PATTERNS OF DEPRESSIVE SYMPTOMS IN HEART FAILURE PATIENTS

By

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ABSTRACT

Depression is a common problem in heart failure (HF) patients and leads to worsened health outcomes. A review of studies treating depression in HF patient’s revealed different patterns of depressive symptoms. Using the Biopsychosocial Holistic Model of Cardiovascular Health as the guiding framework, this study aimed to determine: (a) the prevalence of depressive symptoms; (b) determine if there are patterns of depressive symptoms; (c) investigate if the patterns differ by gender or pharmacologic treatment; and (d) determine the cardiovascular health markers and the biological, psychological, and social factors associated with depressive symptoms in HF patients.

This descriptive, correlational study was a secondary analysis using data from The Self-Management and Care of Heart Failure Trial. Study subjects (N=198) were enrolled from a Midwestern academic medical center and were assigned randomly to receive standard care or the intervention. Information on depression and pharmacological treatment for depression were obtained with other data (e.g., biologic, social, cardiovascular health status) at five time periods over one year. Descriptive statistics, t-tests, plots, and regression analysis were used for analysis.

The Center for Epidemiologic Studies Depression Scale (CES-D) score mean at baseline was 8.94 (SD= 6.55); 42% of the sample were clinically depressed (CES-D Score ≥10). The median CES-D scores at baseline were not statistically significantly different between the intervention and control groups. Both groups had a decrease in depressive symptoms over time. There was not a statistically significant difference in mean CES-D changes scores between the intervention and control groups. The patients in the sample were divided into eight groups based on treatment group, gender, and baseline pharmacologic treatment. Each group experienced a
decrease in depressive symptoms over the course of the study. Significant variables in the final regression model included pharmacologic treatment, income sufficiency, and the Social Support Scale. This model accounts for 30% of variance in depressive symptoms in patients with HF.

All patients with HF should be screened for depressive symptoms. Health care workers should be aware of a patient’s income sufficiency and social support as these may be closely associated with depressive symptoms.
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CHAPTER ONE

INTRODUCTION

Projections show that the prevalence of heart failure (HF) will increase 46% from 2012 to 2030, resulting in greater than eight million adults with HF in the United States (Mozaffarian et al., 2015). Depression is common among patients with HF with an estimated prevalence rate of 22% or two to three times that of the general population (Rutledge, Reis, Linke, Greenberg, & Mills, 2006). The adverse effects of depressive symptoms on HF patients are documented well and include increased cost of care (Welch, Czerwinski, Ghimire, & Bertsimas, 2009), decreased health-related quality of life (Gottlieb, 2004; Sharma, Zehtabchi, Rojas, & Birkhahn, 2009), decreased adherence to medication regimens (DiMatteo, 2000), increased mortality rates (Jiang et al., 2001; van den Broeck et al., 2011), and increased re-hospitalizations (Sherwood et al., 2011).

The most recent American Heart Association (AHA) and American College of Cardiology HF guidelines stress the importance of providing comprehensive care to HF patients, including the assessment and treatment of depression. However, no guidelines or resources on how to do so are provided (Hunt et al., 2009; Yancy et al., 2013). The lack of specificity in the guidelines reflects the consensus in the research literature; there has been insufficient empirical support to guide the treatment of depressive symptoms in adults with HF (Johnson et al., 2012; Lane, Chong, & Lip, 2009; Nair, Farmer, Gongora, & Dehmer, 2012; Silver, 2010).

A systematic review of randomized and non-randomized studies with various interventions to treat depression in HF patients revealed that many different patterns in depressive symptoms were noted in both intervention and control groups. Some studies found that both the intervention and control group had improvements in depression (Fraguas et al.,
One home-based exercise program study reported improvement in depression in the intervention group; however, the results could not be attributed to the intervention directly as this group did not report a higher level of physical activity (Jolly et al., 2009). Researchers from one study noted that average levels of depression increased slightly during the first stages of the study, but then declined substantially by the last measurement period in the study (Flynn et al., 2005).

This study is a secondary analysis using data from The Self-Management and Care of Heart Failure (SMAC-HF) Trial. Smith et al. (2014) reported that the purpose of the SMAC-HF trial was to test the effects of multidisciplinary group clinic appointments on the time to first HF re-hospitalization or death. In this study, 198 HF patients were assigned randomly either to multidisciplinary group clinics focused on HF self-management skills (intervention group) or to standard care (control group). Smith et al. (2014) found that multidisciplinary group clinic appointments were associated with greater adherence to selected HF medications and longer hospitalization-free survival during the time that the intervention was underway.

Statement of Purpose

The purpose of this study, using secondary analysis of the SMAC-HF data, was to evaluate the prevalence and patterns of depressive symptoms in adults with HF. This study was guided by the Biopsychosocial Holistic Model of Cardiovascular Health and was designed to accomplish multiple aims: (a) to determine the prevalence of depressive symptoms in a sample of HF patients; (b) to determine if there are patterns of depressive symptoms in HF patients; (c) to investigate if the patterns of depressive symptoms differ in subjects receiving pharmacologic treatment or by gender; and (d) to determine what cardiovascular health markers and the biological, psychological, and social factors were associated with depressive symptoms.
The long-term goals of this study are to improve understanding of patterns of depressive symptoms in HF patients and the factors that are associated with depressive symptom in HF patients. This knowledge can help healthcare providers in the assessment and diagnosis of depression and guide appropriate treatment. Also, this will aid future research on depressive symptoms in HF patients to appropriately design studies and interpret findings.

**Research Questions**

To meet the aims discussed above, the following research questions will be addressed:

1) At baseline, what is the prevalence of depressive symptoms, measured by CES-D, in a sample of patients with a diagnosis of heart failure who was hospitalized for acute decompensation prior to enrollment in the SMAC-HF trial?

2) At baseline, is there a difference in depressive symptoms between the self-management care intervention group and the control group?

3) What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for the intervention and control groups?

4) What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for those receiving pharmacologic treatment for depression and those who are not by treatment group and gender?

5) What cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support) were associated with depressive symptoms at baseline?
**Theoretical Framework**

The theoretical framework guiding this study is the Biopsychosocial Holistic Model of Cardiovascular Health (BHMCH). This model states that biological, psychological, and social realms interact within each person and are integrated into cardiovascular health (Thomas, 2003). The model was selected because it describes the integration of mind and body into cardiovascular health status and can guide the assessment and treatment of patients with HF and depression. During the development of the model, multiple studies were completed to affirm the critical interrelationship between mind and body for cardiovascular health (DeKeyser, Frazier, Friedmann, Liehr, & Thomas, 2002; Friedmann et al., 2006; Thomas, Friedmann, Wimbush, & Schron, 1997; Thomas & Liehr, 1995).

In the BHMCH, cardiovascular health interacts with factors in each realm (biological, psychological, and social) to affect the other realms. This holistic model, in contrast to a biomedical model of disease, posits that acute and chronic shifts in each of the realms affect health status, which in turn affects biological, social and psychological factors, including depression. The psychosocial factors, including depression, can promote health or disease by either moderating or enhancing pathological processes (Thomas et al., 2008). In the psychological realm stress, anxiety, and depression diminish health. In the social realm, health is promoted by social support (Friedmann et al., 2006). Social and psychological factors affect the biological factors. For instance, depression alters levels of cortisol, catecholamines, and cytokines; autonomic neurocardiac regulation; and factors that influence cardiac functioning (Thomas et al., 2008), creating an interactive non-recursive model. The model (see Figure 1) provides the basis for a dynamic interactive approach to the assessment and treatment of depression in patients with HF (Thomas et al., 2008).
Figure 1. Adapted Biopsychosocial Holistic Model of Cardiovascular Health

This model features the Biopsychosocial Holistic Model of Cardiovascular Health which depicts the relationship between cardiovascular health and the biologic, social, and psychological realms. The existing model was adapted to include the variables that will be addressed in this study.

Definition of Terms

Definitions for concepts that are central to the study are provided in the following section.

Heart Failure (HF)

HF is a complex syndrome with many potential etiologies, diverse clinical features, and many clinical subsets. HF is caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by either left ventricle dilation and/or hypertrophy (Lindenfeld, 2010). Dysfunction can be systolic, diastolic, or both, and leads to neurohumoral and circulatory abnormalities resulting in the characteristic symptoms of fluid retention, shortness of breath, and fatigue (Lindenfeld, 2010). For the purpose of this study HF will be defined as a syndrome in which the heart is unable to fill and/or pump blood sufficiently to meet tissue metabolic needs.

Cardiovascular Health

Cardiovascular health is defined as the integration of an individual’s biological, psychological and social realms. Cardiovascular health interacts with factors in each realm to affect the other realms (Thomas et al., 2008).

Ejection Fraction. The ejection fraction (EF) is the fraction of the end-diastolic ventricular volume ejected (Butterworth, Mackey, & Wasnick, 2013). More simply stated, EF is a measurement of the percentage of blood pumped out of a filled left ventricle with each heart beat.

Charlson Comorbidity Index. The Charlson Comorbidity Index (CCI) is a method of categorizing comorbidities based on diagnoses codes. Each comorbidity category has an associated weight, based on the risk of one-year morality. The sum of all the weights results in a
single score which indicates the level of comorbidity the patient has (Charlson, Pompei, Ales, & MacKenzie, 1987).

**Psychological Factors**

**Depression.** A major depressive episode consists of five or more symptoms present for most of the day for at least two weeks. One of the symptoms must be depressed mood or loss of interest in usual activities and symptoms must cause significant distress (Dekker, Peden, Lennie, Schooler, & Moser, 2009). Researchers have proposed a continuum of depressive illness that ranges from mild depressive symptoms to a diagnosis of major depressive disorder (Dekker et al., 2009). Depressive symptoms, such as depressed mood, guilt, hopelessness, low self-esteem, fatigue, sleep disturbances, appetite change, and inability to concentrate, are what most depression scales actually measure (Dekker et al., 2009).

**Patterns.** Patterns of depressive symptoms were evaluated by looking at the trends (i.e., increased, decreased, or unchanged levels) of mean symptoms plotted over time (baseline, 3 months, 6 months, 9 months, and 12 months).

**Pharmacologic treatment.** Antidepressant use or pharmacologic treatment for depression is defined as patients taking or not taking medication(s) in the antidepressant class of medications.

**Biological Factors**

Biological factors are anything that affects the function and behavior of a living organism. The biological factors that will be addressed in this study include age, gender, and race.
Social Factors

Social factors are defined as factors that influence an individual’s lifestyle. The social factors included in this study are income sufficiency, whether or not the subject lives alone, and a social support scale that includes if the subject has someone to talk to and someone to help them.

Summary

The recognition and treatment of depression in HF patients is a problem in healthcare. A review of literature revealed many studies addressing depression in HF patients noted patterns that were not anticipated. In order to guide future research and practice in this area, a more in-depth examination of patterns of depressive symptoms in HF patients is needed. To assess the patterns of depression in HF patients, a secondary analysis of data from a HF randomized controlled trial was completed.
CHAPTER TWO
LITERATURE REVIEW

This chapter includes an overview of HF, along with studies related to the realms of the guiding framework of cardiovascular health: psychological, biological, and social. Studies were selected to support the variables included in the study. Studies were identified by searching electronic databases and scanning reference lists of articles.

Background

Heart Failure and Depression

HF is a complex syndrome with many etiologies, diverse clinical features, and numerous clinical subsets. HF is caused by cardiac dysfunction, generally resulting from myocardial muscle dysfunction or loss and characterized by either left ventricle dilation and/or hypertrophy (Lindenfeld, 2010). Dysfunction can be systolic, diastolic, or both and leads to neuro-hormonal and circulatory abnormalities resulting in the characteristic symptoms of fluid retention, shortness of breath, and fatigue (Lindenfeld, 2010).

On the basis of data from 2009 to 2012, an estimated 5.7 million American adults have HF (Mozaffarian et al., 2015). The lifetime risk of developing HF for both men and women at the age of 40 is one in five (Mozaffarian et al., 2015). The mortality of HF is high, with approximately 20% dying within one year of their diagnosis and a 5-year mortality rate of 59% in men and 45% in women (Lloyd-Jones et al., 2010). Cardiac function in HF ranges from no apparent symptoms (New York Heart Association [NYHA] class I) to extremely limited function (NYHA classes III-IV).

The incidence of depression in patients with HF is high. Significant depression is reported among 22% of patients with HF in general, with estimates of prevalence varying from
11% to 35% in the outpatient setting and 35% to 70% in the inpatient setting (Rutledge et al., 2006). However, the prevalence rates of depression in HF patients have been found to be highly variable across studies; this partially could be due to the differences between studies that use self-report questionnaires and studies that use diagnostic interviews (Nair et al., 2012).

The cost of treating patients with HF is high and expected to continue to rise. The total cost for HF in 2012 was estimated to be $30.7 billion, with 67% of this cost attributable to direct medical costs (Mozaffarian et al., 2015). By 2030 the total cost of HF is projected to increase almost 127% to $69.7 billion, which is equal to approximately $244 for every U.S. adult (Mozaffarian et al., 2015).

Depression is a common, comorbid condition among patients with HF. The World Health Organization’s Global Burden of Disease study ranks depression second only to heart disease in burden or impact on disability-adjusted life years (WHO, 2008). Researchers have proposed a continuum of depressive illness that ranges from mild depressive symptoms to a diagnosis of major depressive disorder (Dekker et al., 2009). Depressive symptoms, such as depressed mood, guilt, hopelessness, low self-esteem, fatigue, sleep disturbances, appetite change, and inability to concentrate, are what most depression scales actually measure (Dekker et al., 2009). Jiang and colleagues (2007) reported a “dose effect” for the severity of depression on survival. Even low levels of depressive symptoms, typically not considered “clinical depression”, are associated with increased mortality rates. The greater the depressive symptoms a HF patient experiences the greater the mortality rates (Jiang, 2007).

