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Cognition in Acute Decompensated Heart Failure (COGHF)

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Cognition in Acute Decompensated Heart Failure (COGHF)

A dissertation submitted in partial satisfaction of the

requirements for the degree Doctor of Philosophy

in Nursing

by

Kristin Woodward Dixon

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ABSTRACT OF THE DISSERTATION

Cognition in Acute Decompensated Heart Failure (COGHF)

by

Kristin Woodward Dixon

Doctor of Philosophy in Nursing

University of California, Los Angeles, 2019

Professor Lynn Doering, Chair

Objectives: Our objectives were to understand the patterns of cognitive and depressive change during and following a hospital admission for Acute Decompensated heart failure (ADHF) and to examine the relationship of clinical variables related to cognition over time and 30 day readmissions.

Methods: After hospital admission to a medical-surgical floor, within seven days following hospital, and after 30 days following hospital discharge, 40 patients admitted for ADHF (mean [SD] age = 73.8 [11.3] years; 72% male) completed the Montreal Cognitive Assessment (MoCA), Trail Making A & B, the Patient Health Questionnaire (PHQ)-9, and the Brief Symptom Inventory – Anxiety (BSI-A). The Medical Outcomes Study Social Support Survey (MOS-SSS) and the Self-Care Heart Failure Index (SCHFI) was completed in the hospital. Cognitive and depressive symptoms were evaluated using repeated-measures analysis of variance. Demographic and clinical variables associated with trends of cognitive and depressive symptoms were described with Kendall's Tau correlations. Linear regressions were performed to determine if change in fluid volume status measurements were related to change of MoCA scores, controlling for demographical and clinical variables. Separate linear regressions were

performed to determine if variables in the hospital were related to MoCA scores in the hospital, MoCA scores at 30 days post discharge, and the occurrence of 30 day readmissions.

Results: Neither global MoCA or TMT scores improved from hospital to 30 days post discharge. Improvement in the MoCA sub domain Visuospatial/ Executive function and depressive symptoms from hospital discharge to 30 days were observed. Four groups of MoCA change and three groups of depressive symptom change were found and associated with varied clinical and demographic variables. In multivariate analysis, only changes in weight (p=.001), HJR (p=.036), not clinical and demographical variables, were related to change of MoCA score. In multivariate analysis, only hospital variables CCI (p=.014) and anxiety (p=.005) were related to MoCA in the hospital; in a separate analysis only CCI (p=.05) remained related to MoCA post 30 days of discharge. In a fourth multivariate analysis, only CCI (p=.083) trended in association with 30 day readmission.

Conclusions: Executive function and depressive symptoms improve from hospitalization to 30 days after for ADHF. Higher anxiety symptoms and comorbidities are independently associated with worse cognition in the hospital. Findings suggest that when HF patients are in fluid overload, their cognition is worse. Clinicians should assess the patient's cognitive, anxiety and depressive state in the hospital prior to teaching the patient as learning abilities are likely compromised. Further research is needed to explore these relationships and ultimately, to test interventions that may help HF patients with CI avoid unnecessary admissions.

This dissertation of Kristin Woodward Dixon is approved.

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Dedication

No great accomplishment is completed alone. I would like to dedicate my dissertation to my husband, Joshua and my son, Luke. Thank you for your continued unconditional love and support. To my father and mother, thank you for inspiring me to become a nurse, teaching me how to be dedicated to my work and family, and supporting me in every step of this journey. To my brother and my sister-in-law, thank you for having faith in me throughout this journey and role modeling persistence. To my grandma, thank you for believing in me every step of the way. And to my gracious God, thank you for sustaining me on this amazing journey. Psalms 139 9-10: If I rise on the wings of the dawn, if I settle on the far side of the sea, even there your hand will guide me, your right hand will hold me.

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Chapter 1

Introduction

Introduction

Cognitive impairment (CI) is a common phenomenon in patients with heart failure (HF). Its prevalence and its importance to successful multidisciplinary and participatory management of HF have received growing recognition (Pressler, 2008). Pressler (2008) reports 25% to 50% of persons with HF likely live with some degree of CI. Moreover, CI has a major role in health outcomes for cardiac patients (Festa et al., 2011). In the literature, it has been reported that CI is implicated in higher mortality related to HF and is a major contributor to hospital readmissions (Cameron et al., 2010; Harkness, Demers, Heckman, & McKelvie, 2011). Yet, a gap in the literature exists regarding the causal relationship between HF and CI (Harkness et al., 2011).

To date few studies has shown the characteristics of CI in acute decompensated HF (ADHF) patients. Little evidence is available showing how CI changes from an acute decompensated event in the hospital to an improved cognitive recovery after discharge. Understanding the characteristics of CI in ADHF will guide the development of nursing interventions to prevent 30-day readmissions and thus will have a major impact on healthcare costs and mortality associated with this disease. The outcome of needed research in this area could shape future studies on interventions for ADHF patients with CI at time of discharge, and answer questions considering HF patients' non-adherence following a hospital admission.

Significance to Nursing Practice

Similar to other chronic diseases, individuals with HF are involved in managing their psychological and physiological care (Ditewig, Blok, Havers, & van Veenendaal, 2010). The medical management of HF is primarily pharmacologic; however, maximizing patient's quality of life by advocating self-sufficient living, social functioning, and psychosocial welfare is equally important (Hui et al., 2006). This involves preparing the individual to make complex decisions regarding his/her own daily care. The self-care behaviors demonstrated by HF patients are complex, individualized, and dynamic. Cognitive impairment diminishes the individual HF patient's capability to make complex daily self-care decisions and thus contributes to behaviors

such as poor adherence to health care regimens, which in turn result in frequent hospitalizations (Bauer, Johnson, & Pozehl, 2011). There are many factors in this population that could contribute to CI including sleep apnea, depression, dementia, and delirium (Cameron et al., 2010; Kumar et al., 2011; Stanek et al., 2009; Vogels et al., 2007). The characteristics of CI in HF in the outpatient setting have been measured as a decline of attention, concentration, memory loss, psychomotor speed, executive function, memory language, and visuospatial function (Riegel et al., 2002; Stanek et al., 2009). To date, researchers have not adequately examined the relationship of CI, in all of its complexities, to ADHF and to subsequent HF readmissions.

Recent research has illuminated multiple aspects of poor HF self-care after discharge. In turn, these reports have generated increased demands that nurses provide comprehensive HF education to the patients and families prior to discharge (Koelling, Johnson, Cody, & Aaronson, 2005). However, a patient's compliance to an evidence-based HF regimen is dependent on many factors. Particularly important is the individual patient's capability to retain knowledge in the presence of CI. The presence of CI and its characteristics in an individual patient will define interventions that address his specific abilities to comprehend and retain information they are given (Bauer et al., 2011). Knowledge regarding the mechanisms by which CI dimensions influence individual HF patients' ability to learn and participate successfully in self-care after hospital discharge is needed to design and test future nursing interventions aimed at helping HF patients with CI make successful transitions from hospital to home and to prevent repeated hospital readmissions.

Significance for Delivery of Care

Unnecessary readmissions are costly for both patients and hospitals. In 2009, the Medicare Payment Advisory Commission recommended that all hospital readmissions be reduced, and this recommendation become part of the Health Care Reform bill passed into law March 21, 2010. Since October 2012, hospitals have been fined for all-cause HF readmissions

above the national readmission average. In 2007, the cost of HF care surpassed $30 billion dollars, with individual readmissions found to cost over $23,000 (Wang, Zhang, Ayala, Wall, & Fang, 2010). Assuming cost savings of $20,000 per HF readmission, decreasing HF readmissions by ten percent would generate annual savings of more than $500,000. These statistics and changes in hospital reimbursements have created an accelerated response and attention to preventing HF readmissions at every institution across America (Chaudhry et al., 2011). Of note, Cameron et al. (2010) showed that patients with HF and CI have almost two times the risk of hospital admission. Thus, special attention to prevention of hospital readmission in this population is warranted.

The Institute of Medicine Future of Nursing of 2010 advocates that allowing nurses to practice to the full scope of their education and training is essential to the provision of high quality cost efficient health care (Institute of Medicine Committee on the Robert Wood Johnson Foundation Initiative on the Future of Nursing, 2011). Nurses, who are integral members of the health care team, must be involved in developing solutions aimed at reducing HF readmissions. Nurses contribute to the prevention of HF readmissions by providing integration of care and thorough follow-up (Koelling et al., 2005). Development of nursing interventions aimed at HF patients with CI is critical because these HF patients are at the highest risk for hospital readmission. To provide high quality, cost effective care that lowers the risk of hospital readmissions, nurses need tested interventions based on knowledge of the relationship between ADHF and CI.

Summary of Chapter 2: Literature Review

Cognition is defined as the ability to recognize, learn, and remember information, and then use it to reason or problem solve in new situations (Bauer et al., 2011). Pressler (2008) defined CI as the measurable decline within the domains of attention, concentration, memory loss, psychomotor speed, executive function, memory language, and visuospatial function. Mild

CI, defined by Cameron et al. (2010) to be “subtle cognitive deficits that do not meet the criteria for dementia” (p. 509), is less understood than advanced CI. HF patients with moderate and severe CI have more rehospitalizations and poorer clinical outcomes (Harkness et al., 2011; Pressler, 2008). The etiology of CI in HF is unclear. Low ejection fraction (EF) in HF predisposes a person to CI because of reduced blood flow however those with normal EF also suffer from CI. Furthermore it is known that structural brain changes are present in HF patients who have CI (Serber et al., 2008). Depression has also been shown to be an independent predictor for cognitive decline (Pullicino et al., 2008). Fluid retention, electrolyte disturbance, certain medications, anemia, and depression may be interacting to produce a transient cardiac encephalopathy (Pullicino et al., 2008).

One important relationship between CI and HF includes the presence of CI in different types and classes of HF. Cognitive impairment has been reported in all New York Heart Association (NYHA) classes (Athilingam et al., 2011; Harkness et al., 2011). Vogels, Oosterman, et al (2007) found the NYHA class and the duration of HF to be independent risk factors for CI. However, the length of disease is complicated because the majority of HF subjects have comorbid conditions that contribute to CI, which include hypoxic conditions like sleep-disordered breathing and ischemic events from low cardiac output (Kumar et al., 2011), electrolyte disturbances (Pullicino et al., 2008), poor cerebral perfusion or unstable/low blood pressure (Stanek et al., 2009; Vogels et al., 2007).

Mild CI in HF. Cameron et al. (2010) studied mild CI in HF patients through measurement with two tools. Cut-off scores indicating MCI for the Mini-Mental State Exam was 26/27 and for the Montreal Cognitive Assessment (MoCA) was less than 26. They reported elevated risk for CI in elderly males who were functionally compromised, had several co-existing co-morbidities, mostly lived alone, and had depression symptoms. Of these, 73% had unrecognized CI. Furthermore, people with HF and mild CI presented with significantly lower

self-care confidence and self-care management scores than cognitive intact patients (Cameron et al., 2010).

Association of HF with dementia. Heart failure doubles the risk of dementia among older adults (Festa et al., 2011). In those over the age of eighty with HF and dementia, cognition declined more in episodic memory (Hjelm et al., 2011). When testing for dementia using the Watson clock- drawing test, in those who had HF and CI, structural brain changes were found to be significantly correlated with abnormal Watson Clock drawing test scores (Serber et al., 2008).

Association of HF with depression. The majority of the patients with severe HF have CI, depression, or both; 70% percent have depression (Foster et al., 2011). Pullicino et al. (2008) found depression to be an independent predictor of cognitive decline and incident CI irrespective of HF status. Cameron et al. (2010) reported that changes in the cognitive domains of processing speed and executive functions were most common in HF patients with mild CI. These cognitive domains are also impaired in those who have depressive symptoms (Foster et al., 2011; Thomas & O'Brien, 2008). Depression has also been related to the onset of disability and lack of participation in activities within people with CI and HF (Chaudhry et al., 2011; Foster et al., 2011).

Poor outcomes. When an individual has HF, he or she is 1.51 times more likely to have CI than individuals without HF (Pullicino et al., 2008). In HF, CI is associated with relatively poorer health outcomes (Cameron et al., 2010). Foster et al. (2011) found associations between CI in HF with disability, and a fivefold increased risk of death. Cognitive impairment is an independent risk factor for noncompliance with medication use and medical appointments (Festa et al., 2011). Mild CI made the strongest contribution to predicting self-care management; Cameron et al. (2010) found that those with HF and CI are 30% more likely to have inadequate self-care confidence. Festa et al. (2011) found cognitive dysfunction to be an independent risk factor of self-care behaviors. Those with HF and CI are more frequently

admitted to the hospital; Harkness et al. (2011) reported 50% of those with abnormal scores on the MoCA had been hospitalized in the last 6 months compared to 17% of those who had a normal MoCA score. From the data thus far, it is likely that CI negatively affects the capacities of people with HF to assess their day to day status for warning signs, complete self-care behaviors, and follow their medical care plan at home (Bauer et al., 2011).

Summary of Chapter 3: Theoretical Framework

Care for the patient with HF from hospital to home is complex. The ADHF patients need a network of support to transition well. Just as the patient's needs are individualized, the patient's ability to be successful at home is also unique to the individual. The theoretical framework of this study aims to connect the complexities of care for HF patients as they transition home, with the concepts of what it takes to reduce the risk for 30 day readmission to the hospital. Transition theories like Naylor's Transitional Care Model (TCM) and Coleman's Care Transitions Intervention (CTI) describe transitions in general terms that then must be applied to each population and potential patient. The specific steps needed to successfully transition a HF patient who is recovering from an acute decompensated event should be studied with the multitude of patient risk factors. The theoretical framework purposed in this study strives to take into account these variables.

Helping ADHF patients to be successful at home following hospitalization is a dependent process and situational in nature as described in situational learning disability (SLD). Ultimately, the patient's success at home is dependent on the patient and or caregiver's ability to learn and follow the discharge care plan. Thus, the ADHF patient's ability to avoid readmissions is dependent on their ability to learn. The literature and Model of Health Learning (MHL) suggest that the patient's cognitive state is responsible for the patient's ability to learn, yet cognition is rarely assessed in hospitalized patients. New knowledge is needed in order to develop effective interventions for the ADHF patients to avoid readmissions. Understanding cognitive abilities and learning processes of ADHF patients through the transition home is essential.

Bringing together individual theories on transitions and learning define the variables of interest for this study. The merged theory introduces a framework that draws on ideas from learning theory and proposes that associations between factors in heart failure, cognition and readmissions are mediated by transitions interventions involving Naylor's and Coleman's transition models.

Summary of Chapter 4: Methods

This study used five instruments and three standardized assessments across three time points. Cognition was measured by MoCA and Trail Making A & B (TMT). Depression was measured by the Patient Health Questionnaire-9 (PHQ-9). Social support was measured by the Multidimensional Scale of Perceived Social Support (MSPSS). Co-morbidities were measured by the Charlson Comorbidity Index (CCI). Standardized assessments measured ankle edema, jugular venous distention (JVD), and hepatojugular reflex (HJR). A chart review collected other data at the first time point including: age, gender, medical history, medications, recent hospitalization in the prior 30 days, left ventricular EF, presence of sleep apnea, medical comorbidities, volume status, heart rhythm, and lab values [sodium, albumin, blood urea nitrogen, creatinine, and white blood cell count]. The Outpatient Navigator (ON) standard of care intervention and 30-day readmissions was measured at the last time point. This study aimed to understand HF patients' cognition during and following a hospital admission to inform interventions for ADHF patients with CI at time of discharge.

This study's strength was in its novelty. There was little knowledge of the state of cognition in ADHF patients in the hospital. Only one had studied CI over time from in the hospital post discharge (Kindermann et al., 2012). Strength of the research design included the researcher's unique access to the population of interest over time, the availability of validated tests to measure variables of interest, the longitudinal nature of the study, and the incorporation of current clinical practices (i.e. use of clinical data from the work-up of HF patients was within standard of care).

Characterizing patterns of cognition and depressive symptoms in hospitalized HF patients was hypothesized to be different over time. Determining the relationship of the physiologic changes and the cognitive state of the ADHF from hospital admission to 30 days later was believed to be significant. Important variables present during hospitalization that were correlated with cognition in the hospital and at 30-days post discharge were identified. And, variables present during hospitalization that were correlated with likelihood of 30-day all cause readmissions were found.

This research study aimed at understanding the relationship between the patient's cognitive status and their status of heart failure. Other studies have looked at patient's ability to learn, their cognitive status within the outpatient world of HF, and in relation the severity of the HF illness. These have been looked at in isolation, with tests that are not sensitive to the more mild forms of CI, and in relation to mortality. There have been few studies with designs to study concepts over time and in relation to each other. This was why these concepts must first be described, and followed over time in order to understand how the complexities of these patients affect their ability to learn, and ultimately their discharge plan and potential for readmission.

Summary of Chapter 5: Results

Aim 1 explored global inpatient cognition at time point one (T1) and outpatient cognition at time point two and three (T2 and T3) using MoCA, TMT A, TMT B, and TMT B/A scores. At T1, 60% of ADHF patients in this sample were cognitively impaired. Cognition was not stagnant. Once discharged, each participant's cognition trend followed one of four tracks from T1 to T3: abnormal to normal, normal to abnormal, consistently abnormal, or consistently normal. Those who improved by T3 were less likely than others in the sample to have a 30-day readmission. Those who declined by T3 continued to exhibit depressive symptoms after discharge ($p<.05$) and were very sick in the hospital (i.e. had cardiogenic shock [$p=0.004$] and cancer [$p<.05$]). Older age ($p<.05$) and history of myocardial infarction ($p<.05$) was associated with sustained abnormal cognition scores at T3. Only the MoCA Visuospatial subdomain and TMT A improved

from T1 to T3 ($p < 0.004$ and $p < 0.049$, respectively). Overall cognition did not statistically improve from T1 to T3. The most common trend occurred in 30.2% of participants, whose scores moved from abnormal at T1 to normal at T3. Overall, 40% of HF patients remained cognitively impaired at T3.

Regarding depressive symptoms, 34% of ADHF participants endorsed depressive symptoms (as measured by the PHQ-9) in the hospital. Overall, depressive symptoms significantly improved by T2 and remained improved at T3 ($p<0.001$). Once discharged, three PHQ-9 trends emerged from T1 to T3: 1) improvement in depressive symptoms, 2) worsening of depressive symptoms, and 3) no change in level of depressive symptoms. The most common trend was improvement at T3 (60%, n = 24).

The second, third, and fourth aims used multivariate linear regression modeling to explore relationships of cognition with other variables. Aim 2 focused on identification of demographic, clinical or fluid volume measurements associated with changes in MoCA scores (n=40). Changes in MoCA scores demonstrated a range of 11 points (from -5 to +6); improvement of MoCA scores was independently and positively associated with greater weight loss from T1 to T3 ($p< .017$). Aim 3 focused on testing relationships of cognition, anxiety, and comorbidity status. We found that cognition at T1 was inversely correlated with the Brief Symptom Inventory (BSI) anxiety score ($p=.002$) and CCI ($p=.007$); as a model, these variables remained significant ($p=.001$) and explained 22.6% of the variance in MoCA scores at T1. Outpatient cognition at T3 was inversely correlated with CCI ($p=.05$), and explained 7.4% of the MoCA T3 score variance. Aim 4 focused on identification of variables present at T1 that were correlated with likelihood of 30-day all cause unplanned readmissions. There was a positive trend toward independent association of 30-day unplanned readmissions with CCI ($p=.083$).

Summary of Chapter 6: Discussion

In the context of HF, the high prevalence of CI in the hospital should lead clinicians to evaluate each patient's ability to retain necessary self-care education. Today, as part of

standard routine care, clinicians use many resources to educate hospitalized HF patients. Ultimately, the patient's success at home is dependent on the patient and/or caregiver's ability to learn and follow the discharge care plan. This observation is supported theoretically by the MHL, which suggests that the patient's cognitive state is responsible for the patient's ability to learn. Nonetheless, cognition is rarely assessed in hospitalized HF patients (Hajduk, Kiefe, Person, Gore, & Saczynski, 2013; Levin et al., 2014).

Often, as we found in this study, HF patients demonstrate impairment in how they received and processed information (Rakel & Bulechek, 1990). Readiness to learn is evidenced by the state of having both the willingness and ability to understand (Rakel & Bulechek, 1990; Vanetzian, 1997). Specifically for health information, the skills and ability required to gain access to, understand and use information to promote wellness is called health literacy (Serper et al., 2014; WHO, 2009). Health literacy requires memory, processing speed, problem-solving, attained health knowledge, as well as reading and numeracy skills (Serper et al., 2014). In addition to motivation and health literacy, readiness to learn requires a lack of illness-related learning impairments (Rakel & Bulechek, 1990; Wong et al., 2009). Illness-related impairments are any factors that cause disruptions in cognitive processes, such as HF, depression, and anxiety found in this sample.

In this study, we showed that higher anxiety scores were directly associated with poorer cognition in the hospital. Clinicians should assess the patient's anxiety and cognitive state in the hospital prior to teaching the patient. If the patient is found to have anxiety then cognition may be impaired and plans to teach the patient in depth should be made for following discharge. Patient learning is likely compromised in the hospital. These variables may interact with depressive symptoms to produce transient CI or "cardiac encephalopathy" (Pullicino et al., 2008). The complex interaction of these conditions may include physical (i.e., decreased blood flow) or cognitive factors (i.e. depressed mood) and in both instances are associated with disruptions in thinking (Levin et al., 2014). The neuro hormonal effect of ADHF, depression, and

anxiety contributes to overall CI and cannot be overlooked (Yamaji et al., 2009; York, Hassan, & Sheps, 2009). One unique aspect of our study was assessing the relationship between learning ability, readiness to learn, and cognitive impairment in HF patients. Our findings support the prudence of delaying patient education until the patient recovers from the hospital experience (Davis, Himmelfarb, Szanton, Hayat, & Allen, 2015; Kindermann et al., 2012). Further study is needed to design nursing interventions to assess and address readiness to learn in HF patients.

The clinical management of HF is primarily pharmacologic; however, maximizing patients' quality of life through self-sufficient living, social functioning, and psychosocial welfare is equally important (Hui et al., 2006). Both treatment aims (relieving HF symptoms and improving quality of life) involve daily decisions and actions by the individual. Ultimately, HF patients are expected to master a program of complex, individualized, and dynamic self-care management. Decreased decision-making capability contributes to poor self-care management, poor adherence, and frequent hospitalizations (Bauer et al., 2011; Hwang, Moser, & Dracup, 2014).

Treatment of HF requires more than treating the heart alone. We must also treat the brain. It's not just HF, it is mind failure. The body's systems are connected and impairment in one system impacts other symptoms. During treatment, clinicians who treat HF patients must monitor other body systems. For example, acute renal failure occurred in about 50% of the sample in our study. Cognitive impairment was present in 60% of patients at T1. One of the barriers to assessing and treating CI in HF patients is the lack of standardized recommendations for both assessment and treatment. Cognition screening is recommended for all HF patients yet rarely followed (Dodson, Truong, Towle, Kerins, & Chaudhry, 2013; Hajduk et al., 2013). Chart review reveals that when cognition is assessed and found impaired in the hospitalized patient, less than half of those impaired have provider documentation on the issue (Dodson et al., 2013). Despite the Heart Failure Society of America (HFSA) guidelines' support of patient education and assessment of cognition (Yancy et al., 2013), a cognitive assessment

is not standard of care for a HF patient in the inpatient or outpatient setting. Outside of the routine clinician assessment of orientation and “alert/not alert,” cognition status is still not routinely assessed during hospitalization (McDougall, 2017). When CI is diagnosed, it should be addressed in the care plan because of its effect on knowledge retention, complex reasoning, and problem solving (Athilingam et al., 2011; Pressler, 2008). The discharge plan should include a plan to closely follow patients with CI (Davis et al., 2012; Huynh et al., 2016).

To avoid readmissions, those with CI and depressed emotions need extra support while they recover outside the hospital. Even so, as our findings indicate some HF patients remained cognitively impaired at 30 days after hospitalization.

