \) is the difference between the predicted and the observed value of \( Y \), or the error. In MMR, product term(s) must be entered into the equation after the predictor and moderator variables, from which they were created, have been entered (Jaccard & Turrisi, 2003; West, Aiken & Krull, 1996). Covariates can also be included in the MMR to control for the effect of other variables or to estimate change in an outcome variable over time. However, the covariate must be entered at the first step (Frazier, Barron & Tix, 2004). In this study, any baseline measures differing significantly between the two groups were included in the MMR as covariates. By comparing the first order model (\( Y=b_0 + b_1X + b_2Z \)) to the higher order model (\( Y = b_0 + b_1X + b_2Z + b_3XZ \)), a significant change in the \( R^2 \) square indicated that a moderated effect existed and was significant.

To assess the moderator effect of patient characteristics on the relationship between the type of service received and the outcome of re-hospitalization, the logistic regression was used. As in the MMR, variables were entered hierarchically with the predictor variable entered first, followed by the moderator variable and then the product term. The change in the \(-2\log\) Likelihood (\(-2\text{LL}\)) was examined to see whether adding the product term to an existing additive

moderator effect of patient characteristics on telemonitoring and outcomes could be evaluated. Registrations were run separately for each moderator variable.
regression equation would significantly increase the predictability. When the change was significant, a moderator effect was considered.

*Post-hoc Evaluation of Significant Moderator Effects*

A significant moderator effect only tells us that the association between the predictor and the outcome is significantly different across levels of the moderator, but does not specify the conditions. Post-hoc evaluation of the interaction effect (or the moderator effect) provides this important information (Frazier, Barron & Tix, 2004; Holmbeck, 2002; Jaccard & Turrisi, 2003; West, Aikin & Krull, 1996). Frazier et al. (2004) suggest two approaches to post-hoc evaluation. The first approach is to compute predicted values of the outcome variable for representative groups, such as those who score at the mean and one standard deviation above and below the mean on the moderator variables. The second approach is to test the statistical significance of the slopes, representing relations between the predictor and the outcome at specific values of the moderator variable. In this study, the first approach was used for post-hoc evaluation.

**Summary**

This chapter presented the methodology for the study, including study design and data analysis plan. The study of moderator effects provides information on the boundary conditions for the relationships of interest and has the implications for both theory and practice.
CHAPTER FOUR: RESULTS

Introduction

This study had two purposes. The first purpose was to compare the difference between home health care only (HHC only) and home health care plus telemonitoring (HHC plus TM) on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization. The second purpose was to explore which patient characteristics, assessed by nurses during the home health care admission and documented in the OASIS data set, might moderate the effect of telemonitoring on symptom burden and self-care of heart failure. This study addressed two research questions:

1. Is there a significant difference between home health care only and home health care plus telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization?

2. Which patient characteristics, assessed by nurses during the home health care admission and documented in the OASIS data set, significantly moderate the outcomes of telemonitoring on symptom burden, self-care of heart failure and re-hospitalization?

All statistical data analyzes in this chapter were performed using the Statistical Package for Social Science (SPSS) version 16.0. A brief review of the sample recruitment process is presented and followed by the description of sample demographic characteristics. The comparison of both groups at baseline and the difference between initial interview and 40-day follow-up interview in each group are also reviewed. In addition, the results of selected patient characteristics on outcome measurements are presented.
Prior to analyzing the data, variables were examined using descriptive statistics. A $p$-value of < .05 was considered significant for all analyses. Statistical tests were run to check for missing data and entry error, to identify outliers and to examine normal distribution and homogeneity of variance on all continuous variables. Outliers were examined and were not removed from subsequent analyses. Because the data analysis involved comparing groups, the normality of each group was checked rather than the overall distribution. Non-normal distribution was found for some variables and a decision was made not to perform transformation. Discussion regarding the violation of normal distribution will be provided accordingly.

Sample Recruitment

Participants were asked by their home health care manager whether they agreed to be contacted by the investigator. If they agreed, the investigator set up a home visit with the potential participant and explained the purpose of the study. Seventy-nine home health care patients who met the inclusion criteria agreed to be contacted, and 75 were enrolled in the study. Four patients declined enrollment. Reasons for the refusal included: 1) did not think he or she met the criteria; 2) was too busy, and 3) was not interested in the study. A handwritten thank you card was sent to each participant three weeks after the first interview to show appreciation. The thank you card also served as a reminder for the 40-day follow-up interview. Seven participants (9.3%) could not be contacted for the 40-day follow-up interview; one moved out of state, and six died. Sixty-eight participants, 34 in each group, completed both initial and 40-day follow-up interviews. Data collected from both interviews were used in the data analysis; participants missing the second interview were excluded. Figure 5 shows the participant flow.
Figure 5. Participant Flow Chart

Description of the Sample

The typical study participant was 81.63 years old ($SD = 8.45$), white (99%) and female (67.6%). Female participants accounted for more than two-thirds of the sample, consistent with the typical distribution among home health care recipients older than 65 (Center for Disease Control, 2004). One third of the study participants (33.8%) lived alone; only two participants
(2.9%) reported having no social support. Twenty-nine percent of the participants reported (or were observed) anxiety during their home health care admission.

The majority (95.6%) of the participants was classified as having Class II and Class III heart failure following the New York Heart Association Classification guideline. Participants’ average number of chronic conditions, as reported on the OASIS data set, was 4.25 ($SD = .998$). On average, the total severity score for all listed chronic conditions was 8.91 ($SD = 2.65$). Participants reported needing help from others for an average of 6.91 daily living activities ($SD = 2.96$).

Comparison of Study Groups

There were 34 participants in each group, the HHC only and the HHC plus TM. Because the analysis involved comparing group differences, baseline characteristics were compared to assess equivalence. The chi-square test was used to compare categorical data and the one-way ANOVA was used to compare interval and ratio data. A significance level of $p < .05$ was set for all tests.

**Psychosocial Characteristics and Clinical Conditions**

The chi-square test was used to compare the psychosocial characteristics and NYHF classification, oxygen use and dyspnea. ANOVA was used to compare differences in clinical conditions, including age, number of daily living activities needing help, number of chronic conditions listed in the OASIS data set and their severity score. There were no significant differences between the two groups in term of psychosocial characteristics (Table 2). For clinical conditions (Table 3 and Table 4), the two groups differed significantly on the primary home health care diagnosis of heart failure ($p < .05$).
Table 2. *Comparison of Study Groups: Psychosocial Characteristics*

<table>
<thead>
<tr>
<th>Psychosocial Characteristics</th>
<th>HHC only (n = 34)</th>
<th>HHC plus TM (n = 34)</th>
<th>( \chi^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>10 (29.4)</td>
<td>12 (35.3)</td>
<td>( \chi^2 (1) = .269 )</td>
</tr>
<tr>
<td>Female</td>
<td>24 (70.6)</td>
<td>22 (64.7)</td>
<td>( p = .604 )</td>
</tr>
<tr>
<td>Live Alone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>21 (61.8)</td>
<td>24 (70.6)</td>
<td>( \chi^2 (1) = .591 )</td>
</tr>
<tr>
<td>Yes</td>
<td>13 (38.2)</td>
<td>10 (29.4)</td>
<td>( p = .442 )</td>
</tr>
<tr>
<td>No. of sources of support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0 (0)</td>
<td>2 (5.9)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>27 (79.4)</td>
<td>23 (67.6)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>6 (17.6)</td>
<td>9 (26.5)</td>
<td>( \chi^2 (3) = .591 )</td>
</tr>
<tr>
<td>3</td>
<td>1 (3.0)</td>
<td>0 (0)</td>
<td>( p = .270 )</td>
</tr>
<tr>
<td>Presence of anxiety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>during admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>23 (67.6)</td>
<td>25 (75.5)</td>
<td>( \chi^2 (1) = .283 )</td>
</tr>
<tr>
<td>Yes</td>
<td>11 (32.4)</td>
<td>9 (26.5)</td>
<td>( p = .595 )</td>
</tr>
</tbody>
</table>

Table 3. *Comparison of Study Groups: Clinical Conditions (Categorical Variables)*

<table>
<thead>
<tr>
<th>Clinical Conditions</th>
<th>HHC only (n = 34)</th>
<th>HHC plus TM (n = 34)</th>
<th>( \chi^2 )</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHF classification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>20 (58.8)</td>
<td>15 (44.1)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>14 (41.2)</td>
<td>16 (47.1)</td>
<td>( \chi^2 (2) = 3.848 )</td>
</tr>
<tr>
<td>IV</td>
<td>0 (0)</td>
<td>3 (8.8)</td>
<td>( p = .146 )</td>
</tr>
<tr>
<td>Diagnosis of HF as:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>15 (44.1)</td>
<td>25 (73.5)</td>
<td>( \chi^2 (1) = 6.071 )</td>
</tr>
<tr>
<td>Secondary</td>
<td>19 (55.9)</td>
<td>9 (20.5)</td>
<td>( p = .014^* )</td>
</tr>
<tr>
<td>Oxygen use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>16 (47.0)</td>
<td>15 (44.1)</td>
<td></td>
</tr>
<tr>
<td>As needed</td>
<td>7 (20.6)</td>
<td>8 (23.5)</td>
<td>( \chi^2 (2) = .099 )</td>
</tr>
<tr>
<td>Continuous</td>
<td>11 (32.4)</td>
<td>11 (32.4)</td>
<td>( p = .952 )</td>
</tr>
<tr>
<td>When dyspnea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>3 (8.8)</td>
<td>3 (8.8)</td>
<td></td>
</tr>
<tr>
<td>Walking &gt;20 feet</td>
<td>14 (41.2)</td>
<td>17 (50.1)</td>
<td></td>
</tr>
<tr>
<td>Moderate exertion</td>
<td>11 (32.4)</td>
<td>12 (35.3)</td>
<td></td>
</tr>
<tr>
<td>Minimal exertion</td>
<td>5 (14.7)</td>
<td>1 (2.9)</td>
<td>( \chi^2 (1) = 3.000 )</td>
</tr>
<tr>
<td>At rest</td>
<td>1 (2.9)</td>
<td>1 (2.9)</td>
<td>( p = .558 )</td>
</tr>
</tbody>
</table>

* *p < .05*
Table 4. Comparison of Study Groups: Clinical Conditions (Continuous Variables)

<table>
<thead>
<tr>
<th>Clinical Condition</th>
<th>HHC Only (n = 34)</th>
<th>HHC plus TM (n =34)</th>
<th>One-way ANOVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>80.82 (9.120)</td>
<td>82.44 (7.766)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>81</td>
<td>84</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>50 – 94</td>
<td>52 – 94</td>
<td></td>
</tr>
<tr>
<td>No. of daily living activities needing help</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>7.56 (3.017)</td>
<td>6.26 (2.799)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>7.5</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>1 – 13</td>
<td>2 – 13</td>
<td></td>
</tr>
<tr>
<td>No. of chronic conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>4.24 (1.075)</td>
<td>4.26 (0.931)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>4.0</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>2 – 6</td>
<td>3 – 6</td>
<td></td>
</tr>
<tr>
<td>Total severity for all chronic conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>8.68 (2.637)</td>
<td>9.15 (2.687)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>9.0</td>
<td>9.5</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>4 – 14</td>
<td>4 – 15</td>
<td></td>
</tr>
</tbody>
</table>

Comparison of Base
line Measurements

The Memorial Symptom Assessment Scale – Heart Failure (MSAS – HF) was used to
measure the outcome - symptom burden. The same scale was used during the initial interview
(Time 1, T1) and the 40-day follow-up interview (Time 2, T2). Two scores were calculated from
the MSAS – HF; the total symptom score and the total symptom burden score. Self-care of heart
failure was measured using the Self-care of Heart Failure Index (SCHFI). The SCHFI is
comprised of 15 items and divided into 3 subscales. Like MSAS – HF, the SCHFI was assessed
during both interviews. Three scores were calculated from the three subscales; self-care
maintenance score, heart failure management score and self-confidence score.
ANOVA was used to compare group differences on the scores collected at the initial interview (Time 1). The two groups differed significantly in the number of symptoms presented \((p < .05)\) and self-care maintenance \((p < .05)\), as shown in Table 5. Homogeneity of variance was tested using Levene’s test. Only heart failure management was significant.