The Diagnostic and Statistical Manual of Mental Disorders (DSM)-V criteria for major depressive episode are as follows (Diagnostic and statistical manual of mental disorders, 2013):
1) Five (or more) of the following criteria have been present during the same two week period and represent a change from previous functioning; at least one of the symptoms is either depressed mood or loss of interest or pleasure (note: do not include symptoms that are clearly due to a medical condition): (a) depressed mood most of the day, nearly every day, as indicated by either subjective report or observation by others; (b) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day; (c) significant weight loss when not dieting or weight gain (e.g. a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day; (d) insomnia or hypersomnia nearly every day; (e) psychomotor agitation or retardation nearly every day; (f) fatigue or loss of energy nearly every day; (g) feelings of worthlessness or excessive or inappropriate guilt nearly every day; (h) diminished ability to think or concentrate, or indecisiveness, nearly every day; and (i) recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

2) The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

3) The episode is not attributable to the direct physiological effects of a substance or another medical condition.

4) The major depressive episode is not better accounted for by schizoaffective disorder and is not superimposed on schizophrenia, schizophreniform disorder, delusional disorder, or psychotic disorder not classified elsewhere.

5) There has never been a manic episode or a hypomanic episode (Diagnostic and statistical manual of mental disorders, 2013).
Measuring depression. Varied methods are used to determine the presence of depressive symptoms in research literature. Depressive symptoms screening is conducted with the use of self-rated survey instruments; however, the self-rated reports are not meant to be diagnostic of depression. Few studies can afford the time and/or personnel needed to complete the diagnostic interview that is required for the determination of a diagnosis of depression. Consequently, depressive symptom screening scales are frequently used in the research setting (Delville & McDougall, 2008). Screening scales are necessary because the Structured Clinical Interview (SCI) for diagnosing psychiatric disorders takes specially trained mental health professionals, as well as one to two hours to complete.

A systematic review of 16 studies of the instruments used and incidence of depression in HF patients found that 11 studies used screening instruments only, three used both a screening instrument and a diagnostic interview, and two used only a diagnostic interview (Delville & McDougall, 2008). Screening instruments were found to result in higher frequencies of depressive symptoms (21-60%) when compared to diagnostic interviews (14-39%). Another meta-analytic review addressing the prevalence of depression in HF patients found the majority of studies used depressive symptoms inventories as opposed to clinical interviews (Rutledge et al., 2006). One study found that participants were able to identify by self-report many causative factors of depression, and additional factors were identified by a psychiatric nurse specialist, allowing for individualized diagnoses and treatment (Bowden et al., 2011).

The relationship between depression and heart failure. The interaction between depression and HF is understood incompletely despite extensive research (Nair et al., 2012). There appears to be a bi-directional relationship between depression and HF. High rates of depression in HF patients could be explained either by individuals with depression having a
greater risk for HF or HF patients having a greater risk for depression. It is likely that HF and depression create a cycle in which they exacerbate each other, with the combined effects being more severe than the additive effects of each state alone (Nair et al., 2012).

Depressed patients in the Systolic Hypertension in the Elderly Program were twice as likely as non-depressed patients to develop HF that was not mediated by myocardial infarction (Abramson, Berger, Krumholz, & Vaccarino, 2001). This was supported by a retrospective study (n= 236,079 with no baseline cardiovascular disease) that found when compared with unaffected patients, those with anxiety only, Major Depressive Disorder (MDD) only, and both disorders were at increased risk for incident HF in age-adjusted models (hazard ratio [HR] = 1.19, (95% confidence interval [CI]= 1.10-1.28); HR= 1.21, (95% CI = 1.13-1.28); and HR= 1.24, (95% CI 1.17-1.32); respectively (Garfield et al., 2014). Another study found that HF more than doubles the risk of new-onset depression (Luijendijk et al., 2010).

There are four pathological patterns that occur in depressed patients, which correspond to the pathogenesis of heart failure: neuro-hormonal activation, hypercoagulability, autonomic neuro-cardiac dysfunction, and cytokine release (Brown, Varghese, & McEwen, 2004; Joynt, 2004; Thomas, 2003). The authors suggest that the pathological changes mediate the risk for cardiac events with a subsequent poor prognosis in patients with HF who are depressed.

Behavioral actions likely affect the interaction between HF and depression as well. Patients with depression exhibit many behaviors that may contribute to the development and worsening of HF; they are less active, less adherent with medication regimens and diet, and more likely to abuse drugs and alcohol (Nair et al., 2012).
The adverse effects of depressive symptoms in heart failure. The adverse effects of depressive symptoms in patients with HF are documented well in literature. More than two dozen studies have shown depression to be an important risk factor for morbidity and mortality in HF patients, independent of physiologic measures of disease severity (Fulop, Strain, & Stettin, 2003; Go et al., 2014; Jiang et al., 2001; Murberg & Furze, 2004; Rozzini, Sabatini, Frisoni, & Trabucchi, 2002; Rumsfeld et al., 2003; Westlake, Dracup, Fonarow, & Hamilton, 2005). Patients with HF who had depression were more than twice as likely as those without depression to die or be re-hospitalized within three months to one year after hospitalization (Jiang et al., 2011). A seven-year follow-up study of patients with HF found that those with depressive symptoms at baseline were more likely to die than those without depressive symptoms; the risk of death increased by level of depressive symptoms: 21% with mild, 53% with moderate, and 83% with severe (Jiang, 2007).

Patients who have concurrent HF and depression have increased medical costs of 25 to 40 percent (Nair et al., 2012). It is estimated that depression and psychological impairment may be responsible for nearly 25% of the cost associated with treating HF (Mann, 2011). In a sample of 784 patients with HF, depression was found to increase the number of hospitalizations by 50% after controlling for physician adherence to evidence-based medications and HF severity (Johnson et al., 2012). Depression was associated with poor compliance with medical regimens, which has significant consequences for HF patients (Mann, 2011).

The problem of depression in adults with HF is well documented. Despite this problem, there is little research to guide the treatment of depression in this population. The lack of research to guide the assessment and treatment of depression in the HF population leads to
under-diagnosis and under-treatment (Bean, Gibson, Flattery, Duncan, & Hess, 2009; Connerney & Shapiro, 2011; Sullivan et al., 2009).

**Pharmacological treatment for depression.** The data reporting the safety and efficacy of antidepressant use in patients with HF is limited. Many antidepressant drugs have known cardiovascular side effects, and no randomized clinical trials have provided the evidence necessary to support the use of pharmacologic treatment (Johnson et al., 2012). Smith and Book (2001) state that tricyclic antidepressants (a class of antidepressant drugs that inhibit the uptake of both norepinephrine and serotonin) should be avoided in patients with cardiovascular disease, due to the risk of life-threatening arrhythmias. This risk is increased in patients already taking medications that can prolong the QT interval (Tousoulis et al., 2010). Tricyclic antidepressants generally are contraindicated in patients following myocardial infarction, and this class of antidepressant can impair left ventricular function in patients with severe systolic dysfunction (Smith & Book, 2011). Monoaminoxidase inhibitors have known adverse effects, including orthostatic hypotension and increased risk of hypertensive crisis, which would discourage the use of this medication class in patients with HF (Tousoulis et al., 2010).

Selective serotonin reuptake inhibitors (SSRIs) as a class combine safety and efficacy, and are associated with a lower rate of adverse cardiovascular events. However, SSRIs still have adverse effects including increased bleeding risk due to platelet suppression (Tousoulis et al., 2010). SSRIs rarely have been associated with orthostatic hypotension and bradycardia and do not appear to depress cardiac function (Smith & Book, 2011). The SSRIs can affect the cytochrome P450 system, potentially altering the metabolism of drugs that heart failure patients may be using including antiarrhythmic medications, beta blockers, and Coumadin (Smith & Book, 2011). One review of studies found tricyclic antidepressants and SSRIs were associated
with similar rates of major adverse cardiovascular events, but other cardiovascular side effects were more commons with tricyclic antidepressant use (Swenson, Doucette, & Fergusson, 2006).

A majority of the pharmacologic interventions included antidepressants in the SSRI class (paroxetine, sertraline, and citalopram). One study reported that SSRIs might have a beneficial effect on endothelial function and nitric oxide bioavailability (Tousoulis et al., 2010). Paroxetine CR was shown to significantly improve depression when compared to a placebo group (Gottlieb et al., 2007). Of note, six patients (43%) in the placebo group experienced deterioration, with an increase in Becks Depression Inventory (BDI) scores, while only one (7%) in the active treatment experienced this problem ($p= .03$). The reduction in depression was accompanied by improvements in the psychological aspects of quality of life. Gottlieb et al (2007) also found a significant association between the reduction in depression and improvement in social function in placebo patients. Both citalopram (Fraguas et al., 2009) and sertraline (O'Connor et al., 2010) were noted to have high placebo rates that could possibly be associated with the support from psychiatric and nursing attention; no significant difference between intervention or placebo groups were found. In the sertraline trial, it was considered that the level of depression in the study might not have been severe enough to respond to therapy. Both citalopram and sertraline were tolerated well with few side effects reported.

**Other interventions.** Beyond pharmacologic options, exercise, complementary medicine, and behavioral interventions have been used to treat depression in HF patients. To determine the effects of psychological interventions for treating depression in adults with HF, the most recent Cochrane Review reported that no completed studies met the inclusion criteria. The main reasons for exclusion included lack of suitability of study design or intervention, not randomized, no appropriate control group, incomplete randomization, no useful outcome data,
and combined interventions (Lane et al., 2009). Despite this, the review of observational studies suggested that psychological interventions in patients with HF do reduce symptoms of depression, and that randomized controlled trials are needed in this area (Lane et al., 2009). Researchers (Woltz et al., 2012) conducting a more recent systematic review addressing the effects of interventions on depression in HF patients reported that despite some evidence for different pharmacologic and complementary medicine strategies, the review did not support the development of guidelines for the treatment of depression in HF patients due to lack of sufficient evidence.

Treatment of depression in HF patients has the potential to improve quality of life, mortality and morbidity, and decrease the cost of healthcare and re-hospitalizations. Despite the lack of guidelines for treatment of depression in HF patients, there have been a few studies with promising outcomes. Jiang et al. (2011) found that patients who experience remission from depression have significantly lower cardiovascular events than those who did not experience remission. Gottlieb (2004) demonstrated that effective treatment of depression in HF patients reduced the medical costs of HF. The average cost of one HF hospitalization in 2004 was $9,400, and the aggregate cost of a HF-related hospitalization was $10.4 billion (Johnson et al., 2012). Hospitals now are being penalized for avoidable hospitalizations and readmission by the Centers for Medicare and Medicaid Services (Yancy et al., 2013).

**Patterns of Depression.** A review of literature revealed many different patterns of depressive symptoms were noted in both intervention and control groups of clinical trials. Some studies found that both intervention and control groups had improvements in depression (Fraguas et al., 2009; O'Connor et al., 2010; Powell et al., 2010). Fraguas et al. (2009) completed a study to investigate the effectiveness of citalopram treatment for major depressive disorder (MDD) in
elderly patients with HF. The subjects of the study included 72 older outpatients with EFs less than 50% and diagnosed with MDD by means of the structured clinical interview using the DSM-IV. The study was an eight-week, double-blind treatment using the 31-item Hamilton Rating Scale for Depression (HAM-D-31) and Montgomery Asberg Depression Rating Scale (MADRS) to detect depression; additionally the Systematic Assessment for Treatment Emergent Effects was administered to monitor for adverse effects. The MADRS scores showed a trend ( \( p = .082 \) ) towards superiority of citalopram when compared to placebo, but no differences for the HAM-D scores. In both groups, patients had significant ( \( p < .001 \) ) decreases in depressive symptoms that led to the study being concluded early with only 37 patients (Fraguas et al., 2009). The authors concluded the findings possibly were due to weekly psychiatric follow-up, including counseling, for both groups.

Another example, O’Connor et al. (2010) tested the hypothesis that HF patients treated with sertraline would have lower depression scores and fewer cardiovascular events when compared with placebo. This was a randomized, double-blind, placebo-controlled trial of sertraline (dose= 50 to 200mg/day) versus placebo for 12 weeks (O'Connor et al., 2010). Subjects were greater than 45 years old, were diagnosed with clinical depression, and not using antidepressants. This randomized controlled trial found that antidepressants did not result in a significant improvement in depression when compared to the placebo. However, the intervention and placebo group both experienced a considerable reduction in depressive symptoms that was attributed to both groups receiving a nursing intervention. Also, it was considered that the baseline level of depression for the subjects in the study might not have been severe enough to respond to sertraline therapy.
Powell et al. (2010) completed a randomized clinical trial (RCT) to determine the value of self-management counseling plus HF education, when compared with HF education alone on time to HF hospitalization. Depression, measured by the Geriatric Depression Scale (GDS), was a secondary outcome. The RCT included 902 patients who were randomized to one of the groups, HF education alone or HF education plus self-management counseling, and provided education over one year with follow-up between two to three years. At baseline, major depressive symptoms were evident in 29% of the sample. Major depressive symptoms decreased from 136 to 90 (20%) in the self-management group and from 129 to 99 (22%) in the education group ($p = .008$ for time effect). Compared with an enhanced educational intervention alone, the addition of self-management counseling did not reduce death or HF hospitalization in patients with mild to moderate HF. However, the authors did identify that the education component given to both groups appeared to have been a more active treatment than expected.