It is important to know what cognitive deficits remain after the patient has stabilized at home. Ongoing cognitive deficits should be addressed in a care plan to promote potential improvement and improve patient’s quality of life. Recent literature suggests that mild CI improves with cognitive training (Bier et al., 2015). Cognitive training can be performed as an intervention with a neuropsychologist specialist. There are computerized cognitive training programs that have been shown to improve some ranges of cognition (Hajduk et al., 2013; Pressler et al., 2011). Additionally, there are promising results that cognition can improve in healthy subjects with brain training games as an intervention (Al-Thaquib et al., 2018). Further research is needed to know if this intervention will be beneficial for HF patients with CI.

Ongoing reassessment of HF patient’s depressive symptoms is imperative to ensuring a comprehensive care plan. This study showed over a third of HF patients will likely be depressed in the hospital, but it is also likely their depression will improve once discharged. Understanding the patient’s unique variables, and how they may help or hinder recovery, will aid the clinical team to approach the plan of care conversations with the patient (De Vecchis, Manginas, Noutsias, Tschöpe, & Noutsias, 2017). Appropriate treatment of depression is necessary if it does not resolve. Even though HF patient’s presentation of somatic symptoms cross over and may be interpreted as symptoms of ADHF, the cognitive-emotional symptoms must be

purposefully assessed in addition to suicidal ideation. Ideally, American College of Cardiology (ACC)/ the American Heart Association (AHA)/HFSA HF guidelines should recommend routinely screening patients for depression across the continuum.

The dynamic relationship among HF, CI, and depressive symptoms should be assessed on a case by case basis. Particularly important is the patient's capability to retain knowledge in the presence of CI. Specific characteristics of CI in an individual should be considered when planning interventions to improve comprehension and retention of information (Bauer et al., 2011). Findings from the current study will inform the design and testing of nursing interventions aimed at incorporating cognitive assessment into standard of care for HF in order to help patients make successful transitions from hospital to home and to prevent repeated hospital readmissions.

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Chapter 2

Review of Literature

Review of Literature

Introduction

Selection of Articles. The literature search was conducted with the search engines PubMed, CINAHL, and Cochrane. Keywords included and in combination: heart failure (HF), cognitive impairment (CI), depression, readmissions, mild cognitive impairment (MCI), and decompensated HF. Of the research studies reviewed, all were quantitative. The designs included systematic reviews prospective, longitudinal designs, quasi-experimental, cross-sectional, descriptive correlational, comparative, retrospective, and case control studies.

Of the studies of CI in HF, participants were recruited or research was conducted almost entirely in cardiology clinics and in the community. Few were conducted in acute care facilities.

Magnitude of Cognitive Impairment in Heart Failure

The syndrome of HF remains a major health care problem on the rise in the United States (US), in both human suffering and healthcare cost related to readmissions (Mozaffarian et al., 2014). In the US, 6,500,000 adults are estimated to have HF between 2011 and 2014 (Benjamin et al., 2018). Almost 58,309 lives were lost directly to the disease in 2013 (Mozaffarian et al., 2016). Over one million individuals were admitted to a hospital with the principle diagnosis of HF in 2011 and the total healthcare costs for individuals with HF are estimated to rise from 9.7 to 69.7 billion from 2012 to 2030 (Mozaffarian et al., 2014; Mozaffarian et al., 2015). The majority (80%) of expenses are attributed to inpatient care and readmissions (Heidenreich et al., 2013). Thus, strategies to reduce readmissions could have a major impact on healthcare costs associated with this disease as well as a large population.

One of the top reasons for readmission beyond progression of disease is failed self-care behaviors. Although it is known that those with CI are also more likely to have poor self-care behaviors in other disease states cognition status is not routinely assessed in HF patients (O'Connor et al., 2016).

Cognition is defined as the ability to recognize, learn, and remember information, and then use it to reason or problem solve in new situations (Bauer, Johnson, & Pozehl, 2011). Pressler (2008) defined CI as the measurable decline within the domains of attention, concentration, memory loss, psychomotor speed, executive function, memory language, and visuospatial function. Cognitive impairment ranges from mild to moderate, to severe.

Mild CI is defined as when there are detectable abnormalities that can be assessed in one of the seven cognitive domains that do not meet the criteria for dementia (Cameron et al., 2010). Mild CI has been limited by the availability of sensitive assessment tools. The studies that have successfully detected MCI have been in stable HF patients in the community. Athilingam et al. (2011) found that MCI can be detected in people with HF with the Montreal Cognitive Assessment (MoCA) test even when the cerebral perfusion pressure and cardiac index were still normal. It is believed that MCI in HF has impairment in concentration, visuospatial, and executive functions (Cameron et al., 2010). In the hospital setting, 25.2% met criteria for MCI and 21.6% met criteria for moderate-severe cognitive impairment using the MMSE (Dodson, Truong, Towle, Kerins, & Chaudhry, 2013). In elderly patients recently hospitalized in Australia, 22% screened positive for MCI using the MoCA and a cut-off score of 22 (Gallagher et al., 2013). Cameron et al. (2010) showed that 73% had some form of CI within six days of admission. Thus far there is limited knowledge of the prevalence of MCI in HF in the acute decompensated HF patient, how it changes over the transitional period home from the hospital, and its relationship to readmissions.

On the most severe side of the cognitive impairment range is the diagnosis of dementia. Heart failure doubles the risk of dementia among older adults (Festa et al., 2011). Dementia combined with HF worsens patient outcomes. Patients greater than 80 years old with both HF and dementia had a decline in the episodic memory more than those with dementia alone (Hjelm et al., 2011). Dementia in HF is also associated with structural brain changes which represent permanent brain damage (Serber et al., 2008). This can be detected by using the

Watson clock- drawing test. In those who had HF and CI, Serber et al. (2008) found that abnormal test scores were correlated with significant brain injury. Thus some assessment tools can be helpful to determine severity of CI. The comprehensive understanding of the relationship between the spectrum of CI and the acuity of HF has remained unknown for a variety of reasons. Not all CI is a precursor to dementia nor is dementia a precursor to Alzheimer's disease (AD) (DeCarli, 2003). DeCarli (2003) does show that only 30% of patients with CI are clinically and pathologically consistent with early AD. Additionally, studies call for further research to understand the nature of CI in HF as permanent or reversible (Stanek et al., 2009; Vogels et al., 2007; Wolfe, Worrall-Carter, Foister, Keks, & Howe, 2006). To understand the full spectrum and relationships of CI in HF, those with pre-diagnosed dementia should be controlled for and included.

Cognitive impairment in HF is a growing problem. Cognitive impairment affects nearly one fourth of patients with chronic systolic HF (Pressler, Subramanian, et al., 2010). In a review of the literature of cognition and chronic HF, the prevalence of cognitive deficits was between 25% and 50% of those who have HF in the outpatient setting (Pressler, 2008) and up to 80% in the inpatient setting (Davis et al., 2012; Levin et al., 2014). Heart Failure disease is on the rise and the incidence is projected to increase in America so that one in every 33 Americans overall will have HF (Heidenreich et al., 2013). In recent national reports, it was stated over 1,000,000 more Americans now have HF compared to the previous year (Benjamin et al., 2018). Thus, the number of cognitive impaired HF patients is also growing.

The magnitude of importance that the cognition status of a HF patient has to the success of their treatment cannot be overestimated. Beyond increasing inpatient mortality five-fold (Zuccalà et al., 2003) CI in HF patients is particularly destructive because it interferes significantly with successful treatment. The clinical management of HF is primarily pharmacologic; however, maximizing patients' quality of life through self-sufficient living, social

functioning, and psychosocial welfare is equally important (Hui et al., 2006). Both aims of treatment (relieving HF symptoms and improving quality of life) involve daily decisions and actions by the individual. Ultimately, HF patients are expected to master a program of complex, individualized, and dynamic self-care management. Decreased capability to make decisions contributes to patient outcomes of poor self-care management, poor adherence, and frequent hospitalizations (Bauer et al., 2011; Hajduk, Kiefe, Person, Gore, & Saczynski, 2013; Leto & Feola, 2014). Data documenting HF patients' poor self-management at home after hospital discharge has made in-hospital pre-discharge patient and family HF education a priority (Koelling, Johnson, Cody, & Aaronson, 2005). Cameron et al. (2010) showed that there is a relationship between MCI and self-care management in that MCI accounted for the largest variance (9%) in lower self-care management scores. However, the complexities of CI in the context of a HF exacerbation and hospitalization have not been studied entirely. In one study, the researchers performed an educational intervention with HF patients who had MCI in the hospital which resulted in improved knowledge; however, 30-day readmissions were the same in both groups (Davis et al., 2012). Recently, MCI defined by MoCA has been shown to be a useful predictor of readmission and mortality outcomes (Huynh et al., 2016). Thus, the role of CI and MCI in pre-discharge learning, at-home decision-making and self-care management following discharge, remains unknown.

The current standard of care to prepare a HF patient for discharge includes education on disease process, medications, diet, symptoms to watch for, and when to call the doctor. Before time and resources are spent while the patient is hospitalized, it is important to determine the unknown cognitive state of the HF patient because if CI exists then there is a direct effect on the patient's ability to learn while in the hospital. Often, HF patients are impaired in how they receive and process information (Rakel & Bulechek, 1990). For this reason, nursing diagnoses were created in the 1990s to define reasons of impaired learning due to either readiness to learn or to

ability to learn. Readiness to learn is evidenced by the state of having both the willingness and ability to understand (Rakel & Bulechek, 1990; Vanetzian, 1997). Thus, in addition to motivation and health literacy, readiness to learn requires a lack of illness-related learning impairments (Rakel & Bulechek, 1990; Wong et al., 2009). Illness-related impairments are any factors that cause disruptions in cognitive processes. These factors may be physical (i.e., decreased blood flow) or cognitive (i.e. depressed mood) and are associated with disruptions in thinking. There are no studies to date that investigate the relationship of learning ability, readiness to learn, and CI in HF patients.

Poor outcomes. Cognitive impairment in HF is associated with relatively poorer health outcomes (Cameron et al., 2010). Individuals with HF are 1.51 times more likely to have CI than individuals without HF (Pullicino et al., 2008). With CI in HF there is a fivefold increased risk of death (Zuccala et al., 2005). After being diagnosed with HF, disabilities like CI, develop in 23% in four years and 40% in eight years (Chaudhry et al., 2011). Foster et al. (2011) found associations between CI and HF in that participation in activities they enjoyed before their diagnosis will decrease on average 20% more than did patients who had experienced a stroke. Presence of CI is an independent risk factor of noncompliance with medication use and medical appointments (Festa et al., 2011). Mild CI makes the strongest contribution to predicting unsuccessful self-care management; Cameron et al. (2010) found that those with HF and CI are 30% more likely to have inadequate self-care confidence. Festa et al. (2011) found cognitive dysfunction to be an independent risk factor of poor self-care behaviors. Cognitive impairment negatively affects the capacities of people with HF to assess their day to day status for warning signs, complete self-care behaviors, and follow their medical care plan at home (Bauer et al., 2011).

When HF patients are admitted to the hospital, they are at risk for returning to the hospital within 30 days. The problem of how to prevent hospital readmission for HF has been

extensively studied (Bosworth et al., 2004; Duhamel, Dupuis, Reidy, & Nadon, 2007; Koelling et al., 2005; B. Riegel et al., 2002; Timmerman, 1999). Yet, the national median rate of 30 day readmissions for HF is currently 22.5%, one of the highest rates of readmission for chronic disease (Mozaffarian et al., 2014). The studies to prevent hospitalizations have focused on social support, individualized teaching, motivational techniques, and written discharge plans (Barnes, Alexopoulos, Lopez, Williamson, & Yaffe, 2006; Kehler et al., 2008; Mosca, McGillen, & Rubenfire, 1998; Thornhill, Lyons, Nouwen, & Lip, 2008; Yu, Lee, Kwong, Thompson, & Woo, 2008). Those with HF and CI are more frequently admitted to the hospital; Harkness et al. (2011) found 50% of those with abnormal MoCA scores had been hospitalized in the last 6 months compared to 17% of those who had a normal MoCA scores. Unrecognized CI may be contributing to readmissions (Pressler, Kim, Riley, Ronis, & Gradus-Pizlo, 2010). Despite the Heart Failure Society of America (HFSA) guidelines support of patient education and assessing cognition, a cognitive assessment is not standard of care for HF patients (Heart Failure Society of, 2010). Cognition status is still not routinely assessed in during the hospitalization outside of assessment of attention (alert/not alert) and orientation. In the rare case, if CI is diagnosed, it must be accounted for in the care plan because of its effect on knowledge retention, complex reasoning, and problem solving (Athilingam et al., 2011; Pressler, 2008). Mild CI was found to improve readmission and mortality predictions for HF patients (Huynh et al., 2016). Yet, in a large study of 883 patients, CI was not associated with 30-day readmissions in HF patients (Sterling et al., 2018). Research is needed to evaluate fully the influence of CI on hospital readmissions and to assess other putative factors that contribute to hospital readmissions for HF patients. Researchers must design and test nursing interventions that address CI as a means to improve transitional care from hospital to home and, ultimately, to limit readmissions due to CI in this high risk population.

Measurement of Cognitive Impairment in Heart Failure

Screening and measuring the presence of CI in HF is important (Athilingam et al., 2011). When people with HF who did not have a prior diagnosis of CI were screened by Harkness et al. (2011) in the outpatient setting, more than 70% were found to have CI with significant deficits in short term memory, visuospatial function, executive function, and language. Cameron et al. (2010) found that 73% of HF patients had unrecognized CI.

Because sensitive tools to detect subtle cognitive changes across the seven domains of cognition are not yet available, almost all researchers have used more than one measurement when determining if CI was present in HF. Until recently, the most common measurement has been the Mini Mental State Exam (MMSE). The MMSE was first developed by Folstein, Folstein, and McHugh in 1975 to quantify the severity of cognitive impairment in psychiatric patients. The MMSE has 30 questions and takes only five to ten minutes to complete. The test measures orientation, short-term memory, concentration, and visual spatial skills with a Cronbach's alpha of 0.68-0.96 (Folstein, 1975). A score less than 24 indicates the presence of moderate to severe CI. However, the MMSE detects only moderate - severe CI, not MCI (Athilingam et al., 2011; Z. S. Nasreddine et al., 2005).

The MoCA is now more commonly used for measuring cognition because it can detect a wider range of CI. The MoCA was developed from the MMSE by Dr. Nasreddine et al. in 2003. At that time there were emerging treatments for AD and as a neurologist, Dr. Nasreddine and his colleagues were very interested in detecting the earliest signs of CI that could lead to dementia (Z. C. Nasreddine, H. , June 2009). The key finding in the MoCA validation was that patients screened positive for MCI when they performed in normal range for MMSE (Z. S. Nasreddine et al., 2005) The MoCA has 30 items, and a score less than 26 is indicative of MCI. It takes ten minutes and it screens cognition across measures for attention, concentration, executive functions, memory, language, visuoconstructional skills, conceptual thinking, calculations, & orientation. However, MoCA has not been applied to ADHF, or unstable HF.

Therefore, the MoCA is adequate to assess MCI, but must be tested for validity and reliability in the ADHF population.

Etiology of Cognitive Impairment in Heart Failure

The etiology of CI in HF is not well understood (Athilingam et al., 2011). Currently researchers hypothesize that CI in the context of HF is due to widespread brain hypoxia from acute or situational hypoperfusion, or from a series of chronic hypoperfusion events, which lead to neuronal injury (Athilingam et al., 2011; Cameron et al., 2010; Kumar et al., 2011; Pullicino et al., 2008). It is predicted that low perfusion stemming from compromised cardiac output or vascular issues from HF is causal to the brain hypoxia and thus CI (Boyd et al., 2011; Vogels et al., 2007). Additionally, the severity of HF itself, defined by the New York Heart Association (NYHA) class, may influence the initiation and progression of CI in HF. Vogels, Oosterman, et al (2007) found both NYHA class and the duration of the diagnosis to be independent risk factors for CI. Abnormal scores on CI assessments have been found in outpatients with NYHA class II through IV (Athilingam et al., 2011; Harkness, Demers, Heckman, & McKelvie, 2011). In an earlier study Petrucci et al. (2006) studied cognition across severity of HF in 710 HF patients from 1984 to 2002. Each patient's cognition was tested once. The goal of the study was to compare a HF patient cognition across groups. Group one being advanced HF, stage IV, eligible for transplant and stable; Group two being stage IV and unstable on inotropes, and Group three being stage IV, on inotropes in the hospital, in acute status and receiving a heart transplant within 24 hours of exam. Cognitive impairment was significantly different with the least severe in Group one and the most severe in Group three. The cognitive domain that changed the most across severity was mental processing speed. Verbal and visual memory had similar trends that were non-significant. If CI becomes worse even within stage IV, then there is a question of how fast to intervene with even advanced HF therapies like mechanical circulatory support (MCS) or transplant (Petrucci et al., 2006).

Similarly, the effects of low perfusion in HF are linked to blood pressure and the effects on the brain structurally. Vogels, Oosterman, et al. (2007) showed that HF patients with low blood pressure were more likely to have CI than those with normal blood pressure. On the other extreme high blood pressure, hypertension (HTN), was independently associated with worse cognition in the cognitive domains of attention, executive function, and psychomotor speed (Alosco et al., 2012). Ultimately stabilized blood pressure is associated with improved cognitive function (Stanek et al., 2009). The HF effect of inadequate perfusion on the brain is also supported by imaging evidence that HF patients have significant brain injury on computed tomography (CT) (Kumar et al., 2011) in areas of the brain responsible for autonomic, pain, mood, language, and cognitive function (Woo, Kumar, Macey, Fonarow, & Harper, 2009). Although inadequate perfusion as the cause of CI is the dominating theory, Athilingam et al. (2011) showed MCI can be detected when the cerebral perfusion pressure and cardiac index remain normal. This means that CI can still occur in those with HF and a preserved EF (Cameron et al., 2010; Konstam & Lehmann, 2011). Even with hypoxic cells, other covariates that may be present in HF patients can make the hypoxia worse like low levels of thiamine and magnesium (Kumar et al., 2011). Together, these findings suggest that additional correlates may mediate or moderate the relationship between perfusion and CI in HF such as demographics, medication, and associated comorbidities.

Demographics

Researchers have reported associations of CI with multiple demographic characteristics. These include age, gender, level of education, and the factor of genetics.

Age. The majority of people studied with CI and HF are between the age of 45 and 98 years. Older age was found to be a statistically significant factor with CI (Pullicino et al., 2008); but, in another study with a small sample size, older age was not associated with CI (B. Riegel et al., 2002) or only when in combination with other factors like ejection fraction (EF) (Festa et al., 2011). Outside of HF in isolation, it was found in a study of hospitalized elders over the age

of 85 that with a diagnosis of CI (defined as delirium or dementia) there was significant correlation with increased risk of death within the hospital, in the first year post discharge, and overall (Freedberg, Dave, Kurth, Gaziano, & Bludau, 2008).

Gender. With over fifty studies reviewed, the male gender group was predominantly studied. Two studies reported the significance of gender. Being male was found to be a relative risk factor for HF with reduced ejection fraction (HFrEF) (Boyd et al., 2011). In addition, the combination of CI with HF, particularly deficits in memory, psychomotor speed, and visuospatial recall ability, was also associated with male gender (Pressler, Subramanian, et al., 2010).

Level of education. When the education level of HF patients is studied, the consistent finding is that the less education one has the higher risk they are to developing CI (Zuccala et al., 2005). The education comparison point studied is consistently high school. The variable of not finishing high school is significantly associated with poor cognition in HF patients (Festa et al., 2011; Pullicino et al., 2008). Additionally, in the general adult population, those not finishing high school were more likely to have Coronary Heart Disease (CHD), a precursor to HF(Boyd et al., 2011). Boyd et al. (2011) also looked at the relationship between educational level in CHD and risk for readmission, but found it insignificant. Knowing the importance of the educational level is important to take into account when choosing the cognitive assessment tool in a study. The cognitive assessment tool should take educational level into account because, for example, they are designed to test memory. Because working memory is closely related to intelligence, measured by education, (Konstam & Lehmann, 2011), the cognition tests developed are biased toward the educated. As a result, lack of cognition tests may indicate erroneously that a person with limited education has CI. Some cognitive tests, like MoCA, take education into account by supplementing the score of the cognitive tests based on years of education (Gallagher et al., 2013). Thus, the cognitive tests measurement should take into account the educational level of the participant.

Genetics. Kuller et al. (1998) found that the presence of gene apolipoprotein (Apo) E4 allele, a protein involved in the modulation of cholesterol transport and homeostasis. At that time the gene was significantly associated with Alzheimer's disease (AD) in the general population (Kuller et al., 1998). Most recently, Bell et al. (2012) found that ApoE4 activates a reaction that breaks down the blood brain barrier. This breakdown causes microvascular and cerebral blood flow reductions, but the complete extent of this reduction is not known (Bell et al., 2012). Before this discovery in HF patients, Vogels, Oosterman, et al. (2007) found the presence of ApoE4 to be an independent predictor of CI in the HF population. Thus it is the only gene found to date that is independently associated with both HF and decreased cognitive performance.

Medication

Because common cardiac medications may affect cognitive ability through their actions on blood flow and blood pressure, investigators have often withheld them on the day of data collection (Athilingam et al., 2011; Harkness et al., 2011; Kumar et al., 2011; Serber et al., 2008). In fact, antihypertensive medication has been a variable that has differed between groups when studying CI and is important to track and control (Vogels et al., 2007).Two classes of medications have been significantly correlated with CI within multiple regression equations; Zuccalà et al. (2005) found angiotensin converting enzyme inhibitors (ACE-I) and calcium antagonists to have a significant association with CI.

Comorbidities correlated with CI

The severity of CI in HF can be complicated by comorbidities (Athilingam et al., 2011). Currently, depression, dementia, delirium, sleep apnea, anxiety, and anemia have been associated with CI in HF (Cameron et al., 2010; Kumar et al., 2011; Pullicino et al., 2008; Stanek et al., 2009; Vogels et al., 2007). Depression in particular has a close relationship with MCI in its presentation and effect (Cameron et al., 2010). Given the wide range of comorbidities that are associated with CI, determining the unique impact of HF on CI is difficult. However,

these findings suggest that complex relationships exist among HF, CI, and other common chronic diseases. Some investigators have suggested that treating comorbidities associated with CI will improve CI symptoms and may reverse CI itself (Zuccala et al., 2005). However, a causal link between these comorbidities has not been identified and this hypothesis has not been tested.

Depression and depressive symptoms. The incidence of depression is greater among HF patients than in the general population (Russell et al., 2010). It is estimated that four to ten percent of the general population are depressed (Holzapfel et al., 2008) compared to or up to 70% of HF patients have depression (Foster et al., 2011; Haworth et al., 2005). In HF the prevalence of depression is two to three times the general population (Rutledge, Reis, Linke, Greenberg, & Mills, 2006). With appropriate screening, clinically significant depression is expected every one out of five patients (Rutledge et al., 2006). Approximately half of depressed HF patients have moderate to severe depression (Russell et al., 2010). More depression is found in the inpatient HF patients, from 35% (Rutledge et al., 2006) up to 70% (Holzapfel et al., 2008) compared to 11-25% of outpatient HF patients (Holzapfel et al., 2008; Rutledge et al., 2006). The presenting symptoms of depression differ in HF patients compared to patients with other medical illnesses. When a depressed HF group was compared to a depressed non-HF group in the outpatient setting, a significant lower level of depressed mood and worthlessness/ guilt scores were found in those depressed with HF (Holzapfel et al., 2008).