<table>
<thead>
<tr>
<th>Table 5. Comparison of Study Groups: Baseline Measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline Measurement</strong></td>
</tr>
<tr>
<td><strong>No. of symptoms presented</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td><strong>Symptom burden score</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td><strong>Self-care maintenance score</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td><strong>Heart failure management score</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td><strong>Self-confidence score</strong></td>
</tr>
<tr>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
</tbody>
</table>

\(^* p < .05\)

Within-Group Differences

Paired t-tests were used to compare within-group difference between Time 1 (the initial interview) and Time 2 (the 40-day follow-up interview) measurements of each outcome score.
(number of symptoms presented, total symptom burden, self-care maintenance, heart failure management and self-confidence). The HHC only group had a statistically significant decrease in the number of symptoms presented from Time 1 to Time 2 ($p < .05$). HHC only participants had an average of 11.70 symptoms ($SD = 4.62$) presented over the past seven days prior to Time 1, but the number of symptoms presented dropped to an average of 10.41 symptoms ($SD = 4.11$) at Time 2. In addition to the decrease in number of symptoms presented, the HHC only group also showed significant reduction in total symptom burden between the two interviews ($p < .005$). Mean total symptom burden was 25.12 ($SD = 12.00$) at Time 1 decreased to 20.32 ($SD = 10.05$) at Time 2. Heart failure management also improved significantly in the HHC only group ($p < .05$), from 13.52 ($SD = 3.93$) to 15.33 ($SD = 4.26$). In general, the HHC only group improved on all outcome variables from Time 1 to Time 2, with the exception of self-care maintenance. Self-care maintenance was lower at Time 2 for the HHC only group, dropping from 13.38 ($SD = 3.3$) to 12.65 ($SD = 2.96$); however, the difference was not statistically significant. Table 6 shows the contrast of Time 1 with Time 2 for the HHC only group on outcome variables.

The HHC plus TM group made improvements on all the outcome variables at the 40-day follow-up; however, only the improvement in total symptom burden was statistically significantly (Table 7). Mean total symptom burden was 20.24 ($SD = 10.61$) at Time 1 and 17.40 ($SD = 10.33$) at Time 2 ($p < .05$).
Table 6. Contrast of Time 1 with Time 2 for Home Health Care Only Group on Outcome Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time 1</th>
<th>Time 2</th>
<th>t (33)</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td></td>
<td></td>
<td>LL</td>
</tr>
<tr>
<td>Total symptoms presented</td>
<td>11.70 (4.62)</td>
<td>10.41 (4.11)</td>
<td>2.12</td>
<td>.042*</td>
<td>.051</td>
</tr>
<tr>
<td>Total symptom burden score</td>
<td>25.12 (12.00)</td>
<td>20.32 (10.05)</td>
<td>3.30</td>
<td>.002**</td>
<td>1.84</td>
</tr>
<tr>
<td>Self-care maintenance score</td>
<td>13.38 (3.30)</td>
<td>12.65 (2.96)</td>
<td>1.59</td>
<td>.112</td>
<td>-.21</td>
</tr>
<tr>
<td>Heart failure management score</td>
<td>13.52 (3.93)</td>
<td>15.33 (4.26)</td>
<td>-2.33</td>
<td>.030*</td>
<td>-3.43</td>
</tr>
<tr>
<td>Self-confidence score</td>
<td>10.15 (1.94)</td>
<td>10.62 (1.86)</td>
<td>-1.46</td>
<td>.154</td>
<td>-1.13</td>
</tr>
</tbody>
</table>

* p < .05
** p < .005

Table 7. Contrast of Time 1 with Time 2 for Home Health Care Plus Telemonitoring Group on Outcome Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Time 1</th>
<th>Time 2</th>
<th>t (33)</th>
<th>p</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (SD)</td>
<td></td>
<td></td>
<td>LL</td>
</tr>
<tr>
<td>Total symptoms presented</td>
<td>9.56 (3.80)</td>
<td>9.06 (4.21)</td>
<td>.93</td>
<td>.358</td>
<td>-.59</td>
</tr>
<tr>
<td>Total symptom burden score</td>
<td>20.24 (10.61)</td>
<td>17.40 (10.33)</td>
<td>2.22</td>
<td>.033*</td>
<td>.24</td>
</tr>
<tr>
<td>Self-care maintenance score</td>
<td>14.91 (2.71)</td>
<td>14.97 (2.93)</td>
<td>-.09</td>
<td>.927</td>
<td>-1.36</td>
</tr>
<tr>
<td>Heart failure management score</td>
<td>14.81 (4.99)</td>
<td>16.27 (3.91)</td>
<td>-1.63</td>
<td>.116</td>
<td>-3.31</td>
</tr>
<tr>
<td>Self-confidence score</td>
<td>10.73 (2.34)</td>
<td>11.29 (2.18)</td>
<td>-1.72</td>
<td>.095</td>
<td>-1.22</td>
</tr>
</tbody>
</table>

* p < .05
Results by Research Questions

Research Question 1

ANOVA and the chi-square test were used to examine research question #1: Was there a significant difference between HHC only and HHC plus TM on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization? The two groups differed significantly on primary home health care diagnosis of HF ($p < .05$), so the variable was included in the analysis as an independent variable to assess for an interaction effect. Figure 6 shows the statistical model for research question 1.

Figure 6. Statistical Model for Research Question 1

Number of Symptoms Presented

Number of symptoms presented at 40-day follow-up was analyzed using ANOVA. The assumptions for ANOVA that were met included mutually exclusive groups, equal sample size, similar variance and the dependent variable being measured on an interval scale.

Since there was a significant difference in the number of symptoms presented at Time 1, the variable was included as a covariate. Table 8 shows the result of the ANOVA, using type of service and primary home health care diagnosis of HF as independent variables, number of symptoms at 40-day follow-up as the dependent variable, and number of symptoms at the initial
interview as the covariate. The two groups did not differ significantly on the number of symptoms at the 40-day follow-up, $F(1, 63) = .029, p = .865$. By considering the effect of the covariate, the adjusted group means were 9.692 ($SE = .545$) for the HHC only group and 9.835 ($SE = .618$) for the HHC plus TM. The covariate, the number of symptoms presented at initial interview, was significantly related to the number of symptoms presented at 40-day follow-up, $F(1, 63) = 52.054, p < .0001$. There was no significant interaction effect of heart failure when it was either the primary or secondary home health care diagnosis.

Figure 7. Comparison of Group Means on Number of Symptoms Presented at Baseline and 40-day Follow-up
Table 8. Analysis of Variance for Number of Symptoms Presented at 40-day Follow-up

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III sum of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrected Model</td>
<td>562.409</td>
<td>4</td>
<td>140.602</td>
<td>14.454</td>
<td>.000</td>
</tr>
<tr>
<td>Intercept</td>
<td>59.826</td>
<td>1</td>
<td>59.826</td>
<td>6.150</td>
<td>.016</td>
</tr>
<tr>
<td>No. of symptoms presented at T1</td>
<td>506.349</td>
<td>1</td>
<td>506.349</td>
<td>52.054</td>
<td>.000</td>
</tr>
<tr>
<td>Type of service received</td>
<td>.281</td>
<td>1</td>
<td>.281</td>
<td>.029</td>
<td>.865</td>
</tr>
<tr>
<td>Primary home health care diagnosis of HF</td>
<td>.132</td>
<td>1</td>
<td>.132</td>
<td>.014</td>
<td>.907</td>
</tr>
<tr>
<td>Type of service received X Primary home health care diagnosis of HF</td>
<td>.260</td>
<td>1</td>
<td>.260</td>
<td>.027</td>
<td>.871</td>
</tr>
<tr>
<td>Error</td>
<td>612.826</td>
<td>63</td>
<td>9.727</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7620.000</td>
<td>68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>1175.235</td>
<td>67</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent variable: The number of symptom presented at Time 2
a. R Square = .479 (Adjusted R Square = .445)

Total Symptom Burden

ANOVA was used to analyze total symptom burden at 40-day follow-up. Figure 8 compares each group’s mean total symptom burden at baseline and 40-day follow-up. The results, using total symptom burden for all symptoms at 40-day follow-up as the dependent variable, the type of service received, and primary home health care diagnosis of HF as independent variables, are shown in Table 9. The mean total symptom burden score at 40-day follow-up was 20.32 (SD = 10.05) for the HHC only group and 17.40 (SD = 10.33) for the HHC plus TM group. There was no significant difference between the two groups, $F (1, 64) = 1.134, \ p = .291$, and an effect size $\eta = .13$. The two independent variables did not have an interaction effect. The assumptions for ANOVA were met, except that the total symptom burden score at 40-day follow-up was not normally distributed for the HCC plus TM group, given that $D (34) = .158 (\ p = .031)$. However, ANOVA is fairly robust. Even though the assumption is violated, if the group sizes are equal and there are at least 20 degrees of freedom, ANOVA can be accurate
This study met these two criteria. Each group had 34 participants and the degrees of freedom were greater than 20.

![Graph](image)

**Figure 8. Comparison of Group Means on Symptom Burden Score at Baseline and 40-day Follow-up**

**Table 9. Analysis of Variance for Total Symptom Burden Score at 40-day Follow-up**

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III sum of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrected Model</td>
<td>159.972</td>
<td>3</td>
<td>53.324</td>
<td>.499</td>
<td>.685</td>
</tr>
<tr>
<td>Intercept</td>
<td>20937.257</td>
<td>1</td>
<td>20937.26</td>
<td>195.769</td>
<td>.000</td>
</tr>
<tr>
<td>Type of service received</td>
<td>121.320</td>
<td>1</td>
<td>121.320</td>
<td>1.134</td>
<td>.291</td>
</tr>
<tr>
<td>Primary home health care diagnosis of HF</td>
<td>5.729</td>
<td>1</td>
<td>5.729</td>
<td>.054</td>
<td>.818</td>
</tr>
<tr>
<td>Type of service received X Primary home health care diagnosis of HF</td>
<td>7.226</td>
<td>1</td>
<td>7.226</td>
<td>.068</td>
<td>.796</td>
</tr>
<tr>
<td>Error</td>
<td>6844.715</td>
<td>64</td>
<td>106.949</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>31189.242</td>
<td>68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>7004.687</td>
<td>67</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: Total symptom burden score for all symptoms at Time 2

R Squared = .023 (Adjusted R Squared = -.023)
Self-care Maintenance

Self-care maintenance at 40-day follow-up was analyzed using ANOVA. The normal distribution assumption was violated in both groups; however, other assumptions were met. Since there was a significant difference in the baseline self-care maintenance with HHC plus TM group scored higher than the HHC only group, it was entered as a covariate. Figure 9 compares group means on self-care maintenance at baseline and 40-day follow-up. The ANOVA results, using the self-care maintenance score at 40-day follow-up as a dependent variable, the type of service received and the primary home health care diagnosis of HF as independent variables and the baseline self-care maintenance score as a covariate are summarized in Table 10. After considering the effect of the covariate, the adjusted group means were 12.991 (SE = .476) for the HHC only group and 14.742 (SE = .537) for the HHC plus TM group. There was a significant difference between the two groups on self-maintenance at 40-day follow-up, $F (1, 63) = 5.817, p = .019$ with an effect size of $\eta = .29$. The interaction between type of service received and primary home health diagnosis of HF was non-significant.
Figure 9. Comparison of Group Means on Self-care Maintenance Score at Baseline and 40-day Follow-up

Table 10. Analysis of Variance for Self-care Maintenance Score at 40-day Follow-up

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III sum of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrected Model</td>
<td>196.921^a</td>
<td>4</td>
<td>49.230</td>
<td>6.633</td>
<td>.000</td>
</tr>
<tr>
<td>Intercept</td>
<td>204.593</td>
<td>1</td>
<td>204.593</td>
<td>27.565</td>
<td>.000</td>
</tr>
<tr>
<td>Self-care maintenance score at T1</td>
<td>73.226</td>
<td>1</td>
<td>73.226</td>
<td>9.866</td>
<td>.003**</td>
</tr>
<tr>
<td>Type of service received</td>
<td>43.171</td>
<td>1</td>
<td>43.171</td>
<td>5.817</td>
<td>.019*</td>
</tr>
<tr>
<td>Primary home care diagnosis of HF</td>
<td>3.273</td>
<td>1</td>
<td>3.273</td>
<td>.441</td>
<td>.509</td>
</tr>
<tr>
<td>Type of service received X Primary home care diagnosis of HF</td>
<td>6.642</td>
<td>1</td>
<td>6.642</td>
<td>.895</td>
<td>.348</td>
</tr>
<tr>
<td>Error</td>
<td>467.594</td>
<td>63</td>
<td>7.422</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>13631.000</td>
<td>68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>664.515</td>
<td>67</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: Self-care maintenance score at Time2

^a R Squared = .296 (Adjusted R Square = .252)

^b * p < .05; ** p < .005
Heart Failure Management

ANOVA was used to compare group means for heart failure management at the 40-day follow-up. Not all participants experienced shortness of breath or swollen legs or arms during the past month prior to the interview at 40-day follow-up. Thus, only 47 participants had a heart failure management score at 40-day follow-up. The comparison of the two groups was shown in Figure 10. The results of the analysis, using heart failure management score at 40-day follow-up as a dependent variable and type of service received and primary home health care diagnosis of HF as independent variables, are shown in Table 11. All assumptions for ANOVA were met. For the HHC only group, the mean heart failure management score at 40-day follow-up was 15.33 (SD = 4.26) and for the HHC plus TM group, the mean heart failure management score at 40-day follow-up was 16.27 (SD = 3.91). The two groups did not differ significantly on the heart failure management score at 40-day follow-up, $F (1, 43) = .431, p = .515$, and effect size $\eta = .10$. There was no significant interaction between the two independent variables.
Figure 10. Comparison of Group Means on Heart Failure Management Score at Baseline and 40-day Follow-up