Riegel et al. (2006) completed a RCT to test the effectiveness of telephone case management in decreasing hospitalizations and improving health-related quality of life and depression in HF patients of Hispanic or Mexican origin. Hispanics with chronic HF ($n= 134$) were randomized to the intervention or usual care. Depression was assessed with the Patient Health Questionnaire (PHQ-9) at baseline, three months, and six months. At baseline, 10 (7.9%) were on antidepressant therapy. No significant group changes were founds in HF hospitalizations, HF readmission rates, HF days in the hospital, HF cost of care, all-cause hospitalizations or cost, mortality, health-related quality of life, or depression. Improvement in PHQ scores were noted in both groups, but there was no significant difference between groups from baseline to three and six months in terms of depression scores (Usual care: $8.6 \pm 5.4$;
2.3±2.3; 2.0±2.1; and Intervention 8.8±5.8; 1.9±2.1; 1.5±2.1; respectively) (Riegel, Carlson, Glaser, & Romero, 2006).

Another pattern noted was improvement of all patients with minor depression, despite group assignment (Gary, Dunbar, Higgins, Musselman, & Smith, 2010). Gary et al. (2010) completed a RCT with repeated measures to compare the effectiveness of a combined 12-week home-based exercise/cognitive behavior program (EX/CBT) to a group receiving cognitive behavioral program (CBT) alone, a group receiving home-based exercise (EX) alone, and a usual care (UC) group. Of the sample, the majority (77%) reported a prior episode of major depressive disorder (MDD), and 29% were on antidepressants. Only the combined EX/CBT group demonstrated a sustained reduction in depression scores. The greatest reduction in HAM-D scores over time occurred in the EX/CBT group (-10.4), followed by CBT (-9.6), EX (-7.3), and UC (-6.2), but none were statistically significant (Gary et al., 2010). It was noted that all patients who had minor depression (HAM-D scores between 11-14) improved over time despite group assignment, indicating that interventions may not be needed in this group of patients. Patients on antidepressants had no better outcomes than those who were not taking them.

In a RCT, Jolly et al. (2009) aimed to assess the effectiveness of a home-based exercise program in addition to specialist HF nurse care compared to specialist HF nurse care alone. This home-based exercise program study reported improvement in depression in the intervention group; however, the results could not be attributed to the intervention directly as this group did not report a higher level of physical activity (Jolly et al., 2009). The groups were not similar at baseline, the exercise group was younger, had higher Hospital Anxiety and Depression Scale (HADS) depression scores, and lower systolic blood pressure at baseline. Approximately a quarter of participants scored as having possible or probable depression on the HADS at
baseline, so there was some potential for improvement (Jolly et al., 2009). No statistically significant difference between groups were noted on the primary outcome, the Minnesota Living with HF Questionnaire, but depression scores improved in treated patients compared with control subjects at 12 months (6.26 vs 5.50, respectively; \( p = .002 \)). However, at 12-month follow up the exercise group did not report a higher level of physical activity; thus, this does not explain the lower level of depression.

One study noted that average levels of depression increased slightly during the first stages of the study, but then declined substantially by the last measurement time period in the study (Flynn et al., 2005). Flynn et al. (2005) completed a treatment-only pilot study to examine whether a yearlong group-based, self-management intervention was feasible, and if it could improve self-management skills in patients with HF. At baseline 52% of the sample had scores of 10 or higher on the Beck Depression Inventory (BDI), indicating at least mild levels of depression. Average levels of depression increased slightly during the first stages of the study, but they declined substantially by the end of the year with only 20% of patients with at least mild depressive symptoms (Flynn et al., 2005). The intervention group, when compared to baseline, had increases in overall self-efficacy in practicing self-management skills (\( p < .001 \)) and in four out of five specific self-management skills. Compared with baseline levels there was a significant decrease in depressive symptoms (9.9±5.0 to 7.3±5.0, respectively; \( p < .001 \)).

Other patterns were noted as well. Martensson et al. (2005) completed a RCT to determine the effects of a nurse-led intervention to improved self-management of patients with HF in a primary care setting regarding health-related quality of life and depression, measured by Zung Self-Rating Depression Scale (SDS). There was no significant change in mean differences between the two groups at baseline, three month, or twelve month follow-ups. There was no
significant median difference in SDS between the two groups. Using cut-off scores from the SDS revealed that there was a significant difference in moderate and severe depression \((p = .02)\) from baseline to three-month follow-up with the intervention group having significantly less depression (Mårtensson, Strömberg, Dahlström, Karlsson, & Fridlund, 2005). However, at twelve-month follow-up there was no difference between the groups.

Sullivan et al. (2009) in the Support, Education, and Research in Chronic Heart Failure (SEARCH) study demonstrated that a mindfulness-based, psycho-educational intervention successfully reduced anxiety and depression at six months, but the effect was attenuated at one year (Sullivan et al., 2009). This was a prospective cohort study that was designed to assess the impact of a mindfulness-based, psycho-educational intervention on clinical outcomes, depression and quality of life, in a sample 208 adults diagnosed with HF with EF less than forty percent. Subjects in the study had a mean age of 61 years, left ventricular rejection fraction of 26%, and a median NYHA classification of II (Sullivan et al., 2009). It was noted that the treatment group was more depressed at baseline. Over time when compared with controls, treatment results showed lower anxiety and depression, along with improved symptoms, and clinical scores. There was no treatment effect on death or rehospitalization at one year. Scores improved in treated patients when compared with control subjects from baseline to three months (-1.74 vs. 0.46, \(p = .01\)) and from baseline to six months (-1.37 vs. 0.90, \(p = .01\)). However, both groups had improved scores, thereafter, so the treatment impact was attenuated. A possible bias in this study was that 80% of patients in both groups were managed by one cardiology practice.

**Biopsychosocial Holistic Model of Cardiovascular Health**

Variables of interest that represent the Biopsychosocial Holistic Model of Cardiovascular Health will be discussed based on the domains of the model (see Figure 1, p. 5). These domains
include cardiovascular health, the psychological realm, the biological realm, and the social realm.

**Cardiovascular Health**

The factors that represent cardiovascular health include: (a) length of HF diagnosis, (b) EF, and (c) Charlson comorbidity index. Studies relevant to each of these variables are presented below.

**Length of heart failure diagnosis.** Only two studies were identified that discussed length of HF diagnosis and depression. One study, a dissertation, reported that there was no statistically significant difference in mean depression scores by length of time living with HF (Larsen, 2010). Another study noted higher levels of depression in those who had been diagnosed with HF for over a year (Polikandrioti et al., 2010).

**Ejection Fraction.** Two large HF studies found that EF did not differ between subjects with depression (BDI ≥ 10) and those without depression (Gottlieb, 2004; Gottlieb et al., 2009). A more recent study (n= 268) also reported that EF was not related to depression over time in the HF population (Brouwers et al., 2014).

**Charlson Comorbidity Index.** No studies were found in literature review specifically discussing the relationship between comorbidity and depression in HF patients. Despite this lack of discussion, many studies did measure and control for comorbidity in their analysis (Dunagan et al., 2005; Riegel et al., 2006).

**Psychological Realm**

Variables representing the psychological realm include depressive symptoms and pharmacologic treatment for depression. Studies about these topics have been discussed in
previous sections above (depression and heart failure, pp. 9-22; and pharmacological treatment for depression, pp. 15, 16).

**Biological Realm**

Variables of interest in the biological realm include demographic characteristics: (a) gender, (b) age, and (c) race. Studies relevant to each of these variables are presented below.

**Gender.** The annual rates per 1000 population of new HF events for white men are 15.2 for those 65 to 74 years of age, 31.7 for those 75 to 84 years of age and 65.2 for those greater than or equal to 85 years of age; for white women in the same ages groups the rates are 8.2, 19.8, and 45.6, respectively (Go et al., 2014; Mozaffarian et al., 2015). Women made up more than half of older adults and had unique risk factors and differences in the clinical manifestations of HF symptoms when compared to men with HF (Hoppe & Hermann, 2003). Consistent with the trends in the general population, one study found that women with HF had significantly worse depression scores than men (Gottlieb, 2004). This finding is not reported consistently; a more recent study (Kao et al., 2014) of 147 HF patients found that about two-thirds of both male and female patients had significant depressive symptoms (Becks Depression Inventory II score greater than or equal to 14). The study did report that females were more likely to have moderate or severe depressive symptoms when compared to males.

**Age.** HF is principally a disorder of older adults with the prevalence and incidence rates increasing dramatically with age. The prevalence of HF increase with age, from less than 1% in the 20-39 year age group to more than 20% in people age 80 years or older (Mann, 2011). The incidence of HF increases with age, doubling with each successive decade above age 45 for both men and women (Mann, 2011). Older patients with HF have a particular propensity for developing HF with preserved left ventricular systolic function or normal EF. Population-based
reports suggest that more than half of elderly patients with HF have normal EFs and that proportion increases with age (Mann, 2011). Mortality rates from HF increase with age and are threefold higher in patients aged 65 to 74 in comparison to those aged 25 to 54 years (Mann, 2011).

Older adults with HF have chronic exercise intolerance, frequent hospitalizations, and high health care costs. Older adults with HF exhibit higher levels of depression than healthy older adults, with almost three quarters of those with HF having depressive symptoms (Moser et al., 2010). Older adults tend to suffer from subsyndromal or atypical depression that is difficult to diagnose and can be as distressing and disabling as major depression (Ahmed, 2004). Upon hospital admission, elderly patients having HF and depressive symptoms was associated with decrease in functional status at six months, death at three months, six months, and one year, and hospital readmissions at three months and one year (Jiang et al., 2001; Vaccarino, Kasl, Abramson, & Krumholz, 2001). Depressed elders made two to four times as many outpatient medical visits as elders who were not depressed (Fulop et al., 2003). Additionally, older adults frequently were underrepresented in HF clinical trials (Mann, 2011).

**Race.** HF disproportionately affects African Americans, who have greater financial burden, present with symptoms at younger ages, and are less likely to receive evidence-based medical treatment when compared to other races (Bibbins-Domingo, 2009; Peterson & Yancy, 2009). There are multiple factors that have been postulated to play a role in the increased prevalence including: a higher burden of risk factors like hypertension, a genetic predisposition to cardiomyopathy, and exposures to toxins such as drugs and alcohol (Roger et al., 2012; Schocken, 2008; Yancy, 2005). The age-adjusted incidence rate of HF per 1000 person-years is
3.4 for Caucasian women, 6.0 for Caucasian men, 8.1 for African American women, and 9.1 for African American men (Loehr, Rosamond, Chang, Folsom, & Chambless, 2008).

African Americans are likely to have more severe or disabling depressive disorder than individuals of Caucasian or Hispanic ethnicity (Sharma et al., 2009). There is limited evaluation of depression and HF in ethnic groups; some studies have found an increased prevalence of depression in African Americans with HF when compared to other races (Evangelista, Ter-Galstanyan, Moughrabi, & Moser, 2009; Gottlieb et al., 2009; Nair et al., 2012). Other studies have found no difference by race (Albert et al., 2009; Bean et al., 2009).

**Social Realm**

Within the social realm, factors included are: income sufficiency, living along, and social support (i.e., someone to talk with and someone to help). Studies will be discussed in each of these areas.

**Income sufficiency.** Only one study specifically discussed income level in relation to depressive symptoms in HF patients. Havranek in 2004 found four predictors of the development of depressive symptoms in HF patients: living alone, financial burden from medical care, alcohol abuse, and health status measured by the Kansas City Cardiomyopathy Questionnaire.

**Living alone.** One study found no difference in patients with depression (Becks Depression Inventory Score $\geq 10$) among those who live alone or those who lived with others (Gottlieb, 2004). However, another study (Havranek, 2004) reported that patients who developed depressive symptoms were nearly more than twice as likely to live alone than those who did not (40.4% vs 22.9%, $p = .02$).

**Social Support.** One study (Chung, Lennie, Dekker, Wu, & Moser, 2011) reported that poor social support from family, friends, and health care providers may play a role in worsening
health outcomes and quality of life in patients with HF. Chung et al. (2011) found that depressive symptoms and poor social support had a synergistic, negative effect on event-free survival in HF patients. Another recent study demonstrated that social support predicts changes in depression over time; patients in this study with low social support at baseline had increased depression over two years (Friedmann, Heesook, Thomas, Chapa, & Hyeon Joo, 2014). Another study reported that social support was a predictor of depressive symptoms, and further elaborated on the relationship by stating that social support mediated the relationship between HF physical symptoms (Heart Failure Symptom Survey) and depressive symptoms (Graven et al., 2015).

There are two main models, physiologic and behavioral, that explain how social support effects health outcomes. The physiologic model purports that social support provides a generalized positive affect that suppress the harmful neuroendocrine response to negative emotions such as depression and stressful events (Luttik, Jaarsma, Moser, Sanderman, & van Veldhuisen, 2005). Good social support can provide protection from stress and suppress the neuroendocrine system response. The behavioral model states that social support can influence health behaviors, which in turn affect health outcomes. Heart failure patients with social support may be more consistent with their medication and lifestyle changes, while those who are socially isolated may have difficulty changing harmful behavioral patterns (Luttik et al., 2005).

**Summary**

In summary, depression in patients with HF is a complex and commonly occurring problem. The combination of depression and HF lead to worsened health outcomes. However, it is likely these can be improved with the diagnosis and treatment of depression in this patient population. This study provides a more in-depth look into depressive symptoms in a group of individuals with HF. First, the knowledge gained in this study can guide health care providers in
identifying and treating depression in HF patients. Second, it can guide researchers by providing knowledge of possible patterns through use of repeated measures as well as the awareness of factors that are associated with depression.
CHAPTER THREE

METHODS

To better understand the prevalence and patterns of depressive symptoms in adults with HF the following five research questions will be addressed.

1) At baseline, what is the prevalence of depressive symptoms, measured by CES-D, in a sample of patients with a diagnosis of heart failure (HF) who was hospitalized for acute decompensation prior to enrollment in the SMAC-HF trial?

2) At baseline, is there a difference in depressive symptoms between the self-management care intervention group and the control group?

3) What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for the intervention and control groups?

4) What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for those receiving pharmacologic treatment for depression and those who are not by treatment group and gender?

5) What cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support) were associated with depressive symptoms at baseline?

