

The Influence of Cognitive, Affective, and Somatic Symptoms of Depression and Related  
Psychosocial Variables on Cardiovascular Rehabilitation Participation

by

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Background: Cardiac rehabilitation (CR) has been shown to be an efficacious part of disease management to reduce negative outcomes associated with a variety of cardiovascular diseases (CVDs). Despite the significant amount of research support, participation rates in CR programs remain suboptimal. While a plethora of research exists which examines potential reasons for the lack of participation, there are still factors which have yet to be fully examined. For example, while depression has been associated with reduced CR participation, this association has not been fully explored in the literature and some related psychological factors may also be key contributors to the lack of participation in CR.

Purpose: The current research seeks to explore the impact of depression and related psychosocial variables on CR participation. By examining specific symptom clusters of depression and related variables, such as negative illness cognitions and depressive behaviors, the relation between depression and CR participation can be more fully understood.

Methods: 56 patients at a local CR center were asked to complete a set of questionnaires assessing depressive symptoms, negative illness cognitions, and depressive behaviors as soon as possible during their CR program. Then, their progress was tracked through CR and the number of sessions and completion status of the participants was recorded after they finished

the program. Relevant demographics were also analyzed to attempt to determine what may have the greatest impact on CR participation rates.

Results: Results from this study suggested that there was not a significant association between depressive symptom clusters, negative illness cognitions, or depressive behaviors and the outcomes of number of sessions attended or CR completion status. Participant age was a significant predictor of both outcomes, however, which indicated that younger CR patients attended fewer sessions and were less likely to complete the program than older patients. In some analyses, education level was also a significant predictor of CR participation rates, with those having a college degree or higher attending more sessions than those without a college degree.

Discussion: The current research found that there was not a significant association between specific symptoms of depression or related variables and CR participation. Given that these results are not entirely consistent with previous literature in this area, it is possible that methodological limitations hindered the study's ability to fully address the research question. However, the complicated findings in the literature and continued poor rates of participation in CR programs suggests that more research is needed in this area and the relation between depression and CR participation should continue to be evaluated.



The Influence of Cognitive, Affective, and Somatic Symptoms of Depression and Related  
Psychosocial Variables on Cardiovascular Rehabilitation Participation

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## **CHAPTER I: PROBLEM FORMULATION**

Cardiovascular diseases (CVDs) refer to various diseases which involve interrupted blood flow to the heart or heart rhythm irregularities and is one of the most prominent and lethal health problems in the world today. According to the World Health Organization (WHO), CVDs are the number one cause of death globally, accounting for approximately 17.5 million deaths in 2012 (31% of all global deaths) (WHO, 2015). Considering how widespread this issue is, it is extremely important to continue researching means by which to improve the lives of those suffering from CVDs. A key part of CVD care is cardiac rehabilitation (CR), which is a coordinated service involving several types of interventions to maximize a cardiac patient's overall functioning (Contractor, 2011). Many of the risk factors for CVDs are behavioral in nature; poor diet, lack of physical activity, tobacco usage, and excessive alcohol consumption have all been linked to increased risk of CVD (WHO, 2015). Ultimately, CR attempts to reduce the risk factors associated with CVD, slow the progression of disease, and decrease overall and cardiac mortality through improved health behaviors (Heran et al., 2011). These interventions include exercise, education about CVDs, psychological support, and overall health behavior change targeted at CVD risk factors, such as nutritional support (Heran et al., 2011).

There is a plethora of evidence for the effectiveness of CR at reducing overall mortality (Oldridge, Huyatt, Fischer, & Rimm, 1988; Goel, Lennon, Tilbury, Squires, & Thomas, 2011). In a meta-analysis of over 4,300 patients, Oldridge and colleagues (1988) found that the odds ratios for all-cause death and cardiovascular death were both significantly lower among patients who attended CR. A more recent review found similar results of decreased risk of overall and cardiac mortality amongst CR participants (Goel et al., 2011). CR participation is also associated with greater aerobic capacity and a decrease in many CVD risk factors, such as total cholesterol levels, body weight, and smoking behavior (Contractor, 2011; Taylor et al., 2004; Fletcher et al., 1996). Additionally, Hammill, Curtis, Schulman, and Whellan (2010) suggest that

there is a strong dose-response relationship between number of CR sessions attended and long-term outcomes. Although CR participation has not been shown to reduce all negative outcomes (Taylor et al., 2004; Goel et al., 2011), there is considerable evidence that CR is an extremely beneficial component of recovery from CVDs.

Despite the wealth of evidence that CR is effective at reducing mortality, many individuals referred to CR do not attend or do not complete the program (Arena et al., 2012). According to De Vos et al. (2013), international rates of attendance vary from 21% to 75%. In an attempt to understand why more patients do not take advantage of CR, there have been myriad studies which have examined various factors which may contribute to patient non-attendance. Studies have examined physical barriers and disease severity (Clark et al., 2012; Grace et al., 2011; De Vos et al., 2013), demographic factors like age, gender, and ethnicity (Parashar et al., 2012; Valencia, Savage, & Ades, 2011; Buttery, Carr-White, Martin, Glaser, & Lowton, 2014), cognitive factors such as perceived control (Reges et al., 2013; Whitmarsh, Koutantji, & Sidell, 2003), social factors and social support (Meillier, Nielsen, Larsen, & Larsen, 2012; King, Humen, Smith, Phan, & Teo, 2001), and psychological factors like depression and personality variables (Glazer, Emery, Frid, & Banyasz, 2002). Despite the abundance of studies examining these factors, attendance and completion rates remain suboptimal, suggesting the need for additional research in determining more precise factors associated with CR non-attendance, and thus identify intervention targets for increasing attendance.

One of the factors associated with CR non-attendance and CVDs in general which has received some attention in the literature is the impact of depression. When examining the role of baseline depression on CR outcomes, however, some of the findings are mixed. For example, one study determined that baseline depression accounted for 9.5% of the variance associated with increased aerobic capacity in a CR program (Glazer et al., 2002). Another study examining 600 patients in CR found that depression was negatively associated with

likelihood to complete the CR program (Casey, Hughes, Waechter, Josephson, & Rosneck, 2008). On the other hand, a study by Dickens, Cherrington, and McGowan (2011) found that the impact of depression on health-related quality of life (HRQoL) was mediated by other factors, including cardiac anxiety, awareness of somatic symptoms, and negative illness perceptions. A similar study found that the negative association between depression and treatment adherence in a sample of heart failure patients was mediated by self-efficacy (Maeda, Shen, Schwarz, Farrell, & Mallon, 2013).

Therefore, it is possible that other psychological variables closely related to depression may be important to evaluate when examining the relationship between depression and CR participation and outcomes. Several researchers have attempted to accomplish this goal, examining other constructs which may be significantly related to or overlap with depression. For example, Doyle, Conroy, and McGee (2007) performed a review which suggested several other constructs, including vital exhaustion, negative affective states and Type D personality, and negative illness cognitions could all be associated with depression-related mortality among patients with CVDs. Other studies have also examined the relationship between depressive symptoms, cardiac outcomes, and associated factors such as fatigue (Pedersen et al., 2007), negative illness perceptions, and anxiety symptoms (Dickens, Cherrington, & McGowan, 2011).

Additionally, a final aspect of depression which has received little attention in the literature is the influence of behaviors commonly associated with depression, such as avoidance behaviors, on CR attendance and completion. Behavioral activation (BA) treatments view escape and avoidance behaviors as key components of maintaining depression, yet most common depression self-report questionnaires, such as the Beck Depression Inventory (BDI), do not specifically assess for these types of behaviors (Kanter, Mulick, Busch, Berlin, & Martell, 2007). Therefore, it may also be important to also study some of the behavioral components of depression when attempting to understand the effect of depression on CR attendance and

completion. While the presence of depression certainly appears to be important among patients with CVDs, there are plenty of other constructs and psychological factors which have been suggested to be better predictors of poor outcomes. It is likely that depression plays some role in CR attendance and outcomes, but the complexity of findings in the literature suggests that this relation has yet to be entirely illuminated and more research is warranted.

One of the possible ways to further examine the association between depression and CR attendance and outcomes is to examine depressive symptoms individually, rather than depression as a whole. Previous studies in general psychiatric samples, not CR patients, have demonstrated that depressive symptoms can be problematic, even without a full diagnosis of MDD. For example, Lewinsohn, Solomon, Seeley, and Zeiss (2000) found that greater psychosocial distress, indicated by lower ratings of social interactions, life satisfaction, pleasant activities, and self-esteem, was associated with increasing levels of depressive symptoms. Other researchers have attempted to examine depressive symptom clusters, such as cognitive or somatic depressive symptoms. A review by Vanheule, Desmet, Groenvynch, Rosseel, and Fontaine (2008) used a confirmatory factor analysis and found a three-factor model of the Beck Depression Inventory-II (BDI-II) involving cognitive, affective, and somatic symptoms to have the best fit.

Using depressive symptom clusters has also yielded interesting findings in regards to depression and CVDs. Several studies have found that patients with depression post-MI had significantly fewer cognitive symptoms than depressed outpatients without any CVDs (Martens et al., 2006; Groenewold et al., 2013). Additionally, a recent meta-analysis suggested that somatic symptoms of depression, not cognitive or affective symptoms, are primarily responsible for poor CVD prognosis among patients with depression and CVD even after adjustment for disease severity (de Miranda Azevedo, Roest, Hoen, & de Jonge, 2014). The relative importance of somatic symptoms and lack of importance of cognitive symptoms in depressed

patients with CVD has been suggested as one of the reasons why previous attempts to treat depression amongst this population, such as the Enhancing Recovery in Coronary Heart Disease (ENRICHD) study (Berkman et al., 2003), did not yield optimal results (Martens et al., 2006). However, it is important to note that some researchers have questioned the sole importance of somatic depressive symptoms (Carney & Freedland, 2012) and not all studies find that they are the only depressive symptoms that impact CVD prognosis (Frasure-Smith & Lesperance, 2003; Connerney, Sloan, Shapiro, Bagiella, & Seckman, 2010).

While much of the previous research has examined depressive symptom clusters and associated constructs among populations with CVD, only one study was found which examined the impact of specific depressive symptom clusters on CR attendance and outcomes. In the study by Casey and colleagues (2008), exploratory analyses revealed that somatic symptoms of depression predicted dropout due to medical reasons better than cognitive-affective symptoms. However, the exploratory nature of the analyses used in that study and questions about the most accurate way to classify symptoms into symptom clusters both suggest the need for additional research in this area.

It would be beneficial to be able to identify patients who may be at a greater risk of dropping out of CR and not reaping the benefits associated with participation, so examining more specifically what factors are associated with lack of participation is essential. Therefore, there are several aims associated with the current study attempting to explore the association between depression and CR participation. The first aim of this study is to examine the interrelationship between the psychosocial predictor variables: cognitive, affective, and somatic depressive symptom clusters; negative illness perceptions; and depressive behaviors. The second aim and primary purpose of this study is to determine if particular depressive symptom clusters, as defined by the factor analysis conducted by Vanheule et al. (2008), affect the attendance or completion rates of patients participating in a CR program. Based on the

exploratory findings in the study by Casey and colleagues (2008), it is hypothesized that somatic symptoms of depression will have the most negative association with CR attendance and completion. Additionally, due to the complex relationship between depression and the previously discussed associated constructs, the third aim of this study is to determine if other factors, such as negative illness cognitions or depressive behaviors, are better predictors of CR attendance or outcomes than specific clusters of depressive symptoms.

## CHAPTER II: LITERATURE REVIEW

### **Cardiovascular Disease**

Cardiovascular disease (CVD) is one of the most prominent and lethal health problems in the world today. According to the World Health Organization (WHO), CVDs are the number one cause of death globally, accounting for approximately 17.5 million deaths in 2012 (31% of all global deaths) (WHO, 2015). In the United States, it is estimated that approximately \$444 billion was spent on CVDs alone in 2010, with about \$1 out of every \$6 spent on health care being spent on the treatment of CVDs (CDC, 2010). For the purposes of the current project, CVD is considered to be a group of discrete cardiovascular events or diagnoses that can result from either plaque buildup in the coronary arteries (coronary artery disease), which reduces the amount of oxygen and nutrients the heart receives, or electrical conduction and heart rhythm problems, which cause the heart muscle to beat irregularly. Myocardial infarction (MI), stable and unstable angina, heart arrhythmias, and heart failure (HF) will be the primary focuses of this paper because of the prevalence of those conditions among patients in cardiovascular rehabilitation (CR) programs (Ades, 2001). At the CR center where the current study will take place, the majority of patients eligible for referral to CR have coronary artery disease diagnoses, including acute MI, stable angina, and general coronary artery atherosclerosis. Due to these diagnoses, many patients in CR have also recently undergone cardiac surgeries, such as coronary artery bypass graft surgery (CABG) or percutaneous coronary intervention (PCI). Additionally, some of the patients eligible for CR referral have been diagnosed with heart failure, which represents a small but growing number of referrals to the present CR center.

### *Coronary Artery Disease*

One of the main forms of CVD is coronary artery disease (CAD), which affects the blood vessels which supply the heart through an inflammatory process called atherosclerosis.

