THE IMPACT OF PSYCHOLOGICAL DISTRESS AND COGNITIVE IMPAIRMENT ON ADHERENCE TO TREATMENT RECOMMENDATIONS IN HEART FAILURE PATIENTS TREATED WITH AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

A dissertation submitted to Kent State University in partial fulfillment of the requirements for the degree of Doctor of Philosophy

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# TABLE OF CONTENTS

LIST OF FIGURES ................................................................................................................. iv  
LIST OF TABLES .................................................................................................................. v  
ACKNOWLEDGMENTS ........................................................................................................ vi  

## CHAPTER

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1</td>
</tr>
<tr>
<td>II</td>
<td>25</td>
</tr>
<tr>
<td>III</td>
<td>39</td>
</tr>
<tr>
<td>IV</td>
<td>61</td>
</tr>
<tr>
<td>REFERENCES LIST</td>
<td>80</td>
</tr>
</tbody>
</table>

## APPENDIX

<table>
<thead>
<tr>
<th>Appendix</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>100</td>
</tr>
<tr>
<td>B</td>
<td>105</td>
</tr>
<tr>
<td>C</td>
<td>111</td>
</tr>
<tr>
<td>D</td>
<td>124</td>
</tr>
<tr>
<td>Figure</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>1</td>
<td>Adherence rates for diet recommendations for patients with BDI&lt;10 vs BDI&gt;10</td>
</tr>
<tr>
<td>2</td>
<td>Adherence rates for diet recommendations for patients with STAI&lt;40 VS STAI&gt;40</td>
</tr>
<tr>
<td>3</td>
<td>Adherence rates for exercise recommendations for patients with STAI&lt;40 VS STAI&gt;40</td>
</tr>
</tbody>
</table>
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New York Heart Association Classification System for Heart Failure</td>
</tr>
<tr>
<td>2</td>
<td>Association Between Sociodemographic and Cardiac Variables and Adherence at Baseline</td>
</tr>
<tr>
<td>3</td>
<td>Correlation Matrix of Independent Variables</td>
</tr>
<tr>
<td>4</td>
<td>Sociodemographic and Cardiac Characteristics</td>
</tr>
<tr>
<td>5</td>
<td>Adherence to Treatment Recommendations at Baseline</td>
</tr>
<tr>
<td>6</td>
<td>Percentage of Patients That Adhered and Did Not Adhere to Treatment Recommendations at Follow-up</td>
</tr>
<tr>
<td>7</td>
<td>Linear Regressions Examining Association Between Outcome Variables and Adherence to Individual Treatment Recommendations at Baseline</td>
</tr>
<tr>
<td>8</td>
<td>Association Between Sociodemographic and Cardiac Variables and Adherence at One-month Follow-up</td>
</tr>
<tr>
<td>9</td>
<td>Logistic Regressions Examining Association Between Outcome Variables and Adherence to Restricting Sodium at One-month Follow-up</td>
</tr>
<tr>
<td>10</td>
<td>Logistic Regressions Examining Association Between Outcome Variables and Adherence to Daily Weighing at One-month Follow-up</td>
</tr>
<tr>
<td>11</td>
<td>Logistic Regressions Examining Association Between Outcome Variables and Adherence to Taking Medications at One-month Follow-up</td>
</tr>
<tr>
<td>12</td>
<td>Logistic Regressions Examining Association Between Outcome Variables and Adherence to Eliminating Smoking at One-month Follow-up</td>
</tr>
<tr>
<td>13</td>
<td>Logistic Regressions Examining Association Between Outcome Variables and Adherence to Eliminating Alcohol at One-month Follow-up</td>
</tr>
</tbody>
</table>
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CHAPTER 1

INTRODUCTION

This chapter provides background about heart failure and implantable cardioverter defibrillators. In addition, treatment adherence in regards to treatment recommendations for heart failure and the effect of nonadherence on health outcomes in heart failure patients is discussed. Finally, previous research demonstrating the impact of heart failure and ICD therapy on cognition and psychological well-being and the associations between treatment adherence, cognitive impairment, and psychological distress is discussed.

Heart failure is a chronic, progressive, and frequently fatal disease. One common medical treatment for ventricular arrhythmias due to heart failure is the implantable cardioverter defibrillator (Brady et al., 2005). An implantable cardioverter defibrillator stops abnormal arrhythmias by shocking the heart (Bhatia et al., 2004). Heart failure patients treated with an ICD is a high risk population that is growing rapidly (Sears, Strutts, Aranda, Handberg, & Conti, 2006). Consequently, management of the disease through adherence to recommended treatment guidelines is of utmost importance because poor adherence has been found to be related to rehospitalization due to exacerbation of heart failure symptoms and mortality (Miura et al., 2001; Chui et al., 2003). A set of recommended treatment guidelines for heart failure have been published which include taking medications, restricting sodium and fluid intake, daily weightings, and eliminating
smoking and alcohol (Adams et al., 2006). However, adherence rates among heart failure patients are low (van der Wal, Jaarsma, & van Veldhuisen, 2005). Therefore, it is important for researchers to examine potential barriers to adherence in heart failure patients with an ICD in order to decrease morbidity and mortality and improve physical functioning and quality of life.

One potential barrier that may inhibit heart failure patients from adhering to treatment guidelines is cognitive impairment. Patients with heart failure often report difficulties with memory and attention (Bennett & Sauve, 2003). Given the complexity of drug regimens for heart failure and the tracking of sodium and fluid intake that is needed, heart failure patients who have cognitive impairments may have difficulty adhering to these treatment recommendations. To date, there has been no research that has examined the effect of cognitive impairment on adherence to individual treatment guidelines in heart failure patients treated with an ICD.

Psychological distress in particular depression and anxiety is another potential barrier to adherence to treatment recommendations in heart failure patients. Within both heart failure and ICD patient populations, depression has been found in 24% to 42% (Havranek, Ware, & Lowes, 1999; Skotzko et al., 2000) and up to 66% of patients (Kamphuis, de Leeuw, Derkson, Hauer, & Winnubst, 2003), respectively. Depression may result in patients being unmotivated and lacking the energy to incessantly follow the recommended treatment guidelines (DiMatteo, Lepper, & Croghan, 2000). Additionally, depressed patients may socially isolate themselves, thus withdrawing from family and friends who may have been able to assist them.
The majority of research investigating psychological distress in heart failure patients has focused on depression; however anxiety has been extensively researched in ICD patients. Because the ICD delivers a shock to the heart when it detects an arrhythmia, patients treated with an ICD often report difficulties with anxiety. Patients who are dealing with anxiety concerning the unpredictability of shock may lack the cognitive focus to adhere to recommended treatment guidelines. In order to better understand barriers to adherence in heart failure patients treated with an implantable cardioverter defibrillator, the current study will examine the effect of cognitive impairment and depression and anxiety symptoms on adherence to individual treatment recommendations.

Heart Failure

Heart failure is a serious and increasing public health problem. According to the American Heart Association, approximately 5 million patients in the United States have heart failure and roughly 550,000 new cases are diagnosed annually (Thom et al., 2006). Despite advancements in treatment for heart failure, the number of heart failure patients continues to grow. Moreover, with the aging U.S. population, the number of heart failure patients can be expected to increase considering that 6% to 10% of individuals over 65 years old have heart failure (Kannel & Belanger, 1991). Heart failure is associated with many negative sequelae. Within the past 20 years, the number of hospital admissions for heart failure has increased from 399,000 admissions in 1979 to 1,093,000 admissions in 2003 (Thom et al., 2006). The annual mortality rate among patients with heart failure ranges from 10% to 50% and 30-50% of deaths are sudden (Bardy et al., 2005). With
increasing hospital admissions and complexity of drug regimes (Masoudi, et al., 2005), the direct and indirect economic burden of heart failure is estimated to be $29.6 billion in 2006 (Thom et al., 2006). As can be seen from these staggering figures, heart failure is a devastating disease that warrants extensive research efforts to decrease the number of cases and prolong the lives of these patients.

Pathophysiology of Heart Failure

The primary function of the heart is to pump blood to bodily organs and tissue. In order to pump blood throughout the body, the heart has a left and right pump, each with two chambers, the atrium and the ventricles. In a properly functioning heart, blood is ejected from the left ventricle and passes through the body. The deoxygenated blood returns to the right atrium where it is passes to the right ventricle during ventricular diastole. Contraction of the right ventricle (i.e. ventricular systole) pushes blood through the pulmonary artery to the lungs where the blood is reoxygenated. From the lungs, the blood returns to the left atrium and then passes through to the left ventricle (Brownley, Hurwitz, & Schneiderman, 2000).

Heart failure is a clinical syndrome that results from ventricular dysfunction (i.e. the heart is unable to pump adequate amounts of blood to meet the metabolic needs of the body) (Francis, Gassler, & Sonnenblick, 2001). Depending upon the side of the heart that is defective, patients may experience pulmonary edema (i.e. fluid filling the lungs) with left ventricular heart failure or peripheral edema (i.e. fluid build up in the veins especially in the legs and ankles) with right ventricular heart failure. Furthermore, in left ventricular heart failure, the left ventricle loses its ability to contract normally which inhibits the
heart’s ability to forcefully pump blood through the body (AHA, 2006). Additionally, the left ventricle may become unable to relax normally, causing the heart muscle to stiffen, therefore preventing the heart from properly filling with blood. Abnormal function of the left ventricle overloads the right ventricle through increased fluid pressure, thus damaging the right ventricle and decreasing its pumping capability (Francis, Gassler, & Sonnenblick, 2001).

Heart failure can be caused by other cardiovascular diseases such as hypertension or coronary artery disease. Chronic increases in ventricular pressure due to hypertension can increase the thickness of the left ventricular wall and muscle mass resulting in a structural change of the heart (Giles, 2004). As a result, the heart muscle will become either too stiff or too weak to pump blood efficiently. Coronary artery disease is the most common cause of heart failure (Gheorghiade & Bonow, 2004). Atherosclerosis which forms over time causes blood to flow slowly through the narrowed arteries, consequently depriving some areas of the heart of oxygenated blood (Gheorghiade & Bonow, 2004). Heart failure occurs because the oxygen-deprived areas of the heart decrease their pumping capacity.

As the heart loses its capability to pump efficiently, the heart will try to compensate for this by enlarging, increasing muscle mass, and/or pumping faster (AHA, 2006). However, eventually the heart is unable to counteract this deficiency and the individual begins to experience symptoms of heart failure. Heart failure is characterized by symptoms of breathlessness and fatigue that occur either at rest and/or with exertion (Francis & Tang, 2004). Other symptoms include swelling of the legs, ankles, and/or feet,
weight gain, persistent productive cough, nausea or loss of appetite, and increased heart rate (AHA, 2006). The New York Heart Association Functional Classification was developed to categorize patients according to their extent of disability (Table 1). The classification system ranges from class I (no limitation in physical activity) to class IV (inability to carry on any physical activity) (Francis & Tang, 2004).

Table 1. New York Heart Association Classification System for Heart Failure

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<tr>
<th>Class</th>
<th>Description</th>
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<tr>
<td>I</td>
<td>No limitation of physical activity. No shortness of breath, fatigue, or heart palpitations with ordinary physical activity.</td>
</tr>
<tr>
<td>II</td>
<td>Slight limitation of physical activity. Shortness of breath, fatigue, or heart palpitations with ordinary physical activity, but patients are comfortable at rest.</td>
</tr>
<tr>
<td>III</td>
<td>Marked limitation of activity. Shortness of breath, fatigue, or heart palpitations with less than ordinary physical activity, but patients are comfortable at rest.</td>
</tr>
<tr>
<td>IV</td>
<td>Severe to complete limitation of activity. Shortness of breath, fatigue, or heart palpitations with any physical exertion and symptoms appear even at rest</td>
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</tbody>
</table>

**Implantable Cardioverter Defibrillators**

It is estimated that up to 50% of the total mortality in patients with CHF is attributable to sudden cardiac death due to ventricular arrhythmias (Bardy et al., 2005). Individuals who experience ventricular tachycardia or fibrillation (VT/VF) resulting in cardiac arrest require immediate defibrillation to stop the abnormal rhythm and prevent death (Bhatia et al., 2004). Clinical trials have demonstrated the efficacy of the ICD in
reducing mortality due to sudden cardiac death as well as its superiority over anti-
arrhythmic therapy in primary and secondary prevention (Lau et al., 2004, Kadish et al.,
2004, Moss et al., 2002, Connolly et al., 2000). Consequently, ICDs have become a
common medical treatment for life-threatening arrhythmias such that approximately
55,000 devices are implanted in the United States annually (Sinha, Mehta, & Gomes,
2005). Moreover, a marked increase in ICD implantation rates from 23.6% in 1996 to
46.3% in 2001 were found in a representative sample of patients surviving cardiac arrest
in the United States (Voight et al., 2004).

The implantable cardioverter defibrillator system contains a generator which
houses the battery and circuitry for monitoring heart rhythm, delivering shocks, and
recording the date and time of shocks. The generator is implanted beneath the skin of the
chest or abdomen and is connected to the heart by leads which are attached to the inside
of the heart or on its surface (Bhatia et al., 2004). The leads monitor heart rhythm, detect
rhythm disturbances, and deliver electrical shocks to the heart. The average ICD
generator is the size of a wallet. When the ICD detects VT/VF, it delivers an electrical
shock to the heart restoring the normal heart rhythm. Some ICD’s are accompanied by a
biventricular pacemaker that delivers electrical impulses to the heart to produce a more
synchronous left ventricular contraction (Pires, 2006). In addition to monitoring heart
rhythm, ICD’s store information about heart rhythms and devise discharges (shocks) that
enable physicians to assess the effectiveness of the ICD at regular intervals. ICDs have
been found to be efficacious in improving survival in heart failure patients who have or
may experience arrhythmias. Consequently, heart failure patients treated with an ICD is a
rapidly growing and high risk patient population requiring significant lifestyle changes, often recommended by their physician, in order to manage the disease.

*Treatment Guidelines for Heart Failure*

In order for patients with heart failure to reduce their risk for poor health outcomes, it is important that they follow recommended guidelines. The Heart Failure Society of America (HFSA) has recently published practice guidelines for heart failure (Adams et al., 2006). Patients are often prescribed pharmacological therapy to manage and reduce heart failure symptoms. The two most commonly recommended classes of agents are angiotensin-converting enzyme (ACE) inhibitors and β-blockers. The nonpharmacologic management of patients with chronic heart failure includes sodium restriction, fluid restriction, smoking cessation and limited alcohol, and activity as prescribed by a physician (Adams et al., 2006). It is recommended that patients restrict their sodium intake to less than 2g daily especially for patients with moderate to severe heart failure. By restricting sodium intake, patients may require less diuretic therapy which may negatively impact clinical outcomes through neurohormonal stimulation (Francis et al., 1990). As for fluid restriction, patients are encouraged to limit their fluid intake to <2 L daily. In order to monitor volume status, patients are advised to weigh themselves daily and report excessive weight gain (>4 pounds in 3 days) to their physician (Remme & Swedberg, 2001).

It is recommended that heart failure patients stop smoking and limit their alcohol consumption to ≤2 standard drinks per day in men or ≤1 standard drink per day in women (Adams et al., 2006). Light to moderate amounts of alcohol have not been found to
increase the risk of poor clinical outcomes in heart failure patients (Salisbury, House, Conard, Krumholz, & Spertus, 2005). In addition to the above recommendations, heart failure patients are also advised to obtain a pneumococcal and influenza vaccination because it may reduce the risk of lung infection that may exacerbate heart failure (Remme & Swedberg, 2001). The routine use of exercise training is not recommended by the HFSA guideline. Although studies have demonstrated physiological improvements after exercise training (Kobayashi et al., 2003; Selig et al., 2004), research has not yet determined if exercise training reduces mortality and/or morbidity in heart failure patients. However, patients should not be discouraged from carrying out daily activities and leisure time activities if the patient is stable (Remme & Swedberg, 2001). By following the above recommendations, heart failure patients may be able to improve their quality of life, slow disease progression, and reduce the risk of hospitalization.