This chapter describes the research design, the study sample and setting, the measurement of variables, and data analysis.
Research Design

This correlational study uses a secondary data analysis to evaluate the prevalence and patterns of depressive symptoms in adults with HF. Secondary data analysis provides the advantage of resource savings and cost effectiveness, as the data already collected included a depressive symptom measure that will likely be adequate to answer the proposed research questions.

The purpose of the original randomized, controlled clinical trial was to test the effects of multidisciplinary group clinic appointments for individuals with HF on the primary outcome of time to first HF rehospitalization or death (Smith et al., 2014). Depression, as well as many factors known to be associated with depression, were measured at five time points in this study, and the sample was from the target population, making this study a suitable fit for the proposed secondary data analysis. As is important when considering the suitability of secondary data analysis, the parent study: (a) produced high quality data with recently published findings, (b) utilized a research protocol, (c) had standard operations, and (d) had a codebook for the data set (Doolan, 2009). This study focused on the prevalence of depressive symptoms, differences between the intervention and control group, patterns over five time points over the course of a year, differences between those receiving pharmacologic treatment by intervention group and by gender, and what factors were associated with depressive symptoms.

Sample

Patients hospitalized for an exacerbation of HF were enrolled into a randomized controlled clinical trial of multidisciplinary group clinic appointments between March 2007 and April 2011. They were identified by a daily admission records review at a Midwestern academic medical center. Patients were hospitalized with HF and classified as New York Heart
Association (NYHA) Functional Classification III or IV, regardless of EF. Criteria for exclusion included: (a) evidence of transient, reversible HF, (b) a planned heart transplant, (c) end-stage renal disease (serum creatinine > 4mg/dl), (d) unresected malignancy or other terminal illness, (e) discharged to a nursing home, rehabilitation unit, or extended care facility, (f) any condition that would prevent engagement in the intervention including blindness, deafness, dementia, cognitive deficiency, or (g) could not write and speak English (Smith et al., 2014).

The NYHA classification system frequently is used in research during selection and stratification of subjects as well as the measurement of research outcomes (Bennett, 2002; Faller et al., 2009; Pressler et al., 2011; Rohyans & Pressler, 2009). Class III are patients that: (a) have cardiac disease resulting in marked limitation of physical activity, (b) are comfortable at rest, or (c) less than ordinary physical activity causes fatigue, palpitation, dyspnea, or anginal pain. Class IV patients have: (a) cardiac disease resulting in the inability to carry on any physical activity without discomfort, (b) symptoms of HF or (c) anginal syndrome that may be present even at rest, if any physical activity is undertaken the discomfort increases (Bennett, 2002). Only those subjects that were identified as Class III or IV were included in this study.

A total of 774 patients were found to meet the criteria for enrollment; of these 198 (26%) were enrolled. The top reasons for not enrolling in the study were patients were “not interested” or they were unable to be reached by study personal within two weeks of discharge. A total of 198 study subjects were placed into blocks of four to eight subjects based on time of enrollment; then the blocks of subjects were assigned randomly to receive standard care \( n = 106 \) or intervention \( n = 92 \). Of the 198 patients in the parent study, 15.15% \( n = 30 \) withdrew over the course of the study from baseline to 12 months. The reasons for withdrawal were as follows: died \( n = 18 \), lost contact \( n = 9 \), new illness \( n = 2 \), and too busy \( n = 1 \) (Piamjariyakul, 2015).
Setting

Subjects were recruited and enrolled from a cardiology clinic at a Midwestern academic medical center affiliated hospital. The intervention subjects had group appointments at a building attached to the hospital in which they were recruited.

Procedures

Prior to subject recruitment for the primary study, Institutional Review Board (IRB) approval was obtained. IRB approval for non-human subject research approval was obtained prior to the de-identified data being provided by the original research team. Data were transferred through secure email and kept on a secure computer for this study. Nurses with special training in the area of trial enrollment procedures completed the informed consent and baseline data collection (Smith et al., 2014). Double entry of data by independent operators with comparison to verify accuracy was completed. Also, to verify accuracy of the medical record data, three people recorded and reviewed the data. Patients were enrolled during or within two weeks following hospitalization.

During and after hospitalization, health care and HF treatment teams continued treating both arms of the study (Smith et al., 2014). The SMAC-HF intervention included four weekly group visit appointments and a booster appointment at six months. Each group visit included the following multidisciplinary team: a nurse practitioner with HF experience, a mental health clinical nurse specialist, a social worker, a counselor, and a dietician (Smith et al., 2014). The depression screening was obtained with other data at the beginning of each group clinic appointment. The control patients had follow-up data collection at the same time intervals as the intervention group. Patients in both group assignments were given a short HF DVD series to standardize the education information across both groups (Smith et al., 2014). To reduce subject
risk, the parent study protocol included a referral for all patients with severe depression (CES-D score of 20 or greater) for consultation with a psychiatric Clinical Nurse Specialist.

During the course of the study 75 subjects were referred to a mental health clinical nurse specialist due to CES-D scores of greater than 20 (Piamjariyakul, 2015). The topics discussed in the referrals including situational grief or depression over limitations in functional capacity or role reversal, anger or regret associated with chronic illness, psychiatric problems with new diagnosis, family issue including lack of support, and financial problems. The follow-up counseling that was provided included coping strategies, referral to a physician for initiation or adjustment of psychiatric medications, and referral to mental health agencies (Piamjariyakul, 2015).

**Measures**

The Biopsychosocial Holistic Model of Cardiovascular Health (BHMCH) and review of literature were used to select variables that were addressed in this study. Variables representing the psychological, biological, and social realms, as well as the measures of overall cardiovascular health, were selected for inclusion in this study.

**Heart Failure**

In the proposed study, HF was measured by: patients hospitalized with NYHA class III or IV HF, but not required to have a reduced left ventricular ejection fraction (EF).

**Dependent Variable/Psychological Realm**

Two variables from the psychological realm, depressive symptoms and pharmacologic treatment for depression, were included in this study.

**Depressive symptoms.** Depressive symptoms, the dependent variable in the study, were measured by the short Center for Epidemiologic Studies Depression Scale (CES-D) (See Table
1. The short CES-D is a self-administered 10-item scale commonly used to measure depressive symptoms (see Appendix A). The scale was developed for use in the general population in studies of epidemiology of depressive symptoms (Radloff, 1977). The intended purpose of the scale is to measure the current level of depressive symptoms with an emphasis on the affective component, depressed mood; it should be noted that it is not intended to be used for diagnosis (Radloff, 1977). The CES-D measured depressive symptoms experienced over the past four weeks, making it time sensitive and more likely to detect reactive or situational depression. Responses were ranked using a Likert-type scale with responses ranging from zero (less than one day a week) to three (five to seven days a week). Response scores were summated and the final score ranged from 0 to 28 with higher scores reflecting greater levels of depressive symptoms (Ancheta et al., 2009). Generally a score of greater than 16 is used to define patients at risk for clinical depression in the CES-D 20 item, the value of greater than or equal to 10 has been proposed for the CES-D 10 item (Andresen, Malmgren, Carter, & Patrick, 1994; Jaarsma et al., 2010).

Initial testing of the scale demonstrated high internal consistency ($\alpha = 0.85$), acceptable test-retest stability ($r = 0.45$ to 0.70), strong concurrent validity by clinical and self-report criteria, and substantial evidence of construct validity (Radloff, 1977). The short CES-D 10-item questionnaire has been validated against the full-length 20-item CESD and shown to have good predictive accuracy (kappa= 0.97, $p < .001$) (Andresen et al., 1994; Furukawa et al., 1997; Kohout, Berkman, Evans, & Cornoni-Huntley, 1993). The CES-D successfully has been used to screen for depressive symptoms in heart failure patients (Ancheta et al., 2009; Bowden et al., 2011; Lesman-Leegte, Jaarsma, Sanderman, Hillege, & van Veldhuisen, 2008; Sullivan et al.,
2009; van den Broeck et al., 2011) and is sensitive to changes in depressed mood over time (Park, Fenster, Suresh, & Bliss, 2006).

Reliability analysis was completed on the CES-D scale at each time point it was administered for this study. In the secondary data analysis, the CES-D 10 scale had a high internal consistency at all time points during this study as measured by Cronbach’s alpha’s of 0.85 at baseline, 0.88 at three months, 0.87 at six months, 0.86 at nine months, and 0.84 at one year. Information on depressive symptoms reported by subjects were followed over the course of 12 months for the current study, as this was the length of time the parent study protocol followed the subjects; information was not collected beyond the 12-month timeframe.

Pharmacologic treatment. Pharmacologic treatment was defined as the use of an antidepressant and was the second psychological factor that was addressed in this study. The medication lists at three data collection points were reviewed and a variable was created for each subject, sorted into either taking (1) or not taking (0) antidepressants. Antidepressants from the following classes were included: Selective Serotonin Reuptake Inhibitors (SSRIs), tricyclic antidepressants (TCAs), Selective Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), 5-HT2 Antagonists, Monoamine Oxidase Inhibitors (MAOIs), and other/combination (bupropion, Brintellix, Viibryd).
Table 1.

*Description of Study Variables*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Descriptions</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control/Intervention Groups</td>
<td>All participants were in either the control or intervention group</td>
<td>1=treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2= control</td>
</tr>
<tr>
<td>Depressive Symptoms</td>
<td>Depression score measured by the short Center for Epidemiologic Studies Depression Scale (CES-D)</td>
<td>Continuous; Higher score=more depressed</td>
</tr>
<tr>
<td>Pharmacologic Treatment</td>
<td>Taking antidepressant [for example, Selective Serotonin Reuptake Inhibitors (SSRIs), tricyclic</td>
<td>1=Yes 0= No</td>
</tr>
<tr>
<td></td>
<td>antidepressants (TCAs), Selective Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs), 5-HT2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antagonists, Monoamine Oxidase Inhibitors (MAOIs), etc.]</td>
<td></td>
</tr>
<tr>
<td>Length of HF diagnosis</td>
<td>Length of time patient has had HF diagnosis (in days)</td>
<td>Continuous</td>
</tr>
<tr>
<td>EF</td>
<td>Ejection fraction, fraction of the end-diastolic ventricular volume ejected</td>
<td>Continuous</td>
</tr>
<tr>
<td>Charlson Comorbidity Index</td>
<td>Charlson Comorbidity Index</td>
<td>Higher score = more comorbidity</td>
</tr>
<tr>
<td>Gender</td>
<td>Gender</td>
<td>1=male 2=female</td>
</tr>
<tr>
<td>Age</td>
<td>Age of participant calculated as date of T1 survey minus year of birth</td>
<td>Continuous</td>
</tr>
<tr>
<td>Race</td>
<td>Race/ethnicity as reported by subjects</td>
<td>1= Black or African American 0= Others</td>
</tr>
<tr>
<td>Income Sufficiency</td>
<td>Monthly Income</td>
<td>1=can’t make ends need 2=have enough no</td>
</tr>
<tr>
<td></td>
<td></td>
<td>more 3=enough little extra sometimes 4=</td>
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<td></td>
<td></td>
<td>always have money left over</td>
</tr>
<tr>
<td>Live Alone</td>
<td>Live alone</td>
<td>1=live alone 2=live with someone else</td>
</tr>
<tr>
<td>Measure</td>
<td>Descriptions</td>
<td>Values</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Social Support Scale</td>
<td>Two item scale; 1&lt;sup&gt;st&lt;/sup&gt; item measures having someone to talk to; 2&lt;sup&gt;nd&lt;/sup&gt; item measures having someone to help</td>
<td>Range =1-5; Higher score = more social support</td>
</tr>
</tbody>
</table>

**Cardiovascular Health Markers**

The cardiovascular health markers were obtained through medical record data retrieval after the patient consented to be included as a study subject and signed a release of their medical record data. The variables included: (a) length of HF diagnosis, (b) ejection fraction (EF), and (c) Charlson Comorbidity Index.

**Length of heart failure diagnosis.** This variable was retrieved from the medical record and was recorded as number of days since the date of diagnosis with HF.

**Ejection Fraction.** EF is one of most commonly used measurements of systolic function. The EF is the fraction of the end-diastolic ventricular volume ejected (Butterworth et al., 2013). Normal EF is $0.67 \pm 0.08$ (Butterworth et al., 2013). EF can be measured during cardiac catheterization, radionucleotide studies, or transthoracic or tranesophageal echocardiography. EF was a continuous variable.

**Charlson Comorbidity Index.** The Charlson Comorbidity Index is the most extensively studied comorbidity index for predicting mortality (de Groot, Beckerman, Lankhorst, & Bouter, 2003). Comorbidity is measured because it can threaten internal validity, acting as a cofounder, or threaten external validity, acting as an effect modifier in studies (de Groot et al., 2003). The index includes 17 diseases that have been selected and weighted on the basis of the strength of their association with mortality. The disease states included are as follows: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease,
dementia, chronic pulmonary disease, rheumatic disease, peptic ulcer disease, mild liver disease, diabetes without chronic complications, diabetes with chronic complications, hemiplegia or paraplegia, renal disease, any malignancy, moderate or severe liver disease, metastatic solid tumor, and AIDS/HIV (Austin, Wong, Uzzo, Beck, & Egleston, 2015).

Concurrent validity of the Charlson Comorbidity Index was supported in four out of six comparisons with other comorbidity indices; predictive validity has been confirmed; and correlations in anticipated directions with variables supported construct validity. Test-retest reliability was good and interrater reliability was moderate to good (de Groot et al., 2003). The final score is a sum of weights, and it has been used successfully in patients with heart disease. A score of zero indicated no comorbidities and the higher the score the more likely the predicted outcome would result in higher resource use or mortality (Charlson et al., 1987). In the original study the researchers used diagnoses from any hospitalizations in the past year as well as data from the medical record to maximize the sensitivity of identifying comorbidities.