Atherosclerosis occurs when plaque builds up on the walls of arteries, making blood flow more difficult (AHA, 2014c). Atherosclerosis is driven by oxidative stress and increased inflammation of the arterial walls, which combine with the plaque buildup to decrease blood flow and make a complete blockage more likely (Scott, 2004). This entire process progresses slowly over time, usually over many years. One of the most common risk factors for atherosclerosis is the level of circulating LDL cholesterol, which is often trapped in the arterial walls by oxidative processes (Scott, 2004). Other traditional risk factors for atherosclerosis and general vascular obstruction include behavioral factors like smoking (Joosten et al., 2012) and physical inactivity (Laufs et al., 2005). More recent studies have begun to examine other risk factors for atherosclerosis, including insulin resistance related to obesity (Bornfeldt & Tabas, 2011) and general inflammatory processes (Hansson, 2005). When atherosclerosis occurs and plaque builds up on the walls of the coronary arteries, blood flow to the heart is reduced, which limits the amount of oxygen and nutrients the heart receives. If the heart muscle does not receive adequate oxygen, the cells of the heart can be damaged, which is known as ischemia (AHA, 2012).

### *Myocardial Infarction*

Atherosclerosis can lead to a myocardial infarction (MI), commonly known as a heart attack, which occurs when blood flow to a portion of the heart is completely blocked. The key pathology involved in a MI is heart cell death due to ischemia (Thygesen, Alpert, & White, 2007). Depending on the extent of the blockage and ischemia, a MI could be minor and undetected or it could be a major cardiovascular event which leads to sudden death or severe heart damage (Thygesen, Alpert, & White, 2007). Regardless of the severity, the atherosclerotic process and blockage of the coronary arteries is a key cause of ischemia associated with MI. To treat MI, patients may undergo a procedure known as thrombolysis, which involves injecting a clot-dissolving substance into the body to reduce the blockage and restore blood flow (AHA, 2014d). If the clot cannot be effectively dissolved, there are several

types of treatments for MI and other coronary artery diseases. Two of the most common cardiac procedures are percutaneous coronary intervention (PCI), which involves inserting a catheter and stent to keep the coronary artery open for improved blood flow, and coronary artery bypass graft surgery (CABG), which involves using another blood vessel to circumvent the blockage and transport blood to the heart (AHA, 2014d).

### *Angina*

Unstable angina is one of several forms of coronary artery disease which involves reduced blood flow to the heart muscle due to atherosclerosis in the coronary arteries (Anderson et al., 2013). When plaque builds up in the coronary artery the plaque can rupture and injure the blood vessel, resulting in blood clotting and reduced blood flow to the heart (Anderson et al, 2013). Once the rupture has occurred there is often unexpected chest pain, even at rest (AHA, 2013). If the clotting associated with unstable angina is not addressed by a clinical intervention, a patient's risk for subsequent MI and cardiac death is greatly increased (Anderson et al., 2013). Once again, PCI and CABG are two of the main types of treatment for unstable angina to increase blood flow to the heart and reduce the amount of ischemic damage incurred by the heart (AHA, 2013). Stable angina, similarly, is often caused by myocardial ischemic processes and atherosclerosis and results in pain in the chest, jaw, shoulder, back, or arms (Fox et al., 2006). However, unlike unstable angina, the discomfort associated with stable angina is not due to ruptured plaque buildups but rather associated with reduced blood flow to the heart because of atherosclerosis (Fox et al., 2006). Therefore, while unstable angina can result in random and unexpected chest pain, stable angina typically is more predictable and results in chest pain during periods of high cardiovascular exertion, such as during exercise or high emotional stress (Fox et al., 2006).

## *Arrhythmias*

Aside from the coronary artery diseases, which all involve atherosclerosis and reduced blood flow to the heart, CVDs can also include conditions associated with abnormal electrical impulses within the heart. An arrhythmia is any change from the normal pattern of electrical impulses within the heart (AHA, 2015a). Arrhythmias can occur in many different forms, including the heart beating too rapidly (tachycardia), too slowly (bradycardia), and irregularly in either the atria or ventricles (examples include atrial and ventricular fibrillations) (AHA, 2015a). While some arrhythmias are often considered relatively benign, some types, such as ventricular fibrillations, are particularly dangerous because the heart begins to beat chaotically and can no longer pump blood efficiently to the body; cardiac arrest occurs when the heart's electrical functioning begins to falter in this manner (AHA, 2014a). If cardiac arrest occurs, the heart's normal beating needs to be restored as soon as possible. The most effective treatment to restore electrical functioning to the heart is a defibrillator, such as an automated external defibrillator (AED), which provides an electric shock to the heart in an attempt to restore normal rhythm (National Heart, Lung, and Blood Institute (NHLBI), 2011). Cardiopulmonary resuscitation (CPR) is also recommended to attempt to maintain even minimal blood flow (NHLBI, 2011). For people with arrhythmias or who may be at risk for future cardiac arrest, an implantable cardioverter defibrillator (ICD) may be implanted. In a meta-analysis of over 4,900 patients at risk for sudden cardiac death or with other CVDs, ICDs were shown to be effective at preventing sudden cardiac death as both primary and secondary prevention techniques (Ezekowitz, Armstrong, & McAlister, 2003).

While cardiac arrest and arrhythmias are not directly associated with a blockage of blood flow to the heart, ischemic and electrical processes can interact. For example, an MI can cause cardiac arrest and sudden death because ischemic damage to the heart can result in conduction issues (AHA, 2014b). Among patients who suffer sudden cardiac death during an

MI, it is likely that the ischemic event led to a fatal arrhythmia, which then resulted in death (Thygesen, Alpert, & White, 2007). Therefore, while coronary artery diseases such as unstable angina and MI are certainly major concerns, the disturbances in cardiac rhythm associated with arrhythmias are also essential to consider when examining CVDs.

### *Heart Failure*

Another type of CVD, often associated with both coronary artery issues and disturbances in cardiac rhythm, is heart failure (HF). HF occurs when the heart cannot pump blood efficiently enough to meet the body's oxygen and blood needs, and is often considered to be an end stage of CVD (AHA, 2015b). Because the body is not receiving the optimal amount of oxygen and nutrients, the result is often fatigue and shortness of breath and everyday activities becoming difficult (AHA, 2015b). When the heart loses the ability to pump blood efficiently, it often enlarges, develops more muscle mass, and pumps faster to compensate for the lack of power (AHA, 2015b). Additionally, blood vessels throughout the body narrow to increase blood pressure to ensure blood reaches essential organs and provides them with sufficient nutrients (AHA, 2015b). Some of the common risk factors for HF include high blood pressure, previous MI, heart valve damage, diabetes, sleep apnea, and others (AHA, 2015b). Some studies have suggested that coronary artery disease is the largest risk factor for developing HF, although it is often difficult to determine given the multitude of potential risk factors and causes (McMurray & Stewart, 2000).

### **Cardiac Rehabilitation**

A key part of heart disease care is cardiac rehabilitation (CR), which is a coordinated service involving several types of interventions to maximize a cardiac patient's overall functioning (Contractor, 2011). According to the Centers for Medicare and Medicaid Services (CMS), CR programs must contain five distinct components to be eligible to bill Medicare

contractors (CMS, 2010b). First, CR programs must include physician-prescribed exercise. Exercise frequency, intensity, and duration are prescribed for the individual client depending on their unique cardiovascular and medical status (Contractor, 2011). CR often involves both aerobic exercises, in the form of walking, running, or cycling, and resistance exercises, such as hand weights, machines with low resistance, or elastic bands (Contractor, 2011). Second, CR should include cardiac risk factor modification programs. Many of the risk factors for CVDs are behavioral in nature; poor diet, lack of physical activity, tobacco usage, and excessive alcohol consumption have all been linked to increased risk of CVD (WHO, 2015). Therefore, CR attempts to reduce the risk factors associated with CVD and slow the progression of disease through improved health behaviors to decrease overall and cardiac mortality (Heran et al., 2011). For example, many CR programs involve management of common risk factors, such as lipid profiles, cholesterol, diabetes, and hypertension management, along with smoking cessation aid and weight loss strategies (Contractor, 2011). Third, CR programs are required to have psychosocial assessment, which should assess areas such as a patient's family and home environment as it relates to their CR treatment and an evaluation of a patient's response to treatment (CMS, 2010b). The fourth required component in CR is objective outcomes assessment for each individual patient from commencement to conclusion of CR (CMS, 2010b). Finally, each patient is required to have a unique, written treatment plan based on a patient's diagnosis, duration of the CR program, and goals (CMS, 2010b). Overall, CR involves various interventions including exercise, education about CVDs, psychological support, and overall health behavior change targeted at CVD risk factors (Heran et al., 2011).

CR can also occur in a variety of settings. While many CR programs occur at medical centers, there have been studies which have examined the effectiveness of home-based CR programs containing the same types of interventions (Dalal, Zawada, Jolly, Moxham, & Taylor, 2010). To be considered a home-based CR program, there must be a structured format

involving clear objectives, patient monitoring, follow-up visits, letters and phone calls from staff, and some self-monitoring diaries (Dalal et al., 2010). A large Cochrane systematic review found similar outcomes and benefits for cardiac patients among those who participated in center-based and home-based CR programs (Dalal et al., 2010). Therefore, CR appears to be effective at improving cardiac patients' outcomes regardless of the setting.

While CR programs are tailored to individual patients based on their unique needs and initial cardiovascular fitness, the CMS provides general recommendations for program duration. Typically, up to 36 sessions are covered by Medicare, with a usual prescription of three sessions per week for 12 weeks (CMS, 2010a). However, it is acceptable for a patient to complete the CR program early if the CR staff has determined that the patient has met their initial goals (CMS, 2010a). For example, a patient may be identified as a candidate for early program termination if they have achieved a stable level of exercise tolerance without ischemia, have stable symptoms of angina or dyspnea at maximum exercise level, or have resting blood pressure and heart rate within normal limits (CMS, 2010a). Additionally, patients with a cardiovascular stress test which is not indicative of additional problems are also eligible for early completion (CMS, 2010a). On the other hand, coverage can be extended past 36 sessions on a case-by-case basis if sufficient evidence is provided that the exit criteria have not been met, but generally coverage will not exceed a maximum of 24 weeks (CMS, 2010a).

Variability in the number of sessions required for an individual to complete CR has complicated the interpretation of studies examining CR outcomes, because defining what constitutes CR participation and completion has been difficult (Casey et al., 2008). For example, a study by Lane, Carroll, Ring, Beevers, and Lip (2001) considered patients to have completed CR if they attended 50% or more of the prescribed sessions. A study by Glazer and colleagues (2002) defined completion as attending 2/3 or more of the prescribed sessions. Finally, a study by Sanderson and Bittner (2005) defined completion as attending all prescribed

sessions or patients who achieved their prescribed goals and were permitted to discontinue the CR program early. Due to the current CMS guidelines for CR program duration and the possibility for completion occurring before the prescribed number of sessions, utilizing CR goal achievement as a criterion for CR completion appears to be the most accurate way to define CR completion. However, when considering the literature on CR attendance and completion, it is often complicated by these inconsistent definitions. At the Vidant Medical Center CR, participants who were considered to have completed the program participated in approximately 26 sessions, on average.

At the Vidant Medical Center CR where the current study took place, a patient is typically present for a single session of CR for around an hour to an hour and a half. When they first arrive, patients are checked in and measurements are taken to establish safety before beginning exercise. These measurements include weight, blood pressure, blood sugar for diabetic patients, heart rate, and oxygen saturation. Then, patients warm up and participate in their individually prescribed exercise program. Depending on the patient, the exercise segment of CR usually takes 20-45 minutes. The educational components of CR take place in a multitude of settings and forms during the program, ranging from casual conversations between staff and patients during exercise to larger group education classes. Patients normally meet three days per week until they have completed the program.

There is a plethora of evidence for the effectiveness of CR at reducing overall mortality (Oldridge et al., 1988; Goel et al., 2011). In a meta-analysis of over 4,300 patients, Oldridge and colleagues (1988) found that the odds ratios for all-cause death and cardiovascular death were both significantly lower among patients who attended CR. A larger meta-analysis by Taylor et al. (2004), which examined 8,940 patients with coronary heart disease, found reduced all-cause mortality and cardiac mortality compared to usual medical care. These results were maintained even after considering coronary heart disease diagnosis or type of CR (Taylor et al.,

2004). A more recent review used three different types of statistical analyses (propensity score-matched analysis, propensity score stratification, and regression adjustment with propensity score in a 3-month landmark analysis) to examine the outcomes of nearly 2,400 patients who underwent PCI between 1994 and 2008 (Goel et al., 2011). This study found similar results of decreased risk of overall and cardiac mortality amongst CR participants, and these results were the same regardless of gender or age (Goel, et al., 2011).