*Adherence and Outcomes*

Heart failure patients are faced with a demanding set of lifestyle changes that necessitate satisfactory adherence in order to slow the progression of heart failure. In chronic diseases in general, adherence to treatment recommendations has been found to be an important factor in medical outcomes (Dunbar-Jacob & Schlenk, 2001). A meta-analysis spanning thirty years of research on patient adherence and treatment outcomes in various diseases found that adhering to the prescribed treatment plan reduced the risk of a poor outcome by 26% (Dimatteo, Giordani, Lepper, & Croghan, 2002). Additionally, the authors concluded that the adherence-outcome relationship was stronger for chronic diseases than for acute diseases. Adhering to a medication regimen and lifestyle changes
like diet and exercise can be challenging for patients who are experiencing symptoms associated with their illness. However, failing to make these lifestyle changes may result in worsening symptoms and possibly hospitalization.

According to a recent review, diet and fluid restriction, daily weighing, and activity and rest were found to be the lifestyle recommendations with the highest rates of non-adherence in heart failure patients (van der Wal, Jaarsma, & van Veldhuisen, 2005). The rates of non-adherence for these activities were as follows: restricted diet, 33%-50%, daily weighing, 12%-75%, and balance of activity and rest, 41%-58%. Although patients receive information regarding self-care recommendations from their cardiologists and at discharge from the hospital, an overwhelming number of heart failure patients fail to follow these recommendations. For example, in one study, almost 40% of heart failure patients did not comprehend the importance of weighing themselves daily (Ni et al., 1999). Additionally, 80% of patients acknowledged that they should limit their salt intake, however only one third of patients actually restricted their salt intake. These results suggest that patients need to receive, in addition to instructions, education about how making lifestyle changes can slow the progression of heart failure and improve their quality of life.

Limited research has examined nonadherence to nonpharmacologic treatment recommendations and its effect on health outcomes. Excessive salt intake was identified as a primary cause of heart failure events in 15% of heart failure patients who experienced heart failure events (N = 180) during a 43 week drug trial (Tsuyuki et al., 2001). Similarly, a study examining acute precipitants of hospitalization in 435 heart
failure patients found nonadherence with diet recommendations to be a factor contributing to hospitalization in 6% of patients (Chin & Goldman, 1997). To date, there is no randomized controlled trial assessing the independent role of sodium restriction in the morbidity or mortality of heart failure patients. However, studies of multidisciplinary heart failure disease management programs which include sodium restriction and dietary counseling have found improvements in functional capacity, patient satisfaction, and quality of life following the program (Rich, 1999). On the other hand, there is currently an ongoing randomized study designed to determine if fluid restriction is beneficial in heart failure patients (Holst, Stromber, Lindholm, & Willenheimer, 2003). The study investigators will compare the effects of a standardized fluid restriction versus an individualized fluid prescription on quality of life, functional capacity, thirst, left ventricular diastolic function, and hospital readmissions.

Research has focused mostly on the effect of nonadherence to pharmacologic therapy on clinical outcomes. Adherence to medication regimens in heart failure patients is poor with an average nonadherence rate of about 30% (van der Wal, Jaarsma, & van Veldhuisen, 2005). A study examining nonadherence and knowledge of medications prescribed found that 45% of heart failure patients could not correctly name their medications, 50% were unable to state the prescribed doses, and 64% were unable to recall what time of day and when in relation to meals their medication was to be taken (Cline, Bjorck-Linne, Israelsson, Willenheimer, & Erhardt, 1999). Failing to adhere to the prescribed medication regimen whether it is not taking the medications, taking the
wrong medication or dosage, or taking the medication off-schedule has serious repercussions for patients’ health.

A 6-year study of the effects of nonadherence to digoxin on clinical outcomes in heart failure patients found a longer duration and a higher number of hospitalizations in nonadherent patients as compared to adherent patients (Miura et al., 2001). Furthermore, nonadherent patients were found to have a significant decrease in the LVEF whereas adherent patients showed no change in LVEF. Mortality in both groups was exclusively attributed to worsening heart failure, however the mortality rate was higher in nonadherent patients. Even in the short-term, nonadherence to medication can have negative implications for health outcomes. In a 6-month study examining the relationship between medication adherence and hospital admissions in heart failure patients, taking diuretic therapy off-schedule was found to be associated with more cardiovascular-related and heart failure-related hospitalizations (Chui et al., 2003). Interestingly, adherence behavior itself may be associated with outcomes such that even patients who were adherent to placebo were found to have lower rates of mortality and hospital admissions (Granger et al., 2005). These findings underscore the importance of determining potential barriers to adherence in heart failure patients in order to decrease morbidity and mortality and potentially improve quality of life.

Cognitive Impact of Heart Failure

One potential barrier that may inhibit heart failure patients from adhering to treatment guidelines is cognitive impairment. It has been reported, depending on the population under investigation and the methodology utilized, that 30% to 80% of patients
with heart failure exhibit memory and attention deficits (Bennett & Sauve, 2003). There is increasing evidence demonstrating that heart failure is an independent predictor of cognitive dysfunction in heart failure patients (Trojano et al., 2003, Cacciatore et al., 1998). The relationship between cognitive functioning and heart failure is not fully understood, however research is beginning to find evidence for the etiology of cognitive dysfunction among heart failure patients.

The pathophysiological determinants of cognitive dysfunction in patients with heart failure remain uncertain. However, researchers have found evidence to support some possible etiologies for cognitive deficits in heart failure. Impairment of cerebral circulation is one of the most likely etiologies for cognitive dysfunction in heart failure patients. Impaired cerebral circulation can lead to inadequate cerebral perfusion and cerebral hypoxia because the brain may not be receiving adequate amounts of oxygen to function properly due to heart failure (Braunwald, Zipes, & Libby, 2001). In a study comparing heart failure patients with healthy controls, volumetric structural MRI scans found significantly less gray matter volume in specific regions of the brain in heart failure patients than controls (Woo, Macey, Fonerow, Hamilton, & Harper, 2003). The authors concluded that atrophy in specific brain regions were most likely from ischemia and hypotension and have the potential to impact cognitive functioning.

Another potential determinant of cognitive dysfunction is left ventricular systolic dysfunction. Zuccala and colleagues (Zuccala et al., 1997) found heart failure patients with a left ventricular ejection fraction (LVEF) of ≤30 to perform significantly lower on the Mini-Mental State Examination (MMSE) than patients with a LVEF over 30. A more
recent study found LVEF to be a stronger predictor of cognitive impairment than age, prior heart attack, stroke, smoking/alcohol abuse, and complaints of memory or sleep problems (Almedia & Tamai, 2001). These declines in cognitive performance associated with low LVEF may be related to decreased cerebral blood flow. Using transcranial Doppler, significant reductions in cerebrovascular reactivity were identified in patients with heart failure (Georgiadis et al, 2000). Furthermore, LVEF was found to be a significant predictor of cerebrovascular reactivity after controlling for age, sex, medication, and LV end-diastolic pressure.

A review of studies evaluating cognitive dysfunction in heart failure patients concluded that heart failure appears to be associated with impairments in memory and attention, and that attention deficits may explain impairment on other cognitive tasks (Almedia & Flicker, 2001). Among older heart failure patients, studies have found 23% to over 50% of patients to score ≤24 on the Mini Mental Status Examination (MMSE), indicating cognitive impairment (Mauro et al., 2007; Almeida & Tamai, 2001). Moreover, heart failure patients with NYHA class III and IV were found to score significantly worse on tests assessing attention, verbal fluency, and verbal learning than cardiac patients without heart failure (Trojano et al., 2003).

**Cognitive Impairment and Treatment Adherence**

Although cardiac patients, including heart failure patients, may experience cognitive impairment (Bennett, & Sauve, 2003), there is no research to date examining the effect of cognitive impairment on adherence to treatment recommendations in heart failure patients. Heart failure patients are faced with a demanding set of lifestyle changes
which require the patient to remember to weigh themselves daily, take the correct dosage of medications on schedule, and be conscientious of their daily sodium and fluid intake. Furthermore, drug regimens for heart failure are becoming more and more complex (Masoudi et al., 2005) thus presenting the patient with further demands. All in all, the complexity of medication regimens with the added burden of changing one’s lifestyle may involve a great deal of cognitive skill to successfully adhere to the practice guidelines for heart failure patients.

Research has found cognitive impairment to be associated with poor adherence in other diseases. For example, in HIV-infected adults, performing significantly worse on neuropsychological tests of executive function, psychomotor speed, memory, and attention was related to lower adherence rates to antiretroviral medications (Hinkin et al., 2002; Hinkin et al., 2004). In these studies, cognitive impairment was associated with approximately a 2.4 times greater risk of poor adherence. In a sample of elderly patients taking antihypertension medication, the risk of nonadherence in patients with cognitive impairment was 2.0 even after adjusting for sociodemographic variables including age (Salas et al., 2001). Cognitive impairment as indicated by an MMSE score <23 was found to be significantly associated with poorer diabetes self-care (i.e. medication taking, glucose monitoring) in a sample of elderly patients with diabetes (Sinclair, Girling, & Bayer, 2000). These results show that impaired cognitive function can inhibit patients’ ability to adhere to treatment recommendations. Because there is no research to date examining this association in heart failure patients, and the link has been made in patients with other illnesses, the current study examines the effect of cognitive impairment, as
assessed by a neuropsychological battery, on adherence to each individual treatment
guideline for heart failure in heart failure patients treated with an ICD.

Psychological Impact of Heart Failure and ICDs

In addition to cognitive dysfunction, another potential barrier to adherence to
treatment guidelines in heart failure patients is psychological distress, in particular
depression and anxiety. The rates of depression among heart failure patients range from
24% to 42% (Havranek, Ware, & Lowes, 1999; Skotzko et al., 2000). One study found
30% of hospitalized heart failure patients to score ≥10 on the Beck Depression Inventory
indicating depressive symptomatology (Jiang et al., 2007). Additionally, depressive
disorder, assessed by the SCID I, was found in 29% of heart failure patients attending a
community heart failure chronic disease management program (Haworth, Moniz-Cook,
patients is under-researched (MacMahon & Lip, 2002). However, in one study, almost a
fifth (18%) of heart failure patients had at least one anxiety disorder according to the
DSM-IV (Haworth et al., 2005).

Much like heart failure, ICDs also have implications for psychological processes.
Research examining psychiatric symptoms in patients with ICDs has predominately
focused on depression and anxiety. A recent review by Sola and Bostwick (2005)
concluded that approximately 40% of patients with ICDs meet diagnostic criteria for
anxiety disorders. The authors offer several theoretical explanations for the
disproportionately high percentage of patients with anxiety disorders. Classical
conditioning suggests that receiving a shock while engaged in a particular activity may
result in avoidance of that activity in the future due to fear of shock. Patients with ICDs may experience learned helplessness due to the unpredictability and uncontrollability of device firings which may lead to depression. Lastly, ICD firings may be interpreted (i.e., cognitive appraisal) as worsening health status thus leading to feelings of depression and anxiety.

A prospective study found up to 66% of post-implantation ICD patients to report possible clinical depression (Kamphuis, de Leeuw, Derkson, Hauer, & Winnubst, 2003). In a recent study, more severe symptoms of depression were found to predict ventricular tachycardia/ventricular fibrillation (VT/VF) requiring ICD shock (Whang et al., 2005). This suggests that ventricular arrhythmia may be a potential mechanism linking depression and mortality in patients with cardiovascular disease. Furthermore, Dunbar et al. (1999) found that greater mood disturbance (i.e. anxiety, depression, anger, vigor, fatigue, and confusion) increased the risk of experiencing VT/VF that required pacing, cardioversion, or defibrillation by the ICD. Although some research suggests that psychological distress may impact arrhythmic events, others have found ICD shocks to be associated with symptoms of depression and anxiety. For example, patients who reported greater ICD concerns (i.e. perceived limitations, device firing) were at higher risk of anxiety and depression regardless of having experienced shocks (Pederson, van Domburg, Theuns, Jordeans, & Erdman, 2005). Pauli and his colleagues (Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, & Kuhlkamp, 1999) also found that anxiety related to future ICD shocks was associated with higher levels of anxiety and depression. These findings suggest that it may not be the actual occurrence of shock that
is associated with psychological distress but rather the concerns about impending ICD shocks that is triggering psychological disturbances. In our study examining predictors of depression and anxiety in patients with an ICD, we found that having experienced one or more clinical ICD shocks was related to depressive symptoms but not anxiety symptoms (Luyster, Hughes, Waechter, & Josephson, 2006). This finding reinforces the idea that anticipatory anxiety associated with ICD shocks may be a more important contributor to anxiety symptoms than the actual occurrence of ICD shock. Thus, preoccupation with ICD shock may be interfering with patients’ focus on following treatment recommendations.

*Psychological Distress and Treatment Adherence*

The effect of depression on treatment recommendations have been examined in cardiac patients however, research specifically examining depression and adherence in heart failure patients is lacking. Research has established that a significant number of patients experience depressive symptoms following a cardiac event (e.g. MI, coronary artery bypass grafting, ICD implantation) (Kamphuis, de Leeuw, Derkson, Hauer, & Winnubst, 2003; Lesperance & Frasure-Smith, 1996; Rymaszewka, Kiejna, & Hadrys, 2003). Heart failure patients who reported poorer mental health were found to have poor adherence to dietary recommendations (Evangelista, Berg, & Dracup, 2001). In a study of depression and adherence in 204 post-MI patients, 17% were found to have mild or moderate depression according to the Beck Depression Inventory (BDI >10) and 15% were found to have major depression and/or dysthymia based on the DSM-III-R criteria (Ziegelstein et al., 2000). Patients with a BDI score greater than 10 were less likely than
patients with a BDI<10 to follow a low-fat and low-cholesterol diet, exercise regularly, reduce stress, and increase social support. Additionally, those with major depression and/or dysthymia also were less likely to take their medication as prescribed.

Recent research found a relationship between depression and nonadherence in coronary heart disease (CHD) patients even after controlling for demographic, psychosocial, and clinical variables (Gehi, Haas, Pipkin, & Whooley, 2005). The prevalence of depression in the sample of 940 CHD patients was 22%. Depressed patients were more likely than nondepressed patients to report not taking their medication (14% vs. 5%), forgetting to take their medication (18% vs. 9%), and deciding to skip their medication (9% vs. 4%). Moreover, more severe depression was associated with greater nonadherence to medication.

There are several explanations for why depression may increase nonadherence (DiMatteo, Lepper, & Croghan, 2000). In order for patients to adhere to a medical treatment regimen, the patient must believe that the regimen is beneficial and efficacious in order for the patient to follow through with treatment. Because depression is often associated with hopelessness, adherence may be difficult or impossible for the patient if he/she is not optimistic about the outcome of the treatment. Second, depression may interfere with social networks that could provide the patient assistance with adhering to complex medication regimens or lifestyle changes. Third, adhering to treatment recommendations (e.g., taking medication) requires that a patient have adequate cognitive functioning in the areas of memory and attention. However, depressive symptoms may impair patients’ cognitive focus resulting in decreased adherence.
The association between anxiety and adherence is unclear (DiMatteo, Lepper, & Croghan, 2000). However, anxiety was found to account for 3% of the variance in avoiding smoking among heart failure patients (Schweitzer, Head, & Dwyer, 2007). Smoking cessation has been found to be more difficult in individuals with anxiety disorders (Morissette, Tull, Gulliver, Kamholz, & Zimering, 2007; Zvolensky, Baker, Leen-Felner, Bonn-Miller, Feldner, & Brown, 2004). Because the unpredictability of ICD shock, patients may experience anticipatory anxiety (Pauli et al., 2005). As a result, heart failure patients with an ICD may limit their activities in order to reduce the risk of shock (Hegel et al., 1997; Lemon, Edelman, & Kirkness, 2004). Consequently, limiting activities may prevent patients from picking up prescriptions from the pharmacy, going grocery shopping to pick out low-sodium foods, or participating in physical activity. In order to better understand the association between psychological distress and adherence in heart failure patients, the current study examines the effect of depression and anxiety symptoms on adherence to individual treatment guidelines in heart failure patients with an ICD.