**Biological Realm**

The patient demographic form included three self-reported variables: (a) gender (measured as male = 1 or female = 2), (b) age (measured as a continuous variable), and (c) race (measured by categories [African American = 1, Caucasian = 2, and other = 3]) (see Table 1).

**Social Realm**

The variables selected to represent the social realm include: (a) income sufficiency, (b) whether or not the subject lives alone, and (c) a Social Support Scale (see Table 1).

**Income sufficiency.** Income sufficiency was measured by a single-item question, which states, “Which of the following statements describes your ability to get along on your monthly income?” Responses to this question were as follows: 1 (I can’t make ends meet), 2 (I have just
enough, no more), 3 (I have enough, with a little extra sometimes), or 4 (I always have money
left over).

**Live alone.** The question used to measure whether or not participants lived alone, was a
fill in the blank question. The questions stated, “Counting yourself, how many people live in
your household?” This was re-coded as either lives alone (1) or does not (0).

**Social Support.** The Social Support Scale was the mean of two single items with
responses ranging from one to five. A higher score indicated more social support (the responses
below are reverse coded). The first question (someone to talk to) states, “During the past 4 weeks
if you.... felt very nervous, lonely or blue; got sick and had to stay in bed; needed help with daily
chores; or needed help just taking care of yourself. If you needed someone to listen or to help
you, was someone there for you?” The second question (someone to help) stated, “Was someone
available to help you if you needed and wanted help?” Responses were as follows for both social
support questions: 1 (Yes, as much as I wanted), 2 (Yes, quite a bit), 3 (Yes, some), 4 (Yes, a
little) or 5 (No, not at all).

For this study a Social Support Scale was created using responses from the two social
support questions listed above. The decision to create the scale was made because the responses
of the two items were highly correlated with each other, \( r = .80 \) \( (p < .005) \). In this secondary data
analysis, the Social Support Scale, when measured at baseline, had a high level on internal
consistency as measured by *Cronbach’s alpha’s* of 0.88 at baseline.

**Analytic Approach**

After obtaining the de-identified data, data analysis occurred in several phases. To verify
accurate transfer of the data descriptive statistics were calculated and compared to those reported
in the parents study (Doolan, 2009). The number of subjects reported by the parent study was
verified in the data set for this study (Doolan, 2009). Power calculations were completed to ensure the sample size available ($n=198$) provides adequate power to investigate the proposed research questions. Using Greens rule-of-thumb, with a Power of 0.80, Alpha = 0.05, with a medium effect size, and 12 predictors 127 subjects would be needed (Green, 1991).

The data analysis was completed using SPSS 23 for Mac. Descriptive statistics were computed to characterize the sample and to describe study variables. Response rate were calculated and were reported when appropriate. Scatterplots and descriptive statistics were examined for outliers and distributional characteristics. Specifically, for CES-D a histogram was completed to check for normality of the data. A Q-Q plot was completed to check the assumption of normality. The presence of missing data and outliers were examined and it was determined that no procedures were required to replace missing data, except for in the pharmacologic treatment data. In the pharmacologic treatment data there was 1% missing data at baseline, 12.6% at six months and 22.2% at 12 months. After finding no features consistent within those with missing data the decision to carry forward the last observation was made and utilized for the three pharmacologic treatment variables. Some of the subjects with missing data either withdrew from the study or died during the course of the study.

**Research Question 1**

Research question one was: At baseline, what is the prevalence of depressive symptoms, measured by CES-D, in a sample of patients with a diagnosis of heart failure who was hospitalized for acute decompensation prior to enrollment in the SMAC-HF trial? Descriptive statistics were used to describe the level of depressive symptoms at baseline using CES-D means and standard deviations.
Research Question 2:

Research question two was: At baseline, is there a difference in depressive symptoms between the self-management care intervention group and the control group? The assumptions of the t-test were checked and discussed in the results chapter. Differences in the depressive symptoms score between the two groups were going to be compared using a *t-test*, however due to assumption of normality violation a Mann-Whitney U test was completed.

Research Question 3

Research question three was: What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for the intervention and control groups? Means and 95% confidence intervals (CI) were computed and plotted for each time point. The percent of patients depressed were graphed over time for the intervention and control groups. Paired t-tests were completed for each group assignment to measure change in depressive symptoms from baseline to 12 months. The change score was calculated by subtracting the CES-D score at 12 months from the CES-D score at baseline for each participant. Additionally, an independent sample t-test was completed to determine if there were differences in change scores between the intervention and control groups from baseline to 12 months.

Research Question 4

Research question four was: What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for those receiving pharmacologic treatment for depression and those who are not by treatment group and gender? Descriptive statistics were used to further describe the relationship between depressive symptoms with gender and pharmacologic treatment. The mean
CES-D scores were plotted over time by gender to determine the patterns of depressive symptoms. Paired samples t-tests were completed for each gender and by pharmacologic treatment to measure change in depression from baseline to 12 months. The patients in the sample were divided into eight groups based on treatment group, gender, and baseline pharmacologic treatment. The mean CES-D score were plotted over time for each of these eight groups.

**Research Question 5**

Research question five was: What cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support) were associated with depressive symptoms at baseline? Pairwise associations between the variable of interest and CES-D were completed. Appropriate statistical analysis were completed to determine if the selected variables have a statistically significant relationship ($p<.05$) with depressive symptoms, measured by the CES-D. Variable were entered in blocks based on the biological, psychological, and social factors to examine the linear weighted combination of variables that explain depressive symptoms.

Prior to interpreting the regression, evaluation of the assumptions of regression was conducted: normality, linearity, independence, non-multicollinearity and constance of variance. A histogram and normal probability plot were used to check for normality. To evaluate linearity the pairwise associations between each independent variable and the dependent variable, as well as the partial plots for the independent variables, were assessed. Constancy of variance was examined by checking the scatter plots for any patterns. Possible multicollinearity was addressed by looking at the bivariate correlation matrix, also the tolerance and Variance Inflation Factor.
Durbin-Watson were used to check for independence. Case wise diagnostics was used to check for outliers.

**Ethical Considerations**

The SMAC-HF trial was reviewed and approved by the Institutional Review Board of a Midwestern academic medical center and had annual review during the study duration. During the parent study, progress was reviewed and approved by a Data Safety and Monitoring Board (Smith et al., 2014). Only de-identified data were used for this project to protect the confidentiality and anonymity of subjects.
CHAPTER FOUR

RESULTS

The purpose of this study was to evaluate the prevalence and patterns of depressive symptoms in adults with HF. Chapter four presents the demographic characteristics of participants in the study as well as results of the five research questions included in the secondary data analysis. All findings are summarized at the end of the chapter.

Results

Demographic Characteristics

Table 2 presents the patient baseline characteristics between groups that include means, standard deviation, and percentages. The age of patients participating in the study ranged from 24 to greater than 90 years old, with a mean of 62.3 years. The mean ejection fraction was 30.31% and ranged from 7% to 72%. The number of days patients had been diagnosed with HF ranged from four to 14,146, with a mean of 2,258 days. In regards to income, 19.7% (n= 39) of patients reported they can’t make ends meet; 33.8% (n= 67) have enough and no more; 31.3% (n= 62) have enough with little extra sometimes; and 14.1% (n= 28) always have money left over. There were complete CES-D data for all subjects (n= 198) at baseline. Due to subject attrition over the course of the 12 months of the data collection, missing data were as follows: (a) three months, 8.1% (n= 16); b) six months, 11.1% (n=22); (b) nine months, 19.2% (n= 38); and (d) 12 months, 17.2% (n = 34).
Table 2.

*Patient Baseline Characteristics*

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=198)</th>
<th>Intervention (n=92)</th>
<th>Standard Care (n=106)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, M (SD)</td>
<td>62.3 (13.2)</td>
<td>62.6 (14.1)</td>
<td>62.1 (12.5)</td>
<td>0.78</td>
</tr>
<tr>
<td>Male Gender, n (%)</td>
<td>122 (61.6)</td>
<td>52 (56.5)</td>
<td>70 (66.0)</td>
<td>0.17</td>
</tr>
<tr>
<td>African American, n (%)</td>
<td>87 (44)</td>
<td>35 (38.0)</td>
<td>52 (49.1)</td>
<td>0.12</td>
</tr>
<tr>
<td>Caucasian, n (%)</td>
<td>105 (53)</td>
<td>52 (56.5)</td>
<td>53 (50.0)</td>
<td>0.36</td>
</tr>
<tr>
<td>Live Alone, n (%)</td>
<td>60 (30.3)</td>
<td>22 (23.9)</td>
<td>38 (35.8)</td>
<td>0.06</td>
</tr>
<tr>
<td>Married, n (%)</td>
<td>83 (41.9)</td>
<td>42 (45.7)</td>
<td>41 (38.7)</td>
<td>0.32</td>
</tr>
<tr>
<td>Has Children under 18, n (%)</td>
<td>27 (13.6)</td>
<td>12 (13.0)</td>
<td>15 (14.2)</td>
<td>0.84</td>
</tr>
<tr>
<td>Currently employed for pay, n (%)</td>
<td>32 (16.2)</td>
<td>16 (17.4)</td>
<td>16 (15.1)</td>
<td>0.66</td>
</tr>
<tr>
<td>Ejection Fraction (%), M (SD)</td>
<td>30.31 (16.1)</td>
<td>30.64 (15.6)</td>
<td>30.0 (16.6)</td>
<td>0.79</td>
</tr>
<tr>
<td>Charlson Comorbidity Index, M (SD)</td>
<td>3.3 (1.7)</td>
<td>3.4 (1.8)</td>
<td>3.2 (1.6)</td>
<td>0.29</td>
</tr>
<tr>
<td>Antidepressant Use, n (%)</td>
<td>42 (21.2)</td>
<td>17 (18.5)</td>
<td>25 (23.6)</td>
<td>0.40</td>
</tr>
</tbody>
</table>

**Research Question 1**

At baseline, what is the prevalence of depressive symptoms, measured by CES-D, in a sample of patients with a diagnosis of heart failure who was hospitalized for acute decompensation prior to enrollment in the SMAC-HF trial?

Descriptive statistics (e.g., means, standard deviations) were calculated to describe the prevalence of depressive symptoms at baseline in the SMAC-HF trial. The baseline mean CESD
score for the whole sample was 8.94 (SD= 6.55); scores ranged from 0-28 (see Table 3). The histogram depicts the distribution of scores (Figure 2). The findings suggest that most patients did not have clinically significant depressive symptoms. A score of greater than or equal to 10 has been proposed for diagnosing depression for the CES-D 10 item (Andresen et al., 1994; Jaarsma et al., 2010). Using the cut off score of greater than or equal to 10, at baseline 83 participants or 41.9% of the sample were clinically depressed.

Table 3.

*Patient Baseline CES-D scores*

<table>
<thead>
<tr>
<th></th>
<th>Overall (N=198)</th>
<th>Intervention (n=92)</th>
<th>Standard Care (n=106)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CES-D score</strong></td>
<td>8.94 (6.6)</td>
<td>8.92 (6.0)</td>
<td>8.95 (7.0)</td>
<td>0.68</td>
</tr>
</tbody>
</table>
Research Question 2

At baseline, is there a difference in depressive symptoms between the self-management care intervention group and the control group?

The mean CES-D score at baseline for the control group was 8.95 ($SD = 7.00$), ranging from 0-28. The mean CES-D score at baseline for the intervention group was 8.92 ($SD = 6.04$) ranging from 0-24 (see Table 3). The assumptions for the independent t-test were checked. No significant outliers were noted in CES-D by group assignment, as assessed by inspection of a
boxplot. However, the variable was not normally distributed, as evidenced by positive skewness on histograms and a control skewness z-score of 3.17. Due to baseline CES-D violating the assumption of normality it was decided to test the difference in depression scores between groups using the Mann-Whitney U test.

The assumptions of the Mann Whitney U test were checked. The final assumption of the Mann-Whitney U test was met by visually inspecting the shapes of the population pyramid and noting the distributions are similar. The median CES-D scores at baseline were not significantly different ($U= 5,043, z=.42, p=.68$) between the intervention group ($median= 8$) and control group ($median=7$).

**Research Question 3**

What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for the intervention and control groups?

The mean CES-D scores were plotted over time by group assignment to determine the patterns of depressive symptoms. The graph of the mean CES-D scores over time (see Figure 3) reveals that the intervention and control groups both had a decrease in depressive symptoms over time.
Since the mean CES-D score is below the cut-off for depression (CES-D score of $\geq 10$), it is important to look at the percentages of patients depressed over time in the study. Figure 4 depicts the percent of HF patients with depression (CES-D score of $\geq 10$) and shows that it decreased over time in both the control and intervention groups.
Figure 4. Percent of Patients Depressed by Group Assignment

To quantify further the patterns of depressive symptoms by group assignments paired $t$-tests were completed for each group assignment to measure change in depressive symptoms from baseline to 12 months. The assumptions for the paired-sample $t$-test were checked. One significant outlier was assessed by inspection of a boxplot. Further investigation revealed the one outlier case was female, in the control group, and not taking pharmacologic treatment for depression the entire study. This outlier case had a decrease in CES-D scores from 28 at baseline to a score of three at 12 months. The decision was made to retain this case, as the scores for this subject were consistent across time periods (13, 15, and 13 at 3, 6 and 9 months, respectively).
The difference scores from baseline CES-D to 12 month CES-D were normally distributed, as assessed by visual inspection of a Q-Q plot.

Both group assignments noted a statistically significant \((t_{(73)}= 3.90, p< .001)\) mean decrease in depressive symptoms over time; the control group with a mean decrease of 3.40 \((SD= 5.99)\), \(t_{(89)}= 5.38, p< .001\), and the intervention group with a mean decrease of 2.80 \((SD= 6.17)\). An independent sample \(t\)-test was completed to determine if there was a difference in change scores between the intervention and control groups from baseline to 12 months. There was no statistically significant difference \((t_{(154.14)}= -0.63, p= .53)\) in mean CES-D changes scores between the intervention \((M= 2.80, SD= 6.17)\) and control \((M= 3.40, SD= 5.99)\).