CR participation is also associated with improved outcomes aside from mortality. For example, exercise training, a key component of CR, has been associated with greater cardiovascular fitness and aerobic capacity (Fletcher et al., 1996). According to the American Heart Association (AHA), exercise training can result in increased ventilatory oxygen uptake by increasing maximal cardiac output and decreasing the oxygen demands of the heart for the same level of external work (Fletcher et al., 1996). Additionally, in the meta-analysis by Taylor et al. (2004), CR was associated with larger decreases in cholesterol levels, triglyceride levels, systolic blood pressure, and even smoking behavior. These findings would be supported by the AHA, which suggests that exercise training in general improves lipid metabolism and body weight (Fletcher et al., 1996). CR has even been shown to be effective at reducing depression following treatment (Milani & Lavie, 2007).

To obtain all of the benefits of CR, however, it appears to be important to attend as many sessions as possible. Hammill and colleagues (2010) suggest there is a strong dose-response relationship between number of CR sessions attended and long-term outcomes. In an analysis of over 30,000 patients who attended at least one outpatient CR session at a healthcare facility, those who attended 36 sessions had a 47% lower risk of death than those who attended only 1 session (Hammill et al., 2010). Additionally, those who attended 36 sessions had a 14% lower risk of death than those who attended 24 sessions, even after adjustments for demographic characteristics, comorbid conditions, and subsequent

hospitalizations (Hammill et al., 2010). Therefore, while there are numerous studies which have demonstrated the efficacy of CR on a diverse array of outcomes, it may require patients to attend as many sessions as possible to reap the full benefits.

CR participation has not been shown to reduce all negative outcomes, however. For example, some of the aforementioned reviews did not find an association between CR participation and nonfatal MI or revascularization (Oldridge et al., 1988; Goel et al., 2011). The meta-analysis by Taylor et al. (2004) found no significant differences in rates of nonfatal MI or revascularization as well, along with no significant differences in HDL or LDL cholesterol levels and diastolic blood pressure among patients in CR compared to those in usual medical care. Taylor et al. (2004) also found that health-related quality of life improved among both groups, although there was no significant effect of CR participation. Therefore, while CR appears to have many positive effects on the recovery of people with CVDs, regardless of gender or age (Menezes, Lavie, DeSchutter, & Milani, 2014), it has not been shown to reduce all negative consequences of CVDs.

Despite the wealth of evidence that CR is effective at reducing mortality, many individuals referred to CR do not attend or do not complete the program (Arena et al., 2012). According to De Vos et al. (2013), international rates of attendance vary from 21% to 75%. In a study of 526 discharged CR patients in the United States, the rate of completion of a CR program was only 58%, with 63% of those who did not complete the program dropping out due to non-medical reasons such as transportation issues, financial difficulties, or a personal decision not to continue the program (Sanderson, Phillips, Gerald, DiLillo, & Bittner, 2003). The other 37% of the patients who dropped out in this sample did not complete the program due to a medical condition or complication (Sanderson et al., 2003). In an older population of 226 patients aged 62 or older who were diagnosed with acute MI or underwent CABG, Ades, Waldmann, McCann, and Weaver (1992) found a participation rate of only 21%. In a study of

eligible Medicare patients who experienced an MI or underwent a CABG procedure, only 14% to 31% took part in a CR program following these cardiac events (Suaya et al., 2007). Overall, the rates of attendance and completion of CR programs are lower than would be expected considering the immense amount of benefits which have been associated with participation in CR.

#### *Barriers to CR- Disease Severity/Physical Barriers*

In an attempt to understand why more patients do not take advantage of CR, there have been myriad studies which have examined various factors which may contribute to patient non-attendance. Some studies have examined physical barriers and disease severity as possible reasons for sub-optimal CR participation rates. Most studies have found that factors other than disease severity are more important for CR participation; Ades and colleagues (1992) suggest that medical factors such as cardiac diagnosis and left ventricular ejection fraction (LVEF) did not predict CR participation in a study of 226 older patients. Additionally, Clark et al. (2012) found that patients' stated reasons for attending CR were likely to involve a wide range of factors, but medical reasons like symptom severity and comorbidities were not typically discussed. However, some studies have demonstrated various cardiac diagnoses and risk factors are correlated with poorer CR participation. In a review of 18 studies published between 1990 and 2009, Taylor, Wilson, and Sharp (2011) found four studies that reported significant effects of cardiac diagnosis on CR adherence, along with three studies which showed decreased adherence among active smokers and two studies which suggested patients with a higher body mass index (BMI) had worse CR adherence. Some other physical factors which have been consistently associated with decreased CR participation include distance to the CR center, lack of time, cost of the program, lack of transportation, and poor referral strategies (De Vos et al., 2013; Grace et al., 2011; Jackson, Leclerc, Erskine, & Linden, 2005). Additionally, lack of insurance coverage has been associated with both decreased likelihood of being

referred to CR and non-participation in CR programs (Jackson et al., 2005; Sun, Jadotte, & Halperin, 2016).

#### *Barriers to CR- Demographics*

Demographic factors like age, gender, and ethnicity have also been studied in relation to CR attendance and completion. Some studies suggest that there are significant differences in CR participation among different demographic groups. For example, Fletcher et al. (1996) suggests that there may be sex biases in referral rates to CR and attendance rates, with women being referred less and having higher dropout rates and compliance problems. Menezes and colleagues (2014) reviewed the literature and found women and minorities received fewer referrals to CR programs despite the potential to receive similar benefits to men and Caucasians. In a study of almost 2,100 patients with acute MI, Parashar et al. (2012) found similar results for women, discovering that women were less likely to participate in CR at one month post-hospital discharge. Parashar et al. (2012) also found that older patients and minority patients were less likely to participate in CR at 6 months post-hospital discharge. Valencia, Savage, and Ades (2011) reviewed literature on CR participation among minority patients and patients with low SES and found that both of those factors resulted in lower rates of participation. A study of 106 older patients with heart failure, aged 65 years or older, demonstrated that only 21% of this elderly population was even referred to CR, indicating another possible group which is not obtaining the benefits of CR at an acceptable rate (Buttery et al., 2014). Another recent meta-analysis of 21 studies found that odds of CR participation were lower in older individuals, females, those with a high school degree or less, and those without current employment (Sun et al., 2016). Not all studies have found these demographic differences, however. A study of over 4,400 patients enrolled in CR did not find any significant gender differences in program adherence, although minorities were significantly less likely to adhere to treatment (Turk-Adawi, Oldridge, Tarima, Stason, & Shepard, 2013). Therefore, while

CR attendance and completion rates are typically low overall, it appears that specific demographic groups, like minorities or women, may be at an even greater risk of not attending CR or not completing the program.

#### *Barriers to CR- Psychosocial Barriers*

Furthermore, aside from physical barriers and demographic differences, some researchers have examined the effect of various psychosocial variables on CR participation. One of the constructs which has been studied in relation to CR attendance is illness cognition and perception of disease. Reges et al. (2013) studied 420 hospitalized patients with acute MI or acute coronary syndrome (ACS) and found cognitions about the benefits of exercise and perceived control over the disease were both significantly associated with participation in CR. Similarly, a study by Whitmarsh, Koutantji, and Sidell (2003) found that lower perception of symptom number and severity and less controllability and curability of disease was associated with decreased CR attendance. They also looked at the effect of coping strategies on CR attendance and found that the use of problem-focused and emotion-focused coping were correlated with increased CR participation (Whitmarsh et al., 2003). The use of maladaptive coping strategies, such as denial, mental disengagement, and behavioral disengagement, was alternatively associated with poorer CR participation (Whitmarsh et al., 2003).

Some studies have also examined various social factors in an attempt to understand the low levels of CR attendance and completion. King, Humen, Smith, Phan, and Teo (2001) examined the effects of a diverse group of psychosocial variables in a sample of over 300 patients with acute MI or CABG surgery. This study found that women and older participants reported less perceived social support, but there was no significant association between social support and CR attendance (King et al., 2001). These results are in contrast to other findings in the literature, however. A large review of 374 factors from 32 studies, conducted by Murray,

Craigs, Hill, Honey, and House (2012), suggested that support from family and friends was one of the factors which most consistently was associated with increased uptake of lifestyle change programs. Additionally, King and colleagues (2001) found that patients who demonstrated higher levels of role resumption at two weeks post-MI were less likely to participate in CR. These researchers posit that patients who attempt to resume normal roles soon after MI may inherently not believe they are in need of rehabilitation, leading to less CR participation. In one attempt to address social differences, Meillier and colleagues (2012) assigned socially vulnerable patients to an enhanced CR program with the goal of increasing CR attendance. The enhanced CR program involved extra nurse-led consultation, additional time to design and implement idiographic plans for CR, skills-training elements, and extra activities at local community centers. Socially vulnerable patients were described as individuals with low education, living alone, or experiencing high life stress and a lack of social support. By assigning the socially vulnerable patients to the enhanced CR program, this study achieved an attendance rate of 93% for all patients referred to CR (Meillier et al., 2012). The lack of randomization and absence of a control group are significant limitations to that study, but the results are promising for the importance of taking into account psychosocial factors when attempting to remedy the problem of sub-optimal CR participation, especially considering the vulnerability for mental health issues conferred by high stress and lack of social support.

Some studies have even examined the role of personality characteristics, such as optimism and neuroticism, on CR attendance and outcomes, but have not found significant effects (Glazer et al., 2002). Overall, researchers have discovered both primary access issues, such as insurance coverage, transportation problems, and distance to CR center (Jackson et al., 2005), and secondary access issues, such as psychological and social variables (Whitmarsh et al., 2003), which are associated with CR non-attendance and non-completion. While both issues are certainly important and require additional research, many of the primary and

secondary access issues may interact. For example, depending on a patient's perception of their illness, the distance to the CR center may be more or less of an important factor in determining attendance. Additionally, studies have demonstrated that some secondary access issues, such as depression, can significantly reduce compliance to medical regimens (DiMatteo, Lepper, & Croghan, 2000). Even if transportation is available, the avoidance behaviors and avolition associated with depression may inhibit individuals from taking advantage of the opportunities that they do have. Large reviews examining referral and adherence predictors appear to support the heterogeneity of these factors; for example, a large review of over 16,800 eligible patients demonstrated that a wide variety of factors, encompassing both primary and secondary access issues, were independent predictors for CR referral and adherence (Jackson et al., 2005). Therefore, studying secondary access issues like psychosocial predictors of CR attendance and completion should still be viewed as a worthwhile and necessary part of this literature. Despite the abundance of studies examining a multitude of demographic, physical, and psychosocial factors, CR attendance and completion rates remain suboptimal, suggesting the need for additional research in determining more precise factors associated with CR non-attendance.

### **Depression and Cardiovascular Disease**

One of the factors associated with CR non-attendance and CVDs in general which has received some attention is depression. Major Depressive Disorder (MDD), as defined by the DSM-5, occurs when five or more of the following symptoms have been present for at least the same two-week period: depressed mood, anhedonia, weight loss or gain, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue, feelings of worthlessness or guilt, lack of concentration, and recurrent thoughts of death or suicidal ideation (American Psychiatric Association (APA), 2013). At least one of the five symptoms must be either depressed mood or

anhedonia, the symptoms must cause clinically significant distress, and the depressive episode cannot be caused by any substances or other medical conditions (APA, 2013).

When examining the role of baseline depression on CR attendance and outcomes, many studies have found a negative association. For example, one study determined that baseline depressive symptoms, as measured by the BDI, accounted for 9.5% of the variance associated with increased aerobic capacity in a CR program (Glazer et al., 2002). The researchers measured aerobic capacity as maximum oxygen consumption and controlled for relevant demographic variables and attendance rates, but the sample only included 46 patients in a 12-week CR program (Glazer et al., 2002). Another study examining 600 patients in CR for a wide array of CVDs found that depression was negatively associated with likelihood to complete the CR program (Casey et al., 2008). In this study, a logistic regression demonstrated that patients with elevated depression scores (scores of more than 10 on the Beck Depression Inventory) were 2.2 times less likely to complete CR than patients with lower depression scores, even after controlling for age and gender (Casey et al., 2008). Additional analyses suggested that only age also predicted completion, with older patients being more likely to complete CR; gender, BMI, and employment status all failed to significantly predict CR completion (Casey et al., 2008). A study by Swardfager and colleagues (2011) supported these findings, showing that CR patients who met *DSM-IV* criteria for MDD were less likely to complete CR, attended fewer sessions, achieved worse aerobic fitness increases, and reduced body fat to a lesser extent than patients who did not meet criteria for MDD. According to these studies, depression is a significant predictor of poor CR participation and outcomes.

On the other hand, not all studies have demonstrated that depression is a unique predictor of negative outcomes for patients with CVDs, with some research suggesting that other psychological variables related to depression may better account for the negative outcomes. For example, one study by Dickens, Cherrington, and McGowan (2011) found that

depressive symptoms, as measured by the Hospital Anxiety and Depression Scale (HADS), were associated with lower health-related quality of life (HRQoL) in a sample of 255 primary care patients with coronary heart disease; however, the impact of depression on HRQoL was mediated by other psychological factors, including cardiac anxiety, awareness of somatic symptoms, and negative illness perceptions. Another study found that self-efficacy mediated the relationship between depressive symptoms, as measured by the Center for Epidemiological Studies - Depression Scale (CES-D), and treatment adherence in a sample of 252 HF patients, further suggesting that other psychological factors may be intertwined in the association between depression and cardiovascular outcomes (Maeda et al., 2013).