In the general population, a majority of those with depressive symptoms have CI irrespective of HF (Barnes et al., 2006). While the mechanisms of the interaction between depression, CI, and HF are not well understood, several researchers have offered other explanations. Cameron et al. (2010) suggests that depression has a role in CI in HF patients because it has been shown to alter specific cognitive domains of processing speed and executive function. Similarly, Festa et al. (2008) showed depression as a significant predictor to

decreased cognitive domains of recall memory, while also affecting mental flexibility and processing speed; still, only depression accounted for a small portion of the variance of CI. Pullicino et al. (2008) hypothesized that pathologic conditions associated with HF (i.e., fluid retention, electrolyte disturbance, cardiac medications, and anemia) may interact with depression to produce a transient CI, which they coined as “cardiac encephalopathy.” Still others try to attribute the correlation of depression with CI in HF to the lack of recognition and treatment of depression and to the overlap of symptoms between the two conditions (Holzapfel et al., 2008). Notwithstanding these hypotheses, when other factors are controlled depression remains associated with poor outcomes in HF patients. Worsening HF symptoms, self-care behaviors, and increased mortality rates are directly correlated to depression (Holzapfel et al., 2008; Konstam & Lehmann, 2011).

The association of depression and CI are particularly strong in patients with advanced HF. Cognitive impairment, depression, or both were present in three fourths of advanced HF patients, NYHA class III and IV who were awaiting transplant (Foster et al., 2011). Haworth et al. (2005) showed NYHA class as a predictor to depression and anxiety diagnoses in HF patients. Relationships have been recently found between poor self-care, and greater depression, anxiety, lower levels of perceived control, and worse NYHA, despite high recorded HF knowledge (Hwang, Moser, & Dracup, 2014). Those that experience cognitive dysfunction or depressive symptoms tend to participate in fewer social, mental, and physical activities (Foster et al., 2011). Having all three conditions (HF, CI, and depression) has also been shown to be the strongest risk factor related to the onset of disability in activities of daily living within people with CI and HF (Chaudhry et al., 2011). The presence of CI and depression each independently accounted for 11% and together accounted for 34% of the variance in the perceived participation scores in rehab (Foster et al., 2011). It was suggested that depression reduced effort or motivation, and CI reduced learning capacity (Foster et al., 2011). Also, investigators hypothesize a negative feedback loop in which the presence of depressive symptoms

decreased satisfaction with the activity and, in turn, perception of decreased satisfaction decreased the likelihood of continuing the activity (Foster et al., 2011).

Changes in Cognitive Impairment over Time in HF Patients

To date, few studies have researched patterns of cognition in HF patients over time. Riegal et al. (2012) studied cognition in stable outpatient HF patients treated at a specialty HF clinic and showed no significant cognitive changes over a six month period of time. Cognitive impairment was found in 59.9% of the sample. Significant factors associated with CI included demographics (older age, male, Non-Caucasian, and less education), multiple comorbidities, preserved EF, symptoms of excessive daytime sleepiness, and higher body mass index (BMI). In another study, Stanek et al. (2009) tested cognition at two time points, 12 months apart. Significant improvements were found in attention and executive functioning; no declines were reported. Improvement was associated with a higher diastolic blood pressure at baseline. These results support the idea that CI may be modifiable in some HF patients. A third study looked at HF patients from inpatient to outpatient for the purpose of understanding the effect of ADHF on CI (Kindermann et al., 2012). They found those with ADHF to have worse CI than stable HF patients in the outpatient setting. It is believed that decompensated HF worsens CI but further research is needed to understand how other variables in the hospital contribute to CI (Kindermann et al., 2012) In a study with HF patients who receive mechanical circulation support (MCS), Petrucci et al. (2006) measured five domains of cognition at one, three and six months post left ventricular assist device (LVAD) implantation. Significant improvements occurred in four domains (visual memory, executive functions, visual spatial perception, and processing speed) out of five and no significant declines occurred in the remaining domain of language. The LVAD device restores blood flow, hence CI related to inadequate blood flow was repaired. This work is important when comparing therapy results between MCS and transplant options in advanced HF patients (Petrucci et al., 2006).

Intervention Studies for Cognitive Improvement in HF Patients

Intervention studies to directly improve CI in HF patients are limited. To date, only one study has tested an intervention. The aim of this study was to directly improve the memory of HF patients in the outpatient setting (Pressler et al., 2011). In this random experimental designed study, 40 systolic HF patients were enrolled in either an eight week established computer program called Brain Fitness Intervention (BFI) or a standard educational self-review on cardiac health. Prior to use in this study, the BFI had shown to be effective in improving memory in healthy elders. Weekly monitoring of adherence was completed by Advanced Practice Registered Nurses (APRN). Overall data were collected on demographics, comorbidities, severity of illness, cognition, and activities of daily living. Delayed memory did significantly improve in the intervention BFI group, but it is unclear if the improvement was due to other factors besides adherence to the program. A larger randomized control trial is needed to determine the impact of plasticity-based interventions on HF patient's cognition.

The majority of the intervention studies have investigated how to best transition patients with chronic illnesses from the hospital to home. Many of the patients who are assessed to be high risk for 30 day readmission may have CI. Unfortunately, cognition is not routinely assessed in HF patients and therefore cannot be treated. The patient's cognition if impaired would make the patient a higher risk for readmission. One thought leader of these intervention types is currently Dr. Eric Coleman (2014) and his Transition Coach (TC) Model of transitioning home from the hospital (Parry, Coleman, Smith, Frank, & Kramer, 2003). Another is Dr. Mary Naylor who describes the APN role, the Transitional Care Nurse (TCN), within transitions of care (Naylor et al., 2013). The common goal of the similar interventions in these models is to reduce and avoid thirty day readmissions. Although transition programs interventions have shown to be successful across populations, 23% of recently hospitalized HF patients continue to return to the hospital within thirty days. Understanding why the transition interventions work for some HF patients and not others remains a question. Cognitive impairment is associated with increased risk of readmission, but the specific characteristics and related demographics in HF and CI have

not been studied. When 30 day hospital readmissions are analyzed, the dynamic is complex and readmissions are related to co-morbidities, lack of social support, non-adherence to specialized education focused on self-care activities, and lack of individualized care plans that addresses perceived barriers in transition from hospital to home (Barnes et al., 2006; Bosworth et al., 2004; Duhamel et al., 2007; Koelling et al., 2005; Mosca et al., 1998; Barbara Riegel & Lee, 2012; Thornhill et al., 2008; Timmerman, 1999; Yu et al., 2008). This is typically summarized in patient categories of noncompliance or progression of disease. Without objective assessments of the possible contributing factors to the HF patient's noncompliance or progression of disease repeated failure as an outpatient is certain. The contribution of the HF patient's cognitive abilities in this cycle remains un-assessed and unknown.

Gaps in the Research

Biologic and Behavioral Links between CI and HF. Both the biologic and behavioral mechanisms linking CI to HF are unknown at this time. Yet, understanding them will guide the approach to nursing care (Pressler, 2008). The design of future nursing interventions will depend on whether biological mechanisms of CI precede, result from, mediate or moderate biologic mechanisms of HF. Similarly, whether behavioral mechanisms of each condition are bidirectional will also determine the form and content of new nursing interventions. Further, whether CI in the context of HF is preventable, or whether it presages an early, inevitable demise will also influence the nature of future interventions (Pressler, 2008). Another example of an important gap in knowledge is the question of systolic vs. diastolic dysfunction. To date, most studies of CI in HF patients were focused only on HF patients with systolic dysfunction EF < 40%. This is consistent with the currently popular hypothesis that CI in HF is a perfusion issue. However, patients with diastolic HF (i.e. with preserved EF) may have CI as well. There is limited research on CI in HF with preserved EF. Understanding the varying etiologies of CI in HF, the relationship between the mechanisms of CI across the classes of HF, and if it is reversible or modifiable will change the existing approaches to HF care across the continuum.

Cognitive Impairment in Hospitalized HF Patients. To date, there are only six studies describing CI in hospitalized HF patients at a single time point. First, Cameron et al. (2010) used the MoCA and MMSE to describe cognition six ± five days from hospital admission. They found 75% had MCI in their sample of 93 patients (Cameron et al., 2010) and these had significantly lower self-care management and confidence scores on the Self-Care Heart Failure Index (Cameron et al., 2010). They looked at the association between cognition, depression (measures by the Cardiac Depression Scale), and self-care behaviors (measured by the Self-Care Heart Failure Index) and found MCI, Charleston's Comorbidity Index, and NYHA Class III or IV explained 20% of the variance of self-care behaviors (Cameron et al., 2010). Second, Dodson et al. (2013) defined the incidence of CI by screening patients with the MMSE at time of discharge. This true incidence was compared to physician documentation of CI diagnoses retrospectively. They found of the 282 screened at the time of hospital discharge, 132 HF patients (46.8%) had CI. Of the 132, 33 (25.2%) met criteria for MCI and 29 (21.6%) met criteria for moderate-severe CI. However, physician documentation of CI was found in the medical record on only 30 (22.7%) patients. Those with impairment and no documentation were significantly younger (81.3 versus 85.2 years) and having MCI not CI. Mortality and readmissions were tracked at six months. When CI was not documented by the physician at hospital discharge, there were significantly higher six month readmission mortality rates (Dodson et al., 2013). Second, in a study from Australia, Gallagher et al. (2013) studied elderly HF patients who had been recently hospitalized. Participants were screened for CI using the MoCA. Interestingly, they used a cut-off score of 22 to indicate MCI versus the traditional cutoff score of 26 indicating MCI and less than 22 CI. Recruitment occurred during hospitalization, and the only cognitive screen in the study was completed one to two weeks after discharge. Of the 128 HF patients who completed the post-discharge screen, their definition of MCI was found in 28 patients (22%) and 70 patients (55%) were found normal (indicated by their cut-off score of 26). As they noted in their limitations, had they followed the traditional cut-off scores they would

have had 28 patients (22%) with CI, 42 patients (33%) with MCI and 58 patients (45%) that were normal. Additionally in this study, the participant's perception of the CI change and its impact on daily activities was also assessed (Gallagher et al., 2013). With their reported definition of 28 patients with MCI, 13 patients (45%) claimed they noticed the difference and 15 patients (55%) did not. Of the 13 patients that noticed, four patients (15%) claimed the CI change impacted their daily life. When these four patients (15%) MoCA scores were compared to the 15 patients (55%) MoCA scores, the scores of the ones who noticed were significantly lower than those of the ones who did not notice (Gallagher et al., 2013). Meaning that patient awareness of cognition changes and CI is associated with actual impairment. Or, if applied to the clinical setting, if the patient thinks they are having cognitive changes listen to them, test, and treat, they probably are right. Third, Levin et al. (2016) studied Canadian HF patients and found 80% were impaired in at least one cognitive domain of the three that were tested: executive function, processing speed and memory. Global cognition was not assessed. Those who were older, less educated, and had more non-cardiac comorbidities were associated with impairment in one domain (Levin et al., 2014). Those who were defined as having depression, measured by the Geriatric Depression Scale, were twice as likely to be impaired in all three domains (Levin et al., 2014). Fourth, Huynh et al. (2014) measured cognition using the MoCA across the hospitals of Australia. A lower cutoff score than usual (MoCA ≤ 22, as opposed to ≤ 25) found 45% of 565 HF patients with at least mild cognitive impairment (Huynh et al., 2016). They found those with MCI, dementia, depression, or anxiety all were independent predictors of both 30-day readmission and mortality (Huynh et al., 2016). The claims came from screening tools, depression from Patient Health Questionnaire-9 (PHQ-9) assessment and anxiety from Generalized Anxiety Disorder scale, which are not intended to diagnose. The authors added the MCI finding to a previously designed prediction tool and improved their model for a net of 12% of patients who had a readmission or death (Huynh et al., 2016). Fifth, and most recent, Sterling et al. (2018) prospectively studied 883 ADHF patients in Vanderbilt health system to determine

if numeracy, health literacy, and cognition were had associations with 30-day readmissions and none were found significant. Cognition was measured using the ten item Short Portable Mental Status Questionnaire (SPMSQ) (Sterling et al., 2018). They found 33.9% had inadequate health numeracy, 24.6% had inadequate health literacy, and 53% had cognitive impairment (SPMSQ score = 1 or greater) (Sterling et al., 2018). Those with hospital impairment were associated with being older, female, having less education and income, a greater number of comorbidities, and a higher severity of HF during the index admission compared with those with intact cognition (Sterling et al., 2018). There were no repeated measures in this study. Together, these six preliminary studies highlight the need for better screening and treatment strategies to address CI in HF patients.

Summary

In summary, gaps in the literature exist in what is known and understood about CI in people with HF. Even though it is apparent that HF patients are at risk for CI and CI affects them clinically, routine assessment and monitoring of CI is not a standard of practice for HF patients in or out of the hospital. When providers do diagnose CI in HF patients, there are few evidence-based interventions that are easily accessible for this complex patient group. While educational interventions that highlight available resources are routine for HF patients, assessment of CI, which drives the HF patient's ability or motivation to participate, is lacking and is likely to contribute to the high HF readmission and mortality rates nationally. Longitudinal studies that investigate key correlates of CI and evaluate changes in CI from hospital to home are needed to provide the basis for future intervention studies aimed at reducing hospital readmissions and reducing all ranges of CI. Understanding which CI characteristics exist in ADHF, and the relationship with depression, will guide developing nursing interventions that are designed to prevent 30-day readmissions and thus have a major impact on healthcare costs and mortality associated with this disease. Little evidence is available showing how CI changes from an acute decompensated event in the hospital to an improved cognitive recovery after discharge.

The outcome of needed research in this area could shape future studies on interventions for ADHF patients with CI at time of discharge, and answer questions considering HF patients' non-adherence following a hospital admission.

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Chapter 3

Theoretical Framework

Theoretical Framework

The focus of the proposed investigation is on the role of cognitive impairment (CI) in self-care management education as patients with acute decompensated heart failure (ADHF) prepare to leave the hospital and return to community living. The Principal Investigator (PI) is a clinical nurse specialist for the heart failure (HF) population of a multi-institutional care network, which will be the research site for the proposed study. In the context of her quality improvement work, the PI has participated in the development of a program designed to limit hospital readmissions. The program draws on two theoretical frameworks relevant for the proposed study. These are Dr. Mary Naylor's Transitional Care Model (TCM) and Dr. Eric Coleman's Care Transitions Intervention (CTI).

Transitional Care Model

Dr. Mary Naylor's TCM is focused on the process of transition from acute care to home care. The goal of the TCM is to help seniors with chronic diseases receive appropriate outpatient care and maintain a safe home environment (M. D. Naylor, 2010, April 22). This model supports elements that affect the process of transition from hospital to home (See Figure 1). It builds on the paradigms from interdisciplinary teamwork, communication, and healthcare economics. There is a focus on advocating for the best delivery of care to adults who have chronic medical issues. The TCM was designed to accommodate the complex medical issues of patients while hospital stays grew shorter (M. D. Naylor et al., 2004). Because of these attributes, Naylor's model was used as a foundational theory to support the approach of a transition care plan for a person with HF and possible CI.

This model explains the Advanced Practice Registered Nurse's (APRN) role within transitions of care, a role Naylor has dubbed Transitional Care Nurse (TCN). In the TCM, ten key concepts show the relationship between the APRN/TCN and the patient. They are that: 1) the APRN is the coordinator, 2) assessments and evidence-based plans occur in the hospital, 3) regular home visits based on patient needs with the first visit within 28 hours of discharge; and

with 7-day-a-week telephone support available for 2 months, 4) APRN/TCN provide continuity of care by communicating with the outpatient providers 5) patient's needs are managed comprehensively with oversight by the APRN/TCN, 6) the patient is actively engaged with the APRN/TCN in educative/supportive activities, 7) patient or caregiver is trained to recognize early identification of symptoms to avoid hospital admissions, 8) multidisciplinary approach includes patient and family on the team, 9) physician and nurse collaborate, 10) communication to, between, and among the patient, family caregivers, and health care providers.

According to the TCM, the transitions from wellness to illness, resulting in hospitalization, and back to wellness are challenging for patients to manage alone. They need expert nursing interventions to maintain a safe home environment and avoid future hospitalizations. Each concept in the TCM model is related to improving health and preventing decline. For example, in the concept of screening, the APRN/TCN monitors the patient for HF symptoms and assists the patient in recognizing symptom patterns independently. Managing symptoms, another concept in the TCM, requires knowledge of patterns, so the APRN/TCN provides education to the patient/caregiver regarding patterns and provides coordination of care when patterns are observed. Engagement of the patient/caregiver in order to manage symptoms at home is necessary to insure that optimal wellness, the "new normal", is achieved and maintained. The concept of maintaining relationships addresses continuity of care and emphasizes the importance of the APRN/TCN's role in building a therapeutic alliance with the patient/caregivers, providing patient/caregiver education, and insuring collaboration with the interdisciplinary team. In the TCM model, continuity and follow-up, provided by the leadership of the APRN/TCN, is critical to maintaining wellness and safety. All the concepts of the TCM lead to maintenance of health in the environment outside of the hospital.

The research supporting the TCM has advocated for the APRN role and for patients' activation and involvement in their care. Dr. Naylor's model has been studied with both HF patients as well as older adults who are cognitively impaired (M. D. Naylor et al., 2004).

Research studies have supported the TCM model's focus on the central role of the APRN/TCN in maintaining wellness after hospital discharge for the past 18 years. Three randomized control trials (RCT) have compared the TCM to standard of care and have showed many benefits to this population of chronically diseased adults over the age of 65, the providers involved, and the payers of the care (M. Naylor et al., 1994; M. D. Naylor et al., 1999; M. D. Naylor et al., 2004). Most recently in 2013 the TCM was studied in customers who have Aetna's health plan (M. D. Naylor et al., 2013). Similar results as the RCTs occurred in this clinical practice setting of statistically significant reductions of readmissions up to 25% and total hospital days up to 28%, and decreased total health care costs ranging from 439 dollars per member per month (Naylor et al., 2013). Additionally the participants who had the interventions in TCM by APRN/TCNs had statistically significant improvements in functional status, depression, symptom status, and self-reported health and quality of life than those who received standard of care (Naylor et al., 2013). Dr. Naylor's model has not been refuted in the literature, and is recognized as one of the funded evidence-based practice models in the Affordable Care Act for transition of care by Center for Disability and Aging (Policy, 2014).

The second element (assessments and evidence-based planning in the hospital) is the key step at which chronic disease self-care needs of ADHF patients are assessed and education begins. A hospitalization provides a unique opportunity for patient/family assessment. The clinical management of patients recovering from ADHF aims to reduce readmissions by teaching self-care behaviors to patients and their families (Heart Failure Society of, 2010). However, education may be ineffective if the patient has a decreased capability to retain information and make decisions. It is known that decreased capacity, or CI, contributes to poor patient outcomes of low adherence, impaired self-care, and frequent hospitalizations (Bauer, Johnson, & Pozehl, 2011). Thus it is hypothesized that assessing HF patients for the presence of CI while they are in the hospital could change the discharge plan and ultimately prevent

readmissions. Naylor's model does not speak to the complexity of CI specifically, but is consistent with this critical approach to patients with ADHF.

Care Transitions Intervention

Dr. Eric Coleman's work is also a transitional theory. While Dr. Naylor's intervention spans from inpatient throughout the continuum of care, Dr. Coleman's theory focuses on the transition from hospital to home. His intervention was designed to provide encouragement for patients and their caregivers and to promote independence. Dr. Coleman's CTI theory posits that when patients' and their caregivers' needs are met and they take an active role in their care, particularly during a transition, rehospitalizations can be reduced (See Table 1). The CTI can take CI into account, but only if it is a known problem. It is recommended to assess cognitive status (Heart Failure Society of, 2010), but it is not a standard of care in the hospital. Because the cognition state of the inpatient ADHF patient is unknown it is not addressed currently within the CTI model of care.

In 2002, Dr. Coleman and his colleagues began their work to develop a transitional care model by first developing the Care Transitions Measure (CTM). It was developed through focus group methodology with the goal to objectively measure the quality of a transition from hospital to home. From thematic analysis of focus group data, conceptual domains were extracted and subsequently tested to develop the instrument (Coleman et al., 2002). Then in 2003, these same domains were used to design an intervention called the CTI (Parry, Coleman, Smith, Frank, & Kramer, 2003). Through continued research, the CTI model is now a defined copyrighted program (Coleman, 2007).

The CTI model has a key nurse role called a Transitions Coach (TC). As the patient transitions home, the TC maintains continuity and supports the discharge plan for the patient (Coleman, Parry, Chalmers, & Min, 2006). At the research site, the TCs are called Outpatient Navigators (ON) and are certified from Dr. Coleman's center. The role of the TC is to be a source of information and support for the patient through discharge, rather than a traditional

case manager whose relationship ends at discharge from the hospital (Coleman et al., 2004). The goals of the TC are to help the patients identify their questions or concerns, as well as, coach and empower the patients as to when to call their health care provider (Coleman et al., 2004). The TC role initially started with an APRN and by 2006 moved to be a bachelor's prepared Registered Nurse. In the model, the TC meets the patients in the hospital and starts their needs assessment and then follows each patient for 30 days. In following the CTI protocol, during each visit the TC focuses on the four thematic domains, which have been dubbed "pillars' of the CTI protocol (Coleman et al., 2004). The four pillars include coaching and educating the patient/ caregiver on the skills to accomplish: 1) medication self-management, 2) personal health record maintenance, 3) timely primary care follow-up, and 4) ability to respond to specific signs or symptoms, the patient's red flags of a worsening condition and how to respond.

Key in the CTI model is the patient's ability to learn self-management skills. The main tool for insuring the patient's mastery of self-management skills is the personal health record. This is a patient-centered document that has consistent data elements including: an active problem list, medications and allergies, a list of the patient's red flags, a checklist for discharge and a space for patient's to write questions. With the TC's collaboration, the patient/ caregiver maintain and update the personal health record. During the course of the CTI intervention following hospitalization, the TC visits the patient in his/her house once within 48 hours and then does weekly telephone follow-up calls for three weeks.

Outcomes with this model have shown statistically significant reductions in hospital readmission rates and health care costs (Coleman et al., 2006). The CTI model has demonstrated significant reductions in readmission rates at 30 days (3.6%), 90 days (5.8%), and 180 days (5.1%) post discharge and across populations (Coleman et al., 2006). The cost savings of CTI claim a low estimate of $295,594 annually (Coleman et al., 2006). However, despite these outcomes, HF patients remain in the top five patient populations that return to the hospital (Elixhauser & Steiner, 2010). If the approach to HF patients included a cognitive

assessment, it is hypothesized that the CTI intervention would be more effective in this population to reduce readmissions.

Framework Modified for Research Study

Through this prior work it was clear that the interventions in the transition program within Scripps Care Management (SCM) © were successful because they were supported by Dr. Mary Naylor's TCM and Dr. Eric Coleman's CTI theories; yet, not all HF readmissions were prevented (Dixon, 2013a; Nguyen, 2014). In effort to understand why some HF patients were readmitted and some were not, the PI observed that some HF patients struggled to learn while they were in the hospital and some as an outpatient. Systematic observations and active participation by the PI in HF patient education processes with Dr. Meleis' method of describing a phenomenon were completed (Meleis, 2012). This revealed that some HF patients were unable to concentrate, organize thoughts, or remember details discussed (Dixon, 2013b). A concept arose surrounding the learning ability of the patient. Fatigue, anxiety, worry, and illness-related grief, and lack of engagement were also common. Fear, poor understanding of self-care behaviors, and poor short term memory, and/or twenty-four hour recall were also observed. These negative attributes are consistent with the concept situational learning disability (SLD): impaired ability to learn (Rakel & Bulechek, 1990). Analysis of the SLD concept revealed its salience for explaining why ADHF patients do not implement the self-care recommendations they learn in the hospital once at home after discharge. As the concept of SLD is defined, its importance to transitions of care for HF patients and its relationship to CI will be described.

Situational Learning Disability

The concept of SLD is immature, as the most recent publication to describe it as a nursing diagnosis was in 1990 by Rakel and Bulechek. The concept of SLD is mainly used to describe and define the patient's state of ability to learn. There are three main critical attributes that define SLD from other concepts. By explaining its situational nature, the process of

learning, and the meaning of disability as impaired ability, the patient's experience can be defined as an SLD or not.