Table 11. Analysis of Variance for Heart Failure Management Score at 40-day Follow-up

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III sum of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrected Model</td>
<td>22.234*</td>
<td>3</td>
<td>7.411</td>
<td>.434</td>
<td>.730</td>
</tr>
<tr>
<td>Intercept</td>
<td>10727.2</td>
<td>1</td>
<td>10727.26</td>
<td>628.673</td>
<td>.000</td>
</tr>
<tr>
<td>Type of service received</td>
<td>7.352</td>
<td>1</td>
<td>7.352</td>
<td>.431</td>
<td>.515</td>
</tr>
<tr>
<td>Primary home health care diagnosis of HF</td>
<td>9.239</td>
<td>1</td>
<td>9.239</td>
<td>.541</td>
<td>.466</td>
</tr>
<tr>
<td>Type of service received X Primary home health care diagnosis of HF</td>
<td>3.110</td>
<td>1</td>
<td>3.110</td>
<td>.182</td>
<td>.672</td>
</tr>
<tr>
<td>Error</td>
<td>733.723</td>
<td>43</td>
<td>17.063</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>12565.00</td>
<td>47</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Corrected Total</td>
<td>755.957</td>
<td>46</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: Heart failure management score at T2
* R Squared = .029 (Adjusted R Squared = -.038)

Self-Confidence

The same procedure was used to compare group self-confidence means at 40-day follow-up. Self-confidence at 40-day follow-up was used as a dependent variable and type of service
received and primary home health diagnosis of HF as independent variables. The self-confidence at 40-day follow-up was not normally distributed for either group. Other assumptions for ANOVA were met. Figure 11 compares groups’ mean self-confidence at baseline and 40-follow-up. The mean self-confidence score at 40-day follow-up for the HHC only group and HHC plus TM group were 10.62 (SD = 1.86) and 11.29 (SD = 2.18) respectively. The difference between the two groups on self-confidence at 40-day follow-up was non-significant, $F (1, 64) = 2.204, p = .143$, with an effect size $\eta = .18$, as shown in Table 12. There was no significant interaction between independent variables.

Figure 11. *Comparison of Group Means on Self-confidence Score at Baseline and 40-day Follow-up*
Table 12. Analysis of Variance for Self-confidence Score at 40-day Follow-up

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III sum of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrected Model</td>
<td>10.786a</td>
<td>3</td>
<td>3.595</td>
<td>.858</td>
<td>.467</td>
</tr>
<tr>
<td>Intercept</td>
<td>7137.076</td>
<td>1</td>
<td>7137.08</td>
<td>1703.86</td>
<td>.000</td>
</tr>
<tr>
<td>Type of service received</td>
<td>9.233</td>
<td>1</td>
<td>9.233</td>
<td>2.204</td>
<td>.143</td>
</tr>
<tr>
<td>Primary home health care diagnosis of HF</td>
<td>2.763</td>
<td>1</td>
<td>2.763</td>
<td>.660</td>
<td>.420</td>
</tr>
<tr>
<td>Type of service received X Primary home health care diagnosis of HF</td>
<td>.087</td>
<td>1</td>
<td>.087</td>
<td>.021</td>
<td>.886</td>
</tr>
<tr>
<td>Error</td>
<td>268.082</td>
<td>64</td>
<td>4.189</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>8441.000</td>
<td>68</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corrected Total</td>
<td>278.868</td>
<td>67</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dependent Variable: Self-confidence score at Time 2

a R Squared = .039 (Adjusted R Squared = -.006)

Re-hospitalization

Because re-hospitalization was measured at the nominal level, a chi-square test was used to examine the relationship between type of service received and re-hospitalization. Because the two groups differed significantly on the primary home health care diagnosis of HF, a within-group comparison on the primary home health care diagnosis of HF and re-hospitalization was performed first. Table 13 shows the cross tabulation table for type of service received, primary home health care diagnosis of HF and re-hospitalization and the chi-square test results.
Eight participants were re-hospitalized during the 40-day enrollment period in the HCC only group. Of those, three (20%) had a primary home health care diagnosis of HF. Fourteen participants in the HHC plus telemonitoring group were re-hospitalized during the 40-day period, of whom nine (36%) had a primary home health care diagnosis of HF. There was no significant difference in re-hospitalization and having heart failure as primary or second diagnosis within both groups, $\chi^2 (1) = .186, p = .666$ and $\chi^2 (1) = 1.045, p = .307$ for HHC only and HCC plus TM respectively.

Table 14 shows the cross tabulation table for type of service received and re-hospitalization during the 40-day period. The two groups did not differ significantly on re-hospitalization during the 40-day period, $\chi^2 (1) = 2.419, p = .120$. 

---

Table 13. Cross Tabulation Table for Type of Service Received, Primary Home Health Diagnosis of Heart Failure and Re-hospitalization

<table>
<thead>
<tr>
<th>Type of service received</th>
<th>Re-hospitalization during study period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td>HHC Only</td>
<td>12</td>
</tr>
<tr>
<td>Primary home health care diagnosis of HF</td>
<td>%</td>
</tr>
<tr>
<td>Primary Count</td>
<td>80.0%</td>
</tr>
<tr>
<td>Second Count</td>
<td>14</td>
</tr>
<tr>
<td>%</td>
<td>73.7%</td>
</tr>
<tr>
<td>Total Count</td>
<td>26</td>
</tr>
<tr>
<td>%</td>
<td>76.5%</td>
</tr>
<tr>
<td>HHC plus Telemonitoring</td>
<td>16</td>
</tr>
<tr>
<td>Primary home health care diagnosis of HF</td>
<td>%</td>
</tr>
<tr>
<td>Primary Count</td>
<td>64.0%</td>
</tr>
<tr>
<td>Second Count</td>
<td>4</td>
</tr>
<tr>
<td>%</td>
<td>44.4%</td>
</tr>
<tr>
<td>Total Count</td>
<td>20</td>
</tr>
<tr>
<td>%</td>
<td>58.8%</td>
</tr>
</tbody>
</table>
Table 14. Cross Tabulation Table for Type of Service Received and Re-hospitalization

<table>
<thead>
<tr>
<th>Type of service received</th>
<th>Re-hospitalization during study period</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>Yes</td>
<td>Total</td>
</tr>
<tr>
<td>HHC only Count</td>
<td>26</td>
<td>8</td>
<td>34</td>
</tr>
<tr>
<td>%</td>
<td>76.5%</td>
<td>23.5%</td>
<td>100%</td>
</tr>
<tr>
<td>HHC plus Count telemonitoring</td>
<td>20</td>
<td>14</td>
<td>34</td>
</tr>
<tr>
<td>%</td>
<td>58.8%</td>
<td>41.2%</td>
<td>100%</td>
</tr>
<tr>
<td>Total Count</td>
<td>46</td>
<td>22</td>
<td>68</td>
</tr>
<tr>
<td>%</td>
<td>67.6%</td>
<td>32.4%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

$\chi^2 (1) = 2.419$
$p = .120$

Research Question 2

Moderated multiple regression (MMR), ANOVA and logistic regression were used to examine research question 2: Which patient characteristics, assessed by nurses during the home health care admission and documented in the OASIS data set, significantly moderate the outcomes of telemonitoring on symptom burden, self-care of heart failure and re-hospitalization? The choice of statistical test depended on the measurement level of the predictor, the moderator and the dependent variable. When the predictor was categorical and the moderator and dependent variable were continuous, MMR was used. When both predictor and moderator were categorical and the dependent variable was continuous, ANOVA was used. Logistic regression was the choice when the dependent variable was categorical and dichotomous. MMR includes first-order effects as well as a higher order product term including the hypothesized moderator variable. The product term was computed by multiplying the predictor variable and the moderator variable. The variables were entered hierarchically with the predictor variable entered first, then the moderator variable and finally the product term of the predictor and the moderator. By comparing the first order model ($Y=b_0 + b_1X + b_2Z$) to the higher order
model \( Y = b_0 + b_1X + b_2Z + b_3XZ \), a significant change in the R square indicates a significant moderator effect. Assumptions of multiple regression were checked for violation. Residuals were examined using casewise diagnostics. The values of the variance inflated factor (VIP) and tolerance were used to examine the multicollinearity assumption. Homoscedasticity was checked by examining the scatterplot of standardized predicted and residual values. The Durbin-Watson statistic was used to assess the independence of errors. Violation of any assumptions will be described accordingly.

ANOVA was used only to assess the moderator effect of living alone and the presence of anxiety during admission to home health care, which were categorical variables. A significant interaction effect between the predictor and moderator in the ANOVA indicates the existence of a moderated effect. The assumption of homogeneity of variance was examined using Levene’s test.

Because the outcome variable, re-hospitalization, was dichotomous (yes or no), logistic regression was used to examine the moderator effect of patient characteristics on the relationship between the type of service received and re-hospitalization. As in the MMR, variables were entered hierarchically with the predictor variable entered first, followed by the moderator variable and then the product term. Change in the -2 Log Likelihood (-2LL) was examined to see whether adding the product term to an existing additive regression equation would significantly increase the predictability. When the change was significant, a moderator effect was considered. The Cox & Snell R square, which is similar to the \( R^2 \) in linear regression, was reported.

Discussions in this section focus on the significant change in the R square when the product term was added in the MMR, the existence of a significant interaction effect in the
ANOVA and the significant change in the -2LL in the logistic regression when the product term was added. The significance level was set at $p < .05$. A significant result indicated that there was a moderator effect. The three continuous moderators (number of chronic conditions, severity score for all chronic conditions and number of daily living activities needing help) were centered prior to the analysis by making the mean of the variable equal 0. Centering the continuous variables allows for the interpretation of effects as a meaningful value of the continuous variable and does not alter the significant of the interaction or the values of the simple slope (Holmbeck, 2002; West, Aiken & Krull, 1996). Figure 12 shows the statistical model for research question 2. The moderator effects of the five moderators on the six outcomes are presented as follows.

**Type of Service Received**
- HHC only vs. HHC plus TM

**Patient Characteristics**
- Number of chronic conditions
- Severity of chronic conditions
- Functional status
- Living arrangement
- Presence of anxiety

**Type of Service Received X Patient Characteristics**

**Patient Outcomes at 40-day Follow up**
- Symptom burden
  - No. of symptoms presented
  - Total symptom burden
- Self-care of heart failure
  - Self-care maintenance
  - Heart failure management
  - Self-care confidence
- Re-hospitalization

Figure 12. *Statistical Model for Research Question 2*

**Moderator 1: Number of Chronic Conditions**

*Number of symptoms presented at 40-day follow-up.* Because the outcome variable was continuous, MMR was used for the analysis. Because the number of symptoms presented at the
initial interview differed significantly between the two groups, the variable was included in the regression model and was entered first. The $R^2$ for the first order model, which included the number of symptoms presented at the initial interview, the type of service received and the centered number of chronic conditions, was .485. After adding the product term, the $R^2$ for the higher order model was .487, a non statistically significant change of .002, $F(1, 63) = .257, p = .614$.

Total symptom burden at 40-day follow-up. MMR was used in this analysis. Only the type of service received, the centered number of chronic conditions and their product term were included in the analysis. The $R^2$ for the first order model and the higher order model were the same, $R^2 = .021$. The value of the $R^2$ did not change when the product term was added into the model.

Self-care maintenance at 40-day follow-up. MMR was used in this analysis. Because the self-care maintenance score was significantly different between the two groups at the initial interview, the variable was entered first as a covariate, followed by type of service, and the centered number of chronic conditions. The $R^2$ for the first order model was .296. When the product term was added, there was no change in the $R^2$.

Heart failure management at 40-day follow-up. Because the heart failure management was measured at the interval level, MMR was used in this analysis. Not all participants experienced heart failure symptoms of shortness of breath or swollen arms/legs during the month prior to the 40-day follow-up. Thus, only 47 participants had a heart failure management score at their 40-day follow-up. Type of service received, the centered number of chronic conditions, and their product term were used in the analysis. The first order model, which included both type of
service received and the centered number of chronic conditions, had a R^2 of .044. When the product term was added, the R^2 changed to .082, a difference of .038. However, the change was non-significant, F (1, 43) = 1.794, p = .187. Although the change was not statistically significant, Aguinis (2004) suggested that “practically significant” should also be considered. Because statistically significant moderator effect is difficult to find, Evens (1985) suggested that “a rough rule would be to take 1% variance explained as the criterion as to whether or not a significant interaction exists in the model” (p.320). In this case, the .038 difference indicated the proportion of variance in Y explained by the product term above and beyond the first-order effects. The product term explained 3.8% of the variance in Y. Table 15 summarizes the individual predictors of the higher order model. Further post hoc analysis will be presented later in this chapter.