Therefore, it is possible that other psychological variables closely related to depression may be important to evaluate when examining the relation between depression and CR participation and outcomes. Several researchers have attempted to accomplish this goal, examining other constructs which may be significantly related to or overlap with depression. For example, Doyle, Conroy, and McGee (2007) performed a review which suggested several other factors, including vital exhaustion, negative affective states and Type D personality, and negative illness cognitions could all be associated with depression-related mortality among patients with CVDs. According to this review, vital exhaustion is defined as feelings of excess fatigue, energy loss, irritability, and demoralization; it has been associated with poor cardiovascular outcomes and depression, although there are significant overlaps in the constructs (Doyle et al., 2007). Pedersen and colleagues (2007) also examined this association in a study of 534 patients who underwent PCI. At 2-year follow-up, vital exhaustion was associated with poor cardiac outcomes, although after adjustment it was no longer significant (Pedersen et al., 2007). Type D personality, which consists of the combination of negative affectivity and social inhibition, has also been associated with depression and increased mortality in cardiac populations (Doyle et al., 2007). Another construct which has been related

to depression and CVDs is distorted illness cognitions. In their review, Doyle et al. (2007) suggest that some studies have observed relations between illness perception and depression in CHD patients but larger studies often have contradictory results about the influence of negative illness cognitions on depression and health behaviors. Another review, specifically focused on the impact of illness perceptions on CR attendance, found that a few specific illness cognitions significantly predicted CR participation; however, the results from their meta-analysis were often mixed and had small effect sizes (French, Cooper, & Weinman, 2006). While the presence of depression certainly appears to be important among patients with CVDs, there are numerous other constructs and psychological factors which have been suggested to also be predictors of poor outcomes. Depression is likely to play some role in CR attendance and outcomes, but the complexity of findings in the literature suggests that this relation has yet to be entirely illuminated and more research is warranted.

A final aspect of depression which has received little attention in the literature is the influence of behaviors commonly associated with depression, such as avoidance behaviors, on CR attendance and completion. Behavioral activation (BA) treatments view escape and avoidance behaviors as key components of maintaining depression, yet most common depression self-report questionnaires, such as the BDI, do not specifically assess for these types of behaviors (Kanter et al., 2007). Therefore, Kanter and colleagues (2007) created the Behavioral Activation for Depression Scale (BADS) in order to more specifically assess for escape and avoidance behaviors related to depression. In the BADS, some examples of avoidance behaviors include “I stayed in bed too long even though I had things to do” and “I was not social, even though I had opportunities to be”. Some studies have suggested that avoidance may be associated with non-attendance at CR (Farley, Wade, & Birchmore, 2003), but this association has not been consistently examined in the literature. Therefore, it may also

be important to also study some of the behavioral components of depression when attempting to understand the effect of depression on CR attendance and completion.

One of the possible ways to further examine the association between depression and CR attendance and outcomes is to examine depressive symptoms, rather than depression as a whole. Previous studies of psychiatric patients without CVDs have demonstrated that depressive symptoms can be problematic even without a full diagnosis of MDD. For example, Lewinsohn and colleagues (2000) found that psychosocial distress increased with increasing levels of depressive symptoms. In this study, psychosocial distress included measures of social support, social interactions, life satisfaction, pleasant activities, and self-esteem, among others; when depressive symptoms were elevated, patients were more likely to report lower life satisfaction, fewer pleasant activities, lower self-esteem, and other indicators of psychosocial distress. Increased levels of psychosocial distress were observed in patients even with sub-threshold levels of depressive symptoms, indicating that even a few depressive symptoms could be troublesome. According to the researchers, these results support the fact that depressive symptoms can be clinically significant even when a diagnosis of MDD has not been met (Lewinsohn et al., 2000).

Other researchers have attempted to examine depressive symptom clusters, such as depressive cognitions or somatic symptoms, in addition to individual depressive symptoms. Determining how to differentiate which symptoms are included in which clusters has been problematic, however, and different researchers have used varying models to assess depressive symptom clusters throughout the literature. Some researchers have pointed out this discrepancy and called into question many findings which have examined the impact of specific depressive symptom clusters, validly claiming that some symptoms are viewed within one cluster in some studies and within a different cluster in other studies (Carney & Freedland, 2012). In order to more accurately study depressive symptom clusters, a satisfactory model is

needed. A review by Vanheule and colleagues (2008) attempted to accomplish this goal by looking at ten different models of the Beck Depression Inventory-II (BDI-II) and utilizing confirmatory factor analysis to determine which model of depressive symptom clusters demonstrated the best fit. While none of the models which looked at all 21 BDI-II items demonstrated a good fit, several shortened models with items deleted displayed a good fit and were posited as sufficient ways to examine depressive symptom clusters. A two-factor model with a cognitive factor and a somatic-affective factor and a three-factor model involving cognitive, affective, and somatic factors had the best fit, but the researchers preferred the three-factor model because it more clearly differentiates between somatic and affective symptoms (Vanheule et al., 2008). According to this factor structure, symptoms such as pessimism and worthlessness would be considered cognitive symptoms of depression. Loss of pleasure, crying, and loss of interest are included as affective symptoms of depression. Finally, change in sleeping pattern, concentration difficulties, and changes in appetite are examples of somatic symptoms of depression. Therefore, although the literature is mixed with regards to how to best define the clusters of symptoms associated with depression, the three-factor model tested by Vanheule and colleagues (2008) appears to be the most accurate, evidence-based model to date.

Using depressive symptom clusters has also yielded interesting findings in regards to depression and CVD. Several studies have found that patients with depression post-MI had significantly fewer cognitive symptoms than depressed outpatients without any CVDs (Martens et al., 2006; Groenewold et al., 2013). Martens and colleagues (2006) conducted a study which examined 40 depressed patients post-MI, 40 patients without depression post-MI, and 40 psychiatric outpatients with depression to determine if depression was similar in cardiac and non-cardiac populations. Mean levels of depressive cognitions, as measured by the Beck Cognition Checklist-Depression subscale (CCL-D), were significantly higher in the psychiatric

sample than the cardiac sample with depression (Martens et al., 2006). In addition to those findings, Martens et al. (2006) found that psychiatric patients with depression had higher levels of overall depressive symptoms than post-MI patients with depression, indicating that depression between these two populations may be both qualitatively and quantitatively different. Groenewold et al. (2013) performed a similar study with a larger sample, including 194 patients post-MI, 214 patients in primary care settings, and 326 mental health care patients. Patients post-MI and in primary care settings reported significantly lower cognitive/affective symptoms than patients in mental health care settings, even after controlling for recurrence of depression (Groenewold et al., 2013). However, these results were not as strong as Martens and colleagues (2006) found, because the differences disappeared after controlling for age of onset. There were no differences among reported somatic symptoms between the three groups either (Groenewold et al., 2013). Therefore, while there may be other factors involved, depression in cardiac populations may be different than depression seen in mental health care settings.

Additionally, a recent meta-analysis suggested that somatic/affective symptoms of depression, not cognitive/affective symptoms, are primarily responsible for poor CVD prognosis among patients with depression and CVD (de Miranda Azevedo et al., 2014). In this review, 13 studies were included with a total of 11,128 subjects who presented with a wide range of CVDs and whose depression was measured using reliable and valid measures. The breakdown of depressive symptoms into cognitive/affective and somatic/affective was completed by examining the 13 included studies and the individual symptom clusters in those studies; while there was some disagreement amongst the studies included, the agreement on symptom assignment to the two categories was moderate ( $\kappa = 0.60$ ) (de Miranda Azevedo et al., 2014). In analyses that included adjustment for disease severity, somatic/affective symptoms, but not cognitive/affective symptoms, were associated with worse cardiovascular outcomes, such as cardiovascular mortality, all-cause mortality, or cardiovascular events (e.g. rehospitalization) (de

Miranda Azevedo et al., 2014). Specifically, a one standard deviation increase in somatic/affective symptoms was associated with a 32% increased risk in negative outcomes (de Miranda Azevedo et al., 2014). According to this meta-analysis, specific depressive symptoms may be more problematic for patients with CVDs and depression and supports the idea of studying depressive symptom clusters rather than depression as a whole amongst this population.

The relative importance of somatic symptoms and lack of importance of cognitive symptoms in depressed patients with CVD has been suggested as one of the reasons why previous attempts to treat depression amongst patients with CVDs, such as the Enhancing Recovery in Coronary Heart Disease (ENRICHD) study (Berkman et al., 2003), did not yield optimal results (Martens et al., 2006). The main finding of the ENRICHD trial was that psychosocial intervention for post-MI patients successfully reduced depressive symptoms but did not lead to decreased mortality rates (Berkman et al., 2003). It has been suggested that the mode of treatment in the ENRICHD trial, cognitive-behavioral therapy focused on cognitive restructuring, may not have been ideal because of the differences in cognitive and somatic symptoms in patients with depression and CVD (Martens et al., 2006). If somatic symptoms are primarily important for cardiovascular prognosis (de Miranda Azevedo et al., 2014) and there are fewer cognitive symptoms of depression in cardiac populations (Martens et al., 2006), a cognitive approach to treating depression in individuals with depression and CVD may not be effective in reducing CVD mortality. This idea is partially supported by secondary analyses of the ENRICHD study as well. In an analysis of 1,254 patients from the ENRICHD study by Roest et al. (2013), decreases in somatic depressive symptoms among the intervention group (treated with CBT) were associated with reduced risk of recurrent MI and mortality, even after adjusting for baseline depression and demographic and clinical variables. On the other hand, decreases in cognitive symptoms did not have a significant association with cardiovascular outcomes

(Roest et al., 2013). Ultimately, while depression treatment overall did not improve cardiovascular outcomes in the ENRICHD trial, it appears that decreases in somatic depressive symptoms specifically did have a significant effect on improving outcomes.

It is important to note that some researchers have questioned the sole importance of somatic depressive symptoms in cardiac populations (Carney & Freedland, 2012). Carney and Freedland (2012) reviewed the literature on depression within this population and acknowledged the complexity of findings in this area. While some studies have found somatic symptoms to be predictors of worse cardiovascular outcomes, the differences in methodologies and ways of defining the depressive symptom clusters has complicated the interpretation of the findings (Carney & Freedland, 2012). Additionally, the researchers point out criticisms which question whether somatic symptoms of depression are uniquely associated with depression or confounded with CVD symptoms (Carney & Freedland, 2012). However, many studies, including the meta-analysis by de Miranda Azevedo and colleagues (2014), statistically control for disease severity using standard indices for CVD severity and risk factors. The use of well-validated measures is another method which can aid in avoiding confounding somatic symptoms of depression with CVD symptoms. For example, Thombs and colleagues (2010) found that the BDI-II did not appear to inflate somatic symptoms of depression in a sample of post-MI patients with depression.

Another piece of evidence against somatic symptoms being primarily responsible for poor outcomes is that not all studies have found this association (Frasure-Smith & Lespérance, 2003; Connerney et al., 2010). For example, Frasure-Smith and Lespérance (2003) found that lower overall depression scores on the BDI and both cognitive and somatic subscales were associated with decreased cardiac-related mortality at five years post-MI. This study was performed on nearly 900 patients post-MI, and the results retained significance even after adjustment for cardiac disease severity (Frasure-Smith & Lespérance, 2003). A study by

Connerney and colleagues (2010) provides even more counter-evidence; in a prospective study of 309 patients who underwent CABG surgery, the researchers found that overall depressive symptoms and cognitive/affective symptoms, measured by the BDI, were predictors of cardiac mortality. The somatic symptom subscale was not significantly associated with either all-cause mortality or cardiac mortality (Connerney et al., 2010). Considering the wealth of evidence for the importance of somatic depressive symptoms in cardiac patients, it is likely that these symptoms play a significant role in a patient's recovery and well-being. On the other hand, the conflicting findings within the literature suggest that there is a need for more research in this area to clarify the relation between depressive symptom clusters and cardiac outcomes.

### **Aims and Hypotheses of the Current Study**

While much of the previous research has examined depressive symptom clusters and associated constructs among populations with CVD, only one study was found which examined the impact of specific depressive symptom clusters on CR attendance and outcomes. In the study by Casey and colleagues (2008), exploratory analyses revealed that somatic symptoms of depression predicted dropout due to medical reasons better than cognitive-affective symptoms. However, this study used the first 13 items of the BDI-I as cognitive-affective symptoms and the last 8 items as somatic symptoms, which may not be an ideal way to examine the various symptom clusters (Carney & Freedland, 2012). Additionally, because the results were exploratory analyses, the researchers suggest future research is necessary to further elucidate the finding (Casey et al., 2008).

Furthermore, it may also be important to study psychological constructs related to depression in addition to examining depressive symptom clusters. As noted previously, other factors related to depression have also been associated with poor CR outcomes (Doyle et al., 2007). For the current study, illness cognitions and depressive behaviors were chosen as

additional variables. Illness cognitions were chosen because of the lack of evidence in the literature surrounding the importance of cognitive symptoms of depression among populations with depression and cardiovascular disease. It is possible that traditional measures of depression, such as the Beck Depression Inventory (BDI), may not assess depressive cognitions as well in this population because their cognitions are primarily illness-related cognitions, rather than general depressive cognitions. If that is true, it could help explain why negative illness perceptions appear to be related to negative cardiovascular outcomes, while this association is not consistently found for cognitive symptoms of depression.