1. Situational nature: This means the learning disability is not permanent. There are situations that precede the inability to learn. Qualitatively, Wong et al. (2009) showed when participants tried to learn while they were ill, they voiced feelings of depression, and fatigue captured through statements like my "body just wanted to sleep" (p. 31). Medications may also precede impairment of learning. In the PI's observations medications were witnessed to cause drowsiness or decreased alertness that interfered with the way information was processed (Dixon, 2013b). Additionally, physiologic factors, conflicting biorhythms, adaptation to crisis, intense emotions, unmet needs, sensory overload, and unfamiliar language may impair learning (Rakel & Bulechek, 1990). The physiological factors include any disruption of bodily processes that would create disruption in thinking. Most are related to blood flow, although, biorhythms are also involved when a patient's mood may swing can affect mental performance (Rakel & Bulechek, 1990). It is believed that the disruption of blood flow in HF, either acute or situational hypoperfusion, or a series of chronic hypoperfusion events, is related to the patient's mental performance (Athilingam et al., 2011; Cameron et al., 2010; Pressler, 2008). In this research, medications, physiologic factors like sleep apnea, conflicting biorhythms like delirium and depression, and acuteness of HF will be measured.

2. Process of learning: Learning is defined by its processes of obtaining memory, with either declarative memory designated as conscious recall, or procedural memory where repetition is required (Vanetzian, 1997). Learning depends upon intact executive functions (Pitel et al., 2007). Unfamiliar environments, noises, and language evoke sensory overload, which can impede learning and contribute to impaired learning ability (Rakel & Bulechek, 1990).The PI's observations via discharge follow-up telephone calls confirmed this when patients were not able to recall education that took place in the hospital once they arrived home (Dixon, 2013b). Home health nursing also reported a lack of recall from HF patients that were known to have been

given the specialized HF education while in the hospital (Dixon, 2013b). In this research, because learning is dependent on cognitive processes, the patient's cognitive processes will be measured and the education the patient receives will be tracked.

3. Meaning of disability and impaired ability: A learning disability exists when brain function that is needed for learning is compromised. When a learning disability is present one or more of the following defining characteristics exists: attention deficits, perceptual and perceptual-motor problems, memory problems, problems in symbolic function or language, conceptualization difficulties, or other emotional disturbances (Rakel & Bulechek, 1990; Uprichard, Kupshik, Pine, & Fletcher, 2009). All of these defining characteristics impair learning and influence how ADHF patients with CI receive and process information (Rakel & Bulechek, 1990). In fact, HF (or other chronic illnesses) may cause impaired learning by interfering with the brain's capacity to receive and process information (Rakel & Bulechek, 1990).

Through the analysis of the SLD concept, it is clear that HF patients could be in situations where their ability to learn may be compromised. The PI's observations revealed these HF patients as vulnerable and high risk for readmission to the hospital. It is hypothesized that if their ability to learn is compromised while they are in the hospital that they may have an increased risk for readmission. In this study of cognition in HF and its relationship to readmissions, SLD is an important concept to evaluate. If in fact the ADHF patient is found to have CI, then they may have SLD. If their learning is impaired, then how they learn, their Model of Health Learning (MHL) will be altered. The MHL will further define what must be in place for learning to be achieved.

Model of Health Learning (MHL)

The MHL was developed to provide a theoretical foundation for the development, application and testing of health-education materials and instructional strategies to support patients and families across the health care continuum in the Health Literacy and Learning Program (HeLP) (Wolf et al., 2009). In the MHL model, the three main fundamental concepts to

achieving and maintaining one's optimal health are health learning capacity, health knowledge, and health behavior (See Figure 2). The health learning capacity in this model is defined through measuring the cognitive and psychosocial skill sets (Wolf et al., 2009). In the MHL, health learning capacity is foundational to achieving health knowledge defined as the awareness of information that would allow one to understand, interpret, and analyze health information (IOM, 2004). It is also related to health behaviors defined as actions that apply health information over a variety of life events and situations, including active participation in encounters with healthcare professionals, promotion of self-care and treatment, and navigating health systems (IOM, 2004; Wolf et al., 2009). Lastly, in the MHL, health learning capacity is foundational to health outcomes.

Research with this model has identified the important aspects for health learning to occur and it has been used to establish the relationship between learning and health literacy (Wolf et al., 2009). Wolf et al. (2009) recognizes the similarity of the health learning capacity concept to the definition of health literacy from the National Research Council of the Institute of Medicine (IOM) (2004) and the National Library of Medicine as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions"(p.32). Wolf's research on health literacy and learning has found not all variables involved have the same significance within the relationship toward health outcomes in the MHL (Wolf et al., 2012). For example, Serper et al. (2014) found that cognitive function explained a significant proportion of association to physical health outcomes, where health literacy, depression, and anxiety did not. Similarly, Mottus et al. (2014) found that the reason low health literacy was found to be associated with poorer health was due to general cognitive ability, and educational levels. These further support Wolf et al. (2012) work in the LitCog study when cognitive skills were studied among health literacy, ability to perform health tasks, and functional health status. The results suggest the problems of limited health literacy are mostly stemming from individual differences in cognitive skills within the individual

(Wolf et al., 2012). Wolf et al. (2012) calls for more research in this area and hypothesizes that cognitive ability may be able to predict the patient's ability to engage in self-care behaviors and realize health outcomes.

The Merged Theory

A theoretical framework to support this study must include specific characteristics. These include: 1) a chronic disease perspective; 2) concepts and measures important for self-care behaviors; 3) allowing for conditions that can alter the ability to perform self-care behaviors, like cognition and depression. The processes involved in transitions of care for HF patients are complex and one theory does not take all interactions in to account. Due to the limitations of individual theories to explain the complexities of transition for HF patients, three theories relevant to self-care management in HF to prevent readmissions are proposed (See Table 2). Using a merged theory provides a different perspective to this work that one alone cannot provide by itself. Merging these three theories supports the research of CI in HF patients from a health services approach. A model of the merged theory is presented in Figure 3.

In merging the three theories, parts of each theory are applied to define the SLD concept for the HF patient. Three concepts from Naylor's TCM: screening, educating and promoting self-management and coordinating care are used to define SLD. First, screening takes place on admission when the patient is screened for dementia and delirium, two known problems to cause CI. Then, in SLD, the HF patient's situation is assessed while they are hospitalized. The important elements to measure the HF patient's situation are defined by literature. These include the patient's demographics, status of HF, sleep apnea, medications, co-morbidities, and social support. While the patient is hospitalized, SLD will be assessed through the third theory, MHL's concept of health learning capacity. This is when the cognitive and depression screens will be completed. Once the cognitive state and depression symptoms are established, the second concept taken from TCM, educating and promoting self-management, is started in SLD. Thus, HF patient's process of learning can begins. These steps start in the hospital and

continue to the outpatient setting. It is currently a standard of care that all HF patients receive specialized HF education at the research sites. Another assessment of the HF patient's learning process comes from Coleman's CTI model. Before the patient leaves the hospital, the CTI will be offered to all HF patients in the study. Coordinated care will be monitored through the CTI outpatient intervention. Thus, the TCM's third concept, coordinating care crosses here with the Coleman's CTI model. Ultimately 30 day readmissions will be prevented. Understanding the concepts of SLD and CI within the merged theory will explain the needed factors to consider in transitions of care to prevent 30 day hospital readmissions.

Summary

Care for the patient with ADHF is complex. From hospital to home, these patients need a network of support to transition well. Just as the patient's needs are individualized, the patient's ability to be successful at home is also unique to the individual. The theoretical framework of this study aims to connect the complexities of heart failure patients as they transition home, with the concepts of what it takes to reduce the risk for 30 day readmission to the hospital. Transition theories like Naylor's TCM and Coleman's CTI describe transitions in general terms that then must be applied to each population and potential patient. The specific steps needed to successfully transition a HF patient who is recovering from an acute decompensated event should be studied with the multitude of patient risk factors. The theoretical framework purposed in this study strives to take into account these variables.

Helping ADHF patients to be successful at home following hospitalization is a dependent process and situational in nature as described in SLD. Ultimately, the patient's success at home is dependent on the patient and or caregiver's ability to learn and follow the discharge care plan. Thus, the ADHF patient's ability to avoid readmissions is dependent on their ability to learn. The literature and MHL suggest that the patient's cognitive state is responsible for the patient's ability to learn, yet cognition is rarely assessed in hospitalized patients. New knowledge is needed in order to develop effective interventions for the ADHF patients to avoid readmissions.

Understanding cognitive abilities and learning processes of ADHF patients through the transition home is essential.

Bringing together individual theories on transitions and learning define the variables of interest for this study. The merged theory introduces a framework that draws on ideas from learning theory and proposes that associations between factors in heart failure, cognition and readmissions that is mediated by transitions interventions involving Naylor's and Coleman's transition models.

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TABLES

Table 1. Coleman's CTI Model- the Four Pillars (Coleman et al., 2006).

Pillar:	Medication Self-Management	Dynamic Patient-Centered Record	Follow-Up	Red Flags
Goal	Patient is knowledgeable about medications and has system	Patient understands and manages a Personal Health Record (PHR)	Patient schedules and completes follow-up visit with Primary Care Provider/Specialist	Patient is knowledgeable about indications that condition is worsening and how to respond
Hospital Visit	Discuss importance of knowing medications	Explain PHR	Recommend Primary Care Provider follow-up visit	Discuss symptoms and drug reactions
Home Visit	Reconcile pre- and post-hospitalization medication lists Identify and correct any discrepancies	Review and update PHR Review discharge Summary Encourage patient to share PHR with Primary Care Provider and/or Specialist	Emphasize importance of the follow-up visit Practice and role-play questions for the Primary Care Provider	Discuss symptoms and side effects of medications
Follow-Up Calls	Answer any remaining medication questions	Discuss outcome of visit with Primary Care Provider or Specialist	Provide advocacy in getting appointment, if necessary	Reinforce when/if Primary Care Provider should be called

Table 2. Comparison of 3 Theoretical Frameworks

	Concepts	Application	Time Frames	Roles	Research Support
Transitional Care Model (Naylor)	1) Assessments and evidenced based plans occur in the hospital, 2) regular home visits with 7-day-a-week telephone, 3) Continuity of care by communicating with the outpatient providers, 4) all patient's needs are managed, 5)active patient engagement with educative/supportive activities, 6) patient or caregiver is trained to recognize early identification of symptoms to avoid hospital admissions, 7) multidisciplinary approach includes patient and family on team, 8) physician and nurse collaborate, 9) communication to, between, and among the patient, family caregivers, and health care providers.	Transition from Hospital to Home	First visit within 48 hours. Follow for two months	Tran-sitional Care Registered Nurse (APRN)	Since 80s
Care Transitions Intervention (Coleman)	4 Pillars: 1) medication self-management, 2) a personal health record maintained by the patient, 3) assuring timely primary care follow-up, and 4) patient/caregiver education regarding "red flags," specific signs or symptoms of a worsening condition and how to respond	Home inter-vention to keep out of hospital	Importanc e of assessme nt of capability to learn	Transition Coach (RN)	Since late 90s
Model of Health Learning (Wolf)	The dependent model of 1) Health learning capacity, 2) health knowledge, 3) health behavior, 4) health outcomes	First visit within 72 hours. Follow for one month	Ongoing across the continuum	Patient & Educator	Since 2009

FIGURES

Figure 1. Naylor's Transitional Care Model (TCM) (M. D. Naylor et al., 2004).

Figure 2. Wolf's Model of Health Learning (MHL) (Wolf et al., 2009).

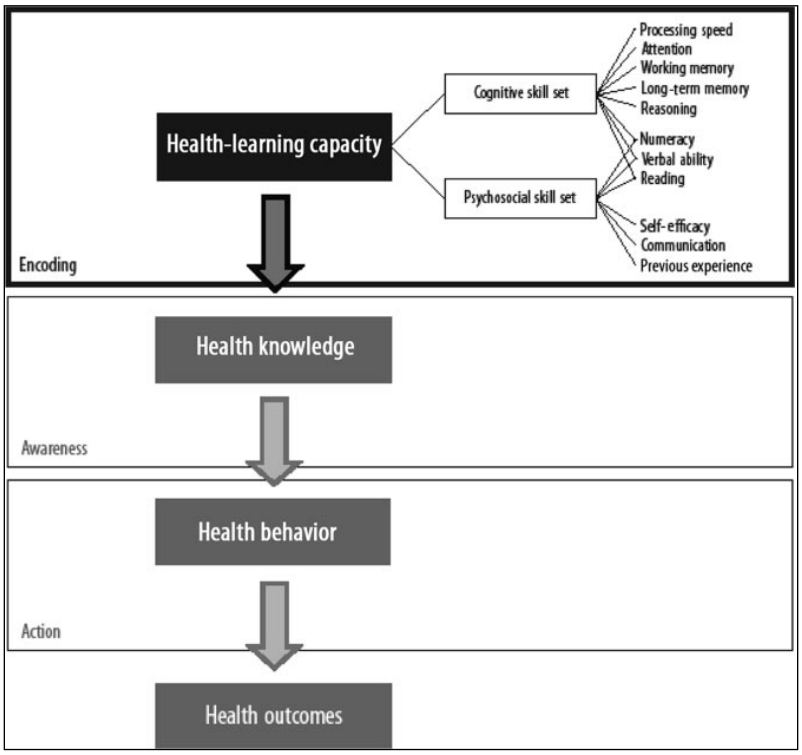
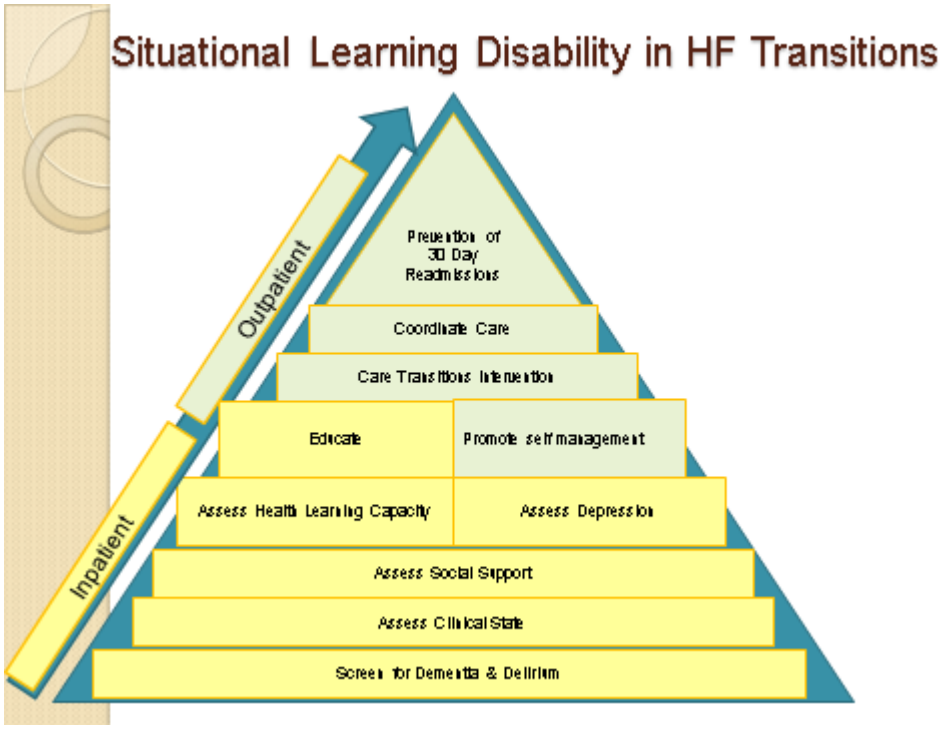


Figure 3. The Merged Model



Chapter 4

Methods

Methods

Problem Statement

Readmission reduction strategies have focused on improving self-care behaviors of heart failure (HF) patients. Patient education that occurs while HF patients are recovering from an acute hospitalization has shown to result in some decrease in readmissions (Koelling, Johnson, Cody, & Aaronson, 2005). However, not all patients are able to learn while they are acutely ill (Wolf et al., 2009). Currently in acute care, adult HF patients' cognition affects their ability to learn. However, cognition is not assessed routinely. It is reported that 25% to 50% of people with HF in the outpatient setting are likely to live with some degree of CI (Pressler, 2008). Little evidence is available about the characteristics of CI in acute decompensated HF (ADHF) patients (Arslanian-Engoren et al., 2014). To date, there is one study that describes the trajectory and character of CI changes in the context of transition from the hospital following an ADHF event (Kindermann et al., 2012).

While CI is associated with increased risk of readmission, the specific characteristics and related demographics in comorbid HF and CI have not been studied. The dynamic is complex because readmissions are related to multiple factors. These include: the presence of other co-morbidities, social support, specialized education focused on self-care activities, and an individualized care plan that addresses perceived barriers in transition from hospital to home (Barnes, Alexopoulos, Lopez, Williamson, & Yaffe, 2006; Koelling et al., 2005; Riegel et al., 2012; Thornhill, Lyons, Nouwen, & Lip, 2008). Additionally, although depression is found in 70% of those with HF (Foster et al., 2011) it is not routinely assessed on HF admissions. Depression has been shown to affect HF patients' processing speed and executive function, two domains of cognition, in the outpatient setting (J. Cameron et al., 2010). Depression is also an independent predictor of cognitive decline irrespective of HF status (Foster et al., 2011; Pullicino et al., 2008). Depression therefore must be measured when studying cognition.

Little is known about the pattern of change over time in CI during an ADHF event. Defining which CI characteristics exist in patients with ADHF will guide nursing interventions that prepare patients for the transitions from hospital to home and will contribute to prevention of 30-day readmissions. Thus, findings from this study are likely to have a major impact on healthcare costs and mortality associated ADHF. The purpose of this study is to describe the cognition state of adults with ADHF who are admitted to the hospital.

The specific aims of this study were to:

1. Characterize patterns of cognition and depressive symptoms of HF patients at three time points: after 48 hours of hospital admission, within seven days of hospital discharge, and 30 days post discharge. *Hypothesis 1: Cognitive impairment and depressive symptoms will be evident in the hospital and improve with time from discharge.*

2. Determine if change in fluid volume status from 48 hours of hospital admission to 30 days later is independently associated with change in cognition status from 48 hours of hospital admission to 30 days later. *Hypothesis 2: After controlling for demographic (age, gender, marital status) and clinical variables (length of hospital stay, comorbidities [as measured by Charlson Comorbidity Index [CCI], medications), change in fluid status (as measured by change in ankle edema, jugular vascular distention [JVD], hepatojugular reflex [HJR]), and daily weight from hospital admission to hospital discharge will be independently associated with change in cognition from hospital discharge to 30 days later.*

3. Identify variables present during hospitalization that are correlated with cognition at hospital discharge and at 30-days post discharge. *Hypothesis 3: When demographic and clinical variables are considered, the patient's status of HF (as measured by NYHA classification), diagnosis of sleep apnea (as measured by chart review), medications (as measured by chart review), co-morbidities (as measured by the CCI), depressive symptoms (as measured by PHQ-9), social support (as measured by the Medical Outcomes Study Social Support Survey*

Instrument (MOS-SSS) and HF self-care behaviors (as measured by SCHFI) will be independently correlated with cognition.

4. Identify variables present during hospitalization that are correlated with likelihood of 30-day all cause readmission. *Hypothesis 4: Cognition (as measured by inpatient MoCA scores), depressive symptoms (as measured by PHQ-9), medical comorbidities (as measured by CCI), social support (as measured by MOS-SSS), length of hospital stay, HF self-care behaviors (as measured by SCHFI), and receiving the full specialized nursing intervention (as measured as received patient education and four contacts with the ON) aimed at successful transmission from hospital to home will be independently correlated with 30-day all cause readmission rates.*

Design

This was a descriptive, correlational, longitudinal design to study cognitive function and 30-day all cause readmission in adult ADHF patients.

Setting. The research site was Scripps Health in San Diego, CA. This is a five hospital system that cares for over 1,000 diverse HF patients annually. This setting was selected because the researcher has access to this location and there is strong leadership support for this study. The target population includes all adult HF patients hospitalized with an acute exacerbation; all such patients at the five Southern California Scripps hospitals were accessible to the researcher. Three sites will be the enrollments sites. Patient participants will be enrolled in the hospital and followed after discharge home.

Sample size. For this study, the goal was to enroll a convenience sample of 100 patients aged 50 and older, who were admitted to the hospital with HF. Using G-power, a priori power analysis indicates that the proposed sample size should be sufficient for linear regression needed in Aim #4. A sample size of 89 would have allowed detection of medium effects (d = .15) in a linear regression including seven predictor variables, with alpha set at .05 and power set at 0.95. With 100 patients, the independent variable of 30 day readmissions would have

been analyzed with the seven predicted independent variables, to detect a medium (Cohen's f^2 = 0.15) effect size, at an alpha of 0.05 and power of 0.95. One hundred patients would have surpassed the reported numbers in studies with repeated measures of cognition assessments were conducted (Z. S. Nasreddine et al., 2005; Stanek et al., 2009; Uprichard, Kupshik, Pine, & Fletcher, 2009). Previous research studies that examined the relationship of similar cognitive tests to biologic parameters in HF samples used Pearson's correlation and yielded medium to large effect sizes ranging from 0.20 to 0.56 (Foster et al., 2011; Riegel et al., 2002). Also, to determine the potential effect size of changes over time in cognitive assessments, the PI calculated the Cohen's d value for changes in cognitive function as small as one point, as measured by the Montreal Cognitive Assessment (MoCA). A one-point change in MoCA scores yielded a large effect size (d = .44) (Becker, 1998). If the patient's MoCA score was on the border of the cut-off number, a one point difference is meaningful to the patient's cognitive status. Thus, a medium effect size should be sufficient to identify both changes over time in CI and variables related to CI.

Inclusion and exclusion criteria. All patients met the following inclusion criteria: 1) HF as a primary admitting diagnosis, and 2) New York Heart Association (NYHA) Classification ≥ Class III: In ADHF, acute symptoms are present in class III and IV HF. Class II HF exhibits mild symptoms and typically does not require hospitalization.

Patients were excluded if they had:

1) Age younger than 50 years old. Other causes of HF (i.e. viral, postpartum, drug-induced, or idiopathic cardiomyopathy) occur in younger populations and induce different physiological mechanisms related to CI.
2) Inability to speak or read English or Spanish, due to the limitations of the tools and researcher to assess and communicate with the patient.
3) A documented diagnosis of psychological disorders other than depression or anxiety: Depression is very common in HF patients with CI; anxiety is highly comorbid with

depression. Tools will be used to measure depression and anxiety. Presence of other psychological disorders for exclusion will be assessed by history of diagnosis by chart review.

4) Known dementia by history of diagnosis or a positive dementia screen. The goal was to study those HF patients without a known history of CI. A positive on the Watson's Clock Drawing instrument was a positive dementia screen. Patients were screened for treatment of memory issues with medications.
5) Presence of delirium at admission (Confusion Assessment Method (CAM) greater than three). Those in delirium would have not been able to complete the cognitive assessment and were excluded from the study.

Instruments

There were seven established testing instruments used in this study, along with two screening instruments and four established clinical assessments. Instructions and samples of each of these are included in the Appendix. The screening instruments 1) Watson Clock-Drawing Test, and 2) Confusion Assessment Method (CAM). The testing instruments are: 1) MoCA; 2) Trail Making A & B (TMT); 3) Patient Health Questionnaire (PHQ)-9; 4) Brief Symptom Inventory-Anxiety (BSI-A); 5) Medical Outcomes Study Social Support Survey Instrument (MOS-SSS); 6) Self-care Heart Failure Index (SCHFI); and 7) Charlson Comorbidity Index (CCI). The four established clinical assessments for fluid volume are: 1) Evaluation of ankle edema; 2) Evaluation of jugular venous distention (JVD); 3) Evaluation of hepatojugular reflex; and 4) Daily weight.

Watson's Clock Drawing. Dementia was screened using the Watson's Clock Drawing. A documented diagnosis of dementia or a score greater than four on the Watson clock-drawing test indicates likely dementia. The patient was asked to draw the hands to indicate a time in a pre-drawn eight centimeter diameter circle. Instruction for the clock drawing and scoring procedures are scripted in the instrument. A score of zero to three is normal and a score greater

than four up to seven indicates dementia. If the patient failed this test as indicated by a score of four of more they were excluded from the study. The mean sensitivity is 85% and specificity 85% (Shulman, 2000).