**Research Question 4**

What are the patterns of depressive symptoms, measured by CES-D, in heart failure patients at five time periods (baseline, 3 months, 6 months, 9 months, and 12 months) for those receiving pharmacologic treatment for depression and those who are not by treatment group and gender?

Descriptive statistics were used to further describe the depressive symptoms differences based on gender and pharmacologic treatment. At baseline, females had more depressive symptoms than males did. The mean CES-D score at baseline was 10.08 \((SD= 7.33)\) for females and 8.23 \((SD= 5.94)\) for males. There was a statistically significant difference \((t_{(122.76)}= -1.95, p= .05)\) in mean CES-D scores between males and females at baseline. At baseline 46.1% of females were depressed, while only 39.3% of males had a CES-D score of greater than or equal to 10, which is the cut-off score for depression. At baseline, 31.6\% (n= 24) of females and 14.8\% (n= 18) of males were on pharmacologic therapy for depression. The number of patients on
pharmacologic treatment increased for both control and intervention groups over the course of the study (see Table 4).

Table 4.

Percent of Patients on Pharmacologic Treatment for Depression by Group Assignment

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 Months</th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>23.6%</td>
<td>26.4%</td>
<td>29.2%</td>
</tr>
<tr>
<td>Intervention Group</td>
<td>18.5%</td>
<td>21.7%</td>
<td>24.2%</td>
</tr>
</tbody>
</table>

The mean CES-D scores were plotted over time by gender to determine the patterns of depressive symptoms. Figure 5 shows the mean CES-D scores over time for male and female participants. The graph reveals that both genders had reduction in depressive symptoms over the course of the study. Paired samples *t*-test did demonstrate that both genders noted a statistically significant mean decrease in depressive symptoms over 12 months; males had a mean decrease of 2.53 (*SD*= 5.82), *t*(99)= 4.35, *p* < .001, and females had a mean decrease of 4.06 (*SD*= 6.36), *t*(63)= 5.11, *p* < .001.
Despite group assignment, those on pharmacologic treatment for depression had higher CES-D scores at baseline than those who were not. Both those taking and those not taking pharmacologic treatment for depression at baseline had decreased mean CES-D scores throughout the study regardless of group assignment (see Table 5). Paired *t*-test results revealed both those taking and those not taking pharmacologic treatment at baseline noted a statistically significant mean decrease in depressive symptoms from baseline to 12 months; those on pharmacologic treatment had a mean decrease of \(5.00 (SD=6.20), t_{(35)}=5.84, p<.001\), and those not on pharmacologic treatment had a mean decrease of \(2.60 (SD=5.97), t_{(126)}=4.91, p<.001\).
Table 5.

*Mean CES-D Scores Over Time by Group Assignment and Pharmacologic Treatment*

<table>
<thead>
<tr>
<th>Group Assignment</th>
<th>Pharmacologic Treatment</th>
<th>Baseline CES-D Mean</th>
<th>3-Month CES-D Mean</th>
<th>6-Month CES-D Mean</th>
<th>9-Month CES-D Mean</th>
<th>12-Month CES-D Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>No</td>
<td>8.04</td>
<td>7.15</td>
<td>5.52</td>
<td>5.01</td>
<td>4.94</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>11.92</td>
<td>10.35</td>
<td>8.75</td>
<td>10.43</td>
<td>7.27</td>
</tr>
<tr>
<td>Intervention</td>
<td>No</td>
<td>8.26</td>
<td>6.18</td>
<td>6.08</td>
<td>5.51</td>
<td>5.49</td>
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<tr>
<td></td>
<td>Yes</td>
<td>12.00</td>
<td>7.65</td>
<td>8.88</td>
<td>4.93</td>
<td>6.64</td>
</tr>
</tbody>
</table>

The patients in the sample were divided into eight groups based on treatment group (intervention/control), gender (male/female), and baseline pharmacologic treatment (yes/no). The mean CES-D score were plotted over time for each of these eight groups. In order to ease comparison, two separate graphs for males and females (see Figure 6 and Figure 7) were created. The group with the highest baseline depression level was the control female group taking pharmacologic treatment. All groups experienced decreases in depressive symptoms over the course of the study. The males not receiving pharmacologic treatment at baseline in the control and intervention groups appeared to have the smallest decrease in depressive symptoms over the course of the study.
Figure 6. Mean CES-D Scores by Group Over Time for Males
Figure 7. Mean CES-D Scores by Group Over Time for Females

**Research Question 5**

What cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support) were associated with depressive symptoms at baseline?
Multiple regression analysis was conducted to examine which predictors influence depressive symptoms in HF patients. Assumptions of regression were checked: (a) independence of residuals, as assessed by a Durbin-Watson statistic of 1.93, was met, (b) assessment of linear relationships by scatter plot of the studentized residuals and unstandardized predicted values showed a linear relationship; (c) partial regression plots with the continuous variables showed linear relationships; and (d) the partial regression plot used to check for homoscedasticity showed that the residuals were mostly equal for all values of the predicted dependent variable.

Multicollinearity was assessed by reviewing the correlation table (see Table 6). All Tolerance values were greater than 0.1 and all VIF values were less than 10.0. The histogram and P-P plot both revealed the normality assumption was not violated. The assumptions of linearity, independence of errors, homoscedasticity, and normality of residuals were met.

Table 6 depicts the Pearson product-moment correlation coefficients among the independent variables and with the dependent variable (CES-D). There were negative small to moderate correlations between baseline CES-D scores and age ($r = -.22$), income sufficiency ($r = -.34$), and the social support scale ($r = -.45$). There was a positive correlation between baseline CES-D score and Pharmacologic drug use ($r = .25$).
Table 6.

*Correlation among All Study Variables (n= 191).*

<table>
<thead>
<tr>
<th></th>
<th>CESD</th>
<th>LOHF</th>
<th>EF</th>
<th>CCI</th>
<th>Sex</th>
<th>Age</th>
<th>AA</th>
<th>PT</th>
<th>IS</th>
<th>LA</th>
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<td>CCI</td>
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<td>.23**</td>
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<tr>
<td>Sex</td>
<td>-.15*</td>
<td>.17**</td>
<td>-.21*</td>
<td>.03</td>
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<td>-</td>
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</tr>
<tr>
<td>Age</td>
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<td>.15*</td>
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<td>-.11</td>
<td>-.14*</td>
<td>-.14*</td>
<td>-.34**</td>
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<td>.13*</td>
<td>-.18**</td>
<td>-.02</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IS</td>
<td>-.34**</td>
<td>.07</td>
<td>.13*</td>
<td>.07</td>
<td>.26**</td>
<td>.51**</td>
<td>-.33**</td>
<td>-.03</td>
<td>-</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LA</td>
<td>.12*</td>
<td>-.06</td>
<td>.02</td>
<td>.04</td>
<td>-.02</td>
<td>-.04</td>
<td>.06</td>
<td>.09</td>
<td>-.06</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>SSS</td>
<td>-.47**</td>
<td>.01</td>
<td>.06</td>
<td>.07</td>
<td>.21**</td>
<td>-.17*</td>
<td>-.07</td>
<td>.31**</td>
<td>-.25**</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

Key: CESD = CES-D Score, LOHF = Length of HF Diagnosis in Days, CCI = Charlson Comorbidity Index, Sex = Male, AA = African American, PT = Pharmacologic Treatment for Depression, IS = Income Sufficiency, LA = Lives Alone, and SSS = Social Support Scale.

*p < .05; **p < .01

A multiple regression analysis was conducted to explain the variance in depressive symptoms using the following variables: cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support). Regression results indicate that the overall model
significantly predicted depressive symptoms ($F_{(10, 180)} = 9.18, \ p< .0005), R- squared = 0.34, adjusted R-Squared = 0.30$. This model accounts for 30.0% of the variance in depressive symptoms in patients with HF. A summary of regression coefficients is presented in Table 7 and indicates pharmacologic treatment, income sufficiency, and the social support scale were the only variables that added statistical significance ($p<.05$) to the explained variance. The Charlson Comorbidity Index was approaching the significance cut-off, and it was categorized into high and low levels of comorbidity, but follow-up analysis with recoded variables was still not statistically significant. Age also had a correlation ($r = -.22$) with depressive symptoms; however, it was not significant in the model testing. This could be due to moderate correlation of age with income sufficiency ($r = .51$), indicating that because of their shared variance, income sufficiency became the significant variable in the model.
Table 7.

*Regression Coefficients for Variables explaining the Variance in CES-D*

<table>
<thead>
<tr>
<th>Variable</th>
<th>$r$</th>
<th>$b$-weight</th>
<th>Std.Error</th>
<th>Beta</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days with HF</td>
<td>.07</td>
<td>.00</td>
<td>.00</td>
<td>.08</td>
<td>.20</td>
</tr>
<tr>
<td>EF</td>
<td>.02</td>
<td>.02</td>
<td>.03</td>
<td>.05</td>
<td>.49</td>
</tr>
<tr>
<td>CCI</td>
<td>.09</td>
<td>.43</td>
<td>.26</td>
<td>.11</td>
<td>.09</td>
</tr>
<tr>
<td>Male</td>
<td>-.15</td>
<td>-.48</td>
<td>.89</td>
<td>-.04</td>
<td>.59</td>
</tr>
<tr>
<td>Age</td>
<td>-.22</td>
<td>-.04</td>
<td>.04</td>
<td>-.08</td>
<td>.27</td>
</tr>
<tr>
<td>African American</td>
<td>.13</td>
<td>.41</td>
<td>.88</td>
<td>.03</td>
<td>.65</td>
</tr>
<tr>
<td>PT</td>
<td>.25</td>
<td>3.12</td>
<td>1.00</td>
<td>.20</td>
<td>.00</td>
</tr>
<tr>
<td>Income Sufficiency</td>
<td>-34</td>
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<td>.52</td>
<td>-.17</td>
<td>.03</td>
</tr>
<tr>
<td>Live Alone</td>
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<td>-.12</td>
<td>.88</td>
<td>-.01</td>
<td>.90</td>
</tr>
<tr>
<td>SSS</td>
<td>.47</td>
<td>-2.14</td>
<td>.36</td>
<td>-.39</td>
<td>.00</td>
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</tbody>
</table>

Key: HF = Heart Failure, EF = Ejection Fraction, CCI = Charlson Comorbidity Index, PT = Pharmacologic Treatment, SSS = Social Support Scale

For parsimony, the linear regression was conducted including only the variables that were statistically significantly ($p < .05$) in explaining the variance of CES-D. The variables included in the second regression analysis were: pharmacologic treatment, income sufficiency, and the Social Support Scale. The final model, which accounts for 30% of variance in depressive symptoms in patients with HF can be viewed in Table 8. The regression coefficients from the final model analysis (see Table 9) showed that the following variables were significant ($p < .05$) in explaining the variance in CES-D at baseline: pharmacologic treatment, income sufficiency, and the social support scale.
Table 8.

*Final Model Summary*

<table>
<thead>
<tr>
<th>Model</th>
<th>R</th>
<th>R Square</th>
<th>Adjusted R Square</th>
<th>Std. Error of the Estimate</th>
<th>F</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final</td>
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<td>.31</td>
<td>.30</td>
<td>5.43</td>
<td>21.31</td>
<td>.00</td>
</tr>
</tbody>
</table>

Table 9.

*Final Model Regression Coefficients*

<table>
<thead>
<tr>
<th>Variable</th>
<th>b weight</th>
<th>Std. Error</th>
<th>Beta</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Pharmacologic Treatment</td>
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<td>.00</td>
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<tr>
<td>Income Sufficiency</td>
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<td>-.22</td>
<td>.00</td>
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<tr>
<td>Social Support Scale</td>
<td>-2.10</td>
<td>.35</td>
<td>-.38</td>
<td>.00</td>
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</table>

Summary of Findings

Depressive symptoms were present in the sample of HF patients from this study. The baseline mean CES-D score for the whole sample was 8.94 (SD= 6.55) and 83 participants or 41.9% of the sample were clinically depressed (CES-D Score ≥10). The median CES-D scores at baseline were not statistically significantly different between the intervention group and control group. The intervention and control groups both had a decrease in the percent of patients with depression and reported depressive symptoms over time. There was not a statistically significant difference in mean CES-D changes scores between the intervention and control groups.
At baseline, females had more depressive symptoms than males. At baseline, 31.6% of females and 14.8% of males were on pharmacologic therapy for depression. The number of patients on pharmacologic treatment increased for both control and intervention groups over the course of the study. Both genders had a reduction in depressive symptoms over the course of the study. Both those taking and those not taking pharmacologic treatment for depression at baseline had decreased mean CES-D scores throughout the study regardless of group assignment or gender. The patients in the sample were divided into eight groups based on treatment group, gender, and baseline pharmacologic treatment. The group with the highest baseline depression level was the control female group on pharmacologic treatment. All groups experienced decreases in depressive symptoms over the course of the study. The males not receiving pharmacologic treatment at baseline in the control and intervention groups appeared to have the smallest decrease in depressive symptoms over the course of the study. Pharmacologic treatment, income sufficiency, and the Social Support Scale in the final model accounted for 30% of variance in depressive symptoms (CES-D scores) in patients with HF.
CHAPTER FIVE
DISCUSSION

This descriptive, correlational study evaluated the prevalence and patterns of depressive symptoms in adults with HF. Cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support) were investigated in relation to depressive symptoms as measured by the CES-D. The variables above were selected on the basis of literature review and The Biopsychosocial Holistic Model of Cardiovascular Health. This final chapter includes a summary of findings, implications of this research, theoretical relevance, strengths and limitations, recommendations for future research, and concludes the research findings.