Table 15. Coefficients for the Moderated Multiple Regression Model in Heart Failure Management

<table>
<thead>
<tr>
<th></th>
<th>B (SE)</th>
<th>Beta</th>
<th>t</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Constant)</td>
<td>15.338 (.879)</td>
<td></td>
<td>17.433</td>
<td>.000</td>
</tr>
<tr>
<td>Type of service received</td>
<td>.901 (1.181)</td>
<td>.112</td>
<td>.763</td>
<td>.450</td>
</tr>
<tr>
<td>Centered number of chronic conditions</td>
<td>-.059 (.844)</td>
<td>-.014</td>
<td>-.070</td>
<td>.945</td>
</tr>
<tr>
<td>Product term of type of service received and number of chronic conditions</td>
<td>1.627 (1.215)</td>
<td>.272</td>
<td>1.393</td>
<td>.187</td>
</tr>
</tbody>
</table>

Dependent variable: Heart failure management at 40-day follow-up

Self-confidence at 40-day follow-up. MMR was used in this analysis. Type of service and the centered number of chronic conditions were included in the first order model. The R^2 for the first order model was .063. When the product term was added to form a higher order model, the R^2 increased to .072, F (1, 64) = .648, p = .424.

Re-hospitalization. When only type of service received and the number of chronic conditions were included in the model, the -2LL was 83.026 and the Cox & Snell R square was .037. By adding the product term to the model, the -2LL decreased to 82.927 and the Cox &
Snell R square increased to .039. The change was non-significant, $\chi^2 (1) = .099, p = .753$.

Residuals in the regression were examined. Cook’s Distance was less than 1. Leverage values for all cases were between 0 and 1. No standardized residuals were greater than 2.56.

Moderator 2: Severity of Chronic Conditions

Number of symptoms presented at 40-day follow-up. MMR was used in this analysis. Because the number of symptoms presented at the initial interview differed significantly between the two groups, it was included in the regression model and was entered first. The R$^2$ for the first order model, which included number of symptoms presented at the initial interview, type of service received and the centered total severity score of all chronic conditions, was .479. Adding the product term of the moderator and the predictor variable did not make a significant change in the R$^2$, $F (1, 63) = .056, p = .813$.

Total symptom burden at 40-day follow-up. Only type of service received, the centered total severity score of all chronic conditions and their product term were included in the MMR. The R$^2$ for the first order model was .021. When the product term was added, the R$^2$ only increased to .026, $F (1, 64) = .322, p = .573$.

Self-care maintenance at 40-day follow-up. Because the two groups differed significantly on the self-care maintenance score at the initial interview, the variable was entered first as a covariate. The R$^2$ for the first order model was .297. When the product term was included, there was a non-significant change in the R$^2$, .007, $F (1, 63) = .673, p = .415$.

Heart failure management at 40-day follow-up. As previously mentioned, not all participants experienced shortness of breath or swollen arms/legs during the month prior to the 40-day follow-up. Only 47 participants had a heart failure management score at their 40-day
follow-up. The first order model, which included both the type of service received and the centered total severity score of all chronic conditions, had a $R^2$ of .092. When the product term of the predictor and the moderator were added, the $R^2$ changed to .105, which was non-significant, $F (1, 43) = .433, p = .514$.

*Self-confidence at 40-day follow-up.* The type of service received, the centered total severity score of all chronic conditions and their product term were included in the analysis. The $R^2$ for the first order model was .042. When the product term was added to form a higher order model, the $R^2$ changed to .057, $F (1, 64) = 1.010, p = .319$.

*Re-hospitalization.* When type of service received and total severity score for all chronic conditions were included in the model, the -2 LL was 81.028 and the Cox & Snell $R^2$ was .065. By adding the product term of both variables into the model, the -2LL changed to 80.932. The change was non-significant, $\chi^2 (1) = .096, p = .756$. The Cox & Snell $R^2$ for the higher order model was .067. The residuals in the regression were examined. Cook’s Distance was less than 1. The Leverage value for all cases was between 0 and 1. No standardized residuals were greater than 2.56.

*Moderator 3: Functional Status*

*Number of symptoms presented at 40-day follow-up.* MMR was used in this analysis. Because the number of symptoms presented at the initial interview differed significantly between the two groups, the variable was included in the regression model and was entered first as a covariate. The $R^2$ for the first order model, which included the number of symptoms presented at the initial interview, the type of service received and the centered number of daily living
activities needing help, was .480. After adding the product term, the $R^2$ for the higher order model was .482, $F(1, 63) = .224, p = .638$.

*Total symptom burden at 40-day follow-up.* Because the outcome variable was continuous, MMR was used in this analysis. Only the type of service received, the centered number of daily living activities needing help and their product term were in the analysis. The $R^2$ for the first order model was .024. The value of $R^2$ only increased .001 when the product term was added to form a higher order model. The increase was non-significant, $F(1, 64) = .045, p = .832$.

*Self-care maintenance at 40-day follow-up.* MMR was used in the analysis. Because the self-care maintenance score was significantly different between the two groups at the initial interview, the variable was entered first as a covariate, followed by the type of service and the centered number of daily living activities needing help. The $R^2$ for the first order model was .284. When the product term was added, the $R^2$ increased to .337. The change in the $R^2$ was significant, $F = 5.000, p = .029$. The product term explained 5.3% of the variance in $Y$. Table 16 summarizes the individual predictors of the higher order model.

Table 16. *Coefficients for the Moderated Multiple Regression Model in Self-care Maintenance*

<table>
<thead>
<tr>
<th></th>
<th>B (SE)</th>
<th>Beta</th>
<th>t</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Constant)</td>
<td>7.570 (1.596)</td>
<td>4.744</td>
<td>.000</td>
<td></td>
</tr>
<tr>
<td>Self-care Maintenance at T1</td>
<td>.388(.112)</td>
<td>.381</td>
<td>3.460</td>
<td>.001*</td>
</tr>
<tr>
<td>Type of service received</td>
<td>1.830 (.671)</td>
<td>.293</td>
<td>2.726</td>
<td>.008*</td>
</tr>
<tr>
<td>Centered number of daily living needing help</td>
<td>-.171(.158)</td>
<td>-.161</td>
<td>-1.082</td>
<td>.283</td>
</tr>
<tr>
<td>Product term of type of service received and number of daily living needing help</td>
<td>.504 (.226)</td>
<td>.319</td>
<td>2.236</td>
<td>.029*</td>
</tr>
</tbody>
</table>

*Dependent variable: Self-care maintenance at 40-day follow-up

* $p < .05
Heart failure management at 40-day follow-up. Because the heart failure management score was measured at the interval level, MMR was used. Not all participants experienced shortness of breath or swollen arms/legs during the month prior to the 40-day follow-up. Only 47 participants had a heart failure management score at their 40-day follow-up. The type of service received, the centered number of daily living activities needing help and their product term were included in the analysis. The first order model had a R² of .016. When the product term was added, the R² changed to .022, a non-significant difference, F (1, 43) = .271, p = .606.

Self-confidence at 40-day follow-up. MMR was used in this analysis. Type of service received and the number of daily living activities needing help were included in the first order model. The R² for the first order model was .065. When the product term was added, the R² changed to .068, a non-significant difference, F (1, 64) = .203, p = .654. The residual plots showed a non-linear relationship.

Re-hospitalization. When type of service received and number of daily living activities needing help were in the model, the -2LL was 82.726 and the Cox& Snell R² was .042. By adding the product term of both variables into the model, the -2 LL changed to 82.190. The change was non-significant, χ² (1) = .536, p =.464. The Cox & Snell R² for the higher order model was .049. The residuals in the regression were examined and the criteria were met.

Moderator 4: Living Alone

Living alone was a categorical dichotomous variable. ANOVA was used to examine the moderated effect of living alone on the relationship between type of service received and the outcome measures. One of the outcome variables, re-hospitalization, was also a dichotomy, so logistic regression was used. The focus of the analysis was on the interaction effect. When the
effect of an independent variable on a dependent variable differs depending on the value of a third variable (a moderator variable), an interaction exists (Jaccard, 1998). In this analysis, type of service received was the independent variable and living alone was the moderator variable, or the focal independent variable.

**Total symptoms presented at 40-day follow-up.** Because the total number of symptoms presented at the initial interview was significantly different between the two groups, the variable was entered as a covariate. Figure 13 shows the adjusted group means for number of symptoms presented at 40-day follow-up within type of service received and living alone. The means were adjusted based on the covariate evaluated at the value of: the number of symptoms at the initial interview = 10.632. There was no significant interaction between type of service received and living alone, $F (1, 63) = .069, p = .793$ and an effect size $\eta = .031$. Levene’s test of equality of error variances was not significant ($p = .489$). For the HHC plus TM group, participants who live alone had a higher number of symptoms at the 40-day follow-up, ten symptoms on average, after controlling the number of symptoms presented at the initial interview ($Mean = 10.03; SE = .989$). For the HHC only group, participants living alone had an average of 9.6 symptoms presented at the 40-day follow-up ($Mean = 9.64; SE = .879$).
Note: The covariate is evaluated at the following value: number of symptoms presented at the initial interview = 10.632.

Figure 13. The Adjusted Group Means for Number of Symptoms Presented at 40-day Follow-up Within Type of Service Received and Living Alone

Total symptom burden at 40-day follow-up. Figure 14 shows group means for total symptom burden score at 40-day follow-up within type of service received and living alone.

There was no significant interaction between type of service received and living alone, $F(1, 64) = .574, p = .451$ and effect size $\eta = .095$. Levene’s test was non-significant ($p = .126$). There was no significant main effect.
Figure 14. Group Means on Total Symptom Burden Score at 40-day Follow-up within Type of Service Received and Living Alone

Self-care maintenance at 40-day follow-up. Because the self-care maintenance score differed significantly at the initial interview, the variable was entered as a covariate. Figure 15 shows the group means for self-care maintenance score at 40-day follow-up within type of service received and living alone. Type of service received had a significant main effect on self-care maintenance at 40-day follow-up, $F(1, 63) = 6.190, p = .016$ and effect size $\eta = .30$. However, there was no significant interaction between type of service received and living alone, $F(1, 63) = .031, p = .860$. Levene’s test was non-significant ($p = .853$).
Note: The covariate is evaluated at the following value: self-care maintenance score at the initial interview = 14.147.

Figure 15. The Adjusted Group Means on Self-care Maintenance Score at 40-day Follow-up within Type of Service Received and Living Alone

Heart failure management at 40-day follow-up. As noted earlier, only 47 participants had a heart failure management score at their 40-day follow-up. Figure 16 shows group means for heart failure management at 40-day follow-up within type of service received and living alone. There was no significant interaction between the type of service received and living alone, $F (1, 43) = .458, p = .502$ and effect size $\eta = .10$. Levene’s test was non-significant ($p = .871$).

Participants living alone and receiving home health care plus telemonitoring service had a lower heart failure maintenance score at 40-day follow-up ($Mean = 14.86; SE = 3.85$) than participants living alone and receiving home health care only ($Mean = 15.22; SE = 3.56$).
Figure 16. Group Means on the Heart Failure Management Score at 40-day Follow-up within the Type of Service Received and Living Alone

Self-confidence at 40-day follow-up. Figure 17 shows the group means for self-confidence at 40-day follow-up. There was no significant interaction between type of service received and living alone, $F(1, 64) = 1.861, p = .177$ and effect size $\eta = .17$. There were no significant main effects. Participants in the HHC only group who lived alone had a better score on self-confidence at the 40-day follow-up ($Mean = 11.153; SE = 1.863$) than participants in the HHC plus TM group ($Mean = 10.900; SE = 2.331$).
Re-hospitalization. The interaction effect for living alone on the relationship between the type of service received and re-hospitalization, which was a dichotomous variable, were examined using logistic regression. This analysis focused on the difference in the -2 Log likelihood (-2LL) between the first order model and the higher order model when the product term was entered. When the type of service received and living alone were in the model, the -2LL was 79.789 and the Cox & Snell R$^2$ was .082. By adding the product term of both variable into the model, the -2LL changed to 79.569; was non-significant, $\chi^2 (1) = .221, p = .639$. The Cox & Snell R$^2$ for the higher order model was .085, only a .003 increase. The residuals in the regression were examined and the criteria were met.

Moderator 5: Presence of Anxiety

Number of symptoms presented at 40-day follow-up. Because the total symptoms presented at the initial interview were significantly different for the two groups, the variable was entered as a covariate. Figure 18 shows the adjusted group means for number of symptoms.
presented at 40-day follow-up within type of service received and presence of anxiety during admission to home health care. The means were adjusted based on the covariate evaluated at the value of: the number of symptoms at the initial interview = 10.632. There was no significant interaction between type of service received and presence of anxiety, $F (1, 63) = .632, p = .430$ and an effect size $\eta = .10$. Levene’s test of equality of error variances was not significant ($p = .819$). For the HHC plus TM group, participants who were anxious had more symptoms presented at the 40-day follow-up ($Mean = 11.063, SE = 1.033$) than participants who were anxious in the HHC only group ($Mean = 9.980; SE = .940$) after controlling the number of symptoms presented at the initial interview.