Purpose and Hypotheses of the Current Study

The overarching goal of the present study is to evaluate the impact of psychological distress and cognitive impairment on adherence to individual treatment guidelines in heart failure patients with an ICD. Investigating the prognostic importance of psychological distress, cognitive impairment, and adherence in heart failure patients treated with an ICD is particularly appropriate for several reasons. First, VT/VF and sudden cardiac death account for only about half of all cardiac deaths in heart failure
(Bardy et al., 2005). Once VT/VF is controlled with ICD treatment, other causes of death become more prominent, such as disease progression to pump failure. In addition, heart failure patients treated with an ICD are at high risk of morbidity and mortality, are very expensive to treat (Chen & Hay, 2004), and are followed at regularly scheduled intervals. Considered with the increasing use of ICDs in heart failure and the new challenges for patient management introduced by the expanding indications for ICD implantation, it is imperative to systematically evaluate how psychological distress and cognitive impairment affect adherence to treatment recommendations in heart failure patients treated with an ICD, toward the goal of improving the management of this severely ill and high risk patient population.

**Aim 1.** The first aim of the present study is to examine the relationship between depression and adherence to treatment recommendations in heart failure patients treated with an ICD.

*Hypothesis 1:* It is predicted that depression will be associated with medication adherence. In other words, patients who report higher levels of depression will report worse adherence to taking prescribed medications.

*Hypothesis 2:* It is predicted that depression will be associated with diet adherence. In other words, patients who report higher levels of depression will report worse adherence to following dietary recommendations, such as restricting sodium and fluid intake.
Hypothesis 3: It is predicted that depression will be associated with exercise adherence. In other words, patients who report higher levels of depression will report worse adherence to exercising regularly.

Hypothesis 4: It is predicted that depression will be associated with smoking adherence. In other words, patients who report higher levels of depression will report worse adherence to eliminating smoking.

Hypothesis 5: It is predicted that depression will be associated with alcohol adherence. In other words, patients who report higher levels of depression will report worse adherence to limiting alcohol.

Aim 2. The second aim of the present study is to examine the relationship between anxiety and adherence to treatment recommendations in heart failure patients treated with an ICD.

Hypothesis 6: It is predicted that anxiety will be associated with medication adherence. In other words, patients who report higher levels of anxiety will report worse adherence to taking prescribed medications.

Hypothesis 7: It is predicted that anxiety will be associated with diet adherence. In other words, patients who report higher levels of anxiety will report worse adherence to following dietary recommendations, such as restricting sodium and fluid intake.

Hypothesis 8: It is predicted that anxiety will be associated with exercise adherence. In other words, patients who report higher levels of anxiety will report worse adherence to exercising regularly.
Hypothesis 9: It is predicted that anxiety will be associated with smoking adherence. In other words, patients who report higher levels of anxiety will report worse adherence to eliminating smoking.

Hypothesis 10: It is predicted that anxiety will be associated with alcohol adherence. In other words, patients who report higher levels of anxiety will report worse adherence to limiting alcohol.

Aim 3. The third aim of the present study is to examine the relationship between cognitive impairment and adherence to treatment recommendations in heart failure patients treated with an ICD.

Hypothesis 11: It is predicted that cognitive impairment will be associated with medication adherence. In other words, patients who exhibit more cognitive impairment will report worse adherence to taking prescribed medications.

Hypothesis 12: It is predicted that cognitive impairment will be associated with diet adherence. In other words, patients who exhibit more cognitive impairment will report worse adherence to following dietary recommendations, such as restricting sodium and fluid intake.

Hypothesis 13: It is predicted that cognitive impairment will be associated with exercise adherence. In other words, patients who exhibit more cognitive impairment will report worse adherence to exercising regularly.

Hypothesis 14: It is predicted that cognitive impairment will be associated with smoking adherence. In other words, patients who exhibit more cognitive impairment will report worse adherence to eliminating smoking.
Hypothesis 15: It is predicted that cognitive impairment will be associated with alcohol adherence. In other words, patients who exhibit cognitive impairment will report worse adherence to limiting alcohol.
CHAPTER 2

METHODS

This chapter presents an explanation of the research methodology that is utilized to address the question of whether depression, anxiety, and cognitive impairment are related to adherence to individual treatment recommendations for heart failure. A description of the sample, setting, data collection process, instrumentation, and statistical analysis are presented.

Participants

The sample consisted of 100 patients with a primary diagnosis of congestive heart failure (CHF) who have been treated with an ICD. Because heart failure populations are heterogeneous (i.e., different etiology, in-patient vs. out-patient), using heart failure patients treated with an ICD will ensure a more homogenous sample (i.e., same treatment, similar etiology, and medications). In order to be eligible for the study, patients had to be diagnosed with heart failure, speak English, and not had a stroke, traumatic brain injury, or Alzheimer’s disease. Patients’ medical records were examined at baseline to gather pertinent information (Appendix A).
Procedure

Prior to the beginning of data collection, the protocol of this study was approved by both the Kent State University and SUMMA Health System Institutional Review Boards (IRBs). If patients were eligible for the study, they were contacted through a recruitment letter sent by their cardiologist approximately one-week prior to a scheduled ICD medical appointment at Akron Cardiology Consultants, Inc. The letter introduced the study and informed patients that the researcher would be present at the time of their scheduled appointment to further discuss the study, to answer any questions about the study, and to invite them to participate.

Once patients provided informed consent, they were instructed to complete questionnaires assessing psychosocial variables and health behaviors. Psychosocial measures included symptoms of depression and anxiety. A questionnaire assessing adherence to treatment recommendations included medication taking, sodium and fluid restriction, daily weighing, smoking status, and alcohol restriction. In addition to questionnaires, patients completed neuropsychological assessments in the areas of memory, attention, language, executive functioning, and motor speed and a global measure of cognitive functioning. If participants were unable to complete the questionnaires at the time of their scheduled ICD appointment, they were asked to complete them at home. A self-addressed stamped envelope was provided and participants were asked to return them via postal mail.

Patients’ medical records were examined to obtain medical information. Patients were contacted via telephone one month following the baseline assessment to assess
adherence to treatment recommendations. Patients were asked to report information about taking medications, diet, daily weighing, smoking, alcohol, and daily activities for the day prior to the telephone interview.

Measures

The current study collected information on depression, anxiety, cognitive functioning, and adherence to treatment recommendations. Adherence to treatment recommendations were assessed via telephone one month following the baseline assessment.

Medical Information and Demographics

Patients’ charts were examined for medical characteristics pertaining to their CHF, ICD, and medical history in general including other medical diagnoses (e.g., CAD, Diabetes), previous medical procedures (e.g., coronary artery bypass graft), current medications, and most recent NYHA classification (Appendix A). Information regarding the patients’ ICDs was collected and included the date of implant and the number and dates of any defibrillations within the past 6 months. Finally, demographic information was attained through self-report regarding participants’ age, gender, marital status, present living arrangement, race, ethnicity, education, and employment status (Appendix A). Marital status, present living arrangement, race, education, and employment status were dummy coded into married vs. not married, living with someone vs. living alone, white vs. everyone else, high school or less vs. some college or more, and unemployed vs. employed, respectively.
Depression

Depression was assessed using the Beck Depression Inventory (BDI; Beck, Ward, Mendelson, Mock, & Erbaugh, 1961) (Appendix B). The BDI is a 21-item scale that asked respondents to choose the responses that best describe how they have been feeling in the past week. The scale represents depressive symptoms, and each symptom is rated on a scale of 0 to 3. Scores of 10 to 15 reflect mild depression; scores of 16 to 23 reflect moderate depression; and scores of 24 to 63 are in the range of severe depression. The total depression score is obtained by summing up the responses to all 21 items (potential range=0-63).

According to Beck, Steer, & Garbin (1988) and their 25-year review on the BDI, internal consistency ranges from .73 to .92 with a mean of .86 and high internal consistency coefficients of .86 and .81 for both psychiatric and nonpsychiatric samples, respectfully. It also has acceptable validity and reliability scores for individuals over the age of 60 years (Halpert, Braunschweig, & Peters, 1998; Scogin, Beutler, Corblishley, & Hamblin, 1988). Results comparing the BDI to the Hamilton Depression Rating Scale and the depression scale from the Brief Symptom Inventory in a population of individuals over 55 years indicated that all three instruments consistently identified major depressive disorder (Stukenberg, Dura, Kiecolt-Glasser, 1990). Additionally, a study by Campbell, Burgess, and Finch (1984) suggests this level of internal consistency holds for cardiac outpatients as well (α=.83).

Although guidelines for cut-off scores have been proposed by the Center for Cognitive Therapy (CCT) for minimal, mild, moderate, and severe depression, the
current study will conceptualize depression as a continuous variable, rather than categorical. The conceptualization of depression as a continuous variable allows for examination of changes in amount of depressive symptomology rather than changes from one depressive category to another.

Anxiety

Anxiety (α=.86) was assessed using the trait items from the Spielberger’s State-Trait Anxiety Inventory (STAI (TRAIT) (Spielberger, Gorsuch, & Lushene, 1970) (Appendix B). The 20-item scale asked respondents to rate how they generally feel. Respondents rate each item on a 4-point scale from 1 (almost never) to 4 (almost always). Sample items include “I feel rested” and “I feel like crying”. The scale represents general anxiety symptomatology, a score of 40 or higher reflecting a risk for clinical anxiety. A total anxiety score is obtained by first reverse coding appropriate items, and then summing responses to all 20 items (potential range=20-80). This scale has internal consistency reliabilities >.80 and test-retest reliabilities ranging from .73 to .86 for intervals up to 103 days (Spielberger, 1983).

Health Behaviors

Patient adherence to treatment recommendations for heart failure patients was assessed using the Heart Failure Compliance Questionnaire (HFCQ) (Evangelista, Berg, & Dracup, 2001) (Appendix C). The HFCQ was originally designed to measure compliance in patients with a myocardial infarction (Hilbert, 1985), but was revised to address treatment recommendations common to patients with heart failure. The HFCQ
has 6 subsections that address the following health behaviors: follow-up appointments, medications, diet, exercise, smoking cessation, and alcohol cessation. Within each subsection, patients are asked to state how important the specific health behavior is to them on a 5-point scale (0 = not at all important to 4 = highly important). Additionally, patients are asked to indicate how much difficulty they had following the specific health behavior using a 4-point scale, with 0 indicating no difficulty and 3 indicating a lot of difficulty. Patients were also asked to indicate why they had difficulty following the specific health behaviors. A list of responses for each health behavior was provided. Finally, patients were asked to rate their own compliance with each health behavior on a 5-point scale (0 = none of the time, 1 = very seldom, 2 = about half the time, 3 = most of the time, 4 = all of the time). Scoring for the smoking and alcohol use sections are reversed scored because of the negatively worded phrases. Compliance scores for the 6 health behaviors are linearly transformed to a 0 to 100 scale, with 100 indicating the highest level of compliance. The Cronbach’s alpha for this measure is .68. The authors acknowledged that this is low, however low internal consistency reliability would be expected considering that these are distinctly different health behaviors and that compliance with one behavior does not necessarily preclude compliance with another behavior (Evangelista et al., 2003).

A nurse’s report of patient adherence was also obtained at baseline (Appendix C). A nurse who works in the device clinic and who sees all of the ICD patients at regular intervals was asked to complete a short questionnaire regarding each patient’s adherence. Using an 11-point Likert scale (0 = never to 10 = always), the nurse answered the
following question: “To what extent do you feel that this patient is taking their medications as prescribed and is restricting their sodium and fluid intake?” There were also two additional questions: “To what extent do you feel that psychological distress (e.g. depression, anxiety) is interfering with this patient taking their medication and restricting their sodium and fluid intake?” and “To what extent do you feel that cognitive problems are interfering with this patient taking their medication and restricting their sodium and fluid intake?” Each question was rated on a 8-point Likert scale (0 = no interference to 7 = a lot of interference). These measures allow us to obtain the opinion of a nurse who works with the patient closely and will serve a measure of patients’ adherence which is not self-report. Thus, nurse’s report of patients’ adherence should correlate with patients’ self-report of adherence at baseline.

In order to obtain a more real-world account of patient adherence and to obtain a measure of their adherence independent of them completing other measures of adherence behaviors, information about patient adherence was obtained one month following their baseline assessment. This measure of treatment adherence was assessed by having patients report information regarding adherence to treatment recommendations for the day prior to the one month telephone interview follow-up (Appendix C). Patients were asked to indicate if they weighed themselves and what their weight was, if they smoked and how many cigarettes they smoked, and if they consumed any alcoholic beverages and how many drinks they consumed. Additionally, patients were asked if they took all of their prescribed medication the previous day and if they took any of these medications off-schedule. Patients were also asked to report the foods and beverages that they
consumed the previous day. Finally, patients were asked to indicate the daily activities that they performed during the previous day. A list of daily activities was provided. For weighing, smoking, alcohol, and medication, patients’ responses were coded as 1 for adherent and 0 for nonadherent. Patients’ total sodium intake (mgs) was determined by first determining the amount of sodium in each food and beverage using the USDA National Nutrient Database for Standard Reference, Release 19 (Gebhardt et al., 2006) and then summing the mgs of sodium for all foods and beverages. Patients’ sodium intake was then coded as 1 for < 2 g of sodium (adherent) and 0 for >2 g of sodium (nonadherent). For analyses assessing one month adherence, exercise adherence will not be included because exercise training is not recommended by the HFSA practice guidelines for heart failure (Adams et al., 2006)

Neuropsychological Assessments

Hopkins Verbal Learning Test

The Hopkins Verbal Learning Test (HLVT) was used to assess impairments in the areas of memory and verbal learning (Brandt, 1991). HVLT is a learning task containing a list of 12 words with four words in three semantic categories. Participants are presented the 12 words and then asked to recall the words for three learning trials (Brandt, 1991). The revised HVLT (HVLT-R) also contains a 20 to 25 minute delayed recall and a 24 word recognition list containing the original 12 words and 12 semantically related and unrelated words (Benedict et al., 1998). A score is obtained for each learning trial and the delayed recall trial by counting the number of correctly recalled words. Recognition
scores are calculated for true hits (original word is correctly identified) and false positives (incorrectly identified words). The HVLT has been found to have acceptable construct and concurrent reliability (Shapiro, Benedict, Schretlen, & Brandt, 1999) and test-retest reliability (Benedict, Schretlen, Gronigner, & Brandt, 1998). The HVLT-R recall and recognition tasks have been found to have similar validity to other memory measures particularly with verbal memory tests (Lacritz, Cullum, Weiner, & Rosenberg, 2001; Shapiro, Benedict, Schretlen, & Brandt, 1999). In a study examining the effects of age, education, and gender on HVLT-R in older adults, age and gender were found to have a significant effect on HVLT-R performance, such that women and the older adults (80-84 yrs old) performed better than men and the “younger” old adults (60-79 yrs old) (Vanderploeg et al., 2000).

*Trails Making Test A*

Trails Making Test A is a reliable and valid measure of complex visual scanning and psychomotor speed (Spreen & Strauss, 1991). Participants are asked to draw lines connecting numbered circles as quickly as possible. The time to completion and the number of errors are recorded (Reitan & Wolfson, 1985). The test-retest reliability is estimated at .79 (Dikmen, Heaton, Grant, & Temkin, 1999).

*Trails Making Test B*

Trails Making Test B is a commonly used measure of executive dysfunction (Spreen & Strauss, 1991). Participants are asked to quickly connect an alternating series of numbers and letters. The time to completion and number of errors are recorded (Reitan
& Wolfson, 1985). The test-retest reliability is estimated at .89 (Dikmen, Heaton, Grant, & Temkin, 1999). The effect of age was found in healthy individuals on component skills such as visual search, sequencing, and motor speed, but not on switching component (Salthouse et al., 2000; Wecker, Kramer, Wisniewski, Delis, & Kaplan, 2000). Education was also found to have an effect on Trails Making Test with stronger effects for Part B than Part A (Stuss, Stethem, Hugenholtz, & Richard, 1989). Additionally, women, in particular older women, had slower performance on Part B than men (Ernst, 1987).