Depressive behaviors are also of interest because traditional measures of depression, such as the BDI, do not specifically assess behaviors which may be maintaining depression. The lack of existing measures to assess depressive behaviors prompted the development of the Behavioral Activation for Depression Scale (BADS) (Kanter et al., 2007). It is possible that behaviors which maintain depression, such as avoidance behaviors, are also significantly detrimental to individuals attending and completing CR programs. Therefore, for the purposes of the current study, illness cognitions and depressive behaviors will also be measured along with depressive symptom clusters.

It would be beneficial to be able to identify patients who may be at a greater risk of dropping out of CR and not reaping the benefits associated with participation, so examining more specifically what factors are associated with lack of participation is essential. Therefore, there will be several aims associated with the current study attempting to explore the association between depression and CR participation. The **first aim** of this study is to examine the interrelationship between the psychosocial predictor variables, such as cognitive, affective, and somatic depressive symptom clusters, negative illness perceptions, and depressive behaviors to determine the uniqueness of these measures and facilitate interpretation of the results of subsequent aims. We hypothesize that the psychosocial predictor variables may be

correlated, but that correlation coefficients will be small (e.g.  $< .3$ ) indicating that they are primarily unique constructs. Based on observed correlation coefficients as described in Aim 1, the **second aim** and primary purpose of this study is to determine if particular depressive symptom clusters, as defined by the factor analysis conducted by Vanheule and colleagues (2008), predict the attendance and completion rates of patients participating in a CR program. Based on the exploratory findings in the study by Casey and colleagues (2008), we hypothesize that somatic symptoms of depression will have the strongest negative association with CR attendance and completion. Additionally, due to the complex relationship between depression and the previously discussed associated constructs, the **third aim** of this study is to explore if other factors, such as negative illness cognitions or depressive behaviors, are better predictors of CR attendance or outcomes than clusters of depressive symptoms.

## CHAPTER III: METHODS

### Participants

Participants were recruited from the Vidant Medical Center Cardiovascular Pulmonary Rehabilitation (CVPR) program. The sample for this study included 56 participants (41.1% female, 35.7% African-American) with an age range of 32-84 years old. Participants with any cardiovascular diagnosis given as the primary reason for referral were invited to participate. Participants in this study were referred to CR for a wide array of CVD conditions, including PCI or CABG procedures, MI events, angina, and HF. Participants in CVPR with a pulmonary diagnosis as the primary reason for attendance were not be recruited for this study; however, participants were not excluded for any other reasons as long as they could read and speak English to consent to the study. According to power analysis, a sample of approximately 55 would be required to achieve acceptable power based on a medium effect size to test the effects of depressive symptom clusters on CR attendance and completion (second aim). Therefore, the minimum goal for participant recruitment was achieved (See Appendix B).

### Measures

**Beck Depression Inventory- II (BDI-II)** (Beck, Steer, & Brown, 1996): The BDI-II is a widely used 21-item self-report questionnaire used to measure depressive symptoms. The BDI-II asks participants to rate the severity of depressive symptoms during the past two week period. It differs from the BDI-I in that four items were deleted (Weight Loss, Body Image Change, Somatic Preoccupation, and Work Difficulty) and replaced by four new items (Agitation, Worthlessness, Concentration Difficulty, and Loss of Energy) (Beck et al., 1996). Additionally, questions about appetite and sleep change were changed to allow for both increases and decreases, and many questions were slightly reworded (Beck et al., 1996). It has been suggested that the BDI-II may be more accurate than the BDI for post-MI patients due to

somatic symptom inflation in the BDI from symptom overlap between depression and MI (Delisle et al., 2012). In one study, 296 patients post-MI and 296 psychiatric outpatients were examined using the BDI and matched on cognitive-affective BDI scores, sex, and age; the researchers found that the post-MI patients endorsed significantly more somatic symptoms than the psychiatric patients (Delisle et al., 2012). In a similar study using the BDI-II, somatic symptom scores were not significantly higher in a post-MI sample than a psychiatric sample (Thombs et al., 2010).

**Behavioral Activation for Depression Scale (BADS)** (Kanter et al., 2007): The BADS is a 25-item self-report questionnaire used to measure avoidance behaviors that lead to a lack of environmental reinforcement and thus maintenance of depressive symptoms (see Appendix C). The BADS contains four subscales, including Activation, Avoidance/Rumination, Work/School Impairment, and Social Impairment. It asks participants to determine how true each of the 25 statements was during the past week on a seven-point scale, ranging from 0 (not at all) to 6 (completely). Some of the items are reverse-coded. Overall, the BADS has been shown to have good internal consistency (Cronbach's  $\alpha = .87$ ; Cronbach's  $\alpha$  for each subscale range from .76 to .86) and acceptable test-retest reliability ( $r = 0.74$ ) (Kanter et al., 2007).

**Brief Illness Perception Questionnaire (Brief IPQ)** (Broadbent, Petrie, Main, & Weinman, 2006): The Brief IPQ is a 9-item self-report questionnaire used to measure cognitive and emotional representations of illness (see Appendix D). The Brief IPQ is based on the Illness Perception Questionnaire-Revised (IPQ-R), which is an 80-item self-report questionnaire (Moss-Morris et al., 2002). The Brief IPQ was developed by creating one question that summarized each subscale of the IPQ-R and adding an open-ended question to determine causal representations (Broadbent et al., 2006). Tests of the psychometric properties of the Brief IPQ have demonstrated that it is a valid and reliable measure of illness perceptions among a diverse group of illnesses (Broadbent et al., 2006). A recent large review of 188 papers which have

used the Brief IPQ suggested that this measure is predictive of a variety of outcomes among a diverse range of illnesses (Broadbent et al., 2015).

## **Procedure**

This study occurred in the Vidant Medical Center Cardiovascular Pulmonary Rehabilitation center. Potential participants were approached by a trained member of the nursing staff as early as possible during their standard CR program. While patients were ideally approached during their first session when they were filling out other paperwork, time constraints with the normal clinic flow did not allow this to always occur; results indicated that participants were approached on average 10 days after program enrollment. When approached by one of the CVPR nurses, patients were informed about the current study and asked if they would be interested in participating. If interested, participants read and signed the informed consent document and then were given three measures to fill out, including the BDI-II, BADS, and Brief IPQ. Additionally, participants filled out a demographics form, including their age, town in which they live, and time that it requires them to reach the CR center. Upon completion of filling out the forms, participants were provided with a small \$5 gift card as compensation for participation. The paper questionnaires did not have identifying information on them, but were stored with the patient's informed consent form in order to match participant questionnaire data with their CR data. These folders were stored in a locked file cabinet in the CVPR center to protect confidentiality, and informed consent forms were removed after collected data were associated with CR data.

After filling out baseline forms, participants were tracked as they progressed through the CR program as part of standard care. Once a participant was no longer attending the program, the patient's record was reviewed and entered into the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) reporting site by CR staff or researchers (including the

PI) as part of standard practice. The AACVPR reporting site includes some demographic and identifying information and outcomes throughout the CR program. Additionally, these data include the number of sessions a patient completed, number of sessions prescribed, and whether they were considered to have completed the CR program. A patient was considered to have completed the program if deemed to have met treatment goals by a member of the CVPR staff. After termination of CR, several pieces of data were utilized from the AACVPR reporting site database. The number of sessions attended by each participant and whether they are considered to have completed the program by CR staff was recorded, along with distance walked during the six-minute walk test. Additionally, covariates which were used for analyses can also be found in this dataset. Data from the three questionnaires were then matched to the participants' CR outcome data. After matching participants' CR data to their psychosocial questionnaire responses, any unnecessary identifying information, such as names, zip codes, and dates of birth, were deleted to protect confidentiality.

## **Analysis**

All data analysis was conducted using IBM SPSS Statistics 24 and  $\alpha$  was set at 0.05 for all analyses. For the initial aim of determining the interrelationship between the predictor variables, a correlation table was utilized and Pearson correlation coefficients were examined. For the second aim, which involved examining the effect of depressive symptom clusters on CR participation, two regressions were used. First, a linear regression with cognitive, affective, and somatic clusters as predictor variables in the same model was conducted to determine if depressive symptom clusters predict number of CR sessions attended. Then, a binary logistic regression was utilized with the same three predictor variables in one model to examine if the depressive symptom clusters predict CR program completion. For the third aim, regression analyses were also conducted to examine the effect of the three depressive symptom clusters, negative illness cognitions, and depressive behaviors on CR participation. First, three linear

regressions were conducted with the BDI-II subscales, Brief IPQ, and BADS subscales in separate models to determine if they predict number of CR sessions attended. Then, three binary logistic regressions were conducted with the same predictor variables to examine if they predict completion of the CR program. Demographic characteristics such as age, gender, education level, and race were analyzed as potential covariates in adjusted analyses. Additionally, AACVPR risk stratification was examined as a potential covariate to adjust for possible influences of disease severity or the type of diagnosis. These covariates can all be found in the data which were downloaded from the AACVPR reporting site. All analyses were completed with crude and adjusted models; crude models were unadjusted, while adjusted models included significant covariates.

## **CHAPTER IV: RESULTS**

### **Demographics of the Sample**

The sample for this study consisted of 56 participants. Overall, the sample contained 23 women (41.1%) and 33 men (58.9%), with an age range of 32-84 years old ( $M=60.00$ ,  $SD=12.00$ ). The sample was predominantly Caucasian (57.1%;  $n=32$ ), with 20 (35.7%) African-American participants (4 participants did not report race). Education level was dichotomized into those who had less than a college degree and those with a college degree or above. Twenty-two participants (39.2%) reported an educational level below that of a college graduate, while 13 participants (23.2%) endorsed being a college graduate or having post-graduate education; twenty-one participants (37.5%) did not report an education level, however. Half of the sample was classified as high risk by the CVPR staff ( $n=28$ ). Overall, 43 participants (76.8%) completed the CR program and 13 participants (23.2%) did not complete. Demographic information is presented in Table 1, which contrasts demographic information between individuals who completed and did not complete the CR program.

Table 1: Demographics of Completers and Non-Completers and of the Overall Sample.

| Demographics              | Completers (N=43) | Non-Completers (N=13) | Total Sample (N=56) |
|---------------------------|-------------------|-----------------------|---------------------|
| Gender                    |                   |                       |                     |
| Male                      | 27 (62.8%)        | 6 (46.2%)             | 33 (58.9%)          |
| Female                    | 16 (37.2%)        | 7 (53.8%)             | 23 (41.1%)          |
| Race                      |                   |                       |                     |
| Caucasian                 | 25 (58.1%)        | 7 (53.8%)             | 32 (57.1%)          |
| African-American          | 15 (34.9%)        | 5 (38.5%)             | 20 (35.7%)          |
| Age                       |                   |                       |                     |
| Mean Age                  | 63.36 ± 10.36     | 50.08 ± 11.62         | 60.00 ± 12.00       |
| Education Level           |                   |                       |                     |
| Below College Graduate    | 13 (30.2%)        | 9 (69.2%)             | 22 (39.2%)          |
| College Graduate or Above | 12 (27.9%)        | 1 (7.7%)              | 13 (22.8%)          |
| AACVPR Risk Category      |                   |                       |                     |
| Low Risk                  | 10 (23.3%)        | 2 (15.4%)             | 12 (21.1%)          |
| Intermediate Risk         | 5 (11.6%)         | 1 (7.7%)              | 6 (10.5%)           |
| High Risk                 | 20 (46.5%)        | 8 (61.5%)             | 28 (49.1%)          |

First, analyses were conducted to determine which demographics were significantly related to the outcomes of number of sessions attended, program completion status, and increase in walk distance from intake to discharge. A correlation table was created for continuous demographics (age) and t-tests were utilized to examine the association between categorical demographics (gender, race, education level, and risk category) and the continuous outcomes of number of sessions attended and increase in walk distance. For the dichotomous outcome of program completion, t-tests were used for continuous demographics (age) and Chi-

square analyses were utilized for categorical demographics (gender, race, education level, and risk category). The results of these analyses are presented in Table 2 below. Briefly, older age ( $r=.429$ ,  $p=.001$ ) and higher level of education ( $t=-2.509$ ,  $p=.017$ ) were significantly correlated with number of sessions attended, and older age ( $t=-3.925$ ,  $p< .001$ ) and higher level of education ( $\chi^2=4.42$ ,  $p= .036$ ) were also significantly associated with completion status. There were no demographics which were significantly associated with increases in walk distance, so no subsequent adjusted model was analyzed for this outcome.