![Graph showing adjusted group means on number of symptoms presented at 40-day follow-up within type of service received and the presence of anxiety during admission to Home Health Care.](image)

*Note: The covariate is evaluated at the following value: number of symptoms presented at the initial interview = 10.632.*

**Figure 18. The Adjusted Group Means on Number of Symptoms Presented at 40-day Follow-up within Type of Service Received and the Presence of Anxiety during Admission to Home Health Care**

*Total symptom burden score at 40-day follow-up.* Figure 19 shows the group means for the total symptom burden at 40-day follow-up within type of service received and presence of
anxiety during admission to home health care. There was no significant interaction between type of service received and presence of anxiety, $F(1, 64) = .055, p = .856$ and effect size $\eta = .003$. Levene’s test was non-significant ($p = .187$). There were no significant main effects.

![Figure 19. Group Means on Total Symptom Burden Score at 40-day Follow-up within Type of Service Received and Presence of Anxiety during Admission to Home Health Care](image)

_Self-care maintenance at 40-day follow-up._ Because the self-care maintenance score differed significantly at the initial interview, the variable was entered as a covariate. Figure 20 shows the group means for self-care maintenance at 40-day follow-up within type of service received and presence of anxiety during admission to home health care. The main effect of type of service was statistically significant, $F(1, 63) = 7.509, p = .008$ with effect size $\eta = .33$. However, there was no significant interaction, $F(1, 63) = 1.118, p = .294$ with effect size $\eta = .13$. Levene’s test was non-significant ($p = .550$).
Note: The covariate is evaluated at the following value: self-care score at the initial interview = 14.147.

Figure 20. The Adjusted Group Means on Self-care Maintenance Score at 40-day Follow-up Within Type of Service Received and Presence of Anxiety During Admission to Home Health Care

Heart failure management score at 40-day follow-up. As noted earlier, only 47 participants had a heart failure management score at their 40-day follow-up. Figure 21 shows the group means for heart failure management at 40-day follow-up within type of service received and presence of anxiety during admission to home health care. There was no significant interaction, $F(1, 43) = .029, p = .866$ with effect size $\eta = .03$. Levene’s test was non-significant ($p = .365$). There were no significant main effects.
Figure 21. *Group Means on Heart Failure Management Score at 40-day Follow-up Within Type of Service Received and Presence of Anxiety During Admission to Home Health Care*

Self-confidence at 40-day follow-up. Figure 22 shows the group means for self-confidence at 40-day follow-up. There was no significant interaction between type of service received and presence of anxiety during admission to home health care, $F(1, 64) = 2.942, p = .091$ and effect size $\eta = .21$. The main effect for type of service received was $F(1, 64) = 3.76, p = .057$ and effect size $\eta = .23$. Participants in the HHC plus TM group who exhibited anxiety during admission to home health had the highest self-confidence score at the 40-day follow-up ($Mean = 11.78, SE = 1.86$).
Figure 22. *Group Means on Self-confidence Score at 40-day Follow-up Within Type of Service Received and Presence of Anxiety During Admission to Home Health Care*

Re-hospitalization. The interaction effect for living alone on the relationship between the type of service received and re-hospitalization were examined using logistic regression. When only type of service received and presence of anxiety during the admission to home health care were included in the model, the -2LL was 80.741 and the Cox & Snell $R^2$ was .069. By adding the product term of both variables into the model, the -2LL changed to 80.711; a difference of only .030 difference. The change in the $R^2$ was non-significant, $\chi^2(1) = .030, p = .862$. The Cox & Snell $R^2$ for the higher order model was .085, only a .003 increase. Residuals in the regression were examined and the criteria were met.

Post-hoc Evaluation of Significant Moderator Effects

Only the number of daily living activities needing help had a significant moderated effect on the relationship between type of services received and self-care maintenance at 40-day follow-up ($p = .029$). A significant moderator effect only tells us that the association between the predictor (type of service received) and the outcome (self-care maintenance at the 40-day follow-
up) different across level of the moderator (number of daily living activities needing help). To understand the moderator effect, the predict values of self-care maintenance for the two groups were computed at the mean and one standard deviation above and below on number of daily living activities needing help. Figure 23 shows the graphical presentation of the post-hoc evaluation and Table 17 shows the computed results of post-hoc probing. There was no significant different between the two groups in self-care maintenance score at the 40-day follow-up when number of daily living activities needing help was one standard deviation below the mean, \( t(1, 33) = .565, p = .574 \). However, when the number of daily living activities needing help reach the average, the two group differed significantly on self-care maintenance score at 40-day follow-up, \( t(1, 33) = 3.219, p = .002 \). As the number of daily activities needing help increased to one standard deviation above the mean, the difference between the two groups on self-care maintenance was obvious, \( t(1, 33) = 3.944, p < .001 \).

** Figure 23. Predicted Mean Self-Care Maintenance as a Function of Type of Service Received at Selected Values of Functional Status **

**p < .005**
Table 17. Predicted Mean Self-Care Maintenance Score as a Function of Type of Service Received at Selected Values of Functional Status

<table>
<thead>
<tr>
<th>No. of Daily Living Activities Needs Help</th>
<th>HHC Only Mean</th>
<th>HHC plus TM Mean</th>
<th>Mean Difference</th>
<th>t</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.951 (M – 1SD)</td>
<td>13.77</td>
<td>14.34</td>
<td>.57</td>
<td>.565</td>
<td>.574</td>
</tr>
<tr>
<td>6.912 (Mean)</td>
<td>12.85</td>
<td>15.14</td>
<td>2.29</td>
<td>3.219</td>
<td>.002</td>
</tr>
<tr>
<td>9.873 (M + 1SD)</td>
<td>11.93</td>
<td>15.95</td>
<td>4.02</td>
<td>3.944</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Although the product term of moderator (number of chronic conditions) and predictor (type of service received) did not have significant interaction effect on heart failure management at 40-day follow-up, it explained 3.8% of the variance on heart failure management and may have the potential to inform practice. Further post hoc analysis, comparing the mean number of chronic conditions (Mean = 4.25) to one more chronic condition above the mean and one less chronic condition below the mean, showed as number of chronic conditions got higher, patients did better in heart failure management with telemonitoring. On the other hand, the HHC only group had a slight decline in heart failure management as number of chronic conditions got higher. Figure 24 shows the predicted mean heart failure management as a function of type of service received at selected values of number of chronic conditions.
The groups differed in the primary home health care diagnosis of heart failure so that variable was included in the subsequent analyses examining the effect of telemonitoring. The two groups also differed significantly on two baseline measurements: the number of symptoms presented and the self-care maintenance score. For the outcome measurements at 40-day follow-up, both groups differed significantly on the self-care maintenance score ($p = .019$). Only the total number of daily living activities needing help had a significant moderator effect on the relationship between the type of services received and self-care maintenance score at 40-day follow-up ($p = .029$).
CHAPTER FIVE: DISCUSSION AND CONCLUSIONS

Introduction

One of the principle reasons for introducing telemonitoring in home health care settings is to create a new way to increase the ability of chronically ill patients to self-manage their conditions successfully at home. Like other chronic conditions, heart failure patients have an important role to play in the day-to-day management of their condition. Heart failure is an exceedingly difficult condition to manage and recognition of changes in signs and symptoms is difficult for most of the patients. The use of telemonitoring allows heart failure patients to not only be more closely and effectively supervised, but also to receive prompt feedback that can enable them and their caregivers to more effectively manage their conditions and take a more active role in their care.

So far the research in telemonitoring has focused on finding the association between telemonitoring and outcomes, such as re-hospitalization rate, mortality, emergency room visits, cost effectiveness and quality of life. Like earlier studies (Hopp et al., 2006; Whitten & Mickus, 2007), recent studies using large scale, multiple site, randomized controlled trials have not confirmed the association between telemonitoring and outcomes (Dansky, Vasey & Bowles, 2008; Dar et al., 2009; Mortara et al., 2009; Wakefield, Holman, Scherubel & Kienzle, 2008). These inconclusive results suggest that telemonitoring may not be appropriate for all heart failure patients. No studies specifically addressed how patient characteristics might moderate the effect of telemonitoring. By exploring the moderator effect of patient characteristics on telemonitoring and outcomes, we may be able to identify which patients will be most responsive to telemonitoring.
In addition to monitoring heart failure patients closely and detecting early deteriorations, one of the goals of using telemonitoring is to enable patients to more effectively manage their conditions and to take a more active role in their care. Whether telemonitoring is able to improve self-management of heart failure is unknown. So far, only a few studies included self-care behaviors and self-efficacy as outcome measures (Artinian et al., 2003; Benatar, Bondmass, Ghitelman & Avitall, 2003; Johnson, Wheeler, Deuser & Sousa, 2000). Although the results of these studies showed improvement in self-care behaviors and self-efficacy, none of the studies found significant differences between a telemonitoring group and a comparison group. The current study was designed to examine the effect of telemonitoring on self-care of heart failure, rather than the typical outcomes of health care utilization, quality of life, mortality or cost effectiveness.

Most telemonitoring systems not only allow clinicians to monitor patients’ vital signs, but also the presence of symptoms. Heart failure patients encounter a variety of physical or psychological symptoms that can serve as a signal to disease progression or the need for additional medical care. Only one study in the literature examined the effect of telemonitoring on changes in symptoms; but only diet-related symptoms were assessed; such as edema, shortness of breath and weight gain (Dansky, Vasey & Bowles, 2008). In this study, a variety of symptoms were assessed.

This study adds to the body of literature not only on the effect of telemonitoring on symptom burden and self-management, but also “for whom” and “when” the effect of telemonitoring will be stronger or weaker. In this chapter, findings from the analyses are
discussed. The study limitations and implications for practice and future research are presented. The usefulness of OASIS in research is also discussed.

Discussion of Findings

Research Question 1

Research question 1: Is there a significant difference between home health care only and home health care plus telemonitoring on heart failure patient’s symptom burden, self-care of heart failure, and re-hospitalization?

Symptom Burden

In this study, patients who received home health care plus telemonitoring did not demonstrate a greater improvement in symptom burden than heart failure patients who received home health care only. Participants’ symptom burden was measured by number of symptoms presented and the symptom burden for all symptoms. Symptom burden for all symptoms was determined by adding the mean of the frequency, severity and distress of each symptom. There was a significant difference on number of symptoms presented at the initial interview between the two groups; however, the difference was not significant at 40-day follow-up. Although both groups experienced a decline in their number of symptoms, only the HHC group improved significantly. The HHC only group had a 11.7% drop in number of symptoms presented over the 40-day period compared to the HHC plus TM group which only had a 5.2% drop. The two groups differed significantly in whether heart failure was the primary diagnosis for home health care. The HHC only group had more participants with heart failure as a second diagnosis, which may explain why they had a higher number of symptoms presented at the initial interview. These
patients may have reported symptoms related to their primary diagnosis in addition to their heart failure symptoms.

There was no significant difference between the two groups in overall symptom burden at the initial interview or the 40-day follow-up. The HHC only group had a higher symptom burden score than the HHC plus TM group at both interviews. Although no between-group differences were found, there was a significant within group improvement on symptom burden over the 40-day period with both groups. The HHC only group had a 19% decrease in symptom burden at the 40-day follow-up, while the HHC plus TM group had a 14% decrease in symptom burden; both were statistically significant.

In sum, there was no statistically significant effect of telemonitoring on patients’ symptom burden. The HHC only group had greater improvement in their number of symptom and overall symptom burden than the HHC plus TM group. This finding differed from a previous study (Dansky, Vasey & Bowles, 2008), where a greater reduction in symptoms was found in the telemonitoring group than in a control group. Although patients having heart failure as a second home health care diagnosis were also included in that study, only a limited number of symptoms were included. With most telemonitoring systems allowing clinicians to not only monitor patients’ vital signs, but also their symptoms, adding a symptom management component to a telemonitoring program may have the potential to improve outcomes. Future research on how to incorporate symptom management in telemonitoring is needed.

*Self-care of Heart Failure*

In this study, self-care of heart failure was assessed on three different dimensions: self-care maintenance, heart failure management and self-confidence. The study findings only
partially supported the conclusions that heart failure patients using telemonitoring would demonstrate better self-care. The HHC plus TM group showed significantly higher self-care maintenance than the HHC only group at the 40-day follow-up. The two groups also differed significantly in self-care maintenance at the initial interview with HHC plus TM group scored higher. While the HHC plus TM group made a slim improvement in their self-care maintenance score (0.4%) over the 40-day period, the HHC only group had a 5.5% decrease in the 40-day follow-up score. The reason for the decline in self-care maintenance in the HHC group is unknown. There was no significant difference between the two groups in the number of chronic conditions or their severity. One might assume that home health care alone would have an impact on self-care maintenance; but it was not the case in this study.

The two groups did not differ significantly in heart failure management at the 40-day follow-up. Although there was no between-group difference in heart failure management, the within-group difference was significant, but only in the HHC only group. While the HHC only group had a 13.4% increase in their heart failure management score over time, the HHC plus TM group only had a 9.9% increase in their score over time. The inability to integrate knowledge with behavioral outcomes has been found to impede the successful self-management of chronic condition (Riegel & Carlson, 2002). Telemonitoring has been assumed to have the capability of providing ongoing and repeated patient teaching, based on both anticipated and demonstrated need. However, the HHC plus TM group did not show a greater improvement in heart failure management than the HHC only group. This finding was consistent with other studies (Artinian et al., 2003; Johnson, Wheeler, Deuser & Sousa, 2000). Thus, future studies on how to integrate
ongoing patient education with telemonitoring, based on both anticipated and demonstrated need and how it may improve patient outcomes are needed.