**Letter-Number Sequencing**

Letter-Number Sequencing is a measure of auditory working memory (Wechsler, 1997). In this test participants listen to series of randomized numbers and letters (in alternating order) of increasing length (from two to eight units). The participant must first remember the numbers and letters and then reorganize the numbers in ascending order and the letters in alphabetical order. For example, the examiner would say “6-F-2-B”, and the participant should respond with “2-6-B-F”. The span of the series is increased until the participant fails all three items for one length. The test-retest reliability for the age group 75-89 is estimated at .75 (Wechsler, 1997). A moderate age effect has been found in normative data. Scores obtained on Letter-Number Sequencing in healthy young adults has been found to correlate with other measures, including the WIS-III Digits Forward and Backward, Arithmetic, Symbol Search, and on visual spatial learning (Crowe, 2000).
Animal Naming

Word fluency tests measure whether and how well individuals organize their thinking (Estes, 1974). Fluency tests can require participants to generate words according to an initial letter, words with the same initial consonant, words with the same theme, or items in a category. Animal naming requires participants to generate items in a category. For this task, participants are asked to name as many animals as they can in 1 minute. The examiner records the participants’ responses. The items generated during each 15 second interval are summed. Age (particularly for those over 70), sex, and education have been found to influence performance on word fluency tests (Benton et al., 1994; Troyer, 2000).

Grooved Pegboard

The grooved pegboard is a measure of motor dexterity (Klove, 1963). It is a small board containing 5x5 set of slotted holes angled in different directions. Each peg has a ridge along one side, requiring it to be rotated into position for correction insertion. Time to completion is recorded. Although both hands should be used, the use of only one hand has been used in prior studies (e.g. Lewis & Rennick, 1979) and therefore only one hand (dominant hand) will be used in the present study. Age effects have been found in numerous studies with slowing increasing with age (Bornstein, 1985; Heaton, Grant, & Matthews, 1991; Heaton, Ryan, Grant, & Matthews, 1996). Furthermore, sex differences have been found such that women had shorter time to completion than men (Bornstein, 1985; Schmidt, Oliveira, Rocha, & Abreu-Villaca, 2000).
Modified Mini-Mental State Examination (3MS)

The 3MS is a modified version of the Mini-Mental State Examination (MMSE) that is used to measure global cognitive performance (Teng & Chui, 1987). The 3MS contains four additional items (listing four-legged animals and identifying similarities between three pairs of items). Additionally, the content and order of other items were modified and the scoring system was more detailed such that the score range is extended to 0-100. This measure is influenced by both age and education, decreasing with age and increasing with education (Anthony, LeResche, Niaz, von Korff, & Folstein, 1982; Tombaugh & McIntyre, 1992). Hence, age and education adjusted norms for the 3MS have been developed (Bravo & Hebert, 1997; Tombaugh, McDowell, Kristjansson, & Hubley, 1996).

Analysis Plan

Covariates

Potential covariates were examined including: age, gender, education, marital status, race, living arrangement, NYHA classification, and previous myocardial infarction, bypass grafting, and cardiac arrest. Including these variables will ensure that any initial inequalities among patients were accounted for in the regressions; thus, allowing for the assessment of the unique effects of the main study variables.

Initial Analysis

Test scores on the neuropsychological tests were converted to demographically corrected t-scores with a mean of 50 and a SD of 10 using published normative data.
Each test in the neuropsychological battery assessed a particular neurocognitive domain (i.e. memory, attention, language, motor speed, executive functioning). A global t-score was calculated by summing the domain t-scores and dividing by the number of domains assessed. The global t-score was calculated in order to have an overall measure of patients’ cognitive functioning which included performance from all five cognitive domains.

A series of hierarchical linear regression analyses were conducted to determine the statistical associations among psychological distress (depression and anxiety) and the 5 specific behavioral/lifestyle recommendations. The same series of hierarchical linear regression analyses were conducted to determine the associations among cognitive functioning (global cognitive t-score and 3MS) and the 5 specific behavioral/lifestyle recommendations. Covariates were included within each hierarchical model.

In order to examine the relationship between psychological distress and adherence at one month follow-up, a series of logistic regressions were conducted. Additionally, the same series of logistic regression analyses were conducted to examine the relationship between cognitive functioning (global cognitive t-score and 3MS) and the 5 specific behavioral/lifestyle recommendations (medication, diet, daily weighing, smoking, and alcohol) at one month follow-up.

**Power Analyses**

Power analyses were conducted using a widely available open-source computer program (GPOWER; Faul & Erdfelder, 1992). The study was powered for the primary regression analyses. The sample size needed to achieve a power of .80 with an estimated
effect size of .08 (medium effect size; Cohen, 1988) and an alpha set at .05 is 102. Thus, a sample size of 100 should allow for adequate power to detect significant associations among the study variables for the primary analyses.
CHAPTER 3

RESULTS

This chapter presents data regarding patients’ demographic and cardiac characteristics and levels of psychological distress and cognitive impairment. In addition, results from statistical analyses examining the relationship between adherence to individual treatment recommendations at baseline and one-month follow-up and psychological distress and cognitive impairment are presented.

Analyses

Covariates

A variety of sociodemographic (e.g., age, race, marital status, education), and cardiac characteristics (e.g., previous procedures, medical diagnoses) were examined as potential covariates. A series of regression analyses with all potential covariates entered simultaneously were conducted to determine which covariates will be used in subsequent analyses (Table 2). Any variables that were significantly associated with a dependent variable at $p < .05$ were retained as control variables. Analyses revealed that none of the covariates were significantly associated with medication, diet, exercise, or alcohol adherence at baseline. Age, gender, and race were significantly associated with smoking adherence at baseline. Therefore, covariates were only entered for regression analyses
Table 2. *Associations between Sociodemographic and Cardiac Variables and Adherence at Baseline*

<table>
<thead>
<tr>
<th></th>
<th>Medication</th>
<th>Diet</th>
<th>Exercise</th>
<th>Smoking</th>
<th>Alcohol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographics</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>-0.02</td>
<td>0.04</td>
<td>0.05</td>
<td>-0.23*</td>
<td>0.01</td>
</tr>
<tr>
<td>Age</td>
<td>0.17</td>
<td>0.23</td>
<td>0.12</td>
<td>-0.27*</td>
<td>0.02</td>
</tr>
<tr>
<td>Living Arrangement</td>
<td>-0.14</td>
<td>-0.07</td>
<td>0.01</td>
<td>-0.08</td>
<td>-0.10</td>
</tr>
<tr>
<td>Race</td>
<td>0.10</td>
<td>0.11</td>
<td>0.08</td>
<td>-0.28*</td>
<td>-0.20</td>
</tr>
<tr>
<td>Marital Status</td>
<td>-0.05</td>
<td>0.15</td>
<td>-0.01</td>
<td>-0.05</td>
<td>-0.06</td>
</tr>
<tr>
<td>Education</td>
<td>-0.05</td>
<td>0.13</td>
<td>0.08</td>
<td>0.14</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Cardiac</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous MI</td>
<td>0.07</td>
<td>-0.08</td>
<td>0.06</td>
<td>0.10</td>
<td>0.03</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>-0.04</td>
<td>-0.11</td>
<td>0.06</td>
<td>-0.07</td>
<td>0.01</td>
</tr>
<tr>
<td>Previous Cardiac Arrest</td>
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<td>-0.01</td>
<td>-0.04</td>
<td>-0.07</td>
<td>0.01</td>
</tr>
<tr>
<td>NYHA</td>
<td>-0.17</td>
<td>-0.08</td>
<td>-0.10</td>
<td>0.15</td>
<td>0.08</td>
</tr>
</tbody>
</table>

Note: Beta coefficients are displayed. MI = myocardial infarction  CABG = Coronary Artery Bypass Grafting  NYHA = New York Heart Association Functional Class  * p<.05
with smoking adherence as the dependent variable. A bivariate correlation matrix of the independent variables was examined for multicollinearity (Table 3).

Table 3. *Correlation Matrix of Independent Variables.*

<table>
<thead>
<tr>
<th></th>
<th>Age</th>
<th>Race</th>
<th>Marital Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>BDI</td>
<td>-0.25*</td>
<td>-0.28**</td>
<td>-0.25*</td>
</tr>
<tr>
<td>STAI</td>
<td>-0.15</td>
<td>-0.29**</td>
<td>-0.18</td>
</tr>
<tr>
<td>Global Cognitive t-score</td>
<td>0.10</td>
<td>-0.03</td>
<td>-0.16</td>
</tr>
<tr>
<td>3MS</td>
<td>-0.23</td>
<td>0.38***</td>
<td>-0.16</td>
</tr>
</tbody>
</table>

BDI - Beck Depression Inventory; STAI – State-Trait Anxiety Inventory; 3MS – Modified Mini Mental State Examination

**Demographics**

149 patients were approached and invited to participate in the study. Of the 149 patients, 100 (71%) patients agreed to participate. After beginning the neuropsychological testing, two patients discontinued participation. Therefore, the final sample size was 98 patients. Of these patients, 89 completed and returned the questionnaire packet and 75 completed the one-month follow-up telephone interview. The characteristics of the final sample are shown in Table 4. The majority of patients were male, married, and living with someone. The average patient was 70 years old. The sample consisted primarily (82%) of Caucasians. Approximately 60% of patients reported having 12 or less years of education. Most patients (74%) were retired.
Table 4. Sociodemographic and Cardiac Characteristics (N=98)

<table>
<thead>
<tr>
<th>Variables</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (%)</td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>76.5</td>
</tr>
<tr>
<td>Females</td>
<td>23.5</td>
</tr>
<tr>
<td>Age in years</td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>70 (10.72)</td>
</tr>
<tr>
<td>Range</td>
<td>39-86</td>
</tr>
<tr>
<td>Race (%)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>82</td>
</tr>
<tr>
<td>African-American</td>
<td>15</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>2</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
</tr>
<tr>
<td>Marital Status (%)</td>
<td></td>
</tr>
<tr>
<td>Currently married</td>
<td>66</td>
</tr>
<tr>
<td>Widow</td>
<td>10</td>
</tr>
<tr>
<td>Divorced</td>
<td>10</td>
</tr>
<tr>
<td>Single</td>
<td>14</td>
</tr>
<tr>
<td>Present Living Arrangement (%)</td>
<td></td>
</tr>
<tr>
<td>Living with someone</td>
<td>82</td>
</tr>
<tr>
<td>Living alone</td>
<td>18</td>
</tr>
<tr>
<td>Education Level (%)</td>
<td></td>
</tr>
<tr>
<td>Less than 12</td>
<td>14</td>
</tr>
<tr>
<td>12 or GED</td>
<td>46</td>
</tr>
<tr>
<td>Some college or more</td>
<td>40</td>
</tr>
<tr>
<td>Employment Status (%)</td>
<td></td>
</tr>
<tr>
<td>Full/Part Time</td>
<td>18</td>
</tr>
<tr>
<td>Unemployed</td>
<td>8</td>
</tr>
<tr>
<td>Retired</td>
<td>74</td>
</tr>
<tr>
<td>Shocks (%)</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>86.5</td>
</tr>
<tr>
<td>At least 1 shock</td>
<td>13.5</td>
</tr>
<tr>
<td>NYHA (%)</td>
<td></td>
</tr>
<tr>
<td>Class 1</td>
<td>46</td>
</tr>
<tr>
<td>Class 2</td>
<td>52</td>
</tr>
<tr>
<td>Class 3</td>
<td>2</td>
</tr>
<tr>
<td>Class 4</td>
<td>0</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>36</td>
</tr>
<tr>
<td>Previous CABG (%)</td>
<td>26</td>
</tr>
<tr>
<td>Previous Cardiac Arrest (%)</td>
<td>25</td>
</tr>
</tbody>
</table>

NYHA = New York Heart Association Functional Class
MI = myocardial infarction
CABG = coronary artery bypass grafting
In regards to the New York Heart Association Functional Class, almost half of the patients were considered Class I heart failure indicating no symptoms or limitations in physical activity and the other half of patients had Class II heart failure indicating mild symptoms and slight limitations during physical activity. Approximately one-quarter of patients had a previous bypass surgery and cardiac arrest. Additionally, about 40% of patients had a previous myocardial infarction.

At baseline, 91% of patients reported being adherent all of the time to taking medications (Table 5). Patients’ adherence to dietary recommendations and exercising regularly were poor such that 16% of patients reported being adherent to dietary recommendations all of the time and 14% reported being adherent all of the time to exercising regularly. Additionally, 82% of patients reported being adherent all of the time to eliminating alcohol. The majority of patients were non-smokers (N = 79) or former smokers (N = 7). Only 3 patients reported being a current smoker. Interesting, only 77 patients reported not smoking in the past week. At one month follow-up, approximately 93% of patients reported taking medications, eliminating smoking, and eliminating alcohol for the previous day (Table 6). About one-third of patients (32%) did not restrict their sodium intake to less than 2000mg. Additionally, approximately half (55%) of patients did not weigh themselves the previous day.

Nurse’s Report of Patient Adherence

Nurse’s rating of the extent to which patients adhere to taking their medication and following dietary recommendations was compared to patient self-report of medication and diet adherence. Nurses’ report of medication and diet adherence was not
Table 5. Adherence to Treatment Recommendations at Baseline

<table>
<thead>
<tr>
<th>In the past week, would you estimate you have...............</th>
<th>All of the time</th>
<th>Most of the time</th>
<th>About half of the time</th>
<th>Very Seldom</th>
<th>None of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taken your medication (N = 89)</td>
<td>(81)91%</td>
<td>(6)7%</td>
<td>(1)1%</td>
<td>(1)1%</td>
<td>(0)0%</td>
</tr>
<tr>
<td>Followed your dietary recommendations (N = 88)</td>
<td>(14)16%</td>
<td>(55)61%</td>
<td>(11)13%</td>
<td>(3)3%</td>
<td>(5)7%</td>
</tr>
<tr>
<td>Exercised as recommended (N = 88)</td>
<td>(12)14%</td>
<td>(28)32%</td>
<td>(16)18%</td>
<td>(21)24%</td>
<td>(11)12%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In the past week, would you estimate you have...............</th>
<th>None of the Time/Not applicable</th>
<th>Very Seldom</th>
<th>About half of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoked</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-smoker (N = 79)</td>
<td>(77)86%</td>
<td>(3)3%</td>
<td>(0)0%</td>
<td>(5)6%</td>
<td>(4)5%</td>
</tr>
<tr>
<td>Former (N = 7)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current (N = 3)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Used alcohol</td>
<td>(71)82%</td>
<td>(4)5%</td>
<td>(3)3%</td>
<td>(4)5%</td>
<td>(5)5%</td>
</tr>
<tr>
<td>(N = 87)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 6. *Percentage of Patients that Adhered and did not Adhere to Treatment Recommendations at Follow-up, (N=75)*

<table>
<thead>
<tr>
<th></th>
<th>N (%) Adherent</th>
<th>N (%) Nonadherent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight - Weighed self?</td>
<td>34(45%)</td>
<td>41(55%)</td>
</tr>
<tr>
<td>Medication – Did you take your medication?</td>
<td>70(93%)</td>
<td>5(7%)</td>
</tr>
<tr>
<td>Diet – Restrict sodium to under 2000mg?</td>
<td>50(68%)</td>
<td>24(32%)</td>
</tr>
<tr>
<td>Smoking – Did you smoke any cigarettes?</td>
<td>69(92%)</td>
<td>6(8%)</td>
</tr>
<tr>
<td>Alcohol –Did you consume any alcoholic beverages?</td>
<td>70(93%)</td>
<td>5(7%)</td>
</tr>
</tbody>
</table>
significantly correlated with patient self-report of medication \((r = -.07, p>.05)\) and diet 
\((r = .16, p>.05)\) adherence. Depression Anxiety symptoms was found to be associated 
with nurses’ report of patient adherence to taking medications and diet adherence
\((\beta = -.31, se = .01, p<.05)\). However, depression symptoms \((\beta = -.03, se = .02, p>.05)\), the
3MS \((\beta = .01, se = .02, p>.05)\), and the global cognitive t-score \((\beta = -.01, se = .02, p>.05)\) 
were not found to be associated with nurses’ report of patient adherence.