Confusion Assessment Method (CAM). The CAM screens for the presence of delirium. A score greater than three indicates delirium. The CAM is a standard method to score observations made before, during, and after interaction and interview with the patient (Inouye et al., 1990). The following were assessed to be yes or no for the four categories: 1) Acute onset or fluctuating course of an acute change in mental status with evidence of fluctuation in the degree of symptoms; 2) Inattention defined as difficulty focusing attention (being easily distractible, or failing to focus on the discussion or sustain an effort); 3) Disorganized speech defined as patient's speech disorganized or incoherent; such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching of subjects; 4) Altered level of consciousness defined as patient's level of alertness either hyper-alert (vigilant, overly sensitive to environmental stimuli, easily startles) or hypo-alert (lethargic, stupor, drowsy, difficult to arouse). For a positive CAM, numbers one & two both must be present and only one of numbers three and/or four must be present. The CAM can detect delirium with a sensitivity of 94% (95% CI 91-97%) and specificity of 89% (Wei, Fearing, Sternberg, & Inouye, 2008).

The Montreal Cognitive Assessment (MoCA). The MoCA is a primary evaluation of the domains of cognition. Recent research shows that the MoCA is the most sensitive and specific tool for measuring mild CI (MCI) (Z. C. Nasreddine, H. , June 2009). Prior to development of the MoCA, the gold standard to measure cognition was the Mini Mental State Exam (MMSE). The MoCA was developed from the MMSE by Dr. Nasreddine et al. in 2003. At that time there were emerging treatments for Alzheimer’s Disease (AD) and as a neurologist, Dr. Nasreddine and his colleagues were very interested in detecting the earliest signs of CI that could lead to dementia (Z. Nasreddine, Collin, I., Chertkow,H., Phillips N., Bergman H., & Whitehead V. , 2003; Z. C. Nasreddine, H. , June 2009). The key finding in the MoCA validation

was that patients screened positive for MCI 73% of the time when they performed in the normal range for MMSE (Z. S. Nasreddine et al., 2005).

Properties. The MoCA measures cognition with seven cognitive subtests. The cognition domains assessed are: visuoconstructional skills and executive function, memory, language, attention and concentration, conceptual thinking, calculations, and orientation. Scores range from zero to 30, with higher scores indicating better cognition. Scores from the MMSE were compared to the MoCA to develop a cut-off score of less than 26 to correctly identify MCI and AD correctly 90% and 100% of the time, respectively (Z. S. Nasreddine et al., 2005). The specificity is 87% & sensitivity 90% to identifying MCI (Z. S. Nasreddine et al., 2005). The one page tool measures each domain separately and usually takes only ten minutes to complete. In English, the tool has three versions and is used in repeated measures. Across the versions there are differences in each domain to avoid learning behavior except for orientation and the second assessment in attention. In the validation study of Nasreddine et al. (2005), high internal consistency (Cronbach's alpha = 0.83) was reported.

To date, 109 published articles on MoCA have spanned research of tools in 17 different languages and across 15 patient populations, including HF. The MoCA has been used in several studies of stable HF patients in outpatient settings. Cameron et al. (2010) compared the MoCA to the MMSE in outpatient HF adults age 45 and older in Australia, and confirmed that the MoCA is superior to MMSE in recognizing MCI in HF patients. Two other groups (Athilingam et al., 2011; Harkness, Demers, Heckman, & McKelvie, 2011) used the MoCA to assess outpatient HF patients aged 50 to 89. Both groups demonstrated that the MoCA performed well in stable HF patients to identify the presence of MCI. Based on the MoCA's ability to measure MCI, its ease of use, and its accessibility, the MoCA was the best tool for this study. The MoCA has been reported in research within the hospital setting only in part (Hajduk et al., 2013).

Trail Making A & B (TMT). The TMT is a sub-test of the Army Individual Test and has two parts A and B (Reitan, 1955). In Part A, the patient is asked to draw a line connecting 25

numbered circles consecutively from low to high (Reitan, 1955). In Part B, the patients asked to connect numbered and lettered circles alternately and consecutively, for example, from one to A, then to two to B and so on (Reitan, 1955). The time it takes to complete Part A and B respectively is measured in seconds (Reitan, 1955). It was first recognized that those with brain damage also had worse scores by Armitage in 1946 (Arbuthnott & Frank, 2000). The validity of recognizing differences in brain function was confirmed in 1955 by Reitan (Arbuthnott & Frank, 2000). He tested matched pairs (one with and one without brain damage) and found a statistically significant between-group difference ($p<.001$) with those having brain damage taking longer to complete Parts A and B (Reitan, 1955). Since then, TMT results have been studied to show that longer times on the TMT provided an evaluation of the specific domains including cognition, specifically attention, concentration, executive function, memory, and language (Arbuthnott & Frank, 2000; Sanchez-Cubillo et al., 2009).

Properties. The tests are scored as the number of seconds required for completion of TMT A and TMT B (Reitan, 1955). Independently, longer seconds in TMT A and TMT B have important meanings. Longer TMT A results mean impairment in motor control and perceptual complexity (Arbuthnott & Frank, 2000). Trail Making Test A has significant correlated relationships to the other cognitive tests including the Digit Symbol ($P<0.01$), Digit Backward ($P<0.01$), and Stroop Color-Word ($P<0.01$) scores which tests the speed of visual search brain function (Sanchez-Cubillo et al., 2009). Longer TMT B results mean impairment in the ability of set-switching tasks (Arbuthnott & Frank, 2000). In addition to the TMT A relationships, TMT B is significantly correlated to the Switch-cost test ($P<0.01$) which overall defines TMT B to assess the ability of the working memory and manipulating information (Sanchez-Cubillo et al., 2009). An abbreviated version of TMT B is present on the MoCA (Z. S. Nasreddine et al., 2005).

The TMT as a whole is a useful tool that measures executive function through analyzing the results in a TMT B to A ratio (Arbuthnott & Frank, 2000). The TMT B to A ratio was significantly correlated ($r=0.37$; $p<0.05$) to the executive function score of the Set Switching

Task, the alternating-switch cost score (Arbuthnott & Frank, 2000). A slowed TMT B relative to TMT A indicates impaired ability to complete or change a plan (Arbuthnott & Frank, 2000). The cut-off ratio of greater than three indicates this set-switch impairment or executive function impairment (Arbuthnott & Frank, 2000). This correlation provided data to support interpreting and indexing executive function with the TMT B to A ratio. It was believed that using the full TMT to calculate a ratio provided a more thorough exploration of the cognitive domains of interest to HF patients than TMT B alone. The seconds it takes to complete TMT A and B as well as the B to A ratio were measured and compared across the three time points.

Patient Health Questionnaire (PHQ)-9. The PHQ-9 has nine questions focusing on depression and is adapted from the three page original PHQ that included major depressive disorder, panic disorder, other anxiety disorder and bulimia nervosa (Kroenke, Spitzer, & Williams, 2001).

Properties. The PHQ-9 scores range from zero to 27. Each of the nine items can be scored from zero, indicating not at all, to three indicating nearly every day. In addition to the nine questions there is an item for those who identified with any problem on the questionnaire that asks “how difficult have these problems made it do work, take care of things at home, or get along with other people?” (Kroenke et al., 2001). The four cut off-points in the scoring range yield different levels of symptom severity, as follows: 1) Less than five = mild to no symptoms; 2) five to nine = mild symptoms; 3) ten to 14 = moderate symptoms; 4) 15 or greater = moderate to severe symptoms; and 5) greater than 20 = severe symptoms (Lee, Lennie, Heo, & Moser, 2012). A cut-off point of 15 is consistent with a diagnosis of major depression, with a specificity of 95% (Kroenke et al., 2001). Further, the PHQ-9 covers all symptoms that are consistent with a diagnosis of major depression, which makes it useful for clinical studies (Lee et al., 2012). The sensitivity of the PHQ-9 to diagnosing major depressive disorder with symptoms over a two week timeframe has a high sensitivity of 73% and a high specificity of 94% (Kroenke et al., 2001).

The PHQ-9 has reported an overall high internal reliability, with Cronbach's alpha of 0.89 and 0.86 in the PHQ Primary Care Study and the PHQ Obstetrics Gynecology Study respectively (Kroenke et al., 2001). Construct validity was assessed by comparing depression severity scores with functional status measurements, the Short Form (SF) 20, which showed a significant relationship between higher PHQ-9 scores and worsening functional status across six health related quality of life scales: mental, social, role, general, pain, and physical. It is known that physical depression symptoms mimic HF symptoms reported by HF patients including changes in appetite, sleep, or fatigue (Lee et al., 2012). Because PHQ-9 assesses depression through an evaluation of both physical and affective depressive symptoms (Kroenke et al., 2001), there is a potential for confounding of symptoms. However, the PHQ-9 does not overestimate the relationship between depressive symptoms and outcomes (Lee et al., 2012). Further, the PHQ-9 has been validated in the HF population in which it demonstrated internal consistency with a high Cronbach's alpha (0.83) (Hammash et al., 2013). However, because of the overlap of depressive symptoms with the somatic symptoms of HF and associated HF comorbidities, a lower cut-off score is recommended (Hammash et al., 2013). A cut-off score of greater or equal to ten yielded a sensitivity of 0.70 and specificity of 0.92 in identifying depressive symptoms (Hammash et al., 2013). A cut-off score of greater than or equal to ten is also recommended in primary care to have a sensitivity of 0.88 and specificity of 0.88 (Kroenke, et al. , 2002). Scores from the Beck Depression Inventory II were used as the criterion for comparison in this analysis (Hammash et al., 2013). A cut-off score of ten was used in this study.

Brief Symptom Inventory-Anxiety (BSI-A). The BSI-A has six questions focusing on anxiety, restlessness, nervousness, and tension. This is adapted from the original BSI which has 53 questions measuring nine primary symptoms including somatization, obsessive-compulsiveness, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation, and psychoticism (Derogatis & Melisaratos, 1983; Khalil, Hall, Moser, Lennie, &

Frazier, 2011). Although lengthy, the BSI is a favored tool in the cardiac population as the items do not include physical symptoms that may affect the validity of the measure (Khalil et al., 2011).The BSI is well tested and each subscale has demonstrated strong internal reliability with Cronbach's coefficient alpha ranging from 0.71 to 0.85 (Derogatis & Melisaratos, 1983; Khalil et al., 2011). For cardiac patients, the BSI-A and depression subscales Cronbach's alpha range from 0.82 to 0.88 in the outpatient and 0.87 in the inpatient setting (Abu Ruz et al., 2010; Khalil et al., 2011) For this study, using the anxiety subscale will be used. It is short, easy and has shown to be reliable in the cardiac population (Khalil et al., 2011).

Properties. The BSI-A scores range from zero to four. Each item is a measurement of how much distress was felt by the participant. The scoring for each item is on a five point Likert scale as follows: zero = not at all; one = a little bit; two = moderately; three = quite a bit; and four = extremely. The BSI-A score is an average of the six items with higher scores indicating greater anxiety (Khalil et al., 2011). It was found BSI-A scores up to 0.35 can be found in a healthy sample whereas BSI-A score of 1.70 were found in outpatient and inpatient psychiatric patients (Derogatis & Melisaratos, 1983). A cutoff score of greater than 0.35 was used for this study to indicate that anxiety symptoms were present.

Medical Outcomes Study Social Support Survey Instrument (MOS-SSS). Researchers show low perceived social support (PSS) in cardiac patients is an independent risk factor for readmissions or death (Chung, Lennie, Dekker, Wu, & Moser, 2011). Additionally, HF patients with low social network have an increased risk of hospital readmission (Rodriguez-Artalejo et al., 2006; Wu et al., 2013). Risk for readmission is increased when low social network status is present with either depression (2.1 times) or medication non-adherence (3.5 times) as independent risk factors (Chung et al., 2011; Wu et al., 2013). The amount of social support available to patients and caregivers of patients with HF is an important metric that affect's patient outcomes (Hwang, Fleischmann, Howie-Esquivel, Stotts, & Dracup, 2011). Measuring social support with the MOS-SSS will reveal the patient's PSS derived in their relationships

across four domains including emotional/informational, tangible, affectionate, and positive social interaction; and as a total score (Sherbourne & Stewart, 1991).

Properties. The tool has 19 questions, takes approximately ten minutes to administer, and is available in several languages including English. Each question is answered on a five point Likert scale from one being none of the time to five being all of the time; the total score is the mean of the scores for all 19 items which will range from zero to 100 with higher scores indicating higher levels of PSS. The questions cover PSS from the four functions that support can serve including emotional/informational, tangible, affection, and positive social interaction. Since its development with those who have chronic disease patients in 1991, it has been validated in health studies including those with HF patients (Cameron, Herridge, Tansey, McAndrews, & Cheung, 2006; Hwang et al., 2011; Sherbourne & Stewart, 1991). In the original study coefficient alphas ranged from 0.91 to 0.97 (Sherbourne & Stewart, 1991). The subsequent studies with the HF population report coefficient alphas ranging from 0.94 to 0.97 (Hwang et al., 2011).

Self-care Heart Failure Index (SCHFI). This tool was used to measure the patient's self-care behaviors both in the hospital and 30 days post discharge. Self-care is defined by this tool as a naturalistic decision making process that involves both choosing behaviors in order to maintain and respond to symptoms (Riegel & Dickson, 2008; Riegel, Lee, Dickson, & Carlson, 2009). The SCHFI was first available for use in the HF population in 2004 (Riegel et al., 2004). Since then, a newer version became available in 2009 that was used in this study (Riegel et al., 2009). It has a revised self-maintenance section that raised the Cronbach's coefficient alpha and the confidence subscale can now be used to measure overall confidence (Riegel et al., 2009). Each subscale is scored separately. Different dimensions of self-care behaviors are available to study within the psychological focus of this study in HF. This tool is well validated within the HF population (Cameron et al., 2010; Riegel et al., 2009; Vellone et al., 2013).

Properties. The SCHFI measures self-care behaviors through a self-reported measure of 22 items that represents three sub-scales of: self-care maintenance, self-care management, and self-care confidence. Each sub-scale has demonstrated a sufficient coefficient alpha of 0.553, 0.597, and 0.827 respectively (Riegel et al., 2009). Scoring is separate for each sub-scale with each standardized to a zero to 100 point range. The sub-scale self-care maintenance consists of ten questions and is answered on a four point Likert scale: One = never; two = sometimes; 3 = frequently; 4 = always or daily. The sub-scale self-care management consists of questions 11 to 16 and should only be scored if the patient answers yes to the question “In the past month, have you had trouble breathing or ankle swelling?” If yes, question 11 is unique in its Likert scale: One = not quickly; two = somewhat quickly; three = quickly; four = very quickly. Questions 12 to 15 are scored on a four point Likert scale: One = not likely; two = somewhat likely; three = likely; four = very likely. Question 16 is unique in its scoring of zero to four: Zero = I did not try anything; one = not sure; two = somewhat sure; three = sure; four = very sure. The third sub-scale, self-care confidence contains questions 17 to 22 and measures on a four point Likert scale: One = not confident; two = somewhat confident; three = very confident; four = extremely confident. A cut-off score of 70 or greater can be used for each sub-score with 70 or greater judged as self-care adequacy (Riegel et al., 2009). Additionally no learning has been demonstrated with repeat administration (Riegel et al., 2009).

Charlson Comorbidity Index (CCI). This tool was used to standardize the method of quantifying total comorbid diseases within the sample. The CCI was created in 1987 for the purpose of having a tool to prospectively classify comorbid conditions that could affect risk of mortality within longitudinal studies (M. E. Charlson, Pompei, Ales, & MacKenzie, 1987). In this weighted index, scores calculated from comorbidities, and age, which are then added together. A total of 16 comorbidities go into the equation and assigned a weight (0-6); then every decade between 40 and 80 adds one point to the score. In the final weighted score, higher scores indicate a larger burden of comorbid conditions (M. Charlson, Szatrowski, Peterson, & Gold,

1994; M. E. Charlson et al., 1987). The CCI has demonstrated the high correlation with other comorbidity measures (Interclass Correlation Coefficient [ICC]= 0.93) (Hall, Groome, Streiner, & Rochon, 2006). It has been validated most recently in acutely hospitalized ACS population by a receiver operator curve (ROC) analysis that compared the discrimination of the CCI for predicting mortality (Radovanovic et al., 2014). In predicting mortality, the CCI together with age was found superior to CCI alone yielding an area-under-the-curve of 0.76 for correct identification of in hospital mortality ($p < 0.001$) (Radovanovic et al., 2014). It has also been used in inpatient studies with HF (Arslanian-Engoren et al., 2014).

Assessment of fluid volume. To objectively assess fluid volume status, ankle edema, jugular venous distention (JVD), the hepatojugular reflex, and body weight were measured systematically.

Evaluation of ankle edema. Measurement of bilateral ankle edema was conducted by a trained clinician using the following standardized procedure, in which the clinician will: 1) elevate the head of the bed to 30 degrees; 2) measure each ankle's circumference at seven centimeters (cm) proximal to the midpoint of the medial malleolus with a tension-controlled measuring tape (Mora, Zalavras, Wang, & Thordarson, 2002). When comparing the ways to assess ankle edema, this method has among the highest inter-examiner reliability (ICC = 0.97) (Brodovicz et al., 2009). This tool's validity is limited outside the ability to determine ankle edema (Brodovicz et al., 2009).

Evaluation of jugular venous distention (JVD). Measurement of JVD was conducted by a trained clinician according to the following standardized procedure, in which the clinician will: 1) position the patient in a supine position with the head at a 30 degree angle; 2) stand on the right side of the patient; 3) turn the patient's chin away so he/she is looking to the left; 4) identify the jugular vein and shine a light on the neck; 5) identify the supra-sternal notch, a concavity at the top of the manubrium, near the level of the second intercostal space; 6) using cm, mark visually the vertical distance from the top of the jugular vein column to this angle and

add five cm. The jugular vein should be less than five to seven cm tall. A JVD measurement greater than seven cm tall is considered indicative of fluid overload (Butman, Ewy, Standen, Kern, & Hahn, 1993; Heywood, 2008). The JVD assessment can indicate higher right heart pressures and lower measures of cardiac performance with sensitivity (81%), specificity (80%), and predictive accuracy of elevation of high pulmonary capillary wedge pressure (81%) (Butman et al., 1993).

Evaluation of hepatojugular reflex (HJR). Measurement of HJR was conducted by a trained clinician according to the following standardized procedure: While looking at the patient's neck in the 30 degree angle, the clinician will apply gentle pressure to the right upper quadrant of the abdomen for five to ten seconds(Goldberg, 2009; Heywood, 2008). In pathologic states, the HJR causes blood pooled in the liver to flow in a retrograde fashion and fill out the internal jugular (IJ) vein, making the transmitted pulsations more apparent (Goldberg, 2009). A positive HJR is noted when there is a sustained increase in IJ vein pulsations of one cm or more that resolves within 15 seconds of the release of pressure (Sochowski, Dubbin, & Naqvi, 1990). A positive HJR test has a sensitivity and specificity for predicting right atrial pressure greater than nine millimeters of mercury (mm Hg) (0.85) and right ventricular end-diastolic pressure greater than 12 mm Hg (0.89) which are indicative of volume overload (Sochowski et al., 1990).

Evaluation of body weight. Measurement of body weight was conducted using a standing weight in pounds. Although this is obtained daily in the hospital today as standard of care for all HF patients, a standing weight on a research scale will be obtained. The hospital standard which will be followed in this study is to weigh the patient wearing only the clothes they are wearing, typically a hospital gown, without shoes. The first weight will be collected on day of data collection on the research identified scale. Once discharged, the weight will be obtained from the research scale at the following two points of measurement following the same protocol (weigh only with the clothes they are wearing with no shoes). Although trusting measurement

completed in the hospital per hospital protocol has shown to be accurate compared to being completed by a trained researcher (DiMaria-Ghalili, 2006) a consistent measurement tool will provide better accuracy in this study.

Study Variables Data Forms

Two Study Variables Data Forms were created to collect the demographic, clinical characteristics, readmission assessment data, and measurement of the specialized nursing intervention in the transitional ON intervention. Data for both forms was collected from the chart and face to face interview. The inpatient form included age, gender, medical history, medications, recent hospitalization in the prior thirty days, left ventricular ejection fraction, presence of sleep apnea, medical comorbidities, volume status, and heart rhythm. At time of the first cognitive evaluation the most recent lab values were recorded if available including electrolytes, sodium, albumin, blood urea nitrogen, creatinine, and white blood cell count. The outpatient form data was collected at the third time point, after 30 days from hospital discharge. The outpatient form included discharge location and days spent in the hospital, the readmissions assessment data, and the measurement of the specialized nursing intervention.

Summary

This study used seven instruments and four standardized assessments across three time points. Cognition was measured by MoCA and TMT A & B. Depression was measured by the PHQ-9. Anxiety was measured by BSI-A. Social support was measured by the MOS-SSS. The role of self-care was measured by the SCHFI. Co-morbidities was measured by the CCI. Standardized assessments measured ankle edema, JVD, HJR, and body weight. A chart review collected other data at the first time point including: age, gender, medical history, medications, recent hospitalization in the prior thirty days, left ventricular ejection fraction, presence of sleep apnea risk factors, medical comorbidities, volume status, heart rhythm, and lab values [sodium, albumin, blood urea nitrogen, creatinine, and white blood cell count]. The specialized nursing intervention and thirty day readmissions was measured at the last time point. This study

evaluated the cognitive state, including the presence of depressive symptoms, and potentiators of readmission during an ADHF admission and 30 days post.

Procedures

After Institutional Review Board (IRB) approval subjects were sought from three hospitals: Scripps Memorial Hospital La Jolla, Scripps Green Hospital, and Scripps Encinitas Hospital to participate based on eligibility. A convenience sample from three of the Scripps Health hospitals was selected to insure the availability of a wide, but diverse population and to insure sufficient availability of personnel to oversee study procedures. Potential participants were referred to the researcher by clinicians involved in their care at each site. Once referred, HF participants were screened for eligibility and consented by the researcher. An example of the consent is provided in the Appendix. Reviewing these records is not a violation of Health Insurance Portability and Accountability Act (HIPAA) regulations since the researcher is already part of the care team providing and overseeing care.

All qualifying participants were invited to participate. After obtaining informed consent, the researcher conducted chart reviews to determine relevant demographic and clinical characteristics (age, gender, medical history, medications, recent hospitalization in the prior thirty days, left ventricular ejection fraction, presence of sleep apnea risk factors, medical comorbidities, volume status, heart rhythm, and lab values [sodium, albumin, blood urea nitrogen, creatinine, and white blood cell count]). The CCI was also completed at this time. Then, after 48 hours of admission to a unit outside of the intensive care unit (ICU), completion of the test battery consisting of the MoCA, TMT A&B, PHQ-9, BSI-A, MOS-SSS, SCHFI and fluid overload assessment measurements was initiated in a quiet room. The inpatient data form was completed. If major depression was identified, the attending physician was notified. If the question that asks about thoughts of hurting oneself was ever positive, it counted as major depression and initiated a psychiatric consult.

After discharge, repeated testing by the researcher or the trained research assistant was scheduled within seven days and after thirty days post discharge. This comprised of the four testing instruments MoCA, TMT A & B, PHQ-9, & BSI-A, as well as, the four fluid overload assessments. At the third time point, the outpatient data form was also completed. The first time point was selected to identify the status of cognitive function while in an acute HF exacerbation. The two post-discharge time points, within seven days of discharge and after thirty days post discharge, were selected for two reasons: First, because they are associated with the greatest and lowest risk for readmission, respectively (Heart Failure Society of, 2010); second, to identify the status of cognitive function post an acute HF exacerbation within 30 days.