Self-confidence, which is similar to self-efficacy, is the belief in one’s ability to perform self-care. In this study, the HHC plus TM group did not demonstrate greater self-confidence at the 40-day follow-up. Both groups showed improvement on self-confidence over the 40-day period, 4% for the HHC only group and 5% for the HHC plus TM group. This finding was similar to another study (Benatar, Bondmass, Ghitelman & Avitall, 2003), where there was improvement in self-confidence within-group, but no significant difference between-groups.

Re-hospitalization

In this study, the HHC plus TM group had 17.7% more re-hospitalizations than the HHC only group. Although earlier literature does not support this finding, Dar et al. (2009), Hoover (2008) and Mortara et al. (2009) found a similar result. In their study, Dar et al (2009) reported an 11% increase in the home telemonitoring group, while Mortara et al. (2009) reported a 5% increase in the home telemonitoring group. In her study, while using the similar telemonitoring system in a home health care environment, Hoover (2008) found a 10% increase in hospitalization for the telemonitoring group. Dar et al. (2009) suggested one of the reasons for the increase might be due to the average age of patients in their study, which was higher than earlier studies, 70s vs. 60s. In the current study, the average age for the HHC plus TM group was 82.44, while the HHC only group was 80.82. Participants in the HHC plus TM group were not only older than the typical patients in earlier studies, but also in the current study as well. The older the patients, the more vulnerable they are to illness. In one study, age was found to be the only factor associated with increased mortality in heart failure (Formiga et al., 2004). Hoover
(2008) suggested that the progression of heart failure might cause more brief and frequent hospitalizations to prevent mortality. Dar et al. (2009) also pointed out home telemonitoring can allow for early detection of worsening symptoms and permit better scheduling of hospitalization with a shorter length of stay.

**Research Question 2**

*Research question 2:* Which patient characteristics, assessed by nurses during home health care admission and documented in the OASIS data set, significantly moderate the outcomes of telemonitoring on heart failure patients’ symptom burden, self-care of heart failure and re-hospitalization?

Only the number of daily living activities for which the patient needed help had a significant moderator effect on the relationship between type of services received and self-care maintenance at 40-day follow-up. Further post hoc analysis clarified the relationship. When the number of daily living activities needing help was low; in other words, when participants were more independent, telemonitoring had less effect on self-care maintenance. When the number of daily living activities needing help increased, the effect of telemonitoring on self-care maintenance became significant. Schnell-Hoehn et al. (2009) has pointed out that physical limitation does not necessarily hinder self-care behavior. These researchers did not find a significant correlation between physical limitations and self-care behavior and suggested that people learn to cope with their limitations to care for themselves. In the current sample, telemonitoring might provide the needed partnership and empowerment for the patient to engage in self-care and take on a more active role in managing their condition.
Statistically significant moderator effects are difficult to find because of the low power in moderator multiple regression (MMR) (Aguinis, 2004; Jaccard & Turrisi, 2003; Aiken & West, 1991). These authors suggested the consideration of “practically significant”. Although there was no statistically significant moderator effect of number of chronic conditions on the relationship between type of service received and heart failure management, the moderator effect may have an implication for practice. Further post hoc analysis revealed an interesting picture. As the number of chronic conditions increased, patients did better with heart failure management if in the telemonitoring group. On the other hand, the HHC only group had a slight decline in heart failure management as the number of their chronic conditions increased. The moderator effect of number of chronic conditions accounted for 3.8% of the variance on heart failure management and may have a practical significant. For example, given that $4.4 billion was paid for heart failure related hospitalization in 2003, if this 3.8% improvement in heart failure management helped to prevent one hospitalization out of 1000, there would be a $4.4 million dollar savings in Medicare spending. Given the increasing number of elderly in our population and the rapid growing number of heart failure patients, the saving can be substantial.

Although the interaction effect between type of service received and presence of anxiety on self-confidence was non-significant based on the study criterion (α = .05), the effect might have been significant if the targeted sample size was met. Nonetheless, there may be an implication for practice. Participants in the HHC plus TM group, who reported or were observed, having anxiety during home health care admission, had the highest self-confidence at the 40-day follow-up. Although they had lower self-confidence at the initial interview compared to the participants in their group (HHC plus TM) who did not have anxiety, they were able to outscore
them at the 40-day follow-up. Anxiety is a negative affective state resulting from perception of threat and a perceived inability to predict, control, or obtain desired results in a given situations (Barlow, 1988). Telemonitoring may help to decrease the uncertainty of heart failure in these patients by providing the needed information and assurance. How telemonitoring achieving this goal will require more investigation.

Usefulness of Outcomes Assessment and Information Set

Home health care nurses routinely collect a significant amount of patient data during admission as part of the OASIS. The OASIS was developed to standardize the collection of data for outcome monitoring. In addition, OASIS data have been used in research to predict clinical outcomes. Although the psychometric properties of the OASIS data have yet to be firmly established, the use of these data sets for research can potentially save resources and time. In this study, patient characteristics were obtained from OASIS data collected by nurses during the home health care admission. In this study, the OASIS data were readily available and at no cost to the investigator. There was no burden on the participants. The only issue of using OASIS data in this study was limited variables. For example, there was only one item for measuring anxiety. Overall, the OASIS data deemed to be useful for research.

Study Limitations

Sample Size

One of the limitations of this study is the sample size. This study initially planned to recruit at least 57 participants in each group. In spite of aggressive recruiting efforts and extended study period to 12 months, the recruitment was not met. The final sample size was 68 participants at Time 2; seven participants did not complete the study. The small number of
participants in the MMR models greatly reduced the statistical power. The moderator effect is
difficult to detect in MMR and some suggested the sample size should be at least over 100

**Generalizability**

The study results cannot be generalized to other populations. Only one recruitment site
was used and most participants were Caucasian, implying that the study may not represent the
average home health care heart failure patients. In future studies, including other population
samples and different home health care agencies will be needed.

**Issues on Testing Moderator Effects Using MMR**

**Measurement Error**

Because the moderator effect is represented a product of the independent and moderator
variables, the measurement error in this product term is a product of the measurement error in the
independent variable and the moderator variable. Thus, tests of the moderator effect are
significantly compromised by any measurement error in the independent and moderator variable
(Hoyle & Robinson, 2004).

**Multicollinearity**

Multicollinearity occurs when two or more variables are closely linearly related (Field,
2005). The presence of multicollinearity may lead to the regression coefficients being unstable
and the increase in error term (Aguinis, 2004). Because the interaction term is a product of the
independent and moderator variables, it will be highly correlated with the independent and
moderator variable or both (Aiken & West, 1991). Centering can reduce the multicollinearity
between predictors and any interaction terms among them (Holmbeck, 2002). In this study, all continuous moderators were centered prior to statistical testing.

**Bilinear Interaction Effect Only**

This study tested only one possible interaction effect, a bilinear interaction effect. The number of possible functional forms of moderated relationships is infinite (Jaccard, Turrisi & Wan, 1990). The absence of moderator relationship may reflect the presence of an alternative functional form. However, theory should guide the specification of an interaction model.

**Limited Variables**

The moderator variables used in this study were limited to the variables available in the OASIS data set; threats to validity were unavailable. In addition, the limited choices and variety of measurements might reduce the possibility of finding significant moderator effects.

**Implications for Research and Practice**

**Implication for Research**

This study did not find significant differences in heart failure patients’ symptom burden or re-hospitalization between the HHC only group and the HHC plus TM group. An increase in re-hospitalization in the HHC plus TM group was found. In self-care of heart failure, the HHC plus TM group showed significantly greater self-care maintenance than the HHC group; however, there was no significant difference between the two groups on heart failure management and self-confidence. Like earlier studies, the effect of telemonitoring on heart failure management remains inconclusive. The use of telemonitoring in managing heart failure has been guided by the development of the technology rather than sound theory or empirical evidence. The rationale behind the use of telemonitoring as an intervention in managing heart
failure is that the technology allows clinicians to manage patients remotely in their home, to detect changes quickly, to provide feedback to patients promptly, to communicate with other health care effectively and to enable patients to take on a more active role in their care. However, most of the research studies primarily focused on evaluating the overall relationship between telemonitoring and outcomes without concern for the transformation process in the middle. Although these evaluations were able to provide us a gross assessment of whether or not the telemonitoring program works, it did not identify the underlying mechanism that generated the effects. Without knowing what made the program work or not working, it would be difficult to pinpoint what needed to be done for future improvement or development. A theory-oriented evaluation is indeed needed in evaluating telemonitoring intervention. Scott and Sechrest (1989) emphasized the importance of using theory-oriented evaluation:

“We may know that an intervention is in place and that it has some effects, but as long as we lack further understanding of it, we will be helpless to improve on it in any way. In fact, without greater understanding of it, efforts to change and improve the intervention may actually have adverse consequence.” (p. 329).

Theory-oriented evaluations not only allow researchers to clarify the connections between a program’s operations and its effects, but also to specify intermediate effects of a program that might become evident and measurable (Chen, 1990).

Theory-oriented evaluation focuses not only to understand the transformational processes between intervention and outcomes, but also the contextual factors under which the processes happen (Chen & Rossi, 1989). This is similar to the idea of Frazier et al. (2004): to advance the science, it is important to move beyond the basic questions and to ask “why” and “how” it happens and “when” and “for whom” it happens. This study provided the starting point to address “when” and “for whom” the effect of telemonitoring happens.
Implication for Practice

Although both groups had significant improvement on symptom burden of all chronic conditions, the added telemonitoring did not make a greater impact. Heart failure patients encounter a variety of physical and psychological symptoms that may negatively affect their quality of life; with some patients placing greater importance on improved symptoms than on longer survival. Most telemonitoring systems allow clinicians not only to monitor vital signs, but also patient’s symptoms. Incorporating symptom management in a telemonitoring program may then have the potential to improve quality of life.

The two groups did not differ significantly in their heart failure management at the 40-day follow-up; however, the HHC only group made a significant improvement over the 40-day period. While patient education will always remains challenging to nurses, telemonitoring will allow them to tailor patient education based on the patient’s demonstrated need, not just what they think the patient needed. Telemonitoring can be a powerful tool for patient education. Clinicians need to find a way to incorporate patient education into a telemonitoring program.

There was a significant moderator effect of daily living activities needing help on the relation between type of service received and self-care maintenance. When the number of daily living activities needing help was low, telemonitoring had less effect on self-care maintenance. When the number of daily living activities needing help increased, so did the effect of telemonitoring on self-care maintenance. Patients, who need more help on their daily living activities, may benefit more from telemonitoring.

Although there was no significant moderator effect of number of chronic conditions on the relation between type of service received and heart failure management, further post hoc
analysis showed that patients with more chronic conditions did better on heart failure management with telemonitoring.

Conclusions

Heart failure is an exceedingly difficult condition to manage. It imposes a burden on our society and individuals. Telemonitoring can provide home health care agencies an effective way to manage their heart failure patients. Telemonitoring allows heart failure patients to be monitored closely and effectively. Also, telemonitoring provides the opportunity for patients to take on a more active role in their care. However, not all patients receiving telemonitoring will benefit from it; some may do as well with home health care alone. Findings from this study demonstrated significantly greater self-care maintenance in telemonitoring patients. Telemonitoring is more effective for patients with a higher number of daily living activities needing help. Patients with a higher number of chronic conditions may also benefit from telemonitoring in heart failure management. For patients with anxiety, telemonitoring may have the potential to improve self-confidence. Findings in this study are inconclusive. For future research, a theory-oriented evaluation on telemonitoring is needed with greater focus on “how” and “why” the effect happens and “for whom” and “when” it happens. This study provided the starting point to address “when” and “for whom” the effect of telemonitoring happens.
APPENDIX A:

INTERNAL REVIEW BOARD APPROVAL LETTERS
9 June 2008

Helen Vallina, Doctoral Student
Advisor: Judith Effken, PhD
College of Nursing
PO Box 210203

RE: PROJECT NO 08-0511-62 USING OASIS DATA TO ASSESS MODERATOR EFFECT ON PATIENT CHARACTERISTICS ON TELEMONITORING OUTCOMES IN HEART FAILURE PATIENTS

Dear Ms. Vallina:

We received your research proposal as cited above. The procedures to be followed in this study pose no more than minimal risk to participating subjects and have been reviewed by the Institutional Review Board (IRB) through an Expedited Review procedure as cited in the regulations issued by the U.S. Department of Health and Human Services [45 CFR Part 46.110(b)(1)] based on their inclusion under research categories 5 and 7. As this is not a treatment intervention study, the IRB has waived the statement of Alternative Treatments in the consent form as allowed by 45 CFR 46.116(d)(2). Please make copies of the attached IRB stamped consent documents to consent your subjects.