Rates of Depression, Anxiety, and Cognitive Impairment

A cutoff score of 10, which has been typically used to indicate the presence of at
least mild depressive symptomatology, was used for BDI. Using this criterion, 24% of
heart failure patients treated with an ICD in this sample had significant symptoms of
depression. A cutoff score of 40 indicating a risk for clinical anxiety (Spielberger, 1983)
was used for STAI. Frequencies of STAI scores indicated that 36% of patients in the
sample had clinical levels of anxiety symptoms.

According to clinical guidelines, t-scores which are one standard deviation below
the mean are indicative of cognitive deficits and t-scores which are one and a half
standard deviations below the mean are indicative of cognitive impairment. Using these
guidelines and the global cognitive t-score, 62% of patients within the sample exhibit
cognitive deficits and 39% of patients had cognitive impairment. The 3MS is a measure
of global cognitive performance. According to clinical guidelines, a score of 95 or less is
indicative of cognitive deficits and a score of 90 or less indicates cognitive impairment.
Based on these cutoffs, 68% of patients had cognitive deficits and 34% of patients had
cognitive impairment.
Adherence at Baseline

The Effect of Depression on Adherence

The relationship between depression and adherence was analyzed using a series of hierarchical linear regressions. As shown in Table 7, depression was not found to be related to medication adherence, smoking adherence, or alcohol adherence after adjusting for appropriate covariates. Depression was related to diet adherence ($\beta = -0.46$, $se = 0.27$, $p<.000$) and exercise adherence ($\beta = -0.22$, $se = 0.38$, $p<.05$). Higher levels of depressive symptoms were related to less adherence to diet recommendations and exercising regularly. Figure 1 shows adherence rates for patients with a BDI $<10$ vs. BDI $\geq 10$.

The Effect of Anxiety on Adherence

The relationship between anxiety and adherence to individual treatment recommendations was analyzed using a series of hierarchical linear regressions. As shown in Table 7, anxiety was not found to be related to medication adherence, smoking adherence, or alcohol adherence even after adjusting for age, marital status, shocks, and race. Anxiety was related to diet adherence ($\beta = -0.43$, $se = 0.18$, $p<.000$) and exercise adherence ($\beta = -0.36$, $se = 0.26$, $p<.00$) after controlling for covariates. Higher levels of anxiety were related to less adherence to diet and exercise recommendations. Figure 2 and 3 show adherence rates for diet and exercise for patients with STAI score $<40$ vs. $\geq 40$. 
Table 7. *Linear Regressions Examining Association between Predictor Variables and Adherence to Individual Treatment Recommendations at Baseline*

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>Medication</th>
<th>Diet</th>
<th>Exercise</th>
<th>Smoking</th>
<th>Alcohol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>-0.14</td>
<td>0.19</td>
<td>-0.51</td>
<td>0.000**</td>
<td>-0.00</td>
</tr>
<tr>
<td></td>
<td>(0.140)</td>
<td></td>
<td>(0.25)</td>
<td>(0.38)</td>
<td>(0.36)</td>
</tr>
<tr>
<td>State Trait Anxiety</td>
<td>-0.11</td>
<td>0.30</td>
<td>-0.48</td>
<td>0.000**</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>(0.09)</td>
<td></td>
<td>(0.17)</td>
<td>(0.25)</td>
<td>(0.24)</td>
</tr>
<tr>
<td>Modified Mini Mental Examination</td>
<td>0.16</td>
<td>0.15</td>
<td>0.09</td>
<td>-0.02</td>
<td>-0.07</td>
</tr>
<tr>
<td></td>
<td>(0.15)</td>
<td></td>
<td>(0.32)</td>
<td>(0.43)</td>
<td>(0.39)</td>
</tr>
<tr>
<td>Cognitive Impairment</td>
<td>-0.17</td>
<td>0.12</td>
<td>-0.13</td>
<td>0.02</td>
<td>0.48</td>
</tr>
<tr>
<td></td>
<td>(0.10)</td>
<td></td>
<td>(0.21)</td>
<td>(0.29)</td>
<td>(0.26)</td>
</tr>
</tbody>
</table>

Note: Cognitive Impairment is the composite variable consisting of the average normed score across 5 cognitive domains.
Figure 1. Adherence Rates for Diet Recommendations for Patients with BDI<10 (N=66) vs. BDI≥10 (N=22)
Figure 2. Adherence Rates for Diet Recommendations for Patients with STAI <40 (N=57) vs. ≥40 (N=30)
Figure 3. Adherence Rates for Exercise Recommendations for Patients with STAI <40 (N=57) vs. STAI ≥40 (N=30)
The Effect of Cognitive Impairment on Adherence

The relationship between the 3MS total score and adherence to individual treatment recommendations was analyzed using a series of hierarchical linear regressions. As shown in Table 7, 3MS was not found to be related to any of the adherence treatment recommendations which include medication adherence, diet adherence, exercise adherence, smoking adherence, and alcohol adherence even after adjusting for age, marital status, shocks, and race.

The same series of regressions were used to examine the relationship between the global cognitive t-score and adherence to individual treatment recommendations. As shown in Table 7, cognitive impairment was not found to be related to any of the adherence treatment recommendations which include medication adherence, diet adherence, exercise adherence, smoking adherence, and alcohol adherence even after adjusting for appropriate covariates.

Adherence at One Month Follow-up

Covariates

A variety of sociodemographic (e.g., age, race, marital status, education), and cardiac characteristics (e.g., previous procedures, medical diagnoses) were examined as potential covariates. A series of regression analyses with all potential covariates entered simultaneously were conducted to determine which covariates will be used in subsequent analyses (Table 8). Any variables that were significantly associated with a dependent variable at $p < .05$ were retained as control variables. Analyses revealed that none of the
Table 8. Associations between Sociodemographic and Cardiac Variables and Adherence at One Month Follow-up

<table>
<thead>
<tr>
<th>Sociodemographics</th>
<th>Sodium</th>
<th>Weighing</th>
<th>Smoking</th>
<th>Alcohol</th>
<th>Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>0.02</td>
<td>-0.01</td>
<td>-0.14*</td>
<td>-0.15</td>
<td>-0.24*</td>
</tr>
<tr>
<td>Age</td>
<td>-0.05</td>
<td>0.22</td>
<td>-0.18</td>
<td>-0.03</td>
<td>0.07</td>
</tr>
<tr>
<td>Living Arrangement</td>
<td>0.15</td>
<td>0.01</td>
<td>0.02</td>
<td>0.11</td>
<td>0.13</td>
</tr>
<tr>
<td>Race</td>
<td>-0.14</td>
<td>0.07</td>
<td>-0.32*</td>
<td>0.13</td>
<td>-0.07</td>
</tr>
<tr>
<td>Education</td>
<td>0.07</td>
<td>0.04</td>
<td>0.01</td>
<td>-0.01</td>
<td>-0.18</td>
</tr>
</tbody>
</table>

Cardiac

| Previous MI       | -0.18  | -0.09   | -0.06   | -0.04   | -0.33*     |
| Previous CABG     | -0.06  | -0.13   | -0.21   | -0.04   | -0.10      |
| Previous Cardiac Arrest | -0.05 | -0.19  | -0.27*  | -0.02   | -0.15      |
| NYHA              | -0.10  | 0.03    | -0.23*  | -0.00   | 0.02       |

Note: Beta coefficients are displayed. MI = myocardial infarction, CABG = Coronary Artery Bypass Grafting, NYHA = New York Heart Association Functional Class * p<.05
covariates were significantly associated with diet, weighing, or alcohol adherence at follow-up. Gender and previous myocardial infarction were significantly associated with medication adherence. Gender, race, NYHA class, and previous arrhythmia were significantly associated with smoking adherence. Therefore, covariates were only entered for regression analyses with medication and smoking adherence as the dependent variable.

*The Effect of Depression on Adherence at One Month Follow-up*

The relationship between depression and adherence to individual treatment recommendations was analyzed using a series of logistic regressions. After analyses were adjusted for appropriate covariates, depression was not found to be significantly associated with adherence to any of the treatment guidelines including diet adherence, weighing adherence, smoking adherence, alcohol adherence, or medication adherence (Table 9-13).

*The Effect of Anxiety on Adherence at One Month Follow-up*

The relationship between anxiety and adherence to individual treatment recommendations was analyzed using a series of logistic regressions. After analyses were adjusted for appropriate covariates, anxiety was not found to be significantly associated with adherence to any of the treatment guidelines including diet adherence, weighing adherence, smoking adherence, alcohol adherence, or medication adherence (Table 9-13).
Table 9. *Logistic Regressions Examining Association between Predictor Variables and Adherence to Restricting Sodium Intake at One Month Follow-up, (N = 73)*

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>B</th>
<th>SEB</th>
<th>(e^b)</th>
<th>C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>-0.02</td>
<td>0.04</td>
<td>1.02</td>
<td>0.95-1.10</td>
</tr>
<tr>
<td>State Trait Anxiety Inventory</td>
<td>0.03</td>
<td>0.03</td>
<td>1.03</td>
<td>0.98-1.08</td>
</tr>
<tr>
<td>Modified Mini Mental Examination</td>
<td>-0.08</td>
<td>0.05</td>
<td>0.88</td>
<td>0.84-1.01</td>
</tr>
<tr>
<td>Global Cognitive t-score</td>
<td>-0.00</td>
<td>0.03</td>
<td>1.00</td>
<td>0.95-1.05</td>
</tr>
</tbody>
</table>

Note: Global Cognitive t-score is the composite variable consisting of the average normed score across 5 cognitive domains. C.I. = 95% confidence interval for exp B. * p<.05
Table 10. *Logistic Regressions Examining Association between Predictor Variables and Adherence to Daily Weighing at One Month Follow-Up, (N = 73)*

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>B</th>
<th>SEB</th>
<th>( e^b )</th>
<th>C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>-0.00</td>
<td>0.04</td>
<td>1.00</td>
<td>0.92-1.08</td>
</tr>
<tr>
<td>State Trait Anxiety Inventory</td>
<td>0.02</td>
<td>0.02</td>
<td>1.02</td>
<td>0.97-1.07</td>
</tr>
<tr>
<td>Modified Mini Mental Examination</td>
<td>-0.07</td>
<td>0.04</td>
<td>0.93</td>
<td>0.86-1.01</td>
</tr>
<tr>
<td>Global Cognitive t-score</td>
<td>-0.02</td>
<td>0.02</td>
<td>0.98</td>
<td>0.94-1.03</td>
</tr>
</tbody>
</table>

Note: Global Cognitive t-score is the composite variable consisting of the average normed score across 5 cognitive domains. C.I. = 95% confidence interval for exp B. *p<.05
Table 11. *Logistic Regressions Examining Association between Predictor Variables and Adherence to Taking Medication at One Month Follow-up, (N = 73)*

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>B</th>
<th>SEB</th>
<th>e^b</th>
<th>C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>-0.05</td>
<td>0.08</td>
<td>0.95</td>
<td>0.81-1.12</td>
</tr>
<tr>
<td>State Trait Anxiety Inventory</td>
<td>-0.03</td>
<td>0.08</td>
<td>0.97</td>
<td>0.83-1.13</td>
</tr>
<tr>
<td>Modified Mini Mental Examination</td>
<td>-28.78</td>
<td>1141.81</td>
<td>0.00</td>
<td>-------</td>
</tr>
<tr>
<td>Global Cognitive t-score</td>
<td>-0.12</td>
<td>0.10</td>
<td>0.89</td>
<td>0.73-1.08</td>
</tr>
</tbody>
</table>

Note: Global Cognitive t-score is the composite variable consisting of the average normed score across 5 cognitive domains. C.I. = 95% confidence interval for exp B. * p<.05
Table 12  *Logistic Regressions Examining Association between Predictor Variables and Adherence to Eliminating Smoking at One Month Follow-up, (N = 73)*

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>B</th>
<th>SEB</th>
<th>e^b</th>
<th>C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>-0.05</td>
<td>0.10</td>
<td>0.95</td>
<td>0.78-1.15</td>
</tr>
<tr>
<td>State Trait Anxiety Inventory</td>
<td>-0.01</td>
<td>0.05</td>
<td>0.99</td>
<td>0.90-1.09</td>
</tr>
<tr>
<td>Modified Mini Mental Examination</td>
<td>0.04</td>
<td>0.09</td>
<td>1.04</td>
<td>0.88-1.23</td>
</tr>
<tr>
<td>Global Cognitive t-score</td>
<td>0.07</td>
<td>0.05</td>
<td>1.07</td>
<td>0.96-1.18</td>
</tr>
</tbody>
</table>

Note: Global Cognitive t-score is the composite variable consisting of the average normed score across 5 cognitive domains.  C.I. = 95% confidence interval for exp B.  * p<.05
Table 13. *Logistic Regressions Examining Association between Predictor Variables and Adherence to Eliminating Alcohol at One Month Follow-up, (N = 73)*

<table>
<thead>
<tr>
<th>Predictor Variables</th>
<th>B</th>
<th>SEB</th>
<th>e^b</th>
<th>C.I.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beck Depression Inventory</td>
<td>-0.02</td>
<td>0.04</td>
<td>1.02</td>
<td>0.95-1.10</td>
</tr>
<tr>
<td>State Trait Anxiety Inventory</td>
<td>0.03</td>
<td>0.03</td>
<td>1.03</td>
<td>0.98-1.08</td>
</tr>
<tr>
<td>Modified Mini Mental Examination</td>
<td>-0.08</td>
<td>0.05</td>
<td>0.88</td>
<td>0.84-1.01</td>
</tr>
<tr>
<td>Global Cognitive t-score</td>
<td>-0.00</td>
<td>0.03</td>
<td>1.00</td>
<td>0.95-1.05</td>
</tr>
</tbody>
</table>

Note: Global Cognitive t-score is the composite variable consisting of the average normed score across 5 cognitive domains.  C.I. = 95% confidence interval for exp B.  * p<.05
The Effect of Cognitive Impairment on Adherence at One Month Follow-Up

The relationship between the 3MS score and adherence to individual treatment recommendations was analyzed using a series of logistic regressions. After analyses were adjusted for appropriate covariates, 3MS was not found to be significantly associated with adherence to any of the treatment guidelines including diet adherence, weighing adherence, smoking adherence, alcohol adherence, or medication adherence.

The relationship between the global cognitive t-score and adherence to individual treatment recommendations was analyzed using a series of logistic regressions. After analyses were adjusted for appropriate covariates, cognitive impairment was not found to be significantly associated with adherence to any of the treatment recommendations including diet adherence, weighing adherence, smoking adherence, alcohol adherence, and medication adherence (Table 9-13).
CHAPTER 4

DISCUSSION

This section outlines the major findings of the current study. In addition, these findings will be discussed in terms of the implications for interventions. Finally, limitations of the current study will be addressed and avenues for future research are proposed.

The purpose of the current study was to examine the effect of psychological distress and cognitive impairment on adherence to treatment recommendations in heart failure patients treated with an ICD. Specifically, the current study sought to answer whether depression and anxiety symptoms were related to patients’ adherence to individual treatment recommendations for heart failure patients. It was hypothesized that higher levels of depressive symptoms and anxiety symptoms would be associated with poor adherence to taking medications, following dietary restrictions, exercising regularly, and eliminating smoking and alcohol. In addition, the current study also sought to answer whether cognitive impairment was related to patients’ adherence to individual treatment recommendations for heart failure patients. It was hypothesized that patients who exhibit more cognitive impairment would report poor adherence to taking medications, following dietary restrictions, exercising regularly, and eliminating smoking and alcohol. The results of the present study provided partial support for the study hypotheses.
Specifically, greater levels of depression and anxiety symptoms were found to be associated with poorer diet and exercise adherence. However, cognitive impairment (3MS and global cognitive t-score) was not found to be related to adherence to any of the recommended treatment guidelines.