Each testing period was expected to take 35 min. During the hospitalization the testing period was part of their routine care. After discharge from the hospitalization the ongoing testing was additional to the patients care. It was completed in a quiet room either at their house per the research assistant or at the physician's office as part of follow-up appointment. At 30 days post discharge, the patient's chart was reviewed for any readmissions to Scripps Health. The day and reason of a readmission was recorded from the patient's chart. As part of the post thirty day data collection, one follow-up question was asked to capture if readmissions occurred outside of Scripps Health system: how many times they visited an emergency department/ urgent care, and/or hospital since their hospital discharge at the first testing.

Specialized Nursing Intervention

At each location, all patients received HF education by a nurse while they are in the hospital. An example of the education provided is in the Appendix. Every patient was eligible to receive a transition intervention called the Outpatient Navigator (ON). The ON has a goal to see all patients stratified as high-risk for readmission, and all HF patients are assessed to be high risk for readmission because it is a chronic disease. The ONs have a bachelor's degree in nursing, are Care Transition Intervention (CTI) certified, and follow the CTI intervention pathway. They follow the patient for 30 days by providing one home visit within 72 hours of

discharge followed by a weekly phone call for an additional three weeks. The ON home visit includes reviewing discharge paperwork, ensuring follow up appointments are scheduled, reconciling all medications, and setting goals with the patient for health promotion. Referrals can be made to community resources for social services. The weekly phone calls reinforce the initial home visit topics of interest, ensure repatriation to their outpatient medical provider, and help trouble shoot any barriers to successful outpatient chronic disease management. The receipt of the specialized HF educational and /or transitional nursing intervention was determined by the receipt of the specialized education intervention from the cardiac rehab nursing team was recorded as a yes or no within the hospital stay from chart review.

Analysis

Measures of central tendency (i.e. means, medians, standard deviations, and proportions) were used to describe the sample. Significance was set at $p < .05$ for all analyses.

Specific Aim #1. Characterize patterns of cognition and depressive symptoms in HF patients at three time points: after 48 hours of hospital admission, within seven days of hospital discharge, and 30 days post discharge. *Hypothesis 1: Cognitive impairment and depressive symptoms will be evident in the hospital and improve with time from discharge.*

Repeated measures statistics were used to summarize and describe separately the patterns of cognition and the patterns of depressive symptoms in HF patients from the acute HF exacerbation to hospital discharge and from hospital discharge to 30 days post discharge. For patterns of cognition, scores of the MoCA and TMT A&B tests were used; for patterns of depressive symptoms, the PHQ-9 were used. For each test, scores at each of the three time points were analyzed using multivariate repeated-measures analysis of variance.

Specific Aim #2. Determine if change in fluid volume status from 48 hours of hospital admission to 30 days later is independently associated with change in cognition status from 48 hours of hospital admission to 30 days later. *Hypothesis 2: After controlling for demographic (age, gender, marital status) and clinical variables (length of hospital stay, comorbidities [as*

measured by Charlson Comorbidity Index [CCI], medications), change in fluid status (as measured by change in weight, ankle edema, jugular vascular distention [JVD], and hepatojugular reflex [HJR]) from hospital admission to hospital discharge will be independently associated with changes in cognition from hospital discharge to 30 days later.

Multivariate linear regression modeling was used for this aim. The dependent variable was change in MoCA scores from hospital discharge to 30 day assessment. The independent predictor variables were included in the regression in three separate blocks. First, demographical variables were entered (age, gender, marital status). Second the clinical variable block was entered (length of hospital stay, medications, CCI). Third the change in fluid volume status (as measured by change in leg edema, JVD, HJD and weight) from hospital admission to hospital discharge was entered.

Specific Aim #3. Identify variables present during hospitalization that are correlated with cognition at hospital discharge and at 30-days post discharge. *Hypothesis 3: When demographic and clinical variables are considered, the patient's status of HF (as measured by NYHA classification), sleep apnea risk factors (as measured by chart review), medications (as measured by chart review), co-morbidities (as measured by the CCI), depressive symptoms (as measured by PHQ-9); and social support (as measured by the Medical Outcomes Study Social Support Survey Instrument [(MOS-SSS]) will be independently correlated with cognition.*

Cognition status was measured by MoCA scores in a two-step process. First, the bivariate relationship of MoCA scores after 48 hours of hospital admission and MoCA scores at 30-days post discharge with putative variables measured after 48 hours of hospital admission was evaluated. Based on review of the literature, these variables included: 1) HF status (as measured by NYHA classification); 2) presence of sleep apnea risk factors (as identified by chart review); 3) medical comorbidities (as measured by the CCI), 4) inpatient depressive symptoms (as measured by PHQ-9), 5) inpatient anxiety symptoms (as measured by BSI-A), and 6) *social support (as measured by the MOS-SSS)*. Bivariate relationships with MoCA

scores will be assessed with Pearson's correlation (CCI, PHQ-9, anxiety (as measured by BSI-A) and *social support (as measured by the MOS-SSS*) and Kendall's tau (HF status, medications and presence of sleep apnea risk factors). In the second step, variables that were significant at the p = 0.10 level were entered as independent variables in two separate multivariate linear regressions, one with MoCA scores within 48 hours of hospital admission and another with MoCA scores at 30 days post discharge, as the dependent variables. Variables were entered into the equation as a single block using simple forced entry.

Specific Aim #4. Identify variables present during hospitalization that are correlated with likelihood of 30-day all cause readmissions. *Hypothesis 4: Cognition (as measured by inpatient MoCA scores), depressive symptoms, anxiety symptoms, medical comorbidities, social support, length of hospital stay, self-care behaviors and receiving the full specialized nursing intervention (as measured as received patient education and four contacts with the ON) aimed at successful transmission from hospital to home will be independently correlated with 30-day all cause readmission rates.*

The same two-step process described for Specific Aim #3 was used for this aim. The dependent variable was the presence/absence of hospital readmission within 30 days of index hospital discharge. The independent variables were: cognition (as measured by inpatient MoCA scores, age, medical comorbidities (as measured by the CCI), presence of sleep apnea risk factors (as identified by chart review), social support (as measured by the MOS-SSS), length of hospitalized stay (as identified by chart review), self-care behaviors (as measured by SCHFI), depressive symptoms (as measured by PHQ-9), anxiety symptoms (as measured by BSI-A), and whether the patient received the specialized nursing intervention (as measured by chart review). The bivariate relationship of these variables with presence/absence of hospital readmission was evaluated with Kendall's tau and Pearson's correlation. Variables that were significant at the p = 0.10 level were entered into a logistic regression. Variables were entered into the equation as a single block using simple forced entry.

Threats to Validity

For this study, mediating the threats to the validity of this study are discussed within the framework of four types of validity: statistical conclusion validity, internal validity, construct validity, and external validity.

Statistical Conclusion Validity. Protecting statistical power was accomplished by using the G-Power program for each aim to choose the largest sample size needed for the study. Anticipating the desired effect size also will help to minimize risk. The smaller the effect size the larger the sample size needed to detect the small differences and avoid type one errors. A medium effect size was selected for this study and used in G-power to calculate the sample size. Reliability of measures has been supported by using validated tools, training by a cognitive specialist and having plans to minimize distractions during testing. The patients were tested in a private room with the door closed or in an area where conversations cannot be overheard by others. All data was collected by the researcher or trained research assistants. The PI and /or designees received special training on how to complete the clinical assessments through instruction and return demonstration of each skill by a HF expert clinician.

Internal Validity. Patient selection was also a risk. By defining the initial testing time period 48 hours from admission to a non-ICU, it provided an opportunity for the ADHF patients who transfer from ICU an opportunity to participate. Additionally, this timeframe was chosen because once the patient is out of ICU, the nurses continue acute treatment, begin teaching the patient and preparing them for discharge. Ideally to measure the cognitive state of someone in ADHF, the patient would be first tested in the emergency department upon diagnosis of ADHF. However, upon presentation of severe ADHF symptoms, cognitive testing is not a priority. Rather stabilization of the patient's breathing and starting treatment of the patient's acute decompensated state are medically the first priorities (Heart Failure Society of, 2010). The potential variation of how long the patient stays in the ICU prior to the assessment may indicate

acuity of HF and other comorbid illness and will be tracked. Intensive care unit induced delirium will be controlled for by screening with the CAM assessment.

Risks associated with instrumentation were diminished. Within this design all the tools were validated within HF English and Spanish speaking patients. The tools were validated within repeated measures studies as well. All the instruments were validated within HF patients. The validity of the MoCA in repeated measures was accomplished through the use slightly different validated versions for use in repeated testing within the same patient.

Because this was a longitudinal study, attrition was problem and posed a threat to internal validity of some aims because of lower sample size. However, patients who were lost to follow-up did not differ from those who complete the study. Some patients were lost to follow-up because they died, left the health-care system, or decided to drop out of the study. To account for this, the PI had planned for an enlarged sample size.

Construct Validity. This ensured that the studies operations match the theoretical framework. In this study three theories were merged to define the concepts of study. The threats of mono-operational and mono-methods were addressed by using different instruments and chart review. Experimenter expectancies were mediated by having and following a standardized method. The threats of reactive self-report changes were a risk in the few self-report questions, particularly on readmissions outside of the research site. The threat of reactivity to experimental situation was addressed by thoughtful wording on the consent form. Since there were no other current cognitive or depressive screens available to assess ADHF patients the threat to not follow the protocol was minimal.

External Validity. This concerned with the ability to generalize findings to other settings and persons. The ability to generalize these findings to inpatient ADHF patients should be high given the inclusion criteria of the study and homogeneity of the sample. Generalization is for English speaking patients only as we had no Spanish speaking only patients participate. These outcomes were measures at baseline for the patients in ADHF. Using the tools and approach to

measure cognition in the future is highly likely. The multiple tests within the hospitalization did not prove to be fatiguing; however the assessment lasted on average 30 to 45 minutes. The external validity could be increased by replication of the findings in larger trials.

Summary

This study's strength was in its novelty. There was little knowledge of the state of cognition in ADHF patients in the hospital. Only one study in Europe has studied CI over time from in the hospital and 30 days post discharge (Kindermann et al., 2012). Strength of the research design included the researcher's unique access to the population of interest over time, the availability of validated tests to measure variables of interest, the longitudinal nature of the study, and the incorporation of current clinical practices (i.e. use of clinical data from the work-up of HF patients was within the standard of care). Other designs were considered for studying the cognitively impaired HF patient in the hospital including cross sectional designs and experimental designs. However, in looking at how cognitive function affects learning, how the ability to learn affects self-care behaviors, and how these effect readmissions, it was apparent that the patient must be followed over time.

Ethical Aspects of Proposed Research

Process of obtaining consent. Patients were admitted to the hospital from many cardiac offices. In an effort to pre-consent to the hospital setting, HF patients were informed of the study and consented to participate if willing while in the physician's office by the Principle Investigator (PI) or designee. Once in the hospital, if not informed, and upon arrival to a non-ICU unit, the patient was screened and approached to participate by the PI or designee. The PI or designee approached potential participants after the attending nurse or physician had ascertained they were interested in being in the study. No patients were approached in the ED or ICU. After explaining the study to the patient and family or caregiver (if requested), the PI or designee emphasized that the consent was voluntary and their decision to participate or to decline did not affect their care in any way. If the participant refused to participate the standard

of care was continued for the patient's HF education and discharge plan; however, contact ceased at time of discharge and the patient's data was not included in the study results. Prior to obtaining consent, the PI or designee asked the patient to verbalize his or her understanding of the study by asking: "Please tell me in your own words what you will be doing as part of this research study." The PI or designee invited questions and reviewed the consent in detail. The consent included a statement about further contact after the hospitalization. Written contact information was available to the participant if for further discussion or contact as needed. No information about the research purpose and design was withheld from the participants.

Inclusiveness of sample. Children were excluded from the study because the incidence of ADHF is extremely rare. Adult men and women of all races, ages, and socioeconomic status were included. Vulnerable subjects included the elderly and underserved minorities that were admitted to the hospital to receive care and were eligible to participate. The disease of HF affected these people as well, and the elderly were more likely to be affected by this disease. The standard of care was provided to these patients and therefore they were protected against coercion.

Potential risks. The consenting process was not found to be a limitation. All those admitted and assessed to be A&0 x3 were eligible to self-consent. There were also potential risks of this study that included psychological, social, or emotional distress resulting from self-disclosure and introspection of their self-care behaviors and emotions. The assessment process involved sensitive issues that were personal and may have caused transient distress, anxiety or concern. Social risk was associated with possible stigma related to cognitive or emotional illness. Testing within the hospitalization did not prove to fatigue participants; however, the assessment lasted on average 30 minutes and was a minimal risk.

Minimizing risks. In order to minimize risks, the following procedures were followed. First, study approval was obtained from the IRB at both University of California Los angles (UCLA) and the facilities included in the inpatient assessment. All patients were consented at

the patient's bedside at a time convenient for them and when privacy was assured. The PI and /or designees received special training on their responsibility to maintain privacy, build trust and insure confidentiality. There was a trained psychiatrist available and on call for any participant who became distressed. Written referral was given to patients who screened positive for depression by their primary physician. At any point, immediate psychiatric consultation was available for order for any patient who exhibited suicidal ideation. Study nurses activated the following Suicide Assessment Plan: 1) if the patient was in the hospital, the attending physician was notified immediately for psychiatric evaluation; 2) if the patient was on the telephone, the PI or designee obtained his or her location, remain on the phone, and call 911 following the hospital policy; 3) the PI and sponsor were notified of any events and actions documented.

To minimize social risks, confidentiality was maintained. All information collected about participants will be kept in a locked drawer for five years following completion of the study and then destroyed. The subjects' risks of losing privacy or confidentiality of this data are evident because their self-care behaviors are being studied. To minimize risk all patient records were coded with anonymous identifiers. The only data that links the patient to the identifier will be the consent. This was completed by the PI or trained research assistant. Only master files have patient identifiers and will be kept in a locked drawer in the PI's office, with access limited to the PI.

Potential benefits. There were possible benefits to the participants as they were assessed closely; receive increased knowledge about themselves or their condition, either through opportunity for introspection and self-reflection or through direct interaction and learning with the researcher. Patients who screened positive for depressive and cognitive symptoms received a referral to their primary doctor or cardiologist for further screening, diagnosis, and treatment. The results of this study will be used to improve HF care in the future.

Conclusions

Characterizing patterns of cognition and depressive symptoms in hospitalized HF patients was hypothesized to be different over time. Determining the relationship of the physiologic changes and the cognitive state of the acute decompensated HF from hospital admission to 30 days later was believed to be significant. Important variables present during hospitalization that were correlated with cognition in the hospital and at 30-days post discharge were identified. And, variables present during hospitalization that were correlated with likelihood of 30-day all cause readmissions were found.

This research study aimed at understanding the relationship between the patient's cognitive status and their status of heart failure. Other studies have looked at patient's ability to learn, their cognitive status within the outpatient world of HF, and in relation the severity of the HF illness. These have been looked at in isolation, with tests that are not sensitive to the more mild forms of CI, and in relation to mortality. There have been few studies with designs to study concepts over time and in relation to each other. This was why these concepts must first be described, and followed over time in order to understand how the complexities of these patients affect their ability to learn, and ultimately their discharge plan and potential for readmission.

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Chapter 5

Results

Results

Study Cohort- Screening

Data collection took place between April 2016 and June 2018. Of the heart failure (HF) patients who were hospitalized at one of the three eligible sites, 795 HF patients were available for study (Figure 1). Of those, 394 were screened and 268 were ineligible for enrollment due to the following reasons: 1) Intensive Care Unit admission (n = 139), 2) the presence of an existing mechanical heart implant (n = 36), 3) deemed too sick by their provider to live 30 days (n = 24), 4) prolonged hospitalization for greater than one week and resolved acute decompensated HF (ADHF) (n = 19), 5) known altered mental status (n = 14), 6) resided outside San Diego County and would not return for follow-up appointments (n = 11), 7) current HF diagnosis ruled out (n = 9), 8) already enrolled in the study and were experiencing a readmission at time of screening (n = 9), 9) did not meet study age criteria (n = 6) 10) not fluent in English or Spanish (n = 3), and 11) had a known psychiatric disorder (n = 1). Thus, 126 individuals were eligible for enrollment. Of those, 28 were discharged before an invitation to participate could be extended. A total of 98 offers were made to potential participants to enter the study. Of the 98, 58 individuals agreed to participate. Of those, four failed the pre-enrollment screen and were not consented. All four of the individuals who failed screening were unable to draw a clock. These four patients did not have altered mental status and had no known history of dementia. Inability to draw a clock is sensitive to cognitive impairment at baseline (Shulman, 2000) and was *a priori* exclusion criterion.

Fifty-four participants were consented and started the study. One participant did not complete the initial intake session and subsequently withdrew from the study. Therefore, 53 participants completed the first intake session. Of those, 44 continued in the study and completed the second intake session within one week following discharge. The nine losses were due to: follow-up (n = 3), withdrawal (n = 3), in-hospital death (n = 2; causes were sepsis and HF), and in-hospital stroke with subsequent deficits incompatible with continued

participation (n = 1). Of the 44 who completed the second intake session, 40 continued in the study to complete the third intake session. The four additional losses were due to deaths (n = 2) and losses to follow-up (n = 2).

Study Participant Characteristics

Participant characteristics are described in Tables 1 to 6. A total of 53 participants (38 [70.4%] male; 15 [28.3%] female) completed the initial intake. Age ranged from 51 to 99 years, with a mean of 73.77 ± 11.28 years; 35 (66%) were married. The only significant difference between completers and non-completers was albumin level, which was lower in the non-completer group (p = .031; Table 2). All labs had some degree of abnormality in the sample (Table 2). Over half the sample had abnormalities showing anemia (males 65.8% [n = 25]; females 73.3% [n = 11]). Blood urea nitrogen (BUN) was impaired in 86.8% (n = 46) with 34% (n = 18) having impairment greater than 43 mg/dl. For each participant, heart rhythm at time of initial intake was recorded; almost half (43.3%) presented with sinus rhythm, and 35 participants (64.8%) presented with atrial fibrillation or flutter. Seven participants had a paced rhythm (13.2%) (Table 3). All participants completed the initial intake while experiencing an exacerbation of HF, which was reflected in the coding of New York Heart Association (NYHA) classification III or IV. One participant was coded as NYHA II even though he/she was admitted and diuresed for HF exacerbation. The majority of the sample had reduced ejection fraction HF (n = 39; 73.6%). Thirteen (33.3%) had a documented ejection fraction of less than 25%, which is considered to be an indicator of end stage HF (Festa et al., 2011; Pressler, Kim, Riley, Ronis, & Gradus-Pizlo, 2010) (Table 3). In this sample, 22.6% (n = 12) entered the study during a 30-day hospital readmission visit. Discharge location of the sample can be seen in Table 1. Mortality of participants was a barrier to participants finishing the study: two died in the hospital, and two more died before 30 days. Thirteen more died after their data collection. Thus, a total of 17 participants (31.5% died during the study (Table 4).

The most common reason for hospital readmission was ADHF (Table 4). Even though they did not experience hospital readmission, another 11 participants (20.8%) had an emergency department (ED) visit within the 30 days following discharge. Reasons for ED visits were not collected; however two participants went on to be admitted and one participant went to the ED twice. The remaining eight participants were treated and discharged from the ED.

Cardiomems is an implantable pulmonary artery pressure reader used in outpatient management to reduce HF admissions (Ayyadurai et al., 2019; Heywood et al., 2017). To qualify for the device, patients must have experienced a hospital admission. By end of the current study, 20.8% of all study participants had received a Cardiomems device (Table 4). Following discharge, 15 (27.8%) participants, none of whom had a Cardiomems device, were readmitted within 30 days.

Pre-admission and discharge medications varied slightly even though the overall count of prescribed medications remained relatively the same (Table 5). As expected in HF, the top prescribed medications were loop diuretics (90.6%), beta blockers (69.8%), statins (54.7%) and aldosterone agents (47.2%). However, only 13 (24.5%) participants were discharged on an ACE-I or ARB class medication. Charleston Comorbidity Index (CCI) ranged from four to 13 points with an average of 8.36 ± 2.2. Twenty-six (48.1%) participants had more than 10 comorbidities with an average of 10.9 ± 3.9 (Table 6). Over half of all participants (n = 35; 66%) had acute renal and/or a chronic renal comorbidity. Nine participants (16.7%) survived cardiogenic shock during their stay and enrolled in the study after leaving the intensive care unit.

Specific Aims

Specific Aim #1. Characterize patterns of cognition and depressive symptoms in hospitalized HF patients at three time points: within 48 hours of hospital admission (T1), within seven days of hospital discharge (T2), and 30 days post discharge (T3). *Hypothesis 1: Cognitive impairment and depressive symptoms will be evident in T1 and improve by T3.*

Specific Aim #1 Results. Forty participants completed all three time points and were used in the repeated measures analysis. At T1, Montreal Cognitive Assessment (MoCA) test scores ranged from 10-29 and averaged 24.45 ± 3.58. No one had a perfect MoCA of 30 at T1. Only 16 participants (40%) achieved normal MoCA scores (i.e. ≥ 26). Twenty three participants (57.5%) achieved MoCA scores consistent with mild cognitive impairment (CI) (i.e. scores of 18-25). Only one participant (2.5%) met MoCA criteria for moderate cognitive impairment (10-17), with a score of ten, which also met criteria for Alzheimer's range cognition (≤ 16) (Figure 2).

At T2, the MoCA administration showed a slightly improved range of 12-30 and no meaningful change in the average score of 24.27 ± 4.12. The frequency of participants who achieved normal MoCA scores (≥ 26) grew slightly to 19 participants (47.5%). Thus, a majority (52.5%) still had abnormal MoCA scores at T2. Of those, 17 participants (42.5%) showed evidence of mild cognitive impairment, and four (10%) demonstrated moderate cognitive impairment. Three of the four had MoCA scores in the Alzheimer's range.

At T3, the range of MoCA scores moved by one point to 13-30, with an average of 25.28 ± 3.85. Most participants achieved normal scores at this time point (Figure 2). While 60% (n = 24) scored in the normal range, 40% (n = 16) of the sample had abnormal scores at 30 days post discharge. Fifteen (37.5%) had mild cognitive impairment and one participant had a score of less than 16, i.e. in the Alzheimer's range.

Using multivariate repeated-measures analysis of variance analysis, 40 participants were compared across all three time points. There was no significant change across the three time points (Figure 3). In a similar analysis of the seven cognitive subscales scores, only the variable MoCA 1 sub score (i.e. Visuospatial) improved by 0.513 points from T1 to T3 (n = 39) (MoCA 3-Visuospatial: F= 6.339, p=0.004) (Figure 4). This domain had 39 participants instead of 40 because only the total MoCA score, and not sub domain scores, was saved for a single participant. Across all seven domains, some participants achieved the maximum amount of points within a domain (Figure 4). However, this was least common in the memory domain with

only five participants (12.8%) attaining maximum points at T1 and only 11 participants (27.5%) attaining maximum points at T3 (Figure 5).

Across participants, some showed improvement in MoCA scores, but some got worse. Four trends of MoCA scores were identified (Figure 6). Sixteen participants started with abnormal MoCA scores and achieved normal scores by T3 (Group 1). Seven participants started with normal MoCA scores and got worse by T3 (Group 2). Eight participants exhibited abnormal MoCA scores at T1 and stayed abnormal through T3 (Group 3). Nine participants achieved normal MoCA scores throughout T1 to T3 (Group 4). Variables significantly associated with each group are presented in Table 7.

The Trail Making Test (TMT) assesses specifically for executive function (Arbuthnott & Frank, 2000). Together with the MoCA subscale for visuospatial function, this instrument was used to provide a more thorough exploration of the executive function domain in HF patients. Trail Making A scores reflect seconds to complete a simple task, while Trail Making B scores constitute seconds to complete a more complicated task involving both focus and attention.