Although full Committee review is not required, notification of the study is submitted to the Committee for their endorsement and/or comment, if any, after administrative approval is granted. This project is approved with an expiration date of 9 June 2009.

The Institutional Review Board (IRB) of the University of Arizona has a current Federalwide Assurance of compliance, FWA00004218, which is on file with the Department of Health and Human Services and covers this activity.

Approval is granted with the understanding that no further changes or additions will be made to the procedures followed without the knowledge and approval of the Human Subjects Committee (IRB) and your College or Departmental Review Committee. Any research-related physical or psychological harm to any subject must also be reported to each committee.

A university policy requires that all signed subject consent forms be kept in a permanent file in an area designated for that purpose by the Department Head or comparable authority. This will assure their accessibility in the event that university officials require the information and the principal investigator is unavailable for some reason.

Sincerely yours,

Elaine Jones, PhD, RN, FNAP
Chair, Social and Behavioral Sciences Human Subjects Committee

cc: Departmental/College Review Committee
Continuing Review Determination

Investigator: Helen Vallina
Project No.: 08-0511-02
Project Title: Using the OASIS Data to Assess Moderator Effect on Patient Characteristics on Telemonitoring Outcomes in Heart Failure Patients

<table>
<thead>
<tr>
<th>Project Status</th>
<th>Status Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Enrollment in Progress or Still Planned</td>
<td>☐ Data Analysis Only</td>
</tr>
<tr>
<td>☐ Enrollment Closed: study procedure/intervention ongoing</td>
<td>☐ Concluded</td>
</tr>
<tr>
<td>☐ Enrollment Closed: follow-up only</td>
<td>☐ Study Not Begun</td>
</tr>
</tbody>
</table>

IRB Comments: N/A

Documents Approved Concurrently: N/A
Documents Reviewed Concurrently:

- ☑ N/A
- ☐ Investigator’s Brochure
- ☐ Progress Reports
- ☐ Protocol Deviation
- ☐ Other

Period of Approval: 6/9/09 – 6/8/10

☑ Expedited Review
☐ Full Committee Review
☐ Facilitated Review

Elaine G. Jones, Ph.D., Chair
IRB2 Committee
UA Institutional Review Board

EGJ/rkd

Date Reviewed: 5/12/09

Reminder: Continuing Review materials should be submitted 30 – 45 days in advance of the current expiration date to obtain re-approval (projects may be concluded or withdrawn at any time using the forms available at www.irb.arizona.edu).
APPENDIX B

SYMPTOM BURDEN AND SELF-CARE OF HEART FAILURE QUESTIONNAIRE
Today’s Date ________________________  ID __________________

Section 1

**Instructions**: We have listed 26 symptoms below. Read each one carefully. If you **HAVE HAD** the symptom during this past week, make an “X” in the box marked “YES”. Let us know how **OFTEN** you had it, how **SEVERE** it was usually and how much it **DISTRESSED** or **BOthered** you by circling the appropriate number.

<table>
<thead>
<tr>
<th>DURING THE PAST WEEK</th>
<th>IF YES How OFTEN did you have it?</th>
<th>IF YES How SEVERE was it usually?</th>
<th>IF YES How much did it DISTRESS or BOTHER you?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y ES</td>
<td>Slight</td>
<td>Moderate</td>
</tr>
<tr>
<td>Shortness of breath</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Lack of energy</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Feeling drowsy</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Difficulty sleeping</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Worrying</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Pain</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Cough</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Feeling sad</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Sweats</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Feeling irritable</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Chest pain</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Feeling bloated</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Difficulty concentrating</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Palpitation</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Itching</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Nausea</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Lack of appetite</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Problem with urination</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Feeling nervous</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
<td>1 2 3 4</td>
</tr>
</tbody>
</table>
DURING THE PAST WEEK

Did you have any of the following symptoms?

<table>
<thead>
<tr>
<th>症狀</th>
<th>頻度</th>
<th>常常</th>
<th>略</th>
<th>中</th>
<th>常常</th>
<th>常常</th>
<th>略</th>
<th>中</th>
<th>常常</th>
</tr>
</thead>
<tbody>
<tr>
<td>呕吐</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>夜晚醒來因呼吸困難而氣喘</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>性欲或活動問題</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>手腳麻木/刺痛</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Section 2:

Instructions: We have listed 6 symptoms below. Read each one carefully. If you HAVE HAD the symptom during this past week, make an “X” in the box marked “YES”. Let us know how SEVERE it was usually and how much it DISTRESSED or BOTHERED you by circling the appropriate number.

DURING THE PAST WEEK

Did you have any of the following symptoms?

<table>
<thead>
<tr>
<th>症狀</th>
<th>輕微</th>
<th>中等</th>
<th>重度</th>
<th>常常</th>
<th>重度</th>
<th>輕微</th>
<th>幾乎不</th>
<th>略微</th>
<th>相當大</th>
<th>非常大</th>
</tr>
</thead>
<tbody>
<tr>
<td>難以平躺時呼吸困難</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>頭部浮腫</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>体重增加</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>体重減少</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>便祕</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>食物的味道改變</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>
Section 3:

Listed below are common recommendations for a person with heart failure. Let us know how often you do the following by circling the appropriate number.

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Never or rarely</th>
<th>Sometimes</th>
<th>Frequently</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Weigh yourself daily?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Eat a low salt diet?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Take part in regular physical activity?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Keep your weight down?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>5. Get flu shot every year?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

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

In the past month, have you had trouble breathing or ankle swelling? **Check one.**

1) **No**

2) **Yes**

6. The **LAST TIME** you had trouble breathing or ankle swelling, **HOW QUICKLY** did you recognize it as a symptom of heart failure?

I did not Not Somewhat Quickly Very quickly recognize it
Listed below are remedies that people with heart failure use. When you have trouble breathing or ankle swelling, how **LIKELY** are you to try one of these remedies? Circle the appropriate number.

<table>
<thead>
<tr>
<th>Remedies</th>
<th>Not Likely</th>
<th>Somewhat Likely</th>
<th>Likely</th>
<th>Very Likely</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Reduce the salt in your diet</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>8. Reduce your fluid intake</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>9. Take an extra water pill</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>10. Call your doctor or nurse for guidance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

11. If you tried any of these remedies the **LAST TIME** you had trouble breathing or ankle swelling, **HOW SURE** were you that the remedy helped or not?

**I did not** Not Sure Somewhat Sure Very Sure
try Sure anything

<table>
<thead>
<tr>
<th>Self-Care Confidence</th>
<th>Not Confident</th>
<th>Somewhat Confident</th>
<th>Very Confident</th>
<th>Extremely Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. How confident are you that you can evaluate the importance of your symptoms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Generally, how confident are you that you can recognize changes in your health if they occur?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Generally, how confident are you that you can do something that will relieve your symptoms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. How confident are you that you can evaluate the effectiveness of whatever you do to relieve your symptoms?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX C:

19 OASIS ITEMS USED IN THIS STUDY IN THEIR EXACT WORDING
OASIS ITEMS USED IN THE STUDY

(M0230) Primary Diagnosis ____________________
Severity Rating ___0 ___1 ___2 ___3 ___4

(M0240) Other Diagnoses ____________________
Severity Rating ___0 ___1 ___2 ___3 ___4

Other Diagnoses ____________________
Severity Rating ___0 ___1 ___2 ___3 ___4

Other Diagnoses ____________________
Severity Rating ___0 ___1 ___2 ___3 ___4

Other Diagnoses ____________________
Severity Rating ___0 ___1 ___2 ___3 ___4

Other Diagnoses ____________________
Severity Rating ___0 ___1 ___2 ___3 ___4

(M0340) Patient Lives With (Mark all that apply.)
1 Lives alone
2 With spouse or significant other
3 With other family member
4 With a friend
5 With paid help (other than home care agency staff)
6 With other than above

(M0350) Assisting Person(s) Other Than Home Care Agency Staff: (Mark all that apply)
1 Relatives, friends, or neighbors living outside the home
2 Person residing in the home (EXCLUDING paid help)
3 Paid help
4 None of the above
5 Unknown

(M0490) When is the patient dysneic or noticeably Short of Breath?
0 Never, patient is not short of breath
1 When walking more than 20 feet, climbing stairs
2 With moderate exertion, (e.g. while dressing, using commode or bedpan, walking
distances less than 20 feet)
3 With minimal exertion (e.g. while eating, talking, or performing other ADLs) or with
agitation
4 At rest (during day or night)
(M0580) **When Anxious** (reported or observed)

- 0  None of the times
- 1  Less often than daily
- 2  Daily, but not constantly
- 3  All of the time
- 4  NA Patient nonresponsive

(M0640) **Grooming** Ability to tend to personal hygiene needs (i.e., washing face and hands, hair care, shaving or make up, teeth or denture care, fingernail care).

- 0  Able to groom self unaided, with or without the use of assistive devices or adapted methods.
- 1  Grooming utensils must be placed within reach before able to complete grooming activities.
- 2  Someone must assist the patient to groom self.
- 3  Patient depends entirely upon someone else for grooming needs.

(M0650) **Ability to Dress Upper Body** (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps:

- 0  Able to get clothes out of closets and drawers, put them on and remove them from the upper body without assistance.
- 1  Able to dress upper body without assistance if clothing is laid out or handed to the patient.
- 2  Someone must help the patient put on upper body clothing.
- 3  Patient depends entirely upon another person to dress the upper body.

(M0660) **Ability to Dress Lower Body** (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes:

- 0  Able to obtain, put on, and remove clothing and shoes without assistance.
- 1  Able to dress lower body without assistance if clothing and shoes are laid out or handed to the patient.
- 2  Someone must help the patient put on undergarments, slacks, socks or nylons, and shoes.
- 3  Patient depends entirely upon another person to dress the lower body.

(M0670) **Bathing**: Ability to wash entire body. **Excludes grooming/washing face and hands only**:

- 0  Able to bathe self in shower or tub independently.
- 1  With the use of devices, is able to bathe self in shower or tub independently.
- 2  Able to bathe in shower or tub with the assistance of another person:
  - For intermittent supervision or encouragement or reminders; **OR**
  - To get in and out of the shower or tub, **OR**
  - For washing difficult to reach areas.
- 3  Participates in bathing self in shower or tub, **but** requires presence of another person throughout the bath for assistance or supervision.
- 4  Unable to use the shower or tub and is bathed in bed or bedside chair.
- 5  Unable to effectively participate in bathing and is totally bathed by another person.
(M680) **Toileting**: Ability to get to and from toilet or bedside commodes.
0. Able to get to and from the toilet independently with or without a device.
1. When remaindered, assisted, or supervised by another person, able to get to and from the toilet.
2. Unable to get to and from the toilet but is able to use a bedsides commode (with or without assistance).
3. Unable to get to and from the toilet or bedside commode but is able to use a bedpan/urinal independently.
4. Is totally dependent in toileting.

(M0690) **Transferring**: Ability to move from bed to chair, on and off toilet or commode, into and out of tub or shower, and ability to turn and position self in bed if patient is bedfast.
0. Able to independently transfer.
1. Transfers with minimal human assistance or with use of an assistive device.
2. Unable to transfer self but is able to bear weight and pivot during the transfer process.
3. Unable to transfer self and is unable to bear weight or pivot when transferred by another person.
4. Bedfast, unable to transfer but is able to turn and position self in bed.
5. Bedfast, unable to transfer and is unable to turn and position self.

(M0700) **Ambulation/Locomotion**: Ability to **SAFELY** walk, once in a standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.
0. Able to independently walk on even and uneven surfaces and climb stairs with or without railing (i.e., needs no human assistance or assistive device).
1. Requires use of device (e.g. cane, walker) to walk alone or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces.
2. Able to walk only with the supervision or assistance of another person at all times.
3. Chairfast, unable to ambulate but is able to wheel self independently.
4. Chairfast, unable to ambulate and is unable to wheel self.
5. Bedfast, unable to ambulate or be up in a chair.

(M0710) **Feeding or Eating**: Ability to feed self meals and snacks. **Note**: this refers only to the process of eating, chewing, and swallowing, not preparing the food to eaten.
0. Able to independently feed self.
1. Able to feed self independently but requires: (a) meal set-up; OR (b) intermittent assistance or supervision from another person; OR (c) a liquid, pureed or ground meal diet.
2. Able to take in nutrients orally and receives supplement nutrients through a nasogastric tube or gastrostomy.
3. Unable to take in nutrients orally and is fed nutrients through a nasogastric tube or gastrostomy.
4. Unable to take in nutrients orally or by tube feeding.
5. Unknown.
(M0720) **Planning and Preparing Light Meals** (e.g., cereal, sandwich or reheat delivered meals)

0. Able to independently plan and prepare all light meals for self or reheat delivered meals; **OR** is physically, cognitively, and mentally able to prepare light meals on a regular basis but has not routinely performed light meal preparation in the past (i.e., prior to this home care admission).