Rates of Depression, Anxiety, and Cognitive Impairment

Analyses revealed elevated rates of depression and anxiety symptoms, 24% and 36% respectively, within the current sample of heart failure patients treated with an ICD. The rate of depression found in the current sample is consistent with rates found in other samples of heart failure patients. Among patients with heart failure, rates of depression range from 24% to 42% (Havranek, Ware, & Lowes, 1999; Skotzko et al., 2000). Specifically, in a sample of 1006 hospitalized heart failure patients, 30% of patients scored $\geq 10$ on the Beck Depression Inventory indicating depressive symptomatology (Jiang et al., 2007). Based on clinical diagnosis of depression using the SCID I, 29% of heart failure patients were found to have a depressive disorder (Haworth et al., 2005). Moreover, the rate of depression found in the current sample of heart failure patients treated with an ICD is similar to rates found in ICD samples. In our previous study of patients with an ICD, rates of depression (22%) were similar to rates in the current study (24%) (Luyster, Hughes, Josephson, & Waechter, 2006).

The prevalence of anxiety in heart failure patients is under-researched (MacMahon & Lip, 2002). In one study, 18% of heart failure patients were found to have an anxiety disorder according to DSM-IV criterion (Haworth et al., 2005). However, approximately 40% of ICD patients meet diagnostic criteria for anxiety disorders (Sola &
Bostwick, 2005) which is consistent with the rate of anxiety found in the current study (36%). Interestingly, in our previous study of ICD patients (Luyster, Hughes, Josephson, & Waechter, 2006), the rate of anxiety (21%) was considerably lower than the rate of anxiety in the current study. In contrast to the present study which only included heart failure patients treated with an ICD, our previous study included all patients treated with an ICD (e.g. heart failure, depressed LVEF, congenital heart defect). This difference in rates of anxiety may indicate that heart failure patients treated with an ICD may be experiencing more anxiety symptoms than the general ICD population possibly because of more severe disease symptomatology.

Results indicate that a significant percentage of heart failure patients treated with an ICD have cognitive impairment. Specifically, 34% of patients scored $\leq 95$ on the Modified Mini Mental Status Examination (3MS), indicating cognitive impairment. In a study of heart failure patients aged 60 years or over, over half (54%) scored lower than 24 on the Mini Mental Status Examination (MMSE) indicating cognitive impairment, as compared to the 33% of elderly controls who scored higher than 24 (Almeida & Tamai, 2001). In a more recent study, 23.3% of heart failure patients (mean age = 65.5) were found to have cognitive impairment as indicated by the MMSE (Mauro et al., 2007). The prevalence of cognitive impairment varies with a range from 30% to 80% which is a result of patient age and characteristics and the methodology utilized (Bennett & Sauve, 2003). In the current study, cognitive impairment was common, thus reinforcing previous findings demonstrating the prevalence of cognitive dysfunction in heart failure patients.
According to a recent review addressing cognitive impairment and heart failure, the most frequent cognitive deficits reported were memory, attention, problem solving, learning, and motor speed (Bennett & Sauve, 2003). The neuropsychological battery used in the current study, aimed at assessing cognitive functioning, showed scores indicative of impairment in a range from 13% to 62% of patients. In fact, in 62% of heart failure patients treated with an ICD, impairment in the area of memory was found (Hopkins Verbal Learning Test – delay). Furthermore, in our heart failure population, impairment in attention (Letter Number Sequencing test) was found in 17% of patients, impairment in language in 13% (Animal Naming Test), and impairment in executive functioning in 43% (Trails B test). Finally, 15 patients were unable complete the Grooved Pegboard test (evaluating motor dexterity) due to numbness in fingers or unsteadiness of hand. With these individuals dropped from the descriptive statistics, 44% of patients exhibited motor impairment. These findings suggest that cognitive impairment appears to be most significant in the areas of memory, executive functioning, and motor dexterity within heart failure patients treated with an ICD. Other studies have also found memory impairment to be highly prevalent in heart failure patients (Trojano et al., 2003; Mauro et al., 2007; Wolfe, Worrall-Carter, Foister, Keks, & Howe, 2006). Impairment in executive functioning as assessed using the Wisconsin Card Sorting Test was found in a sample of heart failure patients (Wolf, Worrall-Carter, Foister, Keks, & Howe, 2006).
Depression and Adherence

It was hypothesized that higher levels of depressive symptoms would be associated with poor adherence to taking medications, following dietary restrictions, exercising regularly, and eliminating smoking and alcohol. Results of the current study provide partial support for these hypotheses. Depression was found to be associated with diet adherence and exercise adherence. Higher levels of depressive symptoms were related to poor adherence to following dietary recommendations. Similar results were found in a study examining adherence in heart failure patients (Evangelista, Berg, & Dracup, 2001). Patients who reported poorer mental health defined as a measure of the patients’ well-being, anxiety, and depression was associated with poor adherence to following dietary recommendations. Depression has also been found to be related to poor adherence to following a low-fat and low-cholesterol diet in patients recovering from a myocardial infarction (Ziegelstein et al., 2000).

Potential reasons for this association may be that depressed patients lack the energy and motivation to keep track of sodium and fluid intake in order to adhere to the recommended restrictions (DiMatteo, Lepper, & Croghan, 2000). Additionally, depression may lead patients to socially isolate themselves thus withdrawing from family and friends who may be able to provide assistance. Finally, depression may impair patients’ cognitive focus resulting in inadequate management of fluid and sodium intake. Current studies suggest that a significant negative relationship exists between depression and adherence in cardiac patients (Gehi, Haas, Pipkin, & Whooley, 2005; Spernak,
Moore, & Hamm, 2007; Ziegelstein et al., 2000), however further examinations of the mechanisms responsible for the effect of depression on adherence are needed.

Higher levels of depressive symptoms were found to be associated with poor adherence to exercising daily. Depressed heart failure patients have been found to report diminished functional abilities and demonstrated diminished effort as indicated by lower respiratory quotient on cardiopulmonary exercise testing (Skotzko et al., 2000). In a study examining predictors of early drop out from cardiac rehabilitation, higher depression scores were found to predict drop out in a sample of 147 cardiac patients referred to a cardiac rehabilitation program (Yohannes, Yalfani, Doherty, & Bundy, 2007). These studies suggest that depression may interfere with patients participating in physical activities.

In order to obtain a more real-world account of patient adherence and to obtain a measure of their adherence independent of them completing other measures of adherence behaviors, information about patient adherence was obtained one month following their baseline assessment. The interview asked patients whether they took their medication, weighed themselves, what they ate and drank, and if they smoked or drank alcohol. Because the time to follow-up was month, which may not have been a long enough time span to produce differential reports of adherence from baseline, these results are considered another cross-sectional analysis of patient adherence rather than a longitudinal analysis. Depression was found to marginally predict smoking adherence such that higher levels of depressive symptoms were found to predict nonadherence to smoking cessation at one month follow-up. This finding is not surprising considering that depressed persons
often have a more difficult time quitting smoking than do those who are not depressed (Berlin & Covey, 2006; Wilhelm, Arnold, Niven, & Richmond, 2004). In sum, elevated depressive symptoms were found to be associated with nonadherence to dietary recommendations and smoking cessation.

Anxiety and Adherence

Higher anxiety symptoms were hypothesized to be associated with less adherence to taking medications, following dietary restrictions, exercising regularly, and eliminating smoking and alcohol. Results of the study provide partial support for these hypotheses. Anxiety was found to be associated with diet and exercise adherence such that higher levels of anxiety symptoms were related to poor adherence to following dietary recommendations and exercising regularly. The relationship between anxiety and adherence is unclear and under-researched, therefore it is difficult to theorize about the mechanisms for anxiety’s effect on adherence (DiMatteo, Lepper, & Croghan, 2000). In regards to the relationship between anxiety and diet adherence, similar reasoning discussed for depression and diet adherence may also be applied to anxiety. Planning meals and reading food labels to adhere to sodium restrictions can be challenging, especially when dealing with emotional problems. Patients who are feeling anxious may lack the cognitive focus needed to make necessary dietary changes.

In the case of ICD patients, anxiety resulting from fear of shock may lead individuals to decrease their activity level. Previous research has shown anxiety to be associated with ICD patients limiting their activities (Hegel et al., 1997; Lemon, Edelman, & Kirkness, 2004). In particular, 39% of ICD recipients reported avoidance of
activities mostly due to fear that increased heart rate would trigger shock (Lemon, Edelman, & Kirkness, 2004). Additionally, the Heart Failure Society of America (Adams et al., 2006) does not include recommendations for exercise in their practice guidelines. Thus, physicians may not address or educate patients on activities that are safe based on the severity of their heart failure. Patients may be anxious about exercising not only because of the potential for shock but also because of the possible exacerbation of heart failure symptoms. Therefore, it is important for health care professionals to provide patients with tentative guidelines for exercise in order to improve functional capacity.

Analyses also revealed that anxiety marginally predicted smoking adherence at one month follow-up, in another words, elevated anxiety symptoms predicted nonadherence to smoking cessation. In a recent study by Schweitzer, Head, & Dwyer (2007), anxiety accounted for about 3% of the variance in avoiding smoking adherence in heart failure patients. Furthermore, previous studies have found individuals with anxiety disorders to have difficulty stopping smoking (Morissette, Tull, Gulliver, Kamholz, & Zimering, 2007; Zvolensky et al., 2004). Therefore, the relationship between anxiety and smoking cessation in the current study appears to be consistent with findings from other studies.

Cognitive Impairment and Adherence

It was hypothesized that patients who exhibit more cognitive impairment would report poorer adherence to taking medications, following dietary restrictions, exercising regularly, and eliminating smoking and alcohol. Contrary to expected, cognitive impairment (3MS and global cognitive t-score) was not found to be associated with
adherence to any of the recommended treatment guidelines at baseline. There may be several possible explanations for these null findings. First, patients may be inaccurately reporting their adherence. For example, 91% of patients in the current study reported that they take their medication all of the time. However, adherence rates for medication in heart failure patients has been reported to be approximately 70% (van der Wal, Jaarsma, & van Velduisen, 2005) thus suggesting that our sample of heart failure patients are over-reporting their adherence. Second, cognitively impaired patients may be receiving more assistance from family members which may result in better adherence to the treatment recommendations. Lastly, more cognitively impaired patients may not realize that they are not following treatment guidelines correctly and therefore may report better adherence than is truly accurate.

As for analyses of adherence at one month, cognitive impairment (3MS and global cognitive t-score) was not found to be related to adherence to any of the treatment guidelines. This is the first study to date to examine the effect of cognitive impairment on treatment adherence in heart failure patients treated with an ICD. Studies with other patient populations have found a relationship between cognitive impairment and adherence. For example, cognitive impairment as indicated by an MMSE score <23 was found to be associated with poorer adherence to taking medication and glucose monitoring in a sample of elderly patients with diabetes (Sinclair, Girling, & Bayer, 2000). In a study of elderly community dwelling elderly participants, the risk of nonadherence to antihypertension medication was twice as high in persons with cognitive impairment as compared to persons with normal cognitive functioning (Salas et al.,
Although the current study did not find an association between cognitive impairment and adherence, it is likely, based on findings in other patient populations, that cognitive impairment may have detrimental effects on heart failure patients’ ability to follow treatment recommendations. Insufficient adherence to these recommendations can result in hospitalizations, exacerbation of heart failure symptoms, or even death, thus it is important for future research to further examine the impact of cognitive impairment on adherence in heart failure patients.

Implications for Interventions

Results from the current study suggest that depression and anxiety are associated with poor adherence to treatment recommendations in heart failure patients treated with an ICD. There is growing evidence demonstrating that nonadherence with medication and other lifestyle changes is a major problem in patients with heart failure (Evangelista & Dracup, 2000; van der Wal, Jaarsma, & Van Veldhuisen, 2005). Consequently, the results of the present study may help to explain why adherence rates among heart failure patients are low (van der Wal, Jaarsma, & Van Veldhuisen, 2005). Because nonadherence has been found to be associated with poor outcomes (e.g., hospital readmissions, exacerbation of heart failure symptoms) (Chin & Goldman, 1997; Chui et al., 2003), interventions addressing barriers to adherence in heart failure patients is crucial.

Currently, there are a limited number of studies investigating interventions aimed at improving adherence in heart failure populations. Furthermore, the majority of these studies are education or counseling based interventions aimed at improving patients’ knowledge about individual treatment recommendations such as sodium and fluid
restrictions or medication. A support-educative intervention which included education and support from a nurse during and following hospitalization and provided educational materials was developed to improve adherence to self-care behaviors in heart failure (Jaarsma, Abu-Saad, Dracup, & Halfens, 2000). Self-care behaviors increased significantly at 1 and 3 months after hospital discharge in the intervention group as compared to the control group. However, self-care behaviors decreased during the subsequent 8 months following discharge in both groups but the increase remained significant in the intervention group only. Even after intensive education and support, several patients in the intervention reported limitations with self-care behaviors. This finding suggests that simply providing patients with information about treatment recommendations may not guarantee improvement in knowledge. Furthermore, providing education only may be unsuccessful in improving self-care behaviors if patients are cognitively impaired.

Additional evidence suggesting that education can improve adherence in heart failure patients was found in a study utilizing a comprehensive disease management system (West, et al., 1997). The intervention sought to improve adherence and clinical outcomes by having nurses educate patients about treatment guidelines and provide behavioral techniques to improve adherence. Additionally, patients were contacted by a nurse weekly for 6 weeks to allow close observation of symptoms and promote adherence. The authors found significant improvements in adherence to taking medication, daily weighing, and dietary sodium intake over the course of the intervention. Furthermore, during the intervention period, medical resource utilization
(e.g. emergency room visits, hospitalizations) decreased and functional status improved significantly. Findings of this study suggest that interventions that are effective at improving adherence to treatment recommendations for heart failure result in improved health outcomes.

Because of limited access to resource-intensive programs, a simplified education program to improve knowledge and self-care behaviors was developed for heart failure patients living in rural areas (Caldwell, Petters, & Dracup, 2005). Patients in the intervention group received a one-on-one education and counseling session by a non-cardiac trained nurse and a follow-up telephone call at one month to reinforce content of the education program. Additionally, patients were given take-home information and a weight diary following the education session. The intervention improved patients’ monitoring of their weight at 3 month follow-up but did not significantly improve symptom management such as seeking help from a physician when needed. This finding demonstrates that a simplified education and counseling program for management of fluid weight can improve patients’ adherence to weighing themselves everyday and maintaining a weight diary.

Taken together, results from these interventions suggest that educating and counseling heart failure patients about treatment recommendations can improve adherence. Patients’ knowledge about particular treatment guidelines may be improved; however it is unknown whether this new knowledge base will moderate the effect of depression and anxiety on adherence. Thus, it may be more beneficial for future studies to develop interventions aimed at identifying patients with depression and/or anxiety and
treating distress in addition to providing additional education. Also, interventions utilizing group support such as having patients talk about heart failure and its treatment in a group format may be helpful in alleviating distress.

Limitations

Although the results are informative, several limitations must be addressed. One limitation is the sample itself. The current study recruited patients with heart failure who had been treated with an implantable cardiac defibrillator and were receiving treatment at a local cardiovascular health center. Individuals were not randomly selected, but rather approached during a scheduled appointment. It is possible that more adherent individuals were more likely to agree to participate. However, there is some evidence to suggest that individuals with poor adherence did participate in the study. Specifically, approximately 21% of patients reported following dietary recommendations half or less of the time and 54% of patients reported exercising regularly half or less of the time.

Another problem with the sample is that it is not known as to whether the results would hold across other populations. Despite the potential problem of sample bias, there are several reasons to suggest that the findings of the current study can be generalized to other populations. Previous research has found that depressive symptoms are associated with poor adherence to treatment recommendations across various populations. A study by Ziegelstein et al. (2000) found depressive symptoms to be related to poor adherence to dietary recommendations and regular exercise in patients with cardiovascular disease recovering from a myocardial infarction. Thus, results from the current study have been
found in other chronic illness populations suggesting that the findings from the present study are generalizable to other samples.

Another limitation of the study is that the relationship between the study variables may be confounded by other factors, such as patient satisfaction (Spernak, Moore, & Hamm, 2007) or self-efficacy (Schweitzer, Head, & Dwyer, 2007). Therefore, the relationship among variables could reflect the influence of third variables not assessed in the current study. Although these measures could have been assessed, the addition of these measures would have increased the time necessary to complete the questionnaire packet, and thus, they were not included in the study. Therefore, the effects of such factors could not be statistically controlled for in the analyses.