Table 2: Association between Demographics and Outcomes

| Demographics         | Association with #sessions attended | Association with Completion status | Association with Increase in walk distance |
|----------------------|-------------------------------------|------------------------------------|--|
| Gender               | $t=1.858$                           | $\chi^2=1.142$                     | $t=.933$                                   |
| Race                 | $t=.575$                            | $\chi^2=0.068$                     | $t=-.239$                                  |
| Education Level      | $t=-2.509^*$                        | $\chi^2=4.418^*$                   | $t=-.711$                                  |
| AACVPR Risk Category | $F=2.069$                           | $\chi^2=0.853$                     | $F=1.904$                                  |
| Age                  | $r=.429^{**}$                       | $t=-3.925^{**}$                    | $r=-.149$                                  |

\*Significant at the  $p<.05$  level \*\*Significant at the  $p<.01$  level

### Hypothesis #1: Interrelationship of the Predictors

To determine the interrelationship between the predictor variables in the study, a correlation table was created and Pearson correlation coefficients were examined. The correlation table for the main predictor variables (BDI-II subscales, Brief IPQ, and BADS subscales) is shown below.

Figure 1: Correlations for Interrelationship of Predictors

|                                      |                     | Correlations  |               |             |                 |                          |                                    |                                      |                                 |
|--------------------------------------|---------------------|---------------|---------------|-------------|-----------------|--------------------------|------------------------------------|--------------------------------------|---------------------------------|
|                                      |                     | BDI Cognitive | BDI Affective | BDI Somatic | IPQ Total Score | BADS Activation Subscale | BADS Avoidance/Rumination Subscale | BADS Work/School Impairment Subscale | BADS Social Impairment Subscale |
| BDI Cognitive                        | Pearson Correlation | 1             | .617**        | .440**      | .457**          | -.187                    | -.591**                            | -.584**                              | -.765**                         |
|                                      | Sig. (2-tailed)     |               | .000          | .001        | .000            | .175                     | .000                               | .000                                 | .000                            |
|                                      | N                   | 57            | 56            | 56          | 56              | 54                       | 54                                 | 53                                   | 54                              |
| BDI Affective                        | Pearson Correlation | .617**        | 1             | .545**      | .423**          | -.162                    | -.600**                            | -.473**                              | -.557**                         |
|                                      | Sig. (2-tailed)     | .000          |               | .000        | .001            | .247                     | .000                               | .000                                 | .000                            |
|                                      | N                   | 56            | 56            | 56          | 55              | 53                       | 53                                 | 52                                   | 53                              |
| BDI Somatic                          | Pearson Correlation | .440**        | .545**        | 1           | .550**          | -.123                    | -.635**                            | -.571**                              | -.503**                         |
|                                      | Sig. (2-tailed)     | .001          | .000          |             | .000            | .381                     | .000                               | .000                                 | .000                            |
|                                      | N                   | 56            | 56            | 56          | 55              | 53                       | 53                                 | 52                                   | 53                              |
| IPQ Total Score                      | Pearson Correlation | .457**        | .423**        | .550**      | 1               | -.126                    | -.643**                            | -.527**                              | -.377**                         |
|                                      | Sig. (2-tailed)     | .000          | .001          | .000        |                 | .365                     | .000                               | .000                                 | .005                            |
|                                      | N                   | 56            | 55            | 55          | 56              | 54                       | 54                                 | 53                                   | 54                              |
| BADS Activation Subscale             | Pearson Correlation | -.187         | -.162         | -.123       | -.126           | 1                        | .010                               | .118                                 | .156                            |
|                                      | Sig. (2-tailed)     | .175          | .247          | .381        | .365            |                          | .941                               | .406                                 | .260                            |
|                                      | N                   | 54            | 53            | 53          | 54              | 54                       | 53                                 | 52                                   | 54                              |
| BADS Avoidance/Rumination Subscale   | Pearson Correlation | -.591**       | -.600**       | -.635**     | -.643**         | .010                     | 1                                  | .583**                               | .522**                          |
|                                      | Sig. (2-tailed)     | .000          | .000          | .000        | .000            | .941                     |                                    | .000                                 | .000                            |
|                                      | N                   | 54            | 53            | 53          | 54              | 53                       | 54                                 | 52                                   | 53                              |
| BADS Work/School Impairment Subscale | Pearson Correlation | -.584**       | -.473**       | -.571**     | -.527**         | .118                     | .583**                             | 1                                    | .639**                          |
|                                      | Sig. (2-tailed)     | .000          | .000          | .000        | .000            | .406                     | .000                               |                                      | .000                            |
|                                      | N                   | 53            | 52            | 52          | 53              | 52                       | 52                                 | 53                                   | 52                              |
| BADS Social Impairment Subscale      | Pearson Correlation | -.765**       | -.557**       | -.503**     | -.377**         | .156                     | .522**                             | .639**                               | 1                               |
|                                      | Sig. (2-tailed)     | .000          | .000          | .000        | .005            | .260                     | .000                               | .000                                 |                                 |
|                                      | N                   | 54            | 53            | 53          | 54              | 54                       | 53                                 | 52                                   | 54                              |

\*\*. Correlation is significant at the 0.01 level (2-tailed).

Many of the predictor variables were significantly correlated with other predictors in the sample. The BDI-II subscales were significantly correlated to one another, the Brief IPQ total score, and all BADS subscales except for the Activation subscale. The Brief IPQ total score was also significantly correlated with all BADS subscales except for the Activation subscale.

### Hypothesis #2a: BDI-II Subscales and Number of Sessions Attended

For the second hypothesis, a linear regression was utilized to examine the effect of the BDI-II depressive symptom clusters on number of CR sessions attended, controlling for known covariates. First, a crude linear regression was utilized with only the BDI-II subscales in the same model. The results can be seen in Table 3. Briefly, none of the BDI-II subscales were statistically significant predictors of number of CR sessions attended. Then, an adjusted model was created utilizing the significant demographics (see Table 2). The BDI-II subscales and age

and education level were included in the same linear regression model, and the results are shown in Table 3. Even in the adjusted model, the BDI-II subscales were not predictive of more sessions attended. Participant age, on the other hand, was significantly associated with number of sessions attended ( $t=2.277$ ,  $p=.031$ ), with older participants being more likely to engage in more sessions. Additionally, there was a trend towards significance with education level ( $t=1.884$ ,  $p=.070$ ), suggesting participants with a college degree or higher were somewhat more likely to attend a greater number of CR sessions.

Table 3: Linear Regression Results for #Sessions Attended

| Predictors                                       | Unstandardized Beta Weight (B) | Test Statistic ( $t$ ) | Significance |
|--|--------------------------------|------------------------|--------------|
| BDI-II Subscales<br>Alone                        |                                |                        |              |
| BDI-II Cognitive                                 | -0.14                          | -0.160                 | $p=.874$     |
| BDI-II Affective                                 | 0.21                           | 0.216                  | $p=.830$     |
| BDI-II Somatic                                   | -0.31                          | -0.752                 | $p=.455$     |
| BDI-II Subscales +<br>Age and Education<br>Level |                                |                        |              |
| BDI-II Cognitive                                 | 0.25                           | 0.191                  | $p=.850$     |
| BDI-Affective                                    | -0.63                          | -0.440                 | $p=.664$     |
| BDI-II Somatic                                   | -0.07                          | -0.134                 | $p=.894$     |
| Age  | 0.26                           | 2.277                  | $p=.031^*$   |
| Education Level                                  | 5.67                           | 1.884                  | $p=.070$     |

\*Significant at the  $p<.05$  level

### **Hypothesis #2b: BDI-II Subscales and Completion Status**

To examine the relation between BDI-II subscales and participant completion status for the CR program, a binary logistic regression was utilized. First, a crude binary logistic regression was utilized with only the BDI-II subscales in the same model. The results can be seen in Table 4. As with number of sessions completed, none of the BDI-II subscales alone were statistically significant predictors of completion status. Then, an adjusted model was created utilizing the significant demographics (see Table 2). The BDI-II subscales and age and education level were included in the same binary logistic regression model, and the results are shown in Table 4. As with the unadjusted model, the BDI-II subscale scores were not significant predictors of completion in the adjusted model either. While the subscale scores were not predictive of completion, age was a significant predictor for completion status ( $\text{Wald } \chi^2=4.199$ ,  $p=.040$ ), even with education level and BDI-II subscale scores in the same model. These results suggest that participants who completed CR were significantly older than those who did not complete CR.

Table 4: Binary Logistic Regression Results for Completion Status

| Predictors                                 | Unstandardized Beta Weights (B) | Test Statistic (Wald $\chi^2$ ) | Significance |
|--|---------------------------------|---------------------------------|--------------|
| BDI-II Subscales Alone                     |                                 |                                 |              |
| BDI-II Cognitive                           | -0.06                           | 0.046                           | p=.830       |
| BDI-II Affective                           | 0.13                            | 0.187                           | p=.666       |
| BDI-II Somatic                             | -0.14                           | 1.356                           | p=.244       |
| BDI-II Subscales + Age and Education Level |                                 |                                 |              |
| BDI-II Cognitive                           | -0.23                           | 0.306                           | p=.580       |
| BDI-Affective                              | 0.41                            | 0.613                           | p=.434       |
| BDI-II Somatic                             | -0.16                           | 0.543                           | p=.461       |
| Age  | 0.10                            | 4.199                           | p=.040*      |
| Education Level                            | 2.08                            | 2.240                           | p=.134       |

\*Significant at the p<.05 level

### Hypothesis #3a: All Predictors and Number of Sessions Attended

For the third hypothesis, linear regressions were utilized to examine the effect of the BDI-II depressive symptom clusters, Brief IPQ total score, and BADS subscales on number of CR sessions attended. First, crude linear regressions were utilized with only the predictors, and the results can be seen in Table 5. Briefly, none of the predictors were significant predictors of number of CR sessions attended. Then, the same adjusted model from the linear regression for hypothesis #2 was utilized using the significant demographics (see Table 2). The predictors were analyzed with age and education level included, and the results are shown in Table 5. Once again, none of the psychosocial predictors were significant predictors in the adjusted model. As with previous analyses, participant age and education level were significant

predictors in nearly all models, except education level became non-significant in the model controlling for BDI-II subscale scores. Even after controlling for Brief IPQ total score and BADS subscales, older participants and those with a college degree or higher were more likely to attend more sessions than younger and less educated participants.

Table 5: Linear Regression Results for #Sessions Attended

| Predictors                                 | Unstandardized Beta Weight (B) | Test Statistic ( <i>t</i> ) | Significance |
|--|--------------------------------|-----------------------------|--------------|
| BDI-II Subscales Alone                     |                                |                             |              |
| BDI-II Cognitive                           | -0.14                          | -0.160                      | p=.874       |
| BDI-II Affective                           | 0.21                           | 0.216                       | p=.830       |
| BDI-II Somatic                             | -0.31                          | -0.752                      | p=.455       |
| BDI-II Subscales + Age and Education Level |                                |                             |              |
| BDI-II Cognitive                           | 0.25                           | 0.191                       | p=.850       |
| BDI-Affective                              | -0.63                          | -0.440                      | p=.664       |
| BDI-II Somatic                             | -0.07                          | -0.134                      | p=.894       |
| Age  | 0.26                           | 2.277                       | p=.031*      |
| Education Level                            | 5.67                           | 1.884                       | p=.070       |
| Brief IPQ Total Alone                      |                                |                             |              |
| Brief IPQ Total                            | -0.02                          | -0.219                      | p=.827       |
| Brief IPQ Total + Age and Education Level  |                                |                             |              |
| Brief IPQ Total                            | 0.09                           | 0.744                       | p=.462       |
| Age  | 0.28                           | 2.748                       | p=.010*      |
| Education Level                            | 6.91                           | 2.405                       | p=.023*      |
| BADS Subscales Alone                       |                                |                             |              |

|   |       |        |         |
|---|-------|--------|---------|
| BADS Activation                             | 0.01  | 0.072  | p=.943  |
| BADS<br>Avoidance/Rumination                | 0.11  | 0.833  | p=.409  |
| BADS Work/School                            | 0.06  | 0.198  | p=.844  |
| BADS Social                                 | -0.13 | -0.492 | p=.625  |
| BADS Subscales + Age<br>and Education Level |       |        |         |
| BADS Activation                             | -0.01 | -0.075 | p=.941  |
| BADS<br>Avoidance/Rumination                | -0.15 | -0.688 | p=.498  |
| BADS Work/School                            | 0.08  | 0.235  | p=.816  |
| BADS Social                                 | 0.06  | 0.134  | p=.894  |
| Age   | 0.28  | 2.455  | p=.021* |
| Education Level                             | 8.70  | 2.321  | p=.029* |

\*Significant at the p<.05 level

### Hypothesis #3b: All Predictors and Completion Status

To examine the association between BDI-II subscales, Brief IPQ total score, and BADS subscales and participant completion status for the CR program, binary logistic regressions were utilized. First, crude binary logistic regressions were used with only the psychosocial predictors. The results can be seen in Table 6. As with previous analyses, none of the predictors were significantly associated with CR completion status. Then, adjusted models were created utilizing the significant demographics (see Table 2). The predictors and age and education level were included in binary logistic regression analyses, and the results are shown in Table 6. As with the previous analyses, psychosocial predictors were non-significant but participant age was a significant predictor of CR completion status when controlling for all psychosocial predictors; older participants were once again more likely to complete CR than

younger participants in this sample. Education level was marginally associated with completion status when controlling for the Brief IPQ total score, but was not significant after controlling for BDI-II subscale or BADS subscale scores.