Research Findings

Using the Biopsychosocial Holistic Model of Cardiovascular Health (BHMCH) as the guiding framework, the study was designed to accomplish multiple aims: (a) to determine the prevalence of depressive symptoms in a sample of HF patients; (b) to determine if there are patterns of depressive symptoms in HF patients; (c) to investigate if the patterns of depressive symptoms differ in subjects receiving pharmacologic treatment or by gender; and (d) to determine the cardiovascular health markers and the biological, psychological, and social factors that were associated with depressive symptoms. The purpose of this study was achieved through analysis of a secondary data set generated from a randomized trial evaluating the effects of multidisciplinary group clinic appointments on the time to first HF re-hospitalization or death. Findings for each of the research questions that were addressed will be explored below.
Prevalence of Depressive Symptoms

The purpose of Question one was to determine the prevalence of depressive symptoms in a sample of HF patients. The baseline mean CES-D score for the entire sample was 8.94, which is lower than the standard cut score of less than 10. These findings suggest that most patients in this study did not have clinically significant depressive symptoms at baseline. However, using the cut of score of greater than or equal to 10, at baseline 41.9% of the sample were clinically depressed. This is higher than reports of significant depression among 22% of patients with HF in general, with estimates of prevalence varying from 11% to 35% in the outpatient setting and 35% to 70% in the inpatient setting (Rutledge et al., 2006). However, the prevalence rates of depression in HF patients have been found to be highly variable across studies; this could be partially due to the differences between studies that use self-report questionnaires and studies that use diagnostic interviews (Nair et al., 2012). The baseline percent depressed may also be higher than other reports, because all of the patients had recently been hospitalized.

Any depressive symptoms in HF patients is concerning as they can negatively affect patient outcomes and quality of life. There is a continuum of depressive illness that ranges from mild depressive symptoms to a diagnosis of major depressive disorder (Dekker et al., 2009). Jiang and colleagues (2007) reported a “dose effect” for the severity of depression on survival. Even low levels of depressive symptoms, typically not considered “clinical depression”, are associated with increased mortality rates (Jiang, 2007).

There was one outlier identified in this study, a female participant in the control group who was not taking pharmacologic treatment for depression the entire study. This outlier case had a decrease in CES-D scores from 28 at baseline to a score of three at 12 months. The decision was made to retain this case, as the scores for this subject were consistent across time.
periods (13, 15, and 13 at 3, 6 and 9 months, respectively). Also, this participant would have been referred to a psychiatric clinical nurse specialist and received evaluation of her depressive symptoms, even though she was in the control group. The study protocol was to refer all patients with CES-D scores of greater than 20.

**Differences in Depressive Symptoms by Study Groups**

The purpose of Question two was to determine if there is a difference in depressive symptoms between the intervention and control group at baseline. The levels of depressive symptoms were similar in the intervention and control group at baseline as there were no differences in median CES-D scores. Had an imbalance between the intervention and control group on depressive symptoms been found at baseline, it could have biased statistical testing that was completed. This finding also assured that the randomization was properly conducted and that both groups came from similar populations (Roberts & Torgerson, 1999).

**Patterns of Depressive Symptoms**

**Comparison by intervention and control groups.** The purpose of Question three was to assess the patterns of depressive symptoms over time in the intervention and control groups. The intervention and control groups both had a decrease in depressive symptoms over time. Also, the percent of HF patients with depression (CES-D score of ≥10) decreased over time in both the control and intervention groups. There was not a statistically significant difference in mean CES-D changes scores between the intervention and control groups. This did not correlate with the anticipated finding of this study, that the intervention group would have a decrease in depressive symptoms over the course of the study, while the depressive symptoms in the control group would remain the same.
Any decrease in depressive symptoms in HF patients is significant; treatment of depression in HF patients has the potential to improve quality of life, mortality and morbidity, and decrease the cost of healthcare and re-hospitalizations. One study found that patients who experience remission from depression have significantly lower cardiovascular events than those who did not experience remission (Jiang et al., 2011). Another study demonstrated that effective treatment of depression in HF patients reduced the medical costs of HF (Gottlieb, 2004). Therefore, it is an important finding to this study that depressive symptoms did decrease over the course of the study.

Despite the decrease in depressive symptoms over time, the patterns of decreased depression were similar in both intervention and control groups. Due to this the effect of the intervention on depressive symptoms, if any, cannot be postulated. The review of literature revealed other studies also have identified the pattern of decreasing depressive scores in both the intervention and control groups (Fraguas et al., 2009; O'Connor et al., 2010; Powell et al., 2010; Sullivan et al., 2009). Fraguas et al. (2009) investigated the effectiveness of citalopram treatment for MDD in elderly patients with HF. In both groups, patients had statistically significant decreases in depressive symptoms (Fraguas et al., 2009). The authors concluded the findings were possibly due to weekly psychiatric follow-up, including counseling, for both groups.

Another example, O’Connor et al. (2010) tested the hypothesis that HF patients treated with sertraline (Zoloft) would have lower depression scores and fewer cardiovascular events when compared with placebo. This randomized controlled trial found that antidepressants did not result in a significant improvement in depression when compared to the placebo. However, the intervention and placebo group both experienced a considerable reduction in depressive symptoms that was attributed to both groups receiving a nursing intervention.
Powell et al. (2010) completed a randomized clinical trial (RCT) to determine the value of self-management counseling plus HF education, when compared with HF education alone on time to HF hospitalization. Depression, measured by the Geriatric Depression Scale (GDS), was a secondary outcome. Major depressive symptoms decreased 20% in the self-management group and 22% in the education group. However, the authors did identify that the education component given to both groups contributed to active treatment, which was more than anticipated.

Sullivan et al. (2009) in the Support, Education, and Research in Chronic Heart Failure (SEARCH) study demonstrated that a mindfulness-based, psycho-educational intervention successfully reduced anxiety and depression at six months, but the effect was attenuated at one year (Sullivan et al., 2009). This was a prospective cohort study of 208 adults diagnosed with HF and EF less than forty percent designed to assess the impact of a mindfulness-based, psycho-educational intervention on clinical outcomes, depression, and quality of life. Scores improved in treated patients when compared with control subjects from baseline to three months and from baseline to six months. However, both groups had improved scores thereafter so the treatment impact was attenuated.

Similar to this study, other large depression studies have found a pattern of decreased depressive symptoms in both intervention and control (or placebo) groups over time. As with other studies discussed previously, it is possible that the education component of this study (a short HF DVD series given to standardize the education information to both control and intervention groups) was an active treatment. Another possibility is the social aspect of data collection—i.e., phone calls for collecting questionnaire data and for recording health service use—became an active treatment. Even though the phone calls took minimal time, the interaction could have provided some support that decreased depressive symptoms. This pattern could be
associated with the fact that all patients in the study had recently been hospitalized. It is possible that participants in both the intervention and control groups were experiencing reactive depression; this is further discussed under the limitations section (p. 76). Further studies to validate the patterns found in this study are needed.

**Comparison by pharmacologic treatment and gender.** The purpose of Question four was to examine the patterns of depressive symptoms over time by pharmacologic treatment group, by control group or intervention group, and by gender. At baseline, females in this study had more depressive symptoms than males did. At baseline 46.1% of females were depressed, while only 39.3% of males had a CES-D score of greater than or equal to 10, which is the cut-off for depression. This is consistent with the trends in the general population as well as other studies, one of which found that women with HF had significantly worse depression scores than men (Gottlieb, 2004). Another study determined that females were more likely to have moderate or severe depressive symptoms when compared to males (Kao et al., 2014).

At baseline, 31.6% of females and 14.8% of males were on pharmacologic therapy for depression. Of other studies that reported the use of pharmacologic treatment for depression in HF patients (Gary et al., 2010; Jimenez et al., 2012), only one (Gary & Lee, 2007) provided data by gender (i.e., study subjects were limited to female patients only). The level of antidepressant use in this study might be slightly lower at 21.2% than reported in other HF studies. The studies found the following percent of patients with HF were taking medications to treat depression at baseline, prior to intervention, 33% (Jimenez et al., 2012), 47% in females (Gary & Lee, 2007), and 29% (Gary et al., 2010).

The number of patients on pharmacologic treatment increased for both control and intervention groups over the course of the study. No other studies addressing depressive
symptoms in HF patients reviewed noted an increase in pharmacologic treatment over the course of the study, but it is unknown whether this was measured. This finding could be due to the protocol in this study to refer all patients with severe depression (CES-D score of 20 or greater) for treatment with a Psychiatric Clinical Nurse Specialist. However, other than that previously discussed (pg. 44), the data regarding the referrals was not included in analysis during this secondary data analysis. Also, patients were given a summary at each group clinic appointment including their depression scores that could have led to discussions between primary care providers or cardiologists and their patients regarding depression and treatment.

Both genders had reduction in depressive symptoms over the course of the study. No other studies were found that described differences in gender response to interventions to treat depressive symptoms in HF data. Even with lower levels of depressive symptoms at baseline, the males also had decreased depressive symptoms. Despite group assignment, those on pharmacologic treatment for depression had higher CES-D scores at baseline than those who were not. This also was found in another research study that showed that despite treatment 64% of patients on antidepressants had at least mild to moderate depressive symptoms compared to 34% who were not on pharmacologic treatment (Jimenez et al., 2012).

Both those taking and those not taking pharmacologic treatment for depression at baseline had decreased mean CES-D scores throughout the study regardless of group assignment or gender. This finding is supported by somewhat mixed evidence regarding the benefit of pharmacologic treatment in HF patients with depression. Researchers (Woltz et al., 2012) who conducted a systemic review addressing the effects of interventions on depression in HF patients, reported that despite some evidence for different pharmacologic and complementary medicine strategies, the review did not support the development of guidelines for the treatment of
depression in HF patients due to lack of sufficient evidence. There was no indication in this study that those on pharmacologic treatment for depressive symptoms had differing patterns of depressive symptoms over the course of the study when compared to those not taking pharmacologic treatment; both groups had decreasing depression over the course of the study. The only clear difference is that those on pharmacologic treatment did have higher levels of depression at baseline.

No other studies that were found in review of literature described patterns of depressive symptoms in different categories similar to what was done in this study. Analysis of the eight groups based on treatment group, gender, and baseline pharmacologic treatment revealed some patterns. All groups experienced decreases in depressive symptoms over the course of the study. The group with the highest baseline level of depressive symptoms was the female control group on pharmacologic treatment. The males not receiving pharmacologic treatment at baseline in the control and intervention groups appeared to have the smallest decrease in depressive symptoms over the course of the study. This finding is not surprising, based on discussion earlier that females and those on pharmacologic treatment have the highest levels of depressive symptoms. The intervention clinics were finished at approximately eight weeks after baseline data collection and then there was a booster session held 6 months after randomization (Smith et al., 2014). The graphs reveal that despite pharmacologic treatment, gender or group assignment depressive symptoms decreased in all groups from baseline to 3 months (after the weekly sessions were completed).

While the trends mentioned above are interesting, the clinical relevance is difficult to determine unless studies could be completed showing that differences in levels of depressive symptoms led to worse outcomes (i.e. HF rehospitalization, death, decreased quality of life, or
non-compliance with medication regimen). This study does reveal the pattern that those on pharmacologic therapy have the most variation in their depressive symptoms over the course of the year that data was collected.

**Depressive Symptom Determinants**

The purpose of Question five was to determine what cardiovascular health markers (i.e., length of HF diagnosis, ejection fraction, and Charlson Comorbidity Index), biological factors (i.e., gender, age, and race), psychological factors (i.e., antidepressant use) and social factors (i.e., income sufficiency, living alone, and social support) were associated with depressive symptoms in HF patients. Regression results indicated that the overall model, with all the variables mentioned above, significantly accounted for about 30% of the variance in depressive symptoms in patients with HF. Pharmacologic treatment, income sufficiency, and the social support scale were the significant variables that accounted for the variance.

Pharmacologic treatment for depression did significantly account for variance in depressive symptoms in this study. As discussed in the previous section, another research study found that despite treatment 64% of patients on antidepressants had at least mild to moderate depressive symptoms compared to 34% who were not on pharmacologic treatment (Jimenez et al., 2012). Healthcare providers need to be aware that just because a patient is on pharmacologic treatment for depression, this does not mean that their depressive symptoms are low or controlled.

The relationship between income sufficiency and depressive symptoms found in this study is supported by findings from one other study. The study found financial burden from medical care was a predictor of the development of depressive symptoms in HF patients (Havranek, 2004). This study found that those with lower income sufficiency also had increased
depressive symptoms. Since income sufficiency helps describe the variance in depressive symptoms, health care workers need to be aware of HF patient’s ability to afford care.

The association between low social support and increased depressive symptoms in HF patients is well documented in the literature, and further supported by the findings in this study. One study found that depressive symptoms and poor social support had a synergistic, negative effect on event-free survival in HF patients (Chung et al., 2011). Another recent study (Friedmann et al., 2014) demonstrated that social support predicts changes in depression over time; patients in this study with low social support at baseline had increased depression over two years.

Health care workers with a good patient relationship should be mindful of a patient’s level of social support, asking if the patient has someone there to help them or to listen to them. They also must be aware of health care system and community resources that can be provided to HF patients who have low social support insufficient income and exhibiting depressive symptoms. Although review of literature revealed mixed results with community-based exercise programs or cardiac rehab for reducing depressive symptoms (Gary et al., 2010; Karapolat et al., 2009; Koukouvou et al., 2004; Kulcu, Kurtais, Tur, Gulec, & Seckin, 2007; van den Berg-Emons, Balk, Bussmann, & Stam, 2004), this could be considered with appropriate follow-up for patients with HF to provide a healthy, social outing.