Another problem with the current study is that it did not assess social support. Previous studies have found social support to be associated with better self-care behaviors (Gallant, 2003; van Dam, 2005). With the significant number of patients in the current study reporting problems with depression, anxiety, and cognitive impairment, it would have been beneficial to measure multiple forms of social support (e.g. emotional, instrumental) in order to examining whether patients with these difficulties are receiving social support and what types of support may be most beneficial in facilitating better adherence. Thus, it is important for future studies to investigate the influence of social support on psychological distress, cognitive impairment, and adherence to treatment recommendations in heart failure patients treated with an ICD.

Another limitation of the current study is that adherence to treatment guidelines was measured by self-report and from telephone interviews. Nonadherence to treatment
recommendations tends to be under-reported and adherence tends to be over-reported in interviews (Burke & Dunbar-Jacob, 1995). Therefore, actual patient adherence as reported by the patients in the current study may have been overestimated. Additionally, the completion of the adherence behaviors questionnaire at baseline may have primed the patient for self-report of adherence at one-month follow-up. In another words, having answered questions about their adherence at baseline may have prompted patients to become more conscientious of following treatment guidelines, thus patients may have been more likely to report being adherent to treatment guidelines at one-month follow-up.

The ideal method of measuring adherence to treatment recommendations, in particular medication and diet, is by objective measures such as pill counts, prescription refills or electronic event monitoring, and serum bioassays (Leventhal, Riegel, Carlson, & De Geest, 2005). However, these methods can be costly and time consuming. Future studies need to utilize a combination of self-report and objective measures of adherence in order to obtain more accurate adherence rates among heart failure patients.

Another problem with the assessment of adherence is that adherence was only assessed at baseline and at one month follow-up. Because the study was not intended to be longitudinal, the assessment of adherence was obtained at one month following baseline assessment in order to provide a more realistic view of patients’ adherence. By limiting the follow-up time points, an account of patient adherence over a prolonged period of time was not available. The addition of follow-up assessments of adherence may enable future researchers to track adherence rates over the course of the disease. Additionally, adherence was only assessed the day prior to the telephone follow-up
interview. A more accurate report of patient adherence may be obtained if adherence were assessed over several days at each time point. It is likely that patients’ adherence may fluctuate depending on the day of the week (e.g. weekends, vacations).

Future Directions

Several important avenues of future research emerged based on the findings of the current study. In order to obtain a clearer understanding of the associations between psychological distress, cognitive impairment, and adherence in heart failure patients treated with an ICD, future research needs to utilize a longitudinal study design with optimal measures of adherence and clinical assessments of depression and anxiety. Although the current study did find relationships between distress and poor adherence, more objective measures of adherence such as medication event monitoring or urinary sodium analysis may provide a more accurate account of patients’ adherence. Additionally, the use of clinical interviews to assess depression and anxiety will provide a better assessment of the prevalence of depression and anxiety in this patient population.

Making lifestyle changes and following a complex medication regimen can be challenging especially for those patients who are cognitively impaired or who are experiencing symptoms. Thus, having a strong social network that can facilitate these recommended behavior and lifestyle changes may be a key component of adherence. In review assessing the influence of social support on chronic illness self-management (Gallant, 2003), greater levels of social support, particularly disease- or regimen-specific support, were related to better self-management behaviors. The research examining social support and adherence to treatment recommendations in heart failure patients is very
limited and remains unclear. Perceived social support was not found to be a predictor of medication, diet, or exercise adherence in a sample of heart failure patients (Evangelista, Berg, & Dracup, 2001). However, the authors noted that the lack of association between social support and adherence may be due to high perceived social support scores reported by patients and the fact that over 90% of patients reported living with a significant other. Accordingly, being unmarried was found to be associated with poor medication and diet adherence and weight monitoring in a heart failure population (Ni, et al., 1999). Findings from these studies suggest that social support may play a crucial role in patient’s adherence. Thus, future researchers need to further investigate the impact of social support on adherence in heart failure patients and examine social support as a moderator of the relationship between distress and cognitive impairment and adherence.

Another potential factor influencing adherence to treatment recommendations in heart failure patients is self-efficacy. Previous research has found self-efficacy to predict poor adherence in heart failure patients and other chronic illness populations (e.g. Barclay, et al., 2007; Williams & Bond, 2002). In a sample of heart failure patients, self-efficacy was found to strongly predict adherence to daily weighing, sodium and fluid restrictions, regular exercise, and smoking and alcohol avoidance (Schweitzer, Head, & Dwyer, 2007). Higher self-efficacy scores were associated with better adherence to medications, following a diabetic meal plan, higher levels of physical activity, and glucose monitoring in veterans with diabetes (Nelson, McFarland, & Reiber, 2007). Furthermore, depressed patients with diabetes were found to be less confident in their ability to adhere to diabetes medication regimens (Chao, Nau, Aikens, & Taylor, 2005).
Additionally, self-efficacy was found to be mediate the relationship between depressive symptoms and medication adherence. Given the findings from these studies suggesting that self-efficacy predicts adherence to treatment recommendations, further research should be conducted in order to broaden our understanding of the relationship between psychological distress and adherence in heart failure patients treated with an ICD.

The current study is the first we are aware of to examine the effects of cognitive impairment on adherence to treatment recommendations in heart failure patients. This is surprising given that cognitive impairment is associated with poor adherence in other chronic illness populations. A study by Hinkin and colleagues (Hinkin et al., 2002) has found cognitive impairment to be associated with a 2.3 times greater risk of nonadherence to antiretroviral medication regimen in HIV+ adults. Specifically, deficits in executive function, memory, and attention were related to poor adherence. Another study by Sinclair, Girling, & Bayer (2000) found patients with diabetes who were cognitively impaired to be less likely to take their diabetes medication, monitor glucose, and attend a specialist diabetes clinic. Given the findings of previous studies (e.g. Hinklin, et al., 2004; Salas, et al., 2001) suggesting that cognitively impaired patients are less likely to adhere to recommended treatment guidelines, future researchers should continue to investigate the association between cognitive impairment and adherence in heart failure patients.
Conclusions

The current study sought to evaluate the impact of psychological distress and cognitive impairment on self-care behaviors in heart failure patients treated with an ICD. It was hypothesized that depression and anxiety symptoms and cognitive impairment would be associated with poor adherence to treatment guidelines. Results of the current study partially support these hypotheses. Specifically, higher levels of depression and anxiety were associated with poor adherence to diet and exercise recommendations and smoking cessation. However, cognitive impairment was not found to be associated with adherence to treatment recommendations. Based on the findings of this dissertation, it is concluded that depression and anxiety symptoms are associated with poor adherence to treatment recommendations in heart failure patients treated with an ICD. However, more research is necessary to gain a broader understanding of these relationships.
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APPENDIX A

PATIENT MEDICAL AND DEMOGRAPHIC INFORMATION
Medical Records Form

Patient Name ____________________________________________

Height _______ Weight _______

Diagnosis/Medical History

Does the patient have the following:

CAD __________ Date: ___________
Congestive Heart Failure _________ Date: ___________

- NYHA Functional Classification
  _____ 1 = No symptoms and no limitation in ordinary physical activity
  _____ 2 = Mild symptoms and slight limitation in ordinary physical activity. Comfortable at rest
  _____ 3 = Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
  _____ 4 = Severe limitations. Experiences symptoms even while at rest.

Hypertension _________ Date: ___________
Diabetes _________ Date: ___________

Has the patient had the following:

Previous MI ______ Date: ___________
Previous bypass surgery ______ Date: ___________
Previous cardiac arrest ______ Date: ___________

Antiarrhythmic drugs:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Other cardiac drugs:
________________________________________________________________________
________________________________________________________________________
Has patient received shocks from the ICD?

_____ YES   number of shocks _______   Dates: ________________________
_____ NO                  ______________________________

Date of 1st ICD implantation: _______________

Is it an ICD with a biventricular pacemaker?  _________ YES       _________ NO
Indication (Why)

________________________________________________________________________

Model Name and Number of ICD
________________________________________________________________________
**Questionnaire Packet**

Last Name: ______________________  First Name: ______________________

Date of Birth: ____________________  Age: _____________________

Current Phone Number ________________  Today’s Date ________________

1. What is your gender?
   - [ ] Male
   - [ ] Female

2. What is your current marital status?
   - [ ] Married
   - [ ] Divorced
   - [ ] Single
   - [ ] Widow
   - [ ] In a committed relationship

3. Present living arrangement:
   - [ ] Living alone
   - [ ] Living with someone

4. Please select **one** of the following that best describes your ethnicity:
   - [ ] Hispanic or Latino
   - [ ] Not Hispanic
5. Please indicate your race (you can select more than one):

- [ ] American Indian or Alaska Native
- [ ] Asian
- [ ] Black or African American
- [ ] Native Hawaiian or Other Pacific Islander
- [ ] White

8. What is the highest grade (or year) of regular school you have completed? (Check one.)

<table>
<thead>
<tr>
<th>Elementary School</th>
<th>High School</th>
<th>College</th>
<th>Graduate School</th>
</tr>
</thead>
<tbody>
<tr>
<td>01___</td>
<td>09___</td>
<td>13____</td>
<td>17____</td>
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<td>02___</td>
<td>10___</td>
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</tr>
<tr>
<td>08___</td>
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</tr>
</tbody>
</table>

9. What is the highest degree you earned?

- [ ] High school diploma or equivalency (GED)
- [ ] Associate degree (junior college)
- [ ] Bachelor's degree
- [ ] Master's degree
- [ ] Doctorate
- [ ] Professional (MD, JD, DDS, etc.)
- [ ] Other specify
- [ ] None of the above (less than high school)

10. What is your current employment status?

- [ ] Full time
- [ ] Part time
- [ ] Unemployed
- [ ] Retired
APPENDIX B

DEPRESSION AND ANXIETY MEASURES
Material under copyright removed
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Material under copyright removed
Material under copyright removed
State-Trait Anxiety Inventory (Trait items only)

A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate number to the right of the statement to indicate how you generally feel. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer that seems to describe how you generally feel.

1. almost never
2. sometimes
3. often
4. almost always

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I feel pleasant</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>I tire quickly</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>I feel like crying</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>I wish I could be as happy as others seem to be</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>I am losing out on things because I can’t make up my mind soon enough</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>I feel rested</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>I am “calm, cool, and collected”</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>I feel that difficulties are piling up so that I cannot overcome them</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>I worry too much over something that really doesn’t matter</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>I am happy</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>I am inclined to take things hard</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>I lack self-confidence</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13</td>
<td>I feel secure</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>I try to avoid facing a crisis or difficulty</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>I feel blue</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>I am content</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17</td>
<td>Some unimportant thoughts run through my mind and bothers me</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18</td>
<td>I take disappointments so keenly that I can’t put them out of my mind</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19</td>
<td>I am a steady person</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20</td>
<td>I get in a state of tension or turmoil as I think over my recent concerns and interests</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
APPENDIX C

ADHERENCE MEASURES
HEART FAILURE COMPLIANCE QUESTIONNAIRE

This survey asks for your view about how well you follow your medical treatments. This information will help keep track of how much difficulty you have with specific lifestyle behaviors. Please answer every question by checking the appropriate box. If you are unsure about how to answer, please give the best answer you can.

I. HEALTH MAINTENANCE

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important do you think it is to keep your appointments with your doctor?</td>
<td>Not at all 0</td>
</tr>
<tr>
<td></td>
<td>Somewhat important 1</td>
</tr>
<tr>
<td></td>
<td>Important 2</td>
</tr>
<tr>
<td></td>
<td>Very important 3</td>
</tr>
<tr>
<td></td>
<td>Highly important 4</td>
</tr>
<tr>
<td>What type of transportation do you use to get to your appointments?</td>
<td>Personal transportation 1</td>
</tr>
<tr>
<td></td>
<td>Bus 2</td>
</tr>
<tr>
<td></td>
<td>Taxi 3</td>
</tr>
<tr>
<td></td>
<td>Van service 4</td>
</tr>
<tr>
<td>Do you go alone or with someone else</td>
<td>Alone 1</td>
</tr>
<tr>
<td></td>
<td>With someone else 2</td>
</tr>
<tr>
<td>How much difficulty have you had keeping your appointments with your doctor?</td>
<td>No difficulty 1</td>
</tr>
<tr>
<td></td>
<td>A little difficulty 2</td>
</tr>
<tr>
<td></td>
<td>Moderate difficulty 3</td>
</tr>
<tr>
<td></td>
<td>A lot of difficulty 4</td>
</tr>
<tr>
<td>What kind of difficulty?</td>
<td>Not applicable 0</td>
</tr>
<tr>
<td></td>
<td>Transportation 1</td>
</tr>
<tr>
<td></td>
<td>No time 2</td>
</tr>
<tr>
<td></td>
<td>No money 3</td>
</tr>
<tr>
<td></td>
<td>Forgot 4</td>
</tr>
<tr>
<td></td>
<td>Didn't know I had one 5</td>
</tr>
<tr>
<td></td>
<td>Other 6 ______________</td>
</tr>
</tbody>
</table>
In the last 3 months, would you estimate you have kept your doctor’s appointments…

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None of the time</td>
</tr>
<tr>
<td>1</td>
<td>Very seldom</td>
</tr>
<tr>
<td>2</td>
<td>About half of the time</td>
</tr>
<tr>
<td>3</td>
<td>Most of the time</td>
</tr>
<tr>
<td>4</td>
<td>All of the time</td>
</tr>
</tbody>
</table>
II. MEDICATIONS

How important do you think it is to take your medications regularly?

☐ Not at all 0
☐ Somewhat important 1
☐ Important 2
☐ Very important 3
☐ Highly important 4

Have you had any difficulties with taking your medications?

☐ Yes 1
☐ No 2

How much difficulty have you had with taking your medications?

☐ No difficulty 1
☐ A little difficulty 2
☐ Moderate difficulty 3
☐ A lot of difficulty 4

What kind of difficulty?

☐ Not applicable 0
☐ Remembering 1
☐ Cost 2
☐ Inconvenience 3
☐ Side effects 4
☐ Other 5 ____________

In the past week, would you estimate you have taken your medications…

☐ None of the time 0
☐ Very seldom 1
☐ About half of the time 2
☐ Most of the time 3
☐ All of the time 4
### III. DIET

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important do you think it is to weigh yourself daily?</td>
<td>Not at all 0, Somewhat important 1, Important 2, Very important 3, Highly important 4</td>
</tr>
<tr>
<td>How important do you think it is to limit your fluid intake?</td>
<td>Not at all 0, Somewhat important 1, Important 2, Very important 3, Highly important 4</td>
</tr>
<tr>
<td>How important do you think it is to limit your salt to 2 grams or less?</td>
<td>Not at all 0, Somewhat important 1, Important 2, Very important 3, Highly important 4</td>
</tr>
<tr>
<td>Have you had any difficulties with following your dietary recommendations?</td>
<td>Yes 1, No 2</td>
</tr>
<tr>
<td>How much difficulty have you had keeping your dietary recommendations?</td>
<td>No difficulty 1, A little difficulty 2, Moderate difficulty 3, A lot of difficulty 4</td>
</tr>
<tr>
<td>What kind of difficulty?</td>
<td>Not applicable 0, Lack of self motivation 1, Unable to control 2, Environmental obstacles 3, Lack of knowledge 4, Other 5 ____________________</td>
</tr>
</tbody>
</table>
In the past week, would you estimate you have followed your dietary recommendations…

- None of the time
- Very seldom
- About half of the time
- Most of the time
- All of the time
## IV. EXERCISE

How important do you think it is to exercise regularly?

- **[ ]** Not at all 0
- **[ ]** Somewhat important 1
- **[ ]** Important 2
- **[ ]** Very important 3
- **[ ]** Highly important 4

Have you had any difficulties with exercising?

- **[ ]** Yes 1
- **[ ]** No 2

How much difficulty have you had with exercising as recommended?