Table 6: Binary Logistic Regression Results for Completion Status

| Predictors                                 | Unstandardized Beta Weights (B) | Test Statistic (Wald $\chi^2$ ) | Significance |
|--|---------------------------------|---------------------------------|--------------|
| BDI-II Subscales Alone                     |                                 |                                 |              |
| BDI-II Cognitive                           | -0.06                           | 0.046                           | p=.830       |
| BDI-II Affective                           | 0.13                            | 0.187                           | p=.666       |
| BDI-II Somatic                             | -0.14                           | 1.356                           | p=.244       |
| BDI-II Subscales + Age and Education Level |                                 |                                 |              |
| BDI-II Cognitive                           | -0.23                           | 0.306                           | p=.580       |
| BDI-Affective                              | 0.41                            | 0.613                           | p=.434       |
| BDI-II Somatic                             | -0.16                           | 0.543                           | p=.461       |
| Age  | 0.10                            | 4.199                           | p=.040*      |
| Education Level                            | 2.08                            | 2.240                           | p=.134       |
| Brief IPQ Total Alone                      |                                 |                                 |              |
| Brief IPQ Total                            | -0.02                           | 0.292                           | p=.985       |
| Brief IPQ Total + Age and Education Level  |                                 |                                 |              |
| Brief IPQ Total                            | 0.02                            | 0.100                           | p=.752       |
| Age  | 0.11                            | 5.680                           | p=.017*      |
| Education Level                            | 2.31                            | 3.058                           | p=.080       |
| BADS Subscales Alone                       |                                 |                                 |              |
| BADS Activation                            | -0.02                           | 0.157                           | p=.692       |
| BADS                                       | 0.04                            | 1.159                           | p=.282       |

|  |       |       |         |
|--|-------|-------|---------|
| Avoidance/Rumination                     |       |       |         |
| BADS Work/School                         | 0.08  | 0.859 | p=.354  |
| BADS Social                              | -0.10 | 1.269 | p=.260  |
| BADS Subscales + Age and Education Level |       |       |         |
| BADS Activation                          | -0.04 | 0.355 | p=.551  |
| BADS Avoidance/Rumination                | 0.02  | 0.058 | p=.809  |
| BADS Work/School                         | 0.01  | 0.011 | p=.917  |
| BADS Social                              | -0.04 | 0.045 | p=.833  |
| Age                                      | 0.10  | 3.899 | p=.048* |
| Education Level                          | 1.91  | 1.602 | p=.206  |

\*Significant at the p<.05 level

### Post-Hoc Exploratory Analyses

Following the main analyses, post-hoc analyses were conducted to explore whether individual BDI-II or BADS subscales were significant predictors of CR attendance or completion status. These analyses were also non-significant, however, suggesting that none of the psychosocial predictors were significant predictors of CR participation even when analyzed in separate models.

## CHAPTER V: DISCUSSION

### Review of the Results

The current study sought to examine the role of depressive symptom clusters and related psychosocial variables on attendance and completion in a cardiac rehabilitation program. Overall, however, the hypotheses were not supported by the data. For the first hypothesis, the psychosocial predictor variables (BDI-II cognitive, affective, and somatic symptoms, Brief IPQ total score, and BADS subscales) were more correlated than hypothesized (see Figure 1). For example, the BDI-II cognitive subscale had a Pearson correlation coefficient of 0.457 with the Brief IPQ total score, indicating that there was significant overlap in these measures. Therefore, while the goal was to measure illness-specific cognitions as a separate construct from general depressive cognitions, that may not have been achieved in this study. It is not as surprising that the subscales of the BDI-II and BADS were significantly correlated, as the BADS was shown to have convergent validity with the BDI-II during its development (Kanter et al., 2007); however, it is difficult to draw distinct conclusions from each measure given that the data suggest they were more correlated than originally hypothesized.

For the main hypothesis of this study, none of the depressive symptom clusters were shown to be predictors of either number of sessions attended or completion status. It was hypothesized that somatic symptoms of depression may be stronger predictors of CR participation given that previous literature has suggested more adverse outcomes for CVD patients with increased somatic symptoms of depression compared to cognitive symptoms (de Miranda Azevedo et al., 2014). Additionally, the null results from this study do not corroborate the exploratory findings from Casey and colleagues (2008), which found that somatic symptoms of depression, but not cognitive-affective symptoms, predicted CR participation rates. As discussed previously, it is possible that utilizing a more standardized way of examining

depressive symptom clusters, rather than simply splitting the BDI measure, resulted in a better view of cognitive, affective, and somatic symptoms of depression and resulted in different findings. Additionally, this study utilized the BDI-II instead of the original BDI, which has been shown to have less somatic symptom inflation in post-MI patients (Delisle et al., 2012; Thombs et al., 2010); this could have also contributed to the discrepant findings from Casey and colleagues (2008).

For the exploratory hypothesis of including the Brief IPQ and BADS as predictors, the results did not support the idea that these measures would be better predictors of CR participation than depressive symptoms. Neither the crude nor adjusted analyses showed that any of the psychosocial predictors were associated with CR sessions attended or completion status. Once again, this result is surprising given that previous studies have shown that a construct like illness perception is often associated with CR attendance (French, Cooper, & Weinman, 2006). While there is not much previous literature on using measures of depressive behaviors as predictors of CR participation, it was hypothesized that individuals who were more behaviorally inactivated, as measured by the BADS, may be less likely to engage in a program like CR. However, the results did not seem to support this hypothesis. Given that CR has been shown to be effective at reducing depression (Milani & Lavie, 2007), it is possible that participants who were slightly depressed and behaviorally inactivated at the beginning of the program began to feel better from engaging in a program like CR, which reinforced them attending sessions.

While the psychosocial predictors were not associated with number of sessions attended or completion status, several demographic factors were significant predictors even while examining depressive symptoms, depressive behaviors, and negative illness cognitions in the same model. Primarily, participant age was a significant predictor of both number of sessions attended and completion status, with younger participants being less likely to participate in the

CR program than older individuals. This finding also appears to be contrary to previous results from the literature, which often suggest that older individuals have lower rates of participation in CR (Parashar et al., 2012; Sun et al., 2016). It is not entirely clear why younger participants would have been less likely to complete the CR program; however, given that this study included a wide range of participant ages, with participants as young as 32 years old, it is possible that younger patients still were employed and had to work, therefore being unable to attend as many sessions or complete the program. Additionally, previous studies have suggested that younger individuals with CVD, like heart failure, may encounter particular difficulties because of how age-discordant their disease seems (Tippey, 2014). Therefore, young individuals may be less inclined to participate in CR because of discomfort or stigma attached to having CVD at such a young age and primarily being surrounded by older patients at a CR center. It is also conceivable that younger patients attending fewer sessions of CR is not indicative of a lack of participation, but the possibility that younger CR patients are able to meet their prescribed CR goals in fewer sessions than older patients. Given that program completion may occur when the CR staff deems a patient has met their CR goals, it is therefore possible that younger individuals are more aerobically fit and require fewer sessions attended to complete the program. On the other hand, younger age was still significant associated with being less likely to complete CR, so this explanation obviously would not explain all of the results from this study. While a higher level of education was significantly associated with increased number of sessions attended, this association was not found in analyses including BDI-II subscale scores. Interestingly, gender and race were not significantly associated with either number of sessions completed or completion status; while some studies have suggested that these demographics are often predictors of CR non-participation (Parashar et al., 2012), the literature in this area is still mixed (Turk-Adawi et al., 2013).

## **Limitations of the Current Research**

As noted above, some of the results of this study appear to be contrasted to results typically found within the literature in this area. Therefore, it is possible that some of the limitations of the methodology of the current study may be affecting the results. In the final sample, nearly 77% of the participants in the study completed the CR program, which is a significantly higher completion rate than previous research has found (Sanderson et al., 2003). Therefore, it is possible that the sample was not representative of the population of CR patients. There are several possible explanations for why the sample in this study may not generalize to other studies. While the ultimate goal was to attempt to obtain baseline psychosocial measures on a patient's first session at CR, it became apparent that the patients were often too busy with normal clinic procedures during that first session to be informed about the study and fill out more questionnaires. Therefore, although the average time between CR initiation and filling out the questionnaires was 10 days, there were likely some CR patients who only showed up for the first session or two and stopped returning before they were approached to participate in this study. Given that previous research has suggested that most patients who drop out of a CR program will do so early, often in the first two weeks (Casey et al., 2008; Yohannes, Yalfani, Doherty, & Bundy, 2007), it is possible that the inability to obtain measures from patients during their first session lowers the generalizability of these findings. Similarly, some patients declined to participate when approached with information about the study; although data were not collected on the number of patients who declined to participate, it is possible that those who voluntarily participated in this study were less depressed or more amenable to the CR program, and therefore less likely to drop out.

In addition to the aforementioned limitations, there were several other potential limitations to the current study which should be considered when interpreting the results. First, the sample size in this study was smaller than many other studies of the CR population. While

the necessary sample size was obtained for adequate power, it is possible that some of the results which were approaching significance would have been observable with a larger sample. Additionally, the current study seemed to have underrepresented the prevalence of non-completers. As noted previously, another possible limitation is that the psychosocial measures were highly correlated; therefore, it is also possible that the unique constructs which we attempted to measure were not adequately measured. This study also utilized self-report measures of depression, depressive behaviors, and illness cognitions, which could have resulted in participants trying to respond favorably to appear as if they were coping with their illness well. Similarly, some of the items on the measures, particularly the Brief IPQ, may not have adequately measured negative cognitions within this population. For example, an illness cognition elicited by the Brief IPQ asks about perceived time the disease will continue; for some patients in this sample, their perceptions of their disease state lasting for the rest of their life may be accurate, not a negative illness cognition. Overall, the limitations to this study should be carefully considered when examining the results.

### **Strengths and Future Directions**

The current study exhibited several notable strengths. For example, the depressive symptom clusters were defined using evidence from the literature, rather than simply splitting up the BDI-II conceptually (Vanheule et al., 2008; Carney & Freedland, 2012). Similarly, based on the difficulty within the literature in defining CR participation, two different measures of participation (number of sessions attended and completion status) were utilized to try and obtain an accurate view of patient participation. Additionally, this is the only study we could find which examined depressive symptom clusters, depressive behaviors, and illness cognitions in the same study, to try and provide a complete view of the role of depression in CR attendance and completion. Finally, the sample which was recruited for this study was also highly diverse, with

patients of a wide age range and approximately 35% of the sample endorsing an African-American race.

There are numerous directions which future research in this area should explore. Given that these results contrast with some of the results in other areas of the literature, more research is needed to further understand the role depression plays in CR attendance and completion. Other methods of determining depression to supplement self-report measures, like structured interviews, may provide additional information about the role of depressive symptoms on CR participation. Future studies could also seek to replicate a study like this with a larger sample and a procedure which allows potential participants to be approached earlier in treatment, to try and examine a more representative population.

## **Final Conclusions**

Overall, the results from this study do not support the idea that specific depressive symptom clusters are associated with a lack of CR participation. None of the psychosocial predictors, including depressive symptom clusters, negative illness perceptions, or depressive behaviors were significantly related to number of CR sessions attended or completion status. In fact, the only consistently significant predictor of CR participation was participant age, with older individuals being more likely to complete CR and attend more sessions. These results should be interpreted cautiously, given that they appear to contrast with several different studies and that the current study had some considerable limitations. Taken altogether, however, it is still likely that psychosocial variables like depression are somehow associated with some of the difficulties noted with CR participation; more studies in this area are needed, however, in order to fully elucidate this association and be better able to design interventions to improve participation in CR programs.

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## APPENDIX A: IRB Approval Letter

 EAST CAROLINA UNIVERSITY  
University & Medical Center Institutional Review Board Office  
4N-70 Brody Medical Sciences Building · Mail Stop 682  
600 Moye Boulevard · Greenville, NC 27834  
Office 252-744-2914 · Fax 252-744-2284 · [www.ecu.edu/irb](http://www.ecu.edu/irb)

**Notification of Initial Approval: Expedited**

From: Social/Behavioral IRB  
To: [John Freeman](#)  
CC: [Matthew Whited](#)  
Date: 8/11/2015  
Re: [UMCIRB 15-000963](#)  
Symptoms of Depression and Related Variables on Cardiovascular Rehabilitation Participation

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s) is for the period of 8/11/2015 to 8/10/2016. The research study is eligible for review under expedited category # 5, 7. The Chairperson (or designee) deemed this study no more than minimal risk.