Trail Making A and B seconds and averages can be seen in Figure 7. The TMT A at T1 includes one participant who was an outlier requiring 22 corrections. Range of required corrections, averages, and number of participants needing correction are presented in Table 8. For TMT B at T1 (n = 38), two participants started the TMT B and then refused to finish only this part of the data intake at T1. Both gave similar reasoning and stated that it was too difficult and they wanted to skip. However, they were able to complete the test and did not refuse the section on T2 and T3 intakes (both n = 40). The TMT B to A ratio was used in the analysis with a cutoff score of greater than three indicating impaired executive function (Arbuthnott & Frank, 2000). Slowed TMT B relative to TMT A indicates impaired ability to complete or change a plan (Arbuthnott & Frank, 2000). Using repeated measures analyses, 38 participants were compared across time. Range of ratios, average, and percent demonstrating scores consistent with cognitive impairment can be seen in Table 8. The TMT B/A ratio did not significantly improve

over time (Figure 8). This pattern is directly opposite of the MoCA Visuospatial sub domain (MoCA 3-Visuospatial: *F*= 6.339, p=0.004). (Figure 9).

The depression screen Patient Health Questionnaire-9 (PHQ-9) used a cutoff score of greater than or equal to 10 for the study. At T1, the average score for the total sample (n = 53) was 8.3 ± 5, with 18 participants (34%) screening positive for depression. Also at T1, eight (15.1%) of the total sample reported suicidal ideation on the PHQ-9. Two of the eight although reporting suicidal ideation, did not screen positive for depression. When comparing scores over time, only participants with complete data at all time points (n=40) were used. The average score for T1 was 7.96 ± 4.73, with 32.5% of participants (n = 13) screening positive for depression (Table 9). The score average significantly improved to 4.95 ± 3.53 by T2 (PHQ-9 SCORE-2: *F*= 12.406, p<0.001) (Figure 10). The improvement was sustained at T3. Thus, 30 days after hospitalization scores were significantly improved (PHQ-9 SCORE-3: *F*=12.406, p<0.001) compared to PHQ-9 hospital scores. Overall, by T3, PHQ-9 scores improved by 3.5 points.

Three PHQ-9 trends over time emerged within the participants (Figure 11). The most common trend was improvement over time (n = 24) (Group 1). In Group 1, the most common progress was from mild to minimal symptoms (n=8). Nine variables were associated with Group 1 (Table 9). In Group 2 (n = 5), all participants experienced worsening PHQ-9 scores over time. Eleven variables were associated with Group 2 (Table 10). In Group 3 (n = 11), from T1 to T3 PHQ-9 scores remained relatively stable. Eight variables were associated to Group 3 (Table 10).

Specific Aim #2. Determine if change in fluid volume status from T1 to T3 is independently associated with change in cognition status from T1 to T3. *Hypothesis 2: After controlling for demographic (age, gender, marital status) and clinical variables (length of hospital stay, comorbidities [as measured by CCI], medications), change in fluid status (as measured by*

change in weight, ankle edema, jugular vascular distention [JVD], and hepatojugular reflex [HJR]) from T1 will be independently associated with changes in cognition from T1 to T3.

Specific Aim #2 Results. In multivariate linear regression modeling, after controlling for demographical variables (age, gender, and marital status), clinical variables (CCI, length of hospital stay, and medications), and fluid volume status (leg edema, JVD, HJR, and weight), two variables change in weight from T3 - T1 (p = .001) and change in HJR from T3 – T1 (p = .036) were significant. Only change in MoCA was independently associated with change in weight from T3 - T1 (p = .017) (Table 11). Variables in this analysis—change of MoCA score and change of fluid volume status—are calculated values of data collected at T3, subtracted from data collected at T1 (Figure 12). Overall the model for estimated change of MoCA was not statistically significant (Change MoCA: F= 2.008, p=.067). All variables entered explain 22.1% of the variance of change of MoCA at T3. The G-Power Program suggested a sample size of 89 to allow detection of a medium effect (d = .15).

Specific Aim #3. Identify variables present at T1 that are correlated with cognition at T1 and T3. *Hypothesis 3: When demographic and clinical variables are considered, the patient's status of HF (as measured by NYHA classification), presence of sleep apnea (as measured by chart review), medications (as measured by chart review), co-morbidities (as measured by the CCI), depressive symptoms (as measured by PHQ-9); and social support (as measured by the Medical Outcomes Study Social Support Survey Instrument [(MOS-SSS]) will be independently correlated with cognition.*

Specific Aim #3 Results. In multivariate linear regression modeling, variables tested for correlations included: HF status (as measured by NYHA classification), presence of sleep apnea (as identified by chart review), medical comorbidities (as measured by the CCI), depressive symptoms at T1 (as measured by PHQ-9), anxiety symptoms at T1 (as measured by BSI-A), social support (as measured by the MOS-SSS*),* and number of medications at discharge. Different variables were found significant at each time point. At T1, two variables,

anxiety score measured by BSI (p=.002) and CCI (p=.007), were inversely correlated with MoCA scores (Table 12). In multivariate linear regression modeling, the estimated model for MoCA scores at T1 was significant (MoCA1TotalScore: F=8.604, p=.001) (Table 13). Together, the two variables explain 22.6% of the variance of T1. For T3 only CCI (p=.05) was significantly correlated with MoCA scores (Table 12). In multivariate linear regression modeling, the estimated model for MoCA at T3 was significant (MoCA3TotalScore: F=4.105, p=.050) (Table 14). The variable CCI explained 7.4% of the variance at T3. The G-Power Program suggested a sample size of 89 to allow detection of a medium effect (d = .15) in a linear regression for seven predictor variables, with alpha set at .05 and power set at 0.95.

Specific Aim #4. Identify variables present at T1 that are correlated with likelihood of 30-day all cause unplanned readmissions. *Hypothesis 4: Cognition (as measured by inpatient MoCA scores), depressive symptoms, anxiety symptoms, medical comorbidities, social support, length of hospital stay, self-care behaviors and receiving the full specialized nursing intervention (as measured as received patient education and four contacts with the Outpatient Nurse Navigator) aimed at successful transmission from hospital to home will be independently correlated with 30-day all cause unplanned readmission rates.*

Specific Aim #4 Results. In multivariate linear regression modeling, after controlling for variables at T1, including MoCA scores, age, medical comorbidities (as measured by the CCI), presence of sleep apnea, social support (as measured by the MOS-SSS), length of hospitalized stay, self-care behaviors (as measured by Self Care Heart Failure Index (SCHFI)), depressive symptoms (as measured by PHQ-9), anxiety symptoms (as measured by BSI-A), and whether an RN followed the patient, none were significant. There was a trend toward association of 30-day readmission with CCI (p=.083) (Table15). In multivariate linear regression modeling, the estimated 30-day unplanned readmission model was not significant (Readmission: F=2.723, p=.105) (Table 16). The variable CCI explained 3.2% of the variance related to the occurrence of 30-day unplanned readmission. The G-Power Program suggested a sample size of 89 to

allow detection of a medium effect (d = .15) in a linear regression for seven predictor variables, with alpha set at .05 and power set at 0.95.

Summary

Aim 1 explored global inpatient cognition (T1) and outpatient cognition (T2 and T3) using MoCA, TMT A, TMT B, and TMT B/A scores. At T1, 60% of ADHF patients in this sample were cognitively impaired. Cognition was not stagnant. Once discharged, each participant's cognition trend followed one of four tracks from T1 to T3: abnormal to normal, normal to abnormal, consistently abnormal, or consistently normal. Those who improved by T3 were less likely than others in the sample to have a 30-day readmission. Those who declined by T3 continued to exhibit depressive symptoms after discharge ($p<.05$) and were very sick in the hospital (i.e. had cardiogenic shock [$p=0.004$] and cancer [$p<.05$]). Older age ($p<.05$) and history of myocardial infarction ($p<.05$) was associated with sustained abnormal cognition scores at T3. Only the MoCA Visuospatial subdomain and TMT A improved from T1 to T3 ($p < 0.004$ and $p < 0.049$, respectively). Overall cognition did not statistically improve from T1 to T3. The most common trend occurred in 30.2% of participants, whose scores moved from abnormal at T1 to normal at T3. Overall, 40% of HF patients remained cognitively impaired at T3.

Regarding depressive symptoms, 34% of ADHF participants endorsed depressive symptoms (as measured by the PHQ-9) in the hospital. Overall, depressive symptoms significantly improved by T2 and remained improved at T3 ($p<0.001$). Once discharged, three PHQ-9 trends emerged from T1 to T3: 1) improvement in depressive symptoms, 2) worsening of depressive symptoms, and 3) no change in level of depressive symptoms. The most common trend was improvement at T3 (60%, n = 24).

The second, third, and fourth aims used multivariate linear regression modeling to explore relationships of cognition with other variables. Aim 2 focused on identification of demographic, clinical or fluid volume measurements associated with changes in MoCA scores (n=40). Changes in MoCA scores demonstrated a range of 11 points (from -5 to +6);

improvement of MoCA scores was independently and positively associated with greater weight loss from T1 to T3 ($p < .017$). Aim 3 focused on testing relationships of cognition, anxiety, and comorbidity status. We found that cognition at T1 was inversely correlated with the BSI anxiety score ($p=.002$) and CCI ($p=.007$); as a model, these variables remained significant ($p=.001$) and explained 22.6% of the variance in MoCA scores at T1. Outpatient cognition at T3 was inversely correlated with CCI ($p=.05$), and explained 7.4% of the MoCA T3 score variance. Aim 4 focused on identification of variables present at T1 that were correlated with likelihood of 30-day all cause unplanned readmissions. There was a positive trend toward independent association of 30-day unplanned readmissions with CCI ($p=.083$).

Tables and Figures

Table 1. Demographic Characteristics of the Sample

Characteristic	Total Sample (n=53) M/SD or n (%)	Completers (n=40) vs. Non-Completers (n=13) M/SD or n (%)	M/SD or n (%)	p [a]
Age	73.77 /11.28	73 /11.1	76.08 /12.1	0.402
Males	38 (71.7%)	27 (67.5%)	11 (84.6%)	0.238
Females	15 (28.3%)	13 (32.5%)	2 (15.4%)	
Married	35 (66%)	28 (70%)	7 (53.8%)	0.290
Length of Stay	8.23 /7.12	8.68 /7.99	7.08 /3.25	0.488
Discharge Measures				
Hospitalized within 30 days prior to entering study	12 (22.6%)	10 (25%)	2 (15.4%)	0.460
Nurse followed patient at discharge	13 (24.5%)	13 (32.5%)	1 (7.7%)	0.081
Discharge location:				
Home	35 (64.8%)	26 (65%)	9 (69.2%)	0.797
Home with HH	7 (13%)	6 (15%)	1 (7.7%)	
SNF	5 (9.3%)	3 (7.5%)	2 (15.4%)	
Acute Rehab	2 (3.7%)	3 (7.5%)	0	
Hospice	4 (7.4%)	2 (5%)	1 (7.7%)	

M = mean; SD = standard deviation
[a] Using t tests or Mann-Whitney U tests.
Home health (HH); skilled nursing facility (SNF)

Table 2. Baseline Laboratory Data

Labs (normal range)	Total Sample (n=53) M/SD or n (%)	Total Sample (n=53) n (%) Abnormal	Completers (n=40) vs. Non-Completers (n=13)		p [a]
			M/SD or n (%)	M/SD or n (%)	
RBC (3.92-5.65)	3.9 /.757	28 (52.8%)	4.02 /0.74	3.74 /0.79	0.240
WBC (3.4-9.6)	7.64 /3.68	12 (22.7%)	8.07 /4.02	6.31 /1.96	0.135
HCT (35.5-48.6)	36.84 /6.59	29 (54.8%)	37.38 /6.94	35.17 /5.27	0.299
HGB (11.6-16.6)	12.1 /2.11	28 (52.8%)	12.25 /2.24	11.65 /1.61	0.384
PLT (135-371)	198.43 /82.68	9 (17%)	207.88 /88.66	169.38 /53.53	0.146
Mag (1.7-2.2)	2.11 /.367	24 (45.2%)	2.12 /0.39	2.11 /0.30	0.951
Na (136-144)	139.6 /5.1	18 (34%)	139.7 /5.21	139.31 /4.91	0.392
K (3.7-5.2)	4.04 /.43	9 (17%)	4.02 /0.36	4.09 /0.61	0.722
Cl (101-111)	99.26 /6.23	30 (56.6%)	98.95 /6.43	100.23 /5.67	0.525
Co2 (20-29)	28.15 /5.11	21 (39.6%)	28.60 /5.37	26.77 /4.09	0.266
Glucose (64-100)	136 /53.51	41 (77.4%)	133.85 /44.59	142.62 /76.72	0.613
BUN (7-20)	39.74 /22.11	46 (86.8%)	36.1 /18.8	50.85 /28.08	0.097
Cr (0.8-1.2)	1.56 /.834	35 (66%)	1.39 /0.54	2.09 /1.29	0.080
Albumin (3.5-5.5)	3.61 /.523	20 (37.7%)	3.70 /0.51	3.34 /0.47	0.031*

[a] Using t tests or Mann-Whitney U tests.
Mean (M); standard deviation (SD); red blood cell (RBC); white blood cell (WBC); hematocrit (HCT); hemoglobin (HGB); platelet (PLT); magnesium (Mag); sodium (Na); potassium (K); chloride (Cl); carbon dioxide (Co2); blood urea nitrogen (BUN); creatinine (Cr)

Table 3. Cardiac Measures of Sample

	n (%)
Rhythms:	
Sinus rhythm	23 (43.4%)
Atrial fibrillation /flutter	35 (64.8%)
with rapid ventricular response (RVR)	6 (11.3%)
Sinus rhythm with block	1 (1.9%)
Paced rhythm	7 (13.2%)
Ventricular tachycardia in hospital	5 (9.1%)
Automatic cardiac defibrillator	20 (37%)
Preserved ejection fraction	29 (54.7%)
Reduced ejection fraction (<40%)	24 (45.3%)
<35%	23 (59%)
<25%	13 (33.3%)
NYHA Class II	1 (1.9%)
NYHA Class III	42 (79.2%)
NYHA Class IV	10 (18.9%)
Acute on chronic diastolic HF	23 (43.4%)
Acute on chronic systolic HF	24 (45.3%)
Acute on chronic combined systolic & diastolic HF	6 (11.3%)
Restrictive (Sarcoidosis, Amyloidosis, chronic pericarditis)	4 (7.4%)
Secondary pulmonary hypertension	17 (31.5%)

New York Hear Association (NYHA); heart failure (HF)

Table 4. Readmission, Discharge, & Survival Measures of Sample

Readmission Measures	n (%)
Cardiomems	11 (20.8%)
Pre study	4 (36.4%)
During study	7 (63.6%)
Planned Readmissions within 30 days of discharge	8 (15.1%)
Unplanned Readmission within 30 days of discharge	9 (17%)
Planned & Unplanned Readmission within 30 days of discharge	16 (30.2%)
Reason for Unplanned Readmission:	
Acute decompensated heart failure	6 (46.7%)
Confusion & Hypoglycemia	1 (6.7%)
Fall /orthostatic	1 (6.7%)
Rapid atrial fibrillation with rapid ventricular response & Pneumonia	1 (6.7%)
Emergency department visit within 30 days	11 (20.8%)
Documented non-compliance	10 (18.5%)
Survival Measures:	
Encounter for palliative care	3 (5.6%)
Do Not Resuscitate order	14 (25.9%)
Total Mortality by End of Study (2 years, 3 months)	17 (31.5%)
Dead in hospital	2 (3.7%)
Dead before 30 days	2 (3.7%)
Dead in 90 days	2 (3.7%)
Dead in 6 months	2 (3.7%)
Dead in 1 year	3 (5.7%)
Dead by 2 years, 3 months	6 (11.3%)

Table 5. Characteristics of Sample: Medications

Medication Measures	M/SD or n (%)
# Medications at Admission	11.6 /4.72
# Medications at Discharge	12.1 /5.1
Medication Classes at Discharge:	
Angiotensin converting enzyme inhibitor	8 (15.1%)
Angiotensin receptive blocker	5 (9.4%)
Beta Blocker	37 (69.8%)
Aldosterone Agent	25 (47.2%)
Statin	29 (54.7%)
Loop Diuretic	48 (90.6%)
Antihypertensive	7 (13.2%)
Anti-Anxiety	8 (15.1%)
Anti-Depressive	11 (20.8%)
Antiarrhythmic	12 (22.6%)
Nitrate	11 (20.8%)
Dobutamine/ Milrinone	3 (5.6%)

Mean (M); standard deviation (SD)

Table 6. Comorbidities of Sample

Active problems at Time 1:	n (%)
Encephalopathy	3 (5.6%)
Stroke	9 (16.7%)
Thyroid Disorder	9 (16.7%)
Diabetes (Type 1 & 2)	26 (48.1%)
Obese or Morbid Obese	11 (20.4%)
Hyperlipidemia	29 (53.7%)
Hypo-osmolality & Hyponatremia (E87.1)	11 (20.4%)
Anemia	19 (35.2%)
Depression	14 (25.9%)
Anxiety disorder	5 (9.3%)
Hypertension	43 (79.6%)
Valve insufficiency or stenosis (Mitral, Tricuspid or Both)	22 (40.7%)
Cardiogenic Shock	9 (16.7%)
Obstructive sleep disorder (G47.33)	14 (25.9%)
Pneumonia (J18.9)	3 (5.6%)
Acute respiratory failure	11 (20.8%)
Acute renal failure	27 (50%)
Urinary tract infection	6 (11.1%)
Cirrhosis, portal hypertension, Hepatorenal syndrome, Ascites, or Hepatomegaly	9 (16.7%)
Pressure ulcer	4 (7.4%)
Gout (M10.9)	10 (18.5%)
Pain (all locations)	7 (13%)
Cancer	2 (3.7%)
Sepsis & systemic inflammatory response syndrome (SIRS)	4 (7.4%)
Drug (opioid or nicotine) or alcohol abuse	4 (7.4%)
History of:	n (%)
Ischemic heart diagnosis	20 (37%)
Coronary angioplasty implant & graft (Z95.5)	14 (25.9%)
Coronary artery bypass graft (CABG) or valve surgery	13 (24.1%)
Chronic obstructive pulmonary disease (COPD), Emphysema, Asthma, Bronchitis, Pulmonary fibrosis	17 (31.5%)
Chronic renal failure	30 (55.6%)

Table 7. Correlates of MoCA Trend groups (n=40)*

Group 1: Abnormal to Normal (n=17)	Bivariate Correlations
Acute-on-chronic combined HF (yes=1, no=0)	0.463
Pneumonia (yes=1, no=0)	0.349
Liver disease (yes=1, no=0)	0.346
Glucose	0.272
Red blood cells	0.287
Chloride	0.269
MOS-SSS- Affectionate	0.309
TMT A Seconds T1	-0.271
TMT B/A Ratio T3	-0.289
TMT B Seconds T3	-0.313
30 day readmission (yes=1, no=0)	-0.318
Group 2: Normal to Worse (n=7)	**Bivariate Correlations**
Cancer	0.348
Malignant Lymphoma	0.348
Cardiogenic Shock	0.428
NYHA Class	0.337
PHQ-9 T2	-0.273
HJR Change (-1=better, 1=worse)	0.323
MOS-SSS-Affectionate	-0.308
MOS-SSS-Tangible	-0.300
MOS-SSS Overall	-0.264
Group 3: Stayed Abnormal (n=10)	**Bivariate Correlations**
Received stent during stay	0.392
Age	0.315
Biologic gender (female =1, male=0)	0.320
History Myocardial infarction	0.357
History peptic ulcer	0.320
Group 4: Stayed Normal (n=10)	**Bivariate Correlations**
White blood cells	-0.302

*All correlates significant at p<.05 as Kendall Tau coefficients
Medical Outcomes Study Social Support Survey Instrument (MOS-SSS); Trail making test (TMT); New York Heart Association (NYHA); Patient Health Questionnaire (PHQ)-9; Hepatojugular Reflux (HJR)

Table 8. Trail Making A, B, and B/A Ratio Characteristics

	Range			Average ±SD			% Abnormal n (%)		
	T1	T2 (n=40)	T3 (n=40)	T1	T2 (n=40)	T3 (n=40)	T1	T2 (n = 40)	T3 (n = 40)
TMT A Error	0-3 (n=40)	0-5	0-6	0.8 ± 3.5 (n=40)	0.33 ± 0.92	.04 ± 1.21	8 (20%) (n = 40)	7 (17.5%)	4 (10%)
TMT B Error	0-13 (n=38)	0-16	0-11	2.21 ±3.35 (n=38)	2.03 ± 3.61	1.4 ± 2.27	22 (57.9%) (n = 38)	21 (52.5%)	20 (50%)
TMT B/A Ratio	1.33-6.17 (n=38)	1.05-4.77	0.67-5.22	2.51 ± 1.02 (n=38)	2.6 ± 0.99	2.5 ± 1.2	7 (18.4%) (n = 38)	11 (27.5%)	12 (30%)

Trail making test (TMT); standard deviation (SD)

Table 9. PHQ-9 Score Trends (n=40)

	T1 n (%)	T2 n (%)	T3 n (%)
Minimal (<5)	8 (20)%	21 (52.5%)	25 (62.5%)
Mild Depression (5-9)	19 (47.5%)	16 (40%)	10 (25%)
Moderate Depression (10-14)	8 (20%)	2 (5%)	4 (10%)
Moderate to Severe Depression (>14)	4 (10%)	1 (2.5%)	1 (2.5%)
Severe Depression (>20)	1 (2.5%)	0 (0%)	0 (0%)

Table 10. Correlates of PHQ-9 Groups*

Group 1: PHQ-9 Scores Improved Over Time (n=24)	Bivariate Correlations
Age	-0.263
MoCA T1 total score	0.300
TMT A T1 mistakes	-0.459**
MoCA T3 Attention	0.321
Greater than 10 Comorbidities	0.328
Weight Change T3-T1	-0.321

T1 active problem: Hypo-osmolality & Hyponatremia (no=0, yes=1)	-0.357
T1 active problem: acute renal failure (no=0, yes=1)	0.368
History liver disease (no=0, mild=1, mod-severe=3)	-0.346
Group 2: PHQ-9 Scores Worsened Over Time (n=5)	Bivariate Correlations
Age	0.373
MoCA T1 Attention	-0.3
MoCA T1 Language	-0.32
TMT A T1 Mistakes	0.37**
TMT A T2 Mistakes	0.618
Right Ankle Change T3-T1	0.319
Discharged on a Statin medication (no=0, yes=1)	0.342
History liver disease (no=0, mild=1, mod-severe=3)	0.448**
History peptic ulcer (no=0, yes=1)	0.424**
History peripheral vascular disease (no=0, yes=1)	0.378
History of GERD (no=0, yes=1)	0.339
Group 3: Stayed in Level of Depression Over Time (n=11)	Bivariate Correlations
Married (no=0, yes=1)	-0.33
MoCA T3 Naming	-0.37
Weight Change T3-T1	0.267
T1 active problem: Septic /SIRS (no=0, yes=1)	0.372
T1 active problem: Hypo-osmolality & Hyponatremia (no=0, yes=1)	0.392
T1 active problem: acute renal failure (no=0, yes=1)	0.343
History Valve insufficiency or stenosis (Mitral, Tricuspid or Both) (no=0, yes=1)	0.343
History peripheral vascular disease (no=0, yes=1)	-0.332

*All correlates significant at p<.05 as Kendall Tau coefficients
**Variable significant at p<.001 as Kendall Tau coefficients
Montreal cognitive assessment (MoCA); Trail making test (TMT); gastro esophageal reflux disease (GERD); systemic inflammatory response syndrome (SIRS)

Table 11. Determinants of Change in Cognition Status 30 Days after Hospital Discharge*

Model	R^2	Adjusted R^2	R^2 Change	*F* Change	*F* Change Significance
Step 1	0.040	-0.04	0.04	0.495	0.688
Step 2	0.046	-0.127	0.007	0.076	0.973
Step 3	0.441	0.221	0.395	3.955	0.008
			95.0% Confidence Interval		
Variables in the Equation at Step 3	Standardized Beta	*t*	Significance	Lower	Upper
(Constant)		0.350	0.729	-6.662	9.404
Age in years	-0.133	-0.658	0.516	-0.157	0.080
Biologic Gender	-0.078	-0.387	0.702	-3.244	2.213
Marital status	-0.028	-0.167	0.869	-2.564	2.178
CCI	0.127	0.667	0.510	-0.383	0.752
Length of Stay	0.226	1.067	0.295	-0.082	0.261
Medication # at DC	0.027	0.128	0.899	-0.323	0.366
Change in RAE	-0.715	-1.685	0.103	-0.976	0.095
Change in LAE	0.566	1.350	0.188	-0.194	0.946
Change in Weight	0.663	3.636	0.001	0.051	0.181
Change in JVD	-0.146	-0.855	0.400	-0.323	0.133
Change in HJR	-0.353	-2.205	0.036	-4.025	0.149

*Linear Regression. Change of MoCA (T3-T1) is Dependent Variable in analysis.