- **[ ]** No difficulty 1
- **[ ]** A little difficulty 2
- **[ ]** Moderate difficulty 3
- **[ ]** A lot of difficulty 4

What kind of difficulty?

- **[ ]** Not applicable 0
- **[ ]** Lack of motivation 1
- **[ ]** No time 2
- **[ ]** Inconvenience 3
- **[ ]** Lack of energy 4
- **[ ]** Physical symptoms 5
- **[ ]** Other 6 _____________

In the past week, would you estimate you have exercised as recommended…

- **[ ]** None of the time 0
- **[ ]** Very seldom 1
- **[ ]** About half of the time 2
- **[ ]** Most of the time 3
- **[ ]** All of the time 4
### V. SMOKING

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important do you think it is to not smoke?</td>
<td>Not at all 0</td>
</tr>
<tr>
<td></td>
<td>Somewhat important 1</td>
</tr>
<tr>
<td></td>
<td>Important 2</td>
</tr>
<tr>
<td></td>
<td>Very important 3</td>
</tr>
<tr>
<td></td>
<td>Highly important 4</td>
</tr>
<tr>
<td>How important do you think it is to limit exposure to second hand smoke?</td>
<td>Not at all 0</td>
</tr>
<tr>
<td></td>
<td>Somewhat important 1</td>
</tr>
<tr>
<td></td>
<td>Important 2</td>
</tr>
<tr>
<td></td>
<td>Very important 3</td>
</tr>
<tr>
<td></td>
<td>Highly important 4</td>
</tr>
<tr>
<td>What is your smoking status?</td>
<td>Current smoker 1</td>
</tr>
<tr>
<td></td>
<td>Former smoker 2</td>
</tr>
<tr>
<td></td>
<td>Never smoked 3</td>
</tr>
<tr>
<td>Have you had any difficulties with stopping to smoke?</td>
<td>Not applicable 0</td>
</tr>
<tr>
<td></td>
<td>Yes 1</td>
</tr>
<tr>
<td></td>
<td>No 2</td>
</tr>
<tr>
<td>How much difficulty have you had with smoking cessation?</td>
<td>No difficulty 1</td>
</tr>
<tr>
<td></td>
<td>A little difficulty 2</td>
</tr>
<tr>
<td></td>
<td>Moderate difficulty 3</td>
</tr>
<tr>
<td></td>
<td>A lot of difficulty 4</td>
</tr>
<tr>
<td>What kind of difficulty?</td>
<td>Not applicable 0</td>
</tr>
<tr>
<td></td>
<td>Lack of self-motivation 1</td>
</tr>
<tr>
<td></td>
<td>Lack of counseling/support 2</td>
</tr>
<tr>
<td></td>
<td>Costs of nicotine replacement 3</td>
</tr>
<tr>
<td></td>
<td>Side effects 4</td>
</tr>
<tr>
<td></td>
<td>Other 5 _______________</td>
</tr>
</tbody>
</table>
In the past week, would you estimate you have stopped smoking …

- [ ] Not applicable 0
- [ ] None of the time 4
- [ ] Very seldom 3
- [ ] About half of the time 2
- [ ] Most of the time 1
- [ ] All of the time 0
### VI. ALCOHOL USE

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important do you think it is to limit alcohol use?</td>
<td>Not at all 0</td>
</tr>
<tr>
<td></td>
<td>Somewhat important 1</td>
</tr>
<tr>
<td></td>
<td>Important 2</td>
</tr>
<tr>
<td></td>
<td>Very important 3</td>
</tr>
<tr>
<td></td>
<td>Highly important 4</td>
</tr>
<tr>
<td>What is your alcohol use status?</td>
<td>Current 1</td>
</tr>
<tr>
<td></td>
<td>Former 2</td>
</tr>
<tr>
<td></td>
<td>Never 3</td>
</tr>
<tr>
<td>How many drinks per week do you currently have?</td>
<td>Not applicable 0</td>
</tr>
<tr>
<td></td>
<td>Beer 1  ____________ cans</td>
</tr>
<tr>
<td></td>
<td>Wine 2 ____________ glasses</td>
</tr>
<tr>
<td></td>
<td>Hard liquor 3____________ glasses</td>
</tr>
<tr>
<td>Have you had any difficulties with limiting alcohol use?</td>
<td>not applicable 0</td>
</tr>
<tr>
<td></td>
<td>yes 1</td>
</tr>
<tr>
<td></td>
<td>no 2</td>
</tr>
<tr>
<td>How much difficulty have you had with limiting alcohol use?</td>
<td>No difficulty 1</td>
</tr>
<tr>
<td></td>
<td>A little difficulty 2</td>
</tr>
<tr>
<td></td>
<td>Moderate difficulty 3</td>
</tr>
<tr>
<td></td>
<td>A lot of difficulty 4</td>
</tr>
<tr>
<td>What kind of difficulty?</td>
<td>Not applicable 0</td>
</tr>
<tr>
<td></td>
<td>Lack of self-motivation 1</td>
</tr>
<tr>
<td></td>
<td>Lack of counseling/support 2</td>
</tr>
<tr>
<td></td>
<td>Side effects 3</td>
</tr>
<tr>
<td></td>
<td>Other 4 ____________</td>
</tr>
<tr>
<td>In the past week, would you estimate you have stopped using alcohol …</td>
<td>Not applicable 0</td>
</tr>
<tr>
<td></td>
<td>None of the time 4</td>
</tr>
<tr>
<td></td>
<td>Very seldom 3</td>
</tr>
<tr>
<td></td>
<td>About half of the time 2</td>
</tr>
<tr>
<td></td>
<td>Most of the time 1</td>
</tr>
<tr>
<td></td>
<td>All of the time 0</td>
</tr>
</tbody>
</table>
Heart Failure Self-Care

When being diagnosed with heart failure, physicians often ask their patients to make some lifestyle changes. We are going to ask you about making these changes in order for us to better understand your daily routine. The information that you report WILL NOT be made available to your physician. ONLY the researcher will have access to your responses. All the questions will ask about what you did yesterday.

Day: Mon Tue Wed Thur Fri Sat Sun

Date: ______________

What time is it right now? _____:____ AM/PM.

Weight

1. Have you weighed yourself yesterday? _____ No _____ Yes

   What was your weight? ______ lbs

Smoking

1. Have you smoked cigarettes yesterday? _____ No _____ Yes

   If yes, how many cigarettes did you smoke yesterday? _______

Alcohol

1. Have you consumed any alcoholic beverages yesterday? ___No ___ Yes

   If yes, how many drinks have you consumed yesterday? _______

Medication

1. Did you take all of the medication that you are prescribed yesterday?
   _____ No _____ Yes

2. Did you take any of your medication off-schedule (you took it earlier or later than you usually do)? ____ No ____ Yes
Please list the foods and beverages that you have consumed yesterday.

Example: One small apple. Two hot dogs with mustard and relish. One cup of coffee with non-dairy creamer and two sugar packets.

**Breakfast:**

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

**Lunch:**

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

**Dinner:**

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

**Snacks:**

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
**Daily Activities**

I am going to list daily activities that people perform. I would like for you to tell me if you have performed each activity yesterday.

- Walk around inside your house
- □ Walk at least one block on level ground
- □ Climb a flight of stairs or walk up a hill
- □ Run a short distance
- □ Light work around the house like dusting or washing dishes
- □ Moderate work around the house like vacuuming, sweeping floors, or carrying groceries
- □ Heavy work around the house like scrubbing floors or lifting or moving heavy furniture
- □ Yard work like raking leaves, gardening, or pushing a power mower
- □ Shoveling snow
- □ Moderate recreational activities like golf, bowling, dancing, doubles tennis, or throwing a baseball or football
- □ Strenuous sports like swimming, singles tennis, football, basketball, or skiing
APPENDIX D

IRB CONSENT FORM AND LETTERS
August 23, 2007

Ms. Faith Luyster
Psychology
Kent Hall

Re: 07-86 – “Living Well with Congestive Heart Failure: Making Recommended Lifestyle Changes in Patients with Congestive Heart Failure”

Dear Ms. Luyster:

I am pleased to inform you that the Kent State University Institutional Review Board approved your Application for Approval to Use Human Research Participants as Level II research. This application was approved on October 25, 2006 and is good for one year.

HHS regulations and Kent State University Institutional Review Board guidelines require that any changes in research methodology, protocol design or principal investigator have the prior approval of the IRB before implementation and continuation of the protocol. The IRB further requests an annual report and a final report at the conclusion of the study.

A periodic review form will be sent following the marked end date of your protocol or within a year of the original date of approval of the application. Please complete the form and return it. If the project is expected to extend beyond the marked end date, please insert the new expected end date on the periodic review form. If the project is complete and all data analysis has concluded, please mark the appropriate box on the form. If data analysis is continuing, research is considered to be continuing.

Kent State University has a Federalwide Assurance on file with the Office for Human Research Protections (OHRP); FWA Number 00001853.

If you have any questions, please contact me at 330.672.2704, klight@kent.edu.

Sincerely,

Katherine Light
IRB Administrator

cc: Dr. Joel Hughes

Division of Research and Graduate Studies
330-672-2851 • Fax: 330-672-2658
Graduate Program Services
330-672-2660 • Fax 330-672-2658
P.O. Box 5190 • Kent, Ohio 44242-0001 • http://www.kent.edu
October 10, 2006

Faith Lyuster, MA
Department of Psychology
Kent State University
118 Kent Hall
Kent, Ohio 44240

SUBJECT: RP #06100
Living Well with Congestive Heart Failure: Making Recommended Lifestyle Changes in Patients with Congestive Heart Failure

Dear Ms. Lyuster:

The MRC Chairman reviewed and approved the above project effective October 10, 2005.

This approval was processed through the expedited review process according to SOP RR 401 and in accordance with the federally defined categories of expedited review per 45 CFR 46.110(b) and 21 CFR 56.110(b)(2). Your project has been approved for a twelve-month period, expiring October 09, 2007.

Your project must be reviewed by the IRB Chairperson and/or the full committee to obtain re-approval no later than October 09, 2007. Federal regulations do not allow for ANY grace period for renewal. As a courtesy, approximately two months prior to the project expiration date, the IRB office will mail you a reminder notice requesting a progress report. If the progress report is submitted too late for IRB review prior to the expiration date stated above, your project will be inactivated and your department notified. This inactivation would mean that you can not accrue patients and/or review charts until proper renewal is obtained.

We wish you success with your project.

Sincerely,

Rebecca A. Garner, CIM, CIP
Coordinator, Human Subject Compliance

www.summahealth.org
Consent Form

LIVING WELL with CHF

Project Title: Living Well with Congestive Heart Failure: Making Recommended Lifestyle Changes in Patients with Congestive Heart Failure.
Investigators: Faith Luyster, M.A., Joel Hughes, Ph.D., Richard Josephson, M.D., Bonnie Newell, RN

We are asking you to be in a research study. The following information is provided to inform you about the study and your participation in it. Please read it carefully and feel free to ask any questions.

PURPOSE OF STUDY: You are being asked to participate in a research study examining lifestyle changes in congestive heart failure patients with implantable cardiac defibrillators. We would like to do this study because individuals with congestive heart failure who receive a cardiac defibrillator may be required to make lifestyle changes. These changes could be affected by a number of things in one's life such as emotional reactions like depression and anxiety, problems with memory, and/or changes in relationships with other people. Understanding how patients make lifestyle changes may help us develop ways to assist patients in making these changes.

PROCEDURES: If you decide to take part in this project, you will be asked to complete a set of questionnaires about quality of life and other possible reactions to the implantable cardiac defibrillator. You will have the option to take the questionnaires home and mail them back. You will be asked to complete a short set of tests that assess your ability to focus and sustain your attention, learn, and remember new information, and other types of thinking skills. This set of tests will need to be completed while you are here for your medical appointment. You will be asked to complete a brief telephone interview in about one month. The interview will ask how you have been doing at making the recommended lifestyle changes. There will also be a chart review to obtain certain information from your medical chart. The chart review will involve looking in your medical chart to record information about your medical condition, your
Project Title: *Living Well with Congestive Heart Failure: Making Recommended Lifestyle Changes in Patients with Congestive Heart Failure.*

Investigators: Faith Luyster, M.A., Joel Hughes, Ph.D., Richard Josephson, M.D., Bonnie Newell, RN

implantable cardiac defibrillator, and the medications you are taking. We will ask your nurse from the device clinic about your current health status.

Information that you provide about making the recommended lifestyle changes will not be shared with the medical staff.

Sometimes after a study we want to know how you are doing so, you may be contacted in the future for a follow-up study. You are free to decline participating in the follow-up study, even if you choose to participate in the current study. If you do not want us to contact you in the future for a follow-up, please be sure to sign the dissent statement at the end of this form.

Today’s questionnaires and tests of memory and other thinking skills will take about 75 minutes to complete. You will be asked to complete the memory and thinking tests and the questions about yourself while you are in the doctor’s office waiting area. It will however only take about 40 minutes to complete the study if you decide to take the questionnaires home.

You will receive a $20 check for completing the questionnaires and the memory and thinking tests. You will receive $5 for completing the telephone interview.

*Your rights as a participant:* Your participation in this study is strictly voluntary and confidential. If you wish to discontinue filling out the questionnaires at any time you may do so without any penalty by simply telling us that you don’t wish to continue participating in this study. If you have any questions, you are encouraged to call Dr. Joel Hughes at (330) 672-7721. The information you provide us with will be identified only by a subject number, and will be examined only by the primary investigator and qualified members of our research team. Regulatory agencies can review the data also. The only copies of the data will remain inside a locked file in a locked office. After the study, data will be published in scientific journals, but data will not be published in any manner that can identify you.

If it becomes apparent during the course of the study that you are severely depressed or pose a risk to yourself, your physician will be notified.
Project Title: *Living Well with Congestive Heart Failure: Making Recommended Lifestyle Changes in Patients with Congestive Heart Failure.*

Investigators: Faith Luyster, M.A., Joel Hughes, Ph.D., Richard Josephson, M.D., Bonnie Newell, RN

**POTENTIAL BENEFITS:** You will not receive any direct medical benefit from being in this study.

**POTENTIAL RISKS:** No risk beyond those normally encountered when filling out questionnaires are involved in this study.

**SPONSORS:** This research involves collaboration between researchers at Summa Health System and researchers at Kent State University. We plan to recruit 100 participants in this study.

If you want to know more about this research project, please call Dr. Joel Hughes at (330) 672-7721. The procedures for this project have been reviewed and approved by the Human Subject’s Committee at Kent State University and at Summa Health System.

If you have questions about Kent State University’s rules for research, please call Peter Tandy, Division of Research and Graduate Studies (Tel. 330-672-0700). If you have questions about Summa Health System’s rules for research, please contact Research Administration, Summa Health Systems, Akron, OH 44309-2090 (Tel. 330-375-4045).

By signing this form you are authorizing the study investigators and appropriate regulatory agencies access to your medical records and/or study related information. This will allow us to obtain information about your medical condition and treatment. By signing this consent form, you agree that you are willing to be contacted in the future by the investigators to see how you are doing. At that time you may choose to participate or to decline to participate in any new procedures (such as a telephone interview or questionnaire).

You will receive a copy of this consent form.
Project Title: *Living Well with Congestive Heart Failure: Making Recommended Lifestyle Changes in Patients with Congestive Heart Failure.*

Investigators: Faith Luyster, M.A., Joel Hughes, Ph.D., Richard Josephson, M.D., Bonnie Newell, RN

**CONSENT STATEMENT**

By signing this form I acknowledge that I have read it, understand it, and have had any questions regarding the risks and benefits of this study satisfactorily answered, and I am voluntarily consenting to participate in this study. Further, I realize that by signing this form I do not waive any of my legal rights, and that I can choose to terminate my participation at any time.

________________________________________ Date: ____________

Participant Signature

________________________________________ Date: ____________

Witness Signature

________________________________________ Date: ____________

Person obtaining consent

________________________________________ Date: ____________

Investigator

**DISSENT STATEMENT**

I do not want to be contacted in the future for a follow-up study.

________________________________________ Date: ____________

Participant Signature