1. Unable to prepare light meals on a regular basis due to physical, cognitive, or mental limitations.

2. Unable to prepare any light meals or reheat any delivered meals.

3. Unknown.

(M0740) **Laundry:** ability to do own laundry – to carry laundry to and from washing machine, to use washer and dryer, to wash small items by hand.

0. Able to independently take care of all laundry tasks; **OR** physically, cognitively, and mentally able to do laundry and access facilities, but has not routinely performed laundry tasks in the past (i.e., prior to this home care admission).

1. Able to do only light laundry, such as minor hand wash or light washer loads. Due to physical, cognitive, or mental limitations, needs assistance with heavy laundry such as carrying large loads of laundry.

2. Unable to do any laundry due to physical limitation or needs continual supervision and assistance due to cognitive or mental limitation.

3. Unknown

(M0750) **Housekeeping:** Ability to safely and effectively perform light housekeeping and heavier cleaning tasks.

0. Able to independently perform all housekeeping tasks; **OR** physically, cognitively, and mentally able to perform all housekeeping tasks but has not routinely participated in housekeeping tasks in the past (i.e., prior to this home care admission).

1. Able to perform only light housekeeping (e.g., dusting, wiping kitchen counter) tasks independently.

2. Able to perform housekeeping tasks with intermittent assistance or supervision from another persons.

3. Unable to consistently perform any housekeeping tasks unless assisted by another person throughout the process.

4. Unable to effectively participation in any housekeeping tasks

5. Unknown
(M0760) **Shopping:** Ability to plan for, select, and purchase items in a store and to carry them home or arrange delivery.

0. Able to plan for shopping needs and independently perform shopping tasks, including carrying packages; **OR** physically, cognitively, and mentally able to take care of shopping, but has not done shopping in the past (i.e., prior to this home care admission).

1. Able to go shopping, but needs some assistance:
   (a) by self is able to do only light shopping and carry small packages, but needs someone to do occasional major shopping **OR**
   (b) unable to go shopping alone, but can go with someone to assist.

2. Unable to go shopping, but is able to identify items needed, place orders, and arrange home delivery.

3. Needs someone to do all shopping and errands.

4. Unknown

(M0770) **Ability to Use Telephone:** Ability to answer the phone, dial numbers, and effectively use the telephone to communicate.

0. Able to dial numbers and answer calls appropriately and as desired.

1. Able to use a specially adapted telephone (i.e., large numbers on the dial, teletype phone for the deaf) and call essential numbers.

2. Able to answer the telephone and carry on a normal conversation but has difficulty with placing calls.

3. Able to answer the telephone only some of the time or is able to carry on only a limited conversation.

4. Unable to answer the telephone at all but can listen if assisted with equipment.

5. Totally unable to use the telephone.

6. NA. Patient does not have a telephone

7. Unknown
APPENDIX D:

INFORMED CONSENT
Informed Consent

Title of the Study: “Using OASIS Data to Assess Moderator Effect of Patient Characteristics on Telemonitoring Outcomes in Heart Failure Patients”

Introduction
You are being invited to take part in a research study. The information in this form is provided to help you decide whether or not to take part. Study personnel will be available to answer your questions and provide additional information. If you decide to take part in the study, you will be asked to sign this consent form. A copy of this form will be given to you.

What is the purpose of this research study?
The purpose of this research study is to identify specific patient characteristics that predict those for whom telemonitoring will be most beneficial.

Why are you being asked to participate?
You are being invited because you are newly admitted to the home care service and meet the following inclusion criteria:
- Age 50 or older
- Newly admitted to home care service within one week of the first home visit
- Admitted to home care having heart failure as the first or second diagnosis
- Classified by nurse case manager as NYHF (New York Heart Association) Class II, III or IV
- Capable of giving informed consent, and
- Capable of speaking and understanding English

How many people will be asked to participate in this study?
Approximately 124 persons will be asked to participate in this study.
What will happen during this study?
If you decide to participate in the study, you will be asked to complete the same questionnaire at two points of time; at the beginning of your enrollment to the study and 40 days later. The questionnaire will take about 20 minutes to complete; however, if you need to take breaks due to fatigue, this may extend the amount of time required to complete the questionnaire. You may choose to complete the questionnaire in paper format or have the questions read to you and your responses recorded by the researcher. Your home care medical record will also be reviewed to collect relevant OASIS data and the number of re-hospitalization episode occurring during the time of your enrollment in the study. No personal identification information, such as name, social security number, medical record number, address or phone number will be collected.

How long will I be in this study?
About 40 days will be needed to complete this study.

Are there any risks to me?
The things that you will be doing have minimal risk of fatigue, frustration or loss of confidentiality. Although we have tried to avoid risks, you may feel that some questions we ask you may be stressful or upsetting. If this occurs you can stop participating immediately.

Are there any benefits to me?
You will not receive any benefit from taking part in this study. The resulting information from the study may be useful to future telemonitoring patients.

Will there be any costs to me?
Aside from your time, there are no costs for taking part in the study.

Will I be paid to participate in the study?
You will not be paid for your participation.
Will video or audio recordings be made of me during the study?
No.

Will the information that is obtained from me be kept confidential?
The only persons who will know that you participated in this study will be the research team members: Helen Vallina, MS, RN, Doctoral Student; Judith Effken, PhD, RN, Professor and Deborah Vincent, PhD, RN, Associate Professor of the University of Arizona.

Your records will be confidential. You will not be identified in any reports or publications resulting from the study. Representatives of regulatory agencies (including The University of Arizona Human Subjects Protection Program) may access your records.

May I change my mind about participating?
Your participation in this study is voluntary. You may decide to not begin or to stop the study at any time. Your refusing to participate will have no effect on your receiving home health care services. You can discontinue your participation with no effect on your receiving home care services. Also any new information discovered about the research will be provided to you. This information could affect your willingness to continue your participation.

Whom can I contact for additional information?
You can obtain further information about the research or voice concerns or complaints about the research by calling the Principal Investigator Helen Vallina, MS, RN, Doctoral Student at (630) 254-3495. If you have questions concerning your rights as a research participant, have general questions, concerns or complaints or would like to give input about the research and can’t reach the research team, or want to talk to someone other than the research team, you may call the University of Arizona Human Subjects Protection Program office at (520) 626-6721. (If out of
state use the toll-free number 1-866-278-1455.) If you would like to contact the Human Subjects Protection Program via the web, please visit the following website: http://www.irb.arizona.edu/contact/.

Your signature
By signing this form, I affirm that I have read the information contained in the form, that the study has been explained to me, that my questions have been answered and that I agree to take part in this study. I do not give up any of my legal rights by signing this form.

________________________
Name (Printed)

________________________  ______________________
Participant’s Signature     Date signed

Statement by person obtaining consent
I certify that I have explained the research study to the person who has agreed to participate, and that he or she has been informed of the purpose, the procedures, the possible risks and potential benefits associated with participation in this study. Any questions raised have been answered to the participant’s satisfaction.

________________________
Name of Study Personnel

________________________  ______________________
Study Personnel Signature     Date signed

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Participant’s Initials____
APPENDIX E:

AUTHORIZATION FORM FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH
Authorization Form for Use and Disclosure of Protected Health Information for Research

Title of Study: Using OASIS Data to Assess Moderator Effect of Patient Characteristics on Telemonitoring Outcomes in Heart Failure Patients

The United States government has issued a new privacy rule to protect the privacy rights of individuals enrolled in research. The Privacy Rule is designed to protect the confidentiality of an individual’s health information. This document hereafter known as an “Authorization for Use and Disclosure of Protected Health Information for Research” describes your rights and explains how your health information will be used and disclosed for this study.

PURPOSE

You are being invited to participate voluntarily in the above-titled research study. The purpose of this study is to identify specific patient characteristics that predict those for whom telemonitoring will be most beneficial. Your home care medical record will be reviewed for information about the start of care patient assessment and the number of re-hospitalization occurred during my enrollment in the study. No personal identifying information, such as name, social security number, medical record number, address or phone number will be collected. The data will be collected from the start of care patient assessment include: primary diagnosis and other diagnoses and their severity, living arrangement and assisting persons, respiratory status, neuro/emotional/behavioral status and functional status. The purpose to use your health information is to learn more about how patient characteristics that recorded in the start of care patient assessment might influence the telemonitoring outcomes.

WHO MAY USE OR DISCLOSE THE INFORMATION

The researcher and research team members will have access to this information.
WHO MAY RECEIVE THE INFORMATION
The institutional Review Board will have access to this information.

DO I HAVE TO SIGN THIS AUTHORIZATION FORM?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Refusing to sign this document will not affect your medical care.

RIGHT TO REVOKE OR WITHDRAW AUTHORIZATION
I have the right to change my mind about allowing access to this information. If I change my mind, I must notify the Principal Investigator in writing. The address for the Principal Investigator is 1305 N. Martin, P.O. Box 210203, Tucson, AZ 85721. If I do refuse, there will be no effect on my receiving home care services.

WHEN WILL MY AUTHORIZATION EXPIRE?
This authorization will expire in six months. That means new information cannot be obtained about me after that time.

CONTACTS
You can obtain further information from the Principal Investigator Helen Vallina, MS, RN, Doctoral Student at (630) 254-3495. If you have questions concerning your rights as a research subject, you may call the Human Subjects Protection Program office at (520) 626-6721. (If out of state use the toll-free number 1-866-278-1455.) If you would like to contact the Human Subjects Protection Program via the web, please visit the following websites: http://www.irb.arizona.edu/contact/.
YOUR SIGNATURE

By signing this form, I affirm that I have read the information contained in the form that the study has been explained to me, that my questions have been answered and that I agree to take part in this study. I do not give up any of my legal rights by signing this form.

________________________________________
Name (Printed)

________________________________________
Participant’s Signature          Date Signed

STATEMENT BY PERSON OBTAINING CONSENT

I certify that I have explained the research study to the person who has agreed to participate, and that he or she has been informed of the purpose, the procedures, the possible risks and potential benefits associated with participation in this study. Any questions raised have been answered to the participant’s satisfaction.

________________________________________
Name of Study Personnel

________________________________________
Study Personnel Signature          Date Signed

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Participant’s Initial _____
APPENDIX F:

RECRUITMENT FLYER
Volunteers Are Needed for a Research Study

“Using OASIS Data to Assess the Moderator Effect of Patient Characteristics on Telemonitoring Outcomes in Heart Failure Patients”

The purpose of this research study is to identify specific patient characteristics that predict those for whom telemonitoring will be most beneficial.

You may participate if you are:

- Age 50 or older
- Newly admitted to home care services
- Admitted to home care having heart failure as the first or second diagnosis
- Classified by nurse case manager as NYHF (New York Heart Association) Class II, III or IV
- Capable of giving informed consent, and
- Capable of speaking and understanding English.

As a participant, you will be asked to complete the same questionnaire at two separate times. The questionnaire will take about 20 minutes to complete and will take place at your home. Your medical record will also be reviewed to collect relevant OASIS data; however, no personal information will be collected. All information will be kept private and confidential.

If you would like to participate in this research study, please let your nurse case manager know. If you have any question regarding your potential involvement in the research study, please feel free to call Helen Vallina, MS, RN, Doctoral Student, at (630) 254-3495.

Thank you very much for your consideration!
APPENDIX G:

RECRUITMENT SCRIPT (VERBAL, ON THE PHONE)
RECRUITMENT SCRIPT (verbal, on the phone)

My name is Helen Vallina. I am a doctoral student from the College of Nursing at the University of Arizona. I would like to invite you to participate in my research study to identify specific patient characteristics that predict those for whom telemonitoring will be most beneficial.

As a participant, you will be asked to complete the same questionnaire at two separate times; when you begin the study and 40 days later. The questionnaire will take about 20 minutes to complete; however, if you need to take breaks due to fatigue, this could make it take a bit longer. You may choose to complete the questionnaire in paper format or have the questions read to you and your responses recorded by me. Your medical record will also be reviewed to collect relevant data; however, no personal identification information, such as name, social security number, medical record number, address or phone number, will be collected. Result of the study will be reported for groups only, not for individuals. You will not be identified in any reports or publications resulting from the study.

If you would like to participate in this research study, I can set up an appointment with you now. If you have a question later, please contact me at (630) 254-3495.
APPENDIX H:

ORAL EXPLANATION OF THE PROJECT (DURING FIRST HOME VISIT)
Oral Explanation of the Project (during first home visit)

My name is Helen Vallina. I am a doctoral student from the College of Nursing at the University of Arizona. I would like to invite you to participate in my research study to identify specific patient characteristics that predict those for whom telemonitoring will be most beneficial.

As a participant, you will be asked to complete the same questionnaire at two separate times; when you begin the study and 40 days later. The questionnaire will take about 20 minutes to complete; however, if you need to take breaks due to fatigue, this could make it take a bit longer. You may choose to complete the questionnaire in paper format or have the questions read to you and your responses recorded by me. Your medical record will also be reviewed to collect relevant data; however, no personal identification information, such as name, social security number, medical record number, address or phone number, will be collected. Result of the study will be reported for groups only, not for individuals. You will not be identified in any reports or publications resulting from the study.
REFERENCES