Charleston Comorbidity Index (CCI); Discharge (DC); Right Ankle Edema (RAE) T3-T1; Left Ankle Edema (LAE) T3-T1; Jugular Vein Distention (JVD); Hepatojugular Reflux (HJR)

Table 12. Correlates of Cognition Status in at Hospital Discharge and Post 30 days Discharge*

Inpatient measures	Inpatient Total MoCA Score (N=53)	P	MoCA Score Post 30 days Discharge (N=40)	P
CCI	-0.337	.014	-0.312	.050
PHQ-9	-0.007	.962	0.198	.220
BSI-A	-0.384	.005	0.045	.781
MOS-SSS Overall	0.192	.169	0.173	.286
HF Status EF	0.087	.537	0.052	.751
HF Status NYHA	0.064	.589	-0.120	.377
Sleep Apnea	-0.072	.545	0.040	.771
Meds on Admission	-0.085	.544	0.048	.766
Meds on Discharge	-0.056	.689	0.011	.948

*Pearson's r or Kendall's Tau correlation coefficients; Charleston Comorbidity Index (CCI); Patient Health Questionnaire (PHQ)-9; Brief Symptom Inventory-Anxiety (BSI-A); Medical Outcomes Study Social Support Survey Instrument (MOS-SSS); Ejection Fraction (EF); New York Heart Association (NYHA); medication (meds)

Table 13. Determinants of Inpatient Cognition Status*

Model	R^2	Adjusted R^2	R^2 Change	*F* Change	*F* Change Significance
Step 1	0.114	0.096	0.114	6.537	0.014
Step 2	0.256	0.226	0.142	9.572	0.003
			95.0% Confidence Interval		
Variables in the Equation at Step 2	Standardized Beta	*T*	Significance	Lower	Upper
(Constant)		17.396	0.000	26.200	33.040
CCI	-0.329	-2.700	0.009	-0.911	-0.134
BSI-A	-0.377	-3.094	0.003	-2.553	-0.543

*Linear Regression. Inpatient MoCA score is Dependent Variable in analysis. Charleston Comorbidity Index (CCI); Brief Symptom Inventory-Anxiety (BSI-A) Multivariable analysis adjusted for patient risk factors, including: NYHA classification, presence of sleep apnea, CCI, T1 PHQ-9, T1 BSI-A, MOS-SSS, and number of medications at discharge.

Table 14. Determinants of Cognition Score post 30 Days Discharge*

Model	R^2	Adjusted R^2	R^2 Change	*F* Change	*F* Change Significance
Step 1	0.097	0.074	0.097	4.105	0.050
			95.0% Confidence Interval		
Variables in the Equation at Step 1	Standardized Beta	*T*	Significance	Lower	Upper
(Constant)		12.926	0.000	25.126	34.457
Charleston Comorbidity Index	-0.312	-2.026	0.050	-1.111	0.000

*Linear Regression. MoCA score post 30 days discharge is Dependent Variable in analysis. Multivariable analysis adjusted for patient risk factors, including: NYHA classification, presence of sleep apnea, Charleston Comorbidity Index (CCI), T1 Patient Health Questionnaire (PHQ)-9; T1 Brief Symptom Inventory-Anxiety (BSI-A); Medical Outcomes Study Social Support Survey Instrument (MOS-SSS); and number of medications at discharge.

Table 15. Correlates of 30 Day Readmission (N=53)*

Inpatient measures:	Planned (n=8)	P	Unplanned (n=9)	P	Unplanned & Planned (n=16)	P
MoCA Score	.176	.140	-.153	.201	0.006	.960
Age	.169	.144	.000	1.00	0.142	.215
CCI	.067	.580	.209	.083	0.210	.079
Sleep Apnea	.055	.693	.120	.387	0.095	.488
Overall Support Index (MOS-SSS)	-.980	.402	-.014	.905	-0.028	.805
Length of Stay	-.215	.067	.026	.821	-0.100	.391
SCHFI-Maintenance	.070	.552	-.090	.440	0.024	.836
SCHFI-Management	-.118	.314	-.146	.212	-0.184	.114
SCHFI- Confidence	.072	.541	-.003	.981	0.081	.489
PHQ-9	-.004	.976	.065	.584	0.007	.953
BSI-A	-.015	.902	-.121	.315	-0.133	.266
Nurse Followed at DC	-.047	.735	.071	.609	0.181	.189

* All Kendall's Tau coefficients
Montreal Cognitive Assessment (MoCA); Charleston Comorbidity Index (CCI); Medical Outcomes Study - Social Support Survey Instrument (MOS-SSS); Self Care Heart Failure Index (SCHFI); Patient Health Questionnaire (PHQ)-9; Brief Symptom Inventory-Anxiety (BSI-A); discharge (DC)

Table 16. Determinants of 30 Day Unplanned Readmission*

Model	R^2	Adjusted R^2	R^2 Change	*F* Change	*F* Change Significance
Step 1	0.051	0.032	0.051	2.723	0.105
			95.0% Confidence Interval		
Variables in the Equation at Step 1	Standardized Beta	*T*	Significance	Lower	Upper
(Constant)		-0.760	0.451	-0.561	0.253
Charleston Comorbidity Index	0.225	1.650	0.105	-0.008	0.086

*Linear Regression. 30 Day Unplanned Readmission is Dependent Variable in analysis.

Figure 1. Screening (April 2016 to June 2018)

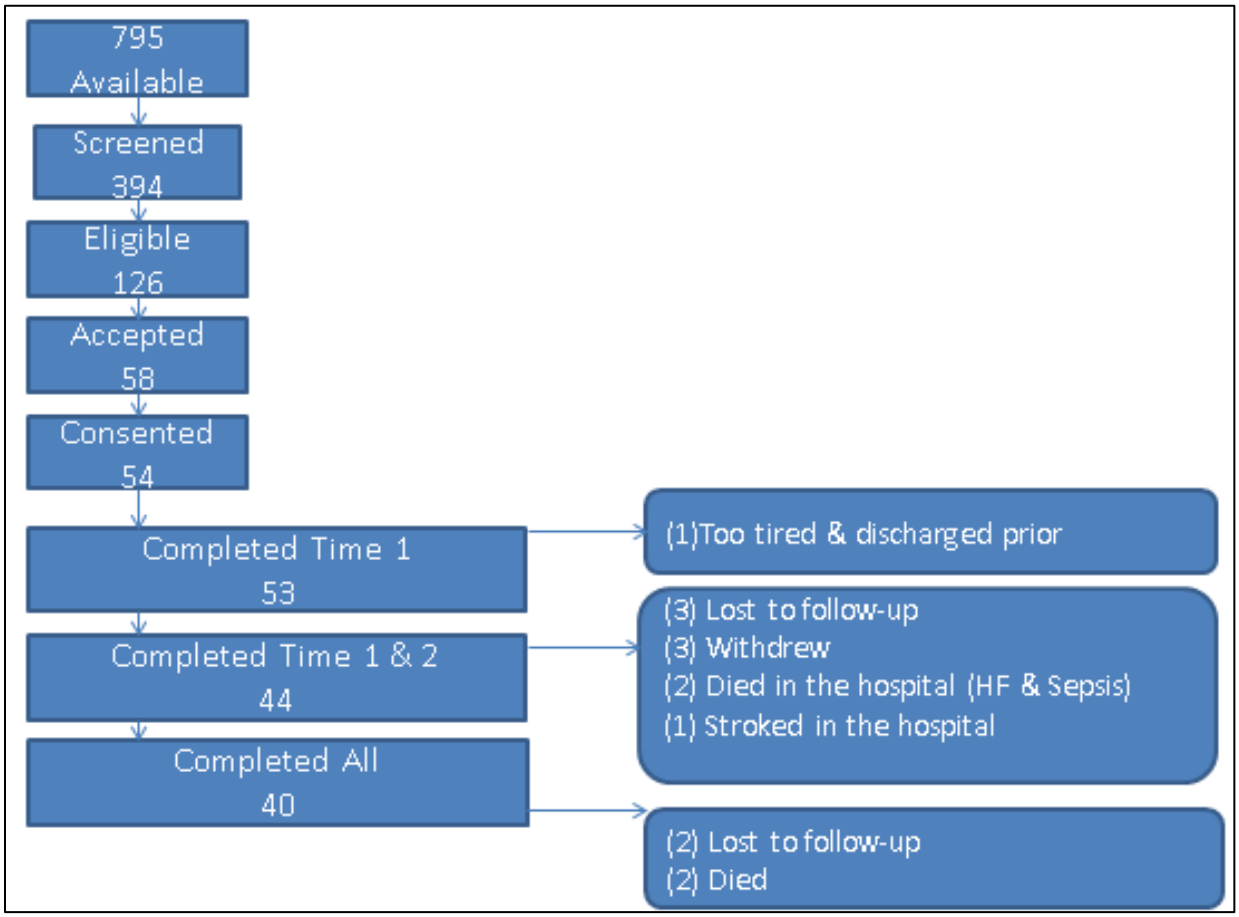


Figure 2. MoCA Score Trends (n=40)

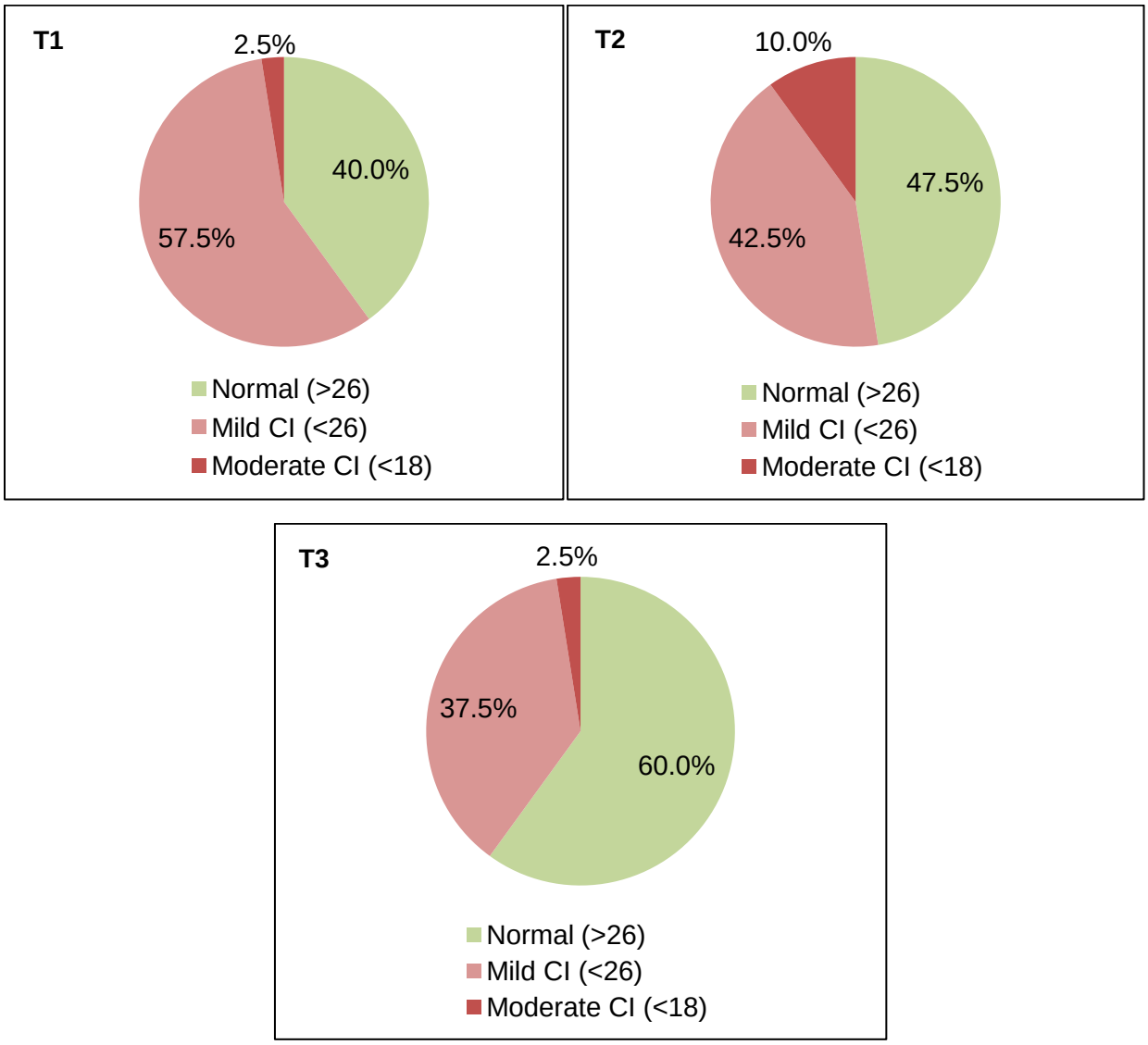


Figure 3. MoCA Mean Scores over Time

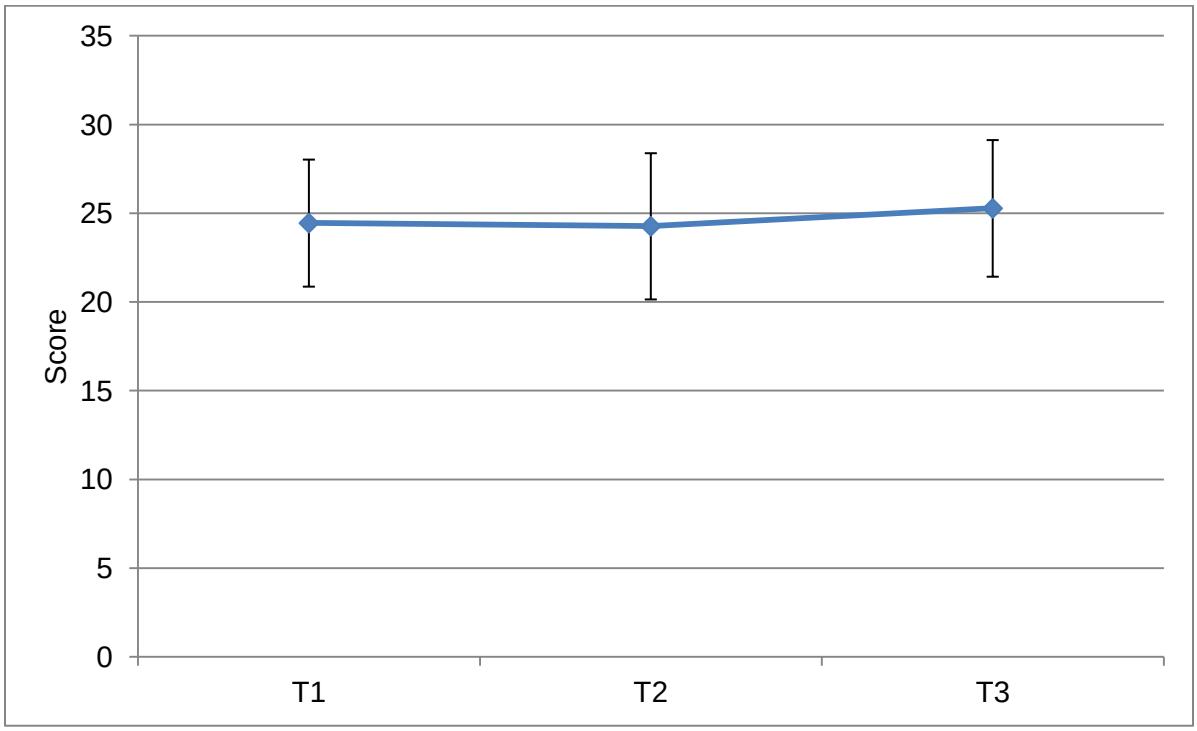
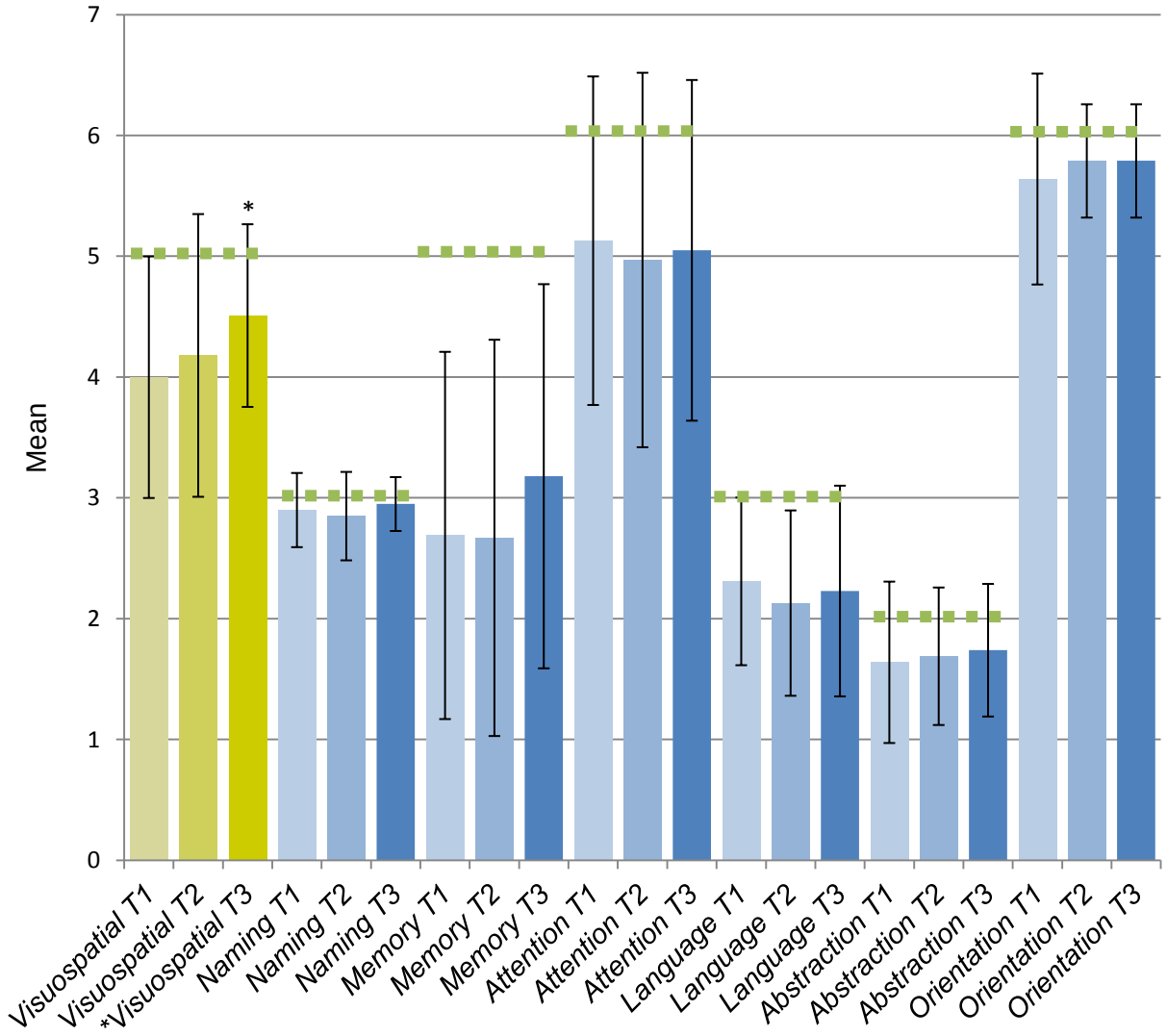


Figure 4. Cognition Doman Sub Scores: Change from T1 to T3



- * p<0.004 compared to Visuospatial T1.
- Bar is a maximum score for that domain.

Figure 5. MoCA Subdomains Percent Correct

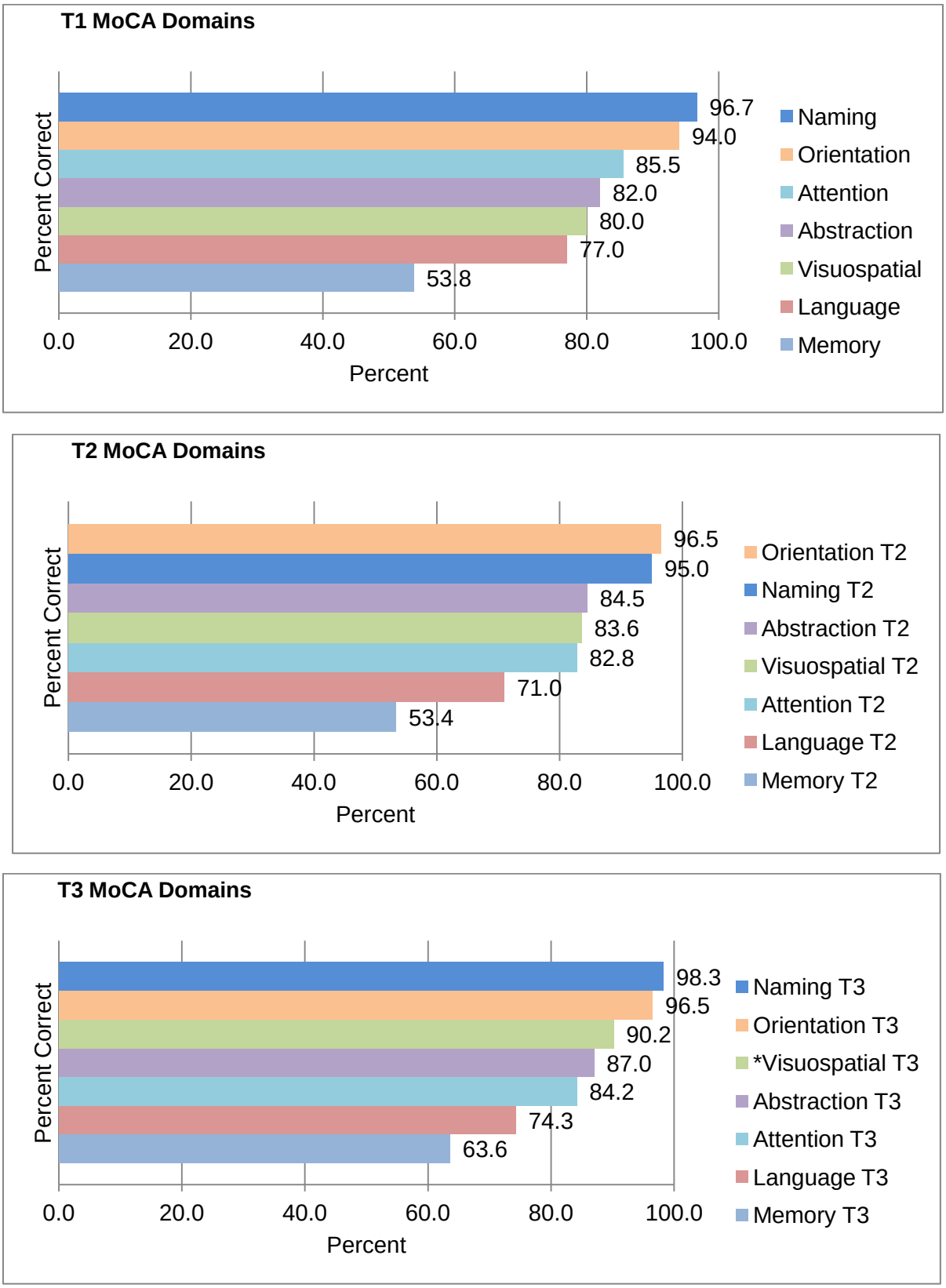