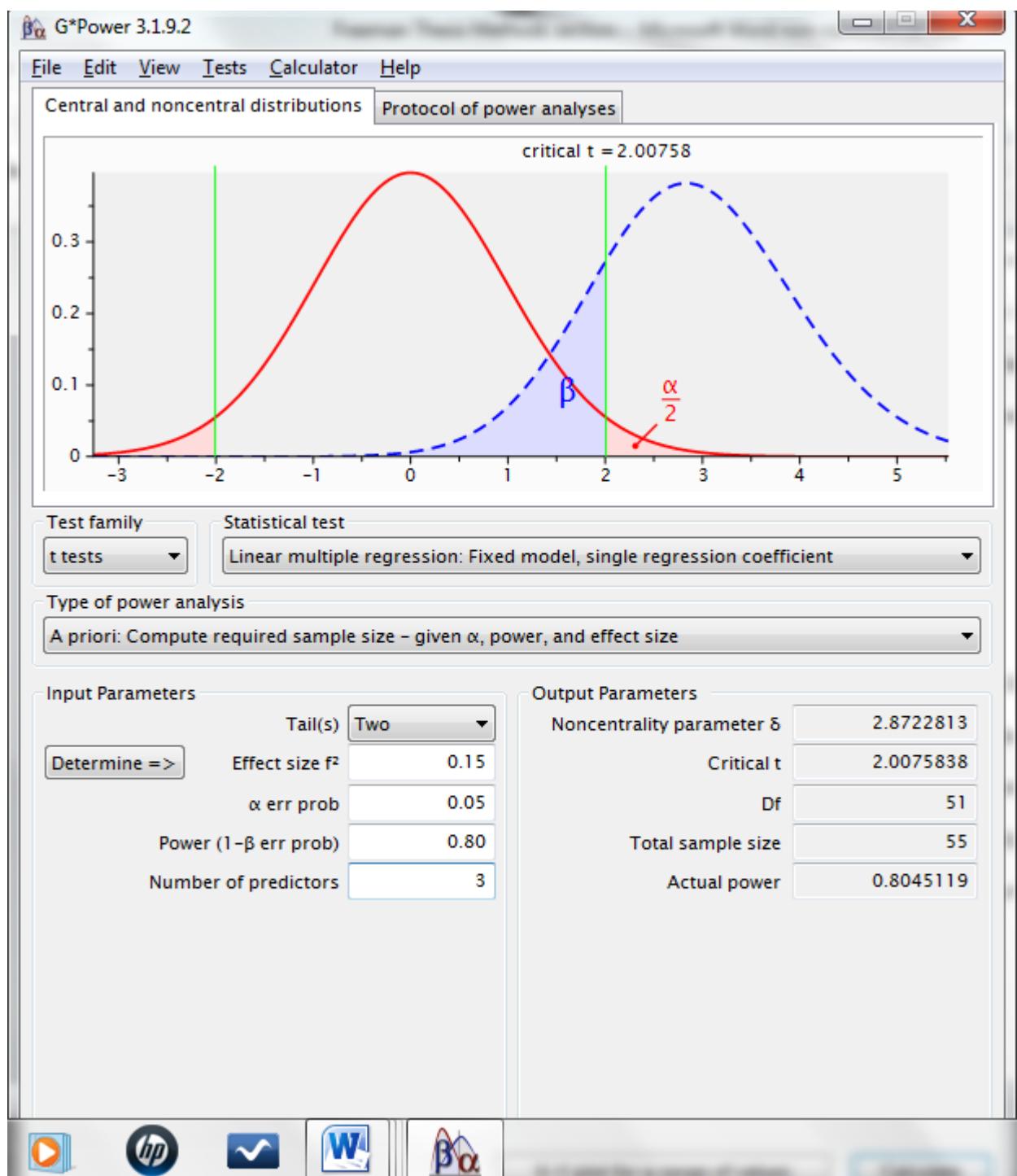
Changes to this approved research may not be initiated without UMCIRB review except when necessary to eliminate an apparent immediate hazard to the participant. All unanticipated problems involving risks to participants and others must be promptly reported to the UMCIRB. The investigator must submit a continuing review/closure application to the UMCIRB prior to the date of study expiration. The Investigator must adhere to all reporting requirements for this study.

Approved consent documents with the IRB approval date stamped on the document should be used to consent participants (consent documents with the IRB approval date stamp are found under the Documents tab in the study workspace).

The approval includes the following items:

| Name  | Description                         |
|---|-------------------------------------|
| BADS.doc                                    | Surveys and Questionnaires          |
| bdi.pdf                                     | Surveys and Questionnaires          |
| Brief Illness Perception Questionnaire.docx | Surveys and Questionnaires          |
| Freeman Thesis Demographics Form.docx       | Surveys and Questionnaires          |
| Freeman Thesis Informed Consent.doc         | Consent Forms                       |
| Freeman Thesis Proposal.docx                | Study Protocol or Grant Application |

## APPENDIX B: Power Analysis



APPENDIX C: Informed Consent Document

*East Carolina University*



## Informed Consent to Participate in Research

Information to consider before taking part in research that has no more than minimal risk.

Title of Research Study: The Influence of Cognitive, Affective, and Somatic Symptoms of Depression and Related Psychosocial Variables on Cardiovascular Rehabilitation Participation

Principal Investigator: John Taylor Freeman (Person in Charge of this Study)

Faculty Supervisor: Matthew C. Whited, Ph.D., Associate Professor of Psychology at East Carolina University

Institution, Department or Division: East Carolina University Psychology Department

Address: 237 RAWL Building, East Carolina University, Greenville, NC 27858

Telephone #: 252-328-1069

Participant Full Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_  
**Please PRINT clearly**

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Researchers at East Carolina University (ECU) **and** Vidant Medical Center Cardiovascular Pulmonary Rehabilitation (CVPR) study issues related to society, health problems, environmental problems, behavior problems and the human condition. To do this, we need the help of volunteers who are willing to take part in research.

### **Why am I being invited to take part in this research?**

The purpose of this research is to examine some psychological factors which may be associated with why people decide to stop participating in a cardiac rehabilitation program. You are being invited to take part in this research because you are eligible to participate in cardiac rehabilitation. The decision to take part in this research is yours to make. By doing this research, we hope to learn why people may decide to stop participating in cardiac rehabilitation programs and possibly design ways to increase attendance rates in cardiac rehabilitation in the future.

If you volunteer to take part in this research, you will be one of about 55 people to do so.

### **Are there reasons I should not take part in this research?**

You should not volunteer for this research if you are participating in the Vidant CVPR program for a pulmonary diagnosis, instead of a cardiac diagnosis. Additionally, if you cannot speak English, you should not take part in this research.

### **What other choices do I have if I do not take part in this research?**

You can freely choose not to participate, and it will not affect your cardiac rehabilitation program at all. If you choose not to participate, you will receive the same cardiac rehabilitation program as anyone else in the program.

### **Where is the research going to take place and how long will it last?**

The research will be conducted at the Vidant Cardiovascular and Pulmonary Rehabilitation (CVPR) center. You will need to come to the Vidant CVPR center one time for the purposes of this study. The total amount of time you will be asked to volunteer for this study is approximately 20-30 minutes during the first day of your regularly prescribed CVPR program.

### **What will I be asked to do?**

You will be asked to do the following: during your first session of CVPR, you will be given three questionnaires to read and fill out. The first questionnaire is the Beck Depression Inventory-II, which is a 21-item survey that measures common depressive symptoms any person may be experiencing. The second questionnaire is the Behavioral Activation for Depression Scale, which is a 25-item survey that measures behaviors a person may engage in which are often associated with depression. The third questionnaire is the Brief Illness Perception Questionnaire, which is a 9-item survey that assesses a person's thoughts and attitudes about their illness. You will be asked to fill out all three surveys during your first session of CVPR, and that will be the only thing you will be asked to do. After you have filled out the questionnaires, you will participate in cardiac rehabilitation as normal. When you are finished with cardiac rehabilitation, we (the researchers) will examine your chart and match up your questionnaire answers with data collected during your cardiac rehabilitation program.

### **What might I experience if I take part in the research?**

We don't know of any risks (the chance of harm) associated with this research. Any risks that may occur with this research are no more than what you would experience in everyday life. We don't know if you will benefit from taking part in this study. There may not be any personal benefit to you but the information gained by doing this research may help others in the future.

### **Will I be paid for taking part in this research?**

You will be provided with a \$5 gift card for participating in this research.

### **Will it cost me to take part in this research?**

It will not cost you any money to be part of the research.

### **Who will know that I took part in this research and learn personal information about me?**

ECU and the people and organizations listed below may know that you took part in this research and may see information about you that is normally kept private. With your permission, these people may use your private information to do this research:

- Any agency of the federal, state, or local government that regulates human research. This includes the Department of Health and Human Services (DHHS), the North Carolina Department of Health, and the Office for Human Research Protections.
- The University & Medical Center Institutional Review Board (UMCIRB) and its staff have responsibility for overseeing your welfare during this research and may need to see research records that identify you.
- People designated by Vidant Medical Center and Vidant Health
- If you are a patient at ECU or Vidant, a copy of the first page of this form will be placed in your medical records.
- Members of the research team

We will share only the PHI listed above with the individuals/agencies listed above. If we need to share other PHI or if we need to send PHI to other individuals/agencies not listed above, we will ask for your permission in writing again.

### **What type of Protected Health Information (PHI) will be collected?**

When taking part in research, protected health information (PHI) is collected, used, and shared with others who are involved in the research. Federal laws require that researchers and health care providers protect your PHI. Also, federal laws require that we get your permission to use collected PHI for the research. This permission is called authorization.

In order to complete the research project in which you have decided to take part, the research team needs to collect and use some of your PHI as described below.

- Medical/clinic records from Vidant Cardiovascular and Pulmonary Rehabilitation (CVPR)
- Records generated during this study

### **How my PHI may be released to others:**

ECU and Vidant Medical Center (VMC) are required under law to protect your PHI. However, those individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it and may share your PHI with others without your permission, if permitted by the laws governing them.

### **What if I do not sign this form?**

You will not be eligible to participate in this study if you do not sign this Authorization form.

### **How may I revoke (take back) my authorization?**

You have the right to stop sharing your PHI. To revoke (or take back) your authorization, you must give the Principal Investigator your request to revoke (or take back) your authorization in writing. If you request that we stop collecting your PHI for the study, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or affect payment, health plan enrollment or benefit eligibility. PHI collected for the research study prior to revoking (or taking back) your Authorization will continue to be used for the purposes of the research study.

### **Restrictions on access to my PHI:**

You will not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

### **How long may the PHI about me be used or disclosed for this study?**

Research information continues to be looked at after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

If you have questions about the sharing of PHI related to this research study, call the principal investigator John Taylor Freeman at phone number 252-328-1069. Also, you may telephone the University and Medical Center Institutional Review Board at 252-744-2914. In addition, if you have concerns about confidentiality and privacy rights, you may phone the Privacy Officer at Vidant Medical Center at 252-847-3310 or the Privacy Officer at East Carolina University at 252-744-5200.

## **How will you keep the information you collect about me secure? How long will you keep it?**

The paper surveys you fill out will be stored in a locked file cabinet in a locked room at the Vidant CVPR site to protect confidentiality. These paper forms will include some of your PHI, including your hometown and age, but all forms will be stored securely in a locked file cabinet in a locked room at Vidant CVPR. When we access your cardiac rehabilitation data, we will use the secure American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) reporting site used by CVPR staff to protect confidentiality. This electronic data will be stored on the secure ECU Psychology department Pirate Drive, which is a password protected file only accessible by authorized individuals. Additionally, when the data is reviewed, unnecessary identifiers, such as your name, date of birth, zip code, and medical record ID, will be deleted. Your age will remain in the electronic data, which is considered PHI if you are older than 89 years old. Therefore, the electronic data may contain some of your PHI, but it will be stored securely on the ECU Psychology department Pirate Drive. The data we collect may be used for presentations and educational opportunities, but all data will be presented based on all participants' scores, and your data will still be anonymous.

## **What if I decide I don't want to continue in this research?**

You can stop at any time after it has already started. There will be no consequences if you stop and you will not be criticized. You will not lose any benefits that you normally receive.

## **Who should I contact if I have questions?**

The people conducting this study will be able to answer any questions concerning this research, now or in the future. You may contact the Principal Investigator at 252-328-1069 (Monday to Friday, 9:00AM to 5:00PM).

If you have questions about your rights as someone taking part in research, you may call the Office of Research Integrity & Compliance (ORIC) at phone number 252-328-9473 (Monday to Friday, 8:00 am-5:00 pm). If you would like to report a complaint or concern about this research study, you may call the Director of the ORIC, at 252-744-1971 and the Vidant Medical Center Risk Management Office at 252-847-5246

## **I have decided I want to take part in this research. What should I do now?**

The person obtaining informed consent will ask you to read the following and if you agree, you should sign this form:

- I have read (or had read to me) all of the above information.
- I have had an opportunity to ask questions about things in this research I did not understand and have received satisfactory answers.
- I know that I can stop taking part in this study at any time.
- By signing this informed consent form, I am not giving up any of my rights.
- I have been given a copy of this consent document, and it is mine to keep.

---

**Participant's Name (PRINT)**

**Signature**

**Date**

**Person Obtaining Informed Consent:** I have conducted the initial informed consent process. I have orally reviewed the contents of the consent document with the person who has signed above, and answered all of the person's questions about the research.

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**Person Obtaining Consent (PRINT)**

**Signature**

**Date**

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Principal Investigator (PRINT)  
(If other than person obtaining informed consent)

Signature

Date