Although not significant in the model testing, an increase in depressive symptoms was associated with younger age, i.e., younger patients exhibited more depressive symptoms in this HF sample. Similar finding from another study revealed that the patients with higher levels of depressive symptoms tended to be younger than non-depressed patients (Connerney & Shapiro, 2011; Gottlieb, 2004). Though all patients with HF should be screened for depressive symptoms,
careful attention should be provided to younger patients who may find that it is more difficult to accept the physical and emotional limitations caused by HF (Gottlieb, 2004). The Charlson Comorbidity Index was not significant in the model. No studies were found in literature review specifically discussing the relationship between comorbidity and depression in HF patients.

**Theoretical Relevance**

The theoretical framework guiding this study was the Biopsychosocial Holistic Model of Cardiovascular Health (see Figure 1, p. 5. This model states that biological, psychological, and social realms interact within each person and are integrated into cardiovascular health (Thomas, 2003). Findings in this secondary analysis partially supported the use of variables representing the realms of the Biopsychosocial Holistic Models (i.e., psychological, social, and biologic) in explaining the variance in depressive symptoms for the HF population. Specifically, this study supports the relationship between insufficient social support and income (i.e., social realm) and increased depressive symptoms, as well as pharmacologic treatment (psychologic realm) with decreased depressive symptoms. Variables representing the cardiovascular health markers (i.e., Charlson Comorbidity Index) and the biologic realms (age) were not significant in the model. The model provides the basis the assessment of depressive symptoms and treatment if necessary in patients with HF (Thomas et al., 2008). In addition to screening for depressive symptoms, it is important to include an evaluation of sufficient social support and income for all patients with HF. If deficiencies are noted appropriate referrals to community resources and social services need to be provided.

**Summary of Findings**

This study adds to the body of literature about concomitant depression and HF. Study results supported use of variables that represented some aspects of the Biopsychosocial Holistic
Model of Cardiovascular Health. The body of knowledge supporting the devastating effects that depressive symptoms can have in HF patients is large and growing. At this time, there was a lack of studies focusing on patterns of depressive symptoms in HF patients and limited well-designed studies assessing treatment options.

Key findings of this study are discussed below. Depressive symptoms were present in this sample of HF patients. The mean CES-D score (8.94) at baseline for the entire sample was below the cutoff score of ten. However, 41.9% of the sample was clinically depressed (CES-D Score ≥10). There were no differences between the intervention group and control group on their median CES-D scores at baseline or on the mean CES-D changes scores between time periods. The intervention and control groups both had a decrease in depressive symptoms and percent of patients with depression over time.

At baseline, females had more depressive symptoms than males did, and more females were using pharmacologic therapy for depression. The number of patients on pharmacologic treatment increased for both control and intervention groups over the course of the study. Both genders had reduction in depressive symptoms over the course of the study. Both those taking and those not taking pharmacologic treatment for depression at baseline had decreased mean CES-D scores throughout the study regardless of group assignment or gender.

The final regression model included pharmacologic treatment, income sufficiency, and the Social Support Scale and explained 30% of variance in depressive symptoms in patients with HF. All of these variables in the model were significant. In addition to screening for depressive symptoms, it is important to include an evaluation of sufficient social support and income for all patients with HF. If deficiencies are noted appropriate referrals to community resources and social services need to be provided.
Implications

Based on the review of literature and the prevalence of depressive symptoms noted in this study, all patients with HF should be screened for depressive symptoms. It is important for health care workers to be aware of a patient’s income sufficiency and social support, as these may be closely associated with depressive symptoms. Also, just because a patient with HF is on pharmacologic treatment for depressive symptoms, it should not be assumed that their depressive symptoms are under good control.

Nurses play an important role in the health care of patients with HF. Both inpatient nurses and advanced practice nurses spend a significant amount of time directly caring for the patient and building a trusting relationship in a stressful time of decompensation during the hospitalization. Equally important are those nursing professionals in the outpatient setting who develop a long-term relationship with patients and see them through health and decompensation. Inpatient and outpatient nurses play a crucial role in identifying patients who are experiencing depressive symptoms and patients who are at risk for depression. The development of strong nurse and patient relationships, supported by a holistic care model, puts nursing professionals in the position to actively identify depressive symptoms, lack of social support, and insufficient income and provide patient-centered treatment to improve the patient’s quality of life and cardiac outcomes.

Until further specific guidelines for screening for depression in HF patients are provided, healthcare providers can consider the guidelines for patients with coronary heart disease. The American Heart Association (AHA) recommends screening for depressive symptoms in patients with coronary heart disease using the Patient Health Questionnaire (PHQ) two-item scale (Lichtman et al., 2009). The use of the PHQ-2 also is recommended in an editorial discussing the
treatment of depressive symptoms in HF patients by cardiologist in the Journal of the American College of Cardiology (Connerney & Shapiro, 2011). The PHQ-2 states, “Over the past 2 weeks, how often have you been bothered by any of the following problems?” with responses of a) little interest or pleasure in doing things or (b) feeling down, depressed, or hopeless (Lichtman et al., 2009). Patients who answered, “yes” to either one or both of the questions should be further screened with the PHQ nine-item scale.

The guidelines also include an algorithm for care that puts patients into four arms based on screening results. The first arm is no changes in patients with negative PHQ-2, that represents no depressive symptoms. The second arm is support, education, and follow-up within one month for patients with positive PHQ-2 and PHQ-9 score less than ten, that represents minimal symptoms of short duration. The third arm is referral for more comprehensive evaluation by a professional qualified in the diagnosis and management of depression to determine appropriate therapy and provide careful monitoring of patient is indicated for (a) patients in previous group with worsening or persistent symptoms, (b) patients with mild to moderate depressive symptoms (PHQ-9 score 10-19), (c) patients with major depression (PHQ-9 score greater than 20), and (d) those who are safe but have had suicidal thoughts. The final arm is emergency department referral for all those who are suicidal and at risk for harm (Lichtman et al., 2009). The PHQ-9 is a clinically validated and reliable depression screening instrument that has been successfully used in the HF patient population (Bowden et al., 2011). A study of HF patients found that a positive PHQ-2 screen has been associated with subsequent mortality, providing increased evidence for use of this simple scale (Rollman et al., 2012).

More awareness regarding the prevalence, as well as the mortality and morbidity associated with concomitant HF and depression is needed. Upon diagnosis with HF, as with
other chronic disease, it is important to assess a patient’s social support system and provide education regarding the importance of maintaining social support in reducing depressive symptoms. It also is important that undergraduate and masters nursing programs include information on screening, diagnosing, and treating depressive symptoms.

**Strengths and Limitations**

This study provided information about patterns of depressive symptoms in HF patients, promoting a better understanding of these disease states. The use of an existing data set with HF patients and depression data provided a cost-effective way to explore depressive symptoms in this patient population. In this study, depressive symptoms were similar at baseline in the control and intervention groups. Patients who participated in this study were generally well representative of the HF patient population. This study represents HF patients of all age ranges which is important since older adults are frequently underrepresented in HF clinical trials (Mann, 2011).

Despite the strengths of this study, the limitations must be considered. One limitation of doing secondary data analysis is that the data were not originally obtained for the purpose of addressing depressive symptoms or patterns of depression in HF patients (Castle, 2003). The parent study was limited as it was a single-center study at an academic health center, the parent study researchers stated that results might differ in settings where HF care is either more or less regimented (Smith et al., 2014). Another limitation is that there are other variables that could explain depressive symptoms not included in this data set.

This study was limited by missing data in the pharmacologic treatment variable at the 6-month and 12-month time points. The decision to use the last observation may not have been representative of the use of pharmacologic treatment. Another important consideration is that
74% of patients invited to join the study did not participate; the main reason given was that they were not interested. Patients with high level of depressive symptoms may be less likely or unwilling to participate in a research study. Therefore the sample of this study could have underrepresented the depressive symptoms of the general HF population.

Depressive symptoms screening was conducted with the use of self-rated survey instruments; however, the self-rated reports are not meant to be diagnostic of depression. Few studies can afford the time and/or personnel needed to complete the diagnostic interview that is required for the determination of a diagnosis of depression. Consequently, depressive symptom screening scales are frequently used in the research setting (Delville & McDougall, 2008). Screening instruments were found to result in higher frequencies of depressive symptoms (21-60%) when compared to diagnostic interviews (14-39%). Though the implications to the findings of this study are unclear, it is possible higher frequencies of depressive symptoms were noted in this study due to the use of a screening scale.

The CES-D measures depressive symptoms experienced over the past four weeks, making it time sensitive and more likely to detect reactive or situational depression. It is important to consider the possibility that depressive symptoms decreased in all participants in the study because they were all recruited during or within two weeks of hospitalized for an exacerbation of HF. Patients were randomized and depending on the rate of recruitment, it typically took up to three weeks after hospitalization for baseline data collection to occur (Smith et al., 2014). There is no way to test this hypothesis as all patients had been recently hospitalized.

This study is a secondary data analysis of data that was collected for a different purpose than studying depression. The sampling of patients just discharged from the hospital with HF exacerbation is major limitation to this study that was not considered prior to data analysis.
While looking at the results of this study, planning of future studies, and caring for patients with HF it is important to consider that patients may be at increased risk for depressive symptoms after HF hospitalization.

**Recommendations for Future Research**

The prevalence of depressive symptoms in HF patients is overwhelming and the negative effects of these diseases in combination are well documented. Current understanding of the patterns of depressive symptoms in HF patients remains incomplete. More research is needed to further clarify the relationship between depressive symptoms and HF, as well as identify factors associated with increased depressive symptoms, in order to develop new screening and treatment protocols for this patient population.

There are further analyses that could be completed with the rich data set used for this secondary data analysis. Subsequent analysis could be used to further evaluate what factors were associated with reduction in depressive symptoms scores by using multiple regression with similar variables utilized in this study with the change in depressive score as the dependent variable.

The use of triangulation with qualitative data that was collected could provide rich details to further understand the relationship between other variables and changes in depressive symptoms. Analysis of the qualitative data gathered in this study could also be used to support the findings of this study and possibly add insight into the pattern noted with all groups having reduction in depressive symptoms. Qualitative data may also provide insight into whether reactive depression from recent hospitalization occurred in this study. Additional qualitative studies could examine the lived patient experience of having HF and depression, as well as determine the factors that the patients consider important to improving their mood.
Strategies to encourage screening for depressive symptoms in all patients with HF are needed. More research is needed to guide practice guidelines, including which depressive scales perform best in HF patients and best options for treatment. More pharmacologic and non-pharmacologic studies looking at the effectiveness of existing options to treat depression in HF patients are needed. Also, the continued development of safe and effective pharmacologic and non-pharmacologic interventions to reduce depressive symptoms in HF patients is a priority.

This study had one main finding that impacts design for future studies. Looking at the patterns of depressive symptoms over time revealed that depressive symptoms decreased in both control and interventions groups, regardless of gender or pharmacologic treatment for depression. The researcher postulates two possibilities for why this occurred: (a) participation in control group and being studied reduced depressive symptoms, and/or (b) both groups experienced reactive depression from recent hospitalization. Researchers designing future studies in this area need to be mindful of sampling procedures and which depression scale is appropriate based on time between data collection points. Also, special consideration needs to be given to the potential that the control group may benefit just from being studied.

Conclusions

There has been limited research conducted on patterns of depressive symptoms in HF patients. This study has improved nursing knowledge by demonstrating the prevalence of depressive symptoms in HF patients, identifying patterns of depressive symptoms, and the relationship between social support, income sufficiency, and pharmacologic treatment with depressive symptoms. Depressive symptoms decreased with a multidisciplinary support group (intervention), but there also was a decrease in depressive symptoms in the control group.
possibly due to factors discussed and mental health evaluation of all significantly depressed patients in the study.
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Appendix A

Center for Epidemiologic Studies Depression Scale (CES-D)

We are wondering about how you have felt over the past four weeks. Using the scale below, circle the ONE number that best describes how often you felt or behaved this way.

<table>
<thead>
<tr>
<th>During the past four weeks, how often have you:</th>
<th>Less than 1 day of the week</th>
<th>1-2 days of the week</th>
<th>3-4 days of the week</th>
<th>5-7 days of the week</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Felt depressed.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Felt that everything you did was an effort.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Felt your sleep was restless.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Felt happy.*</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Felt lonely.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Felt that people were unfriendly.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Enjoyed life.*</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Felt sad.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Felt that people dislike you.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. Felt you could not get “going”.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

(*when scoring, reverse the positive statement items # 4 [Felt happy] & #7 [Enjoyed life], meaning 0=3, 1=2, 2=1, 3=0)
Appendix B

Patient Health Questionnaire-9 (PHQ-9) Depression Screening Scales

Over the past 2 weeks, how often have you been bothered by any of the following problems?

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Little interest or pleasure in doing things.</td>
<td></td>
</tr>
<tr>
<td>(2) Feeling down, depressed, or hopeless.</td>
<td></td>
</tr>
<tr>
<td>(3) Trouble falling asleep, staying asleep, or sleeping too much.</td>
<td></td>
</tr>
<tr>
<td>(4) Feeling tired or having little energy.</td>
<td></td>
</tr>
<tr>
<td>(5) Poor appetite or overeating.</td>
<td></td>
</tr>
<tr>
<td>(6) Feeling bad about yourself, feeling that you are a failure, or feeling that you have let yourself or your family down.</td>
<td></td>
</tr>
<tr>
<td>(7) Trouble concentrating on things such as reading the newspaper or watching television.</td>
<td></td>
</tr>
<tr>
<td>(8) Moving or speaking so slowly that other people could have noticed. Or being so fidgety or restless that you have been moving around a lot more than usual.</td>
<td></td>
</tr>
<tr>
<td>(9) Thinking that you would be better off dead or that you want to hurt yourself in some way.</td>
<td></td>
</tr>
</tbody>
</table>

*Questions are scored: not at all= 0; several days= 1; more than half the days= 2; and nearly every day=3. Add together the item scores to get a total score for depression severity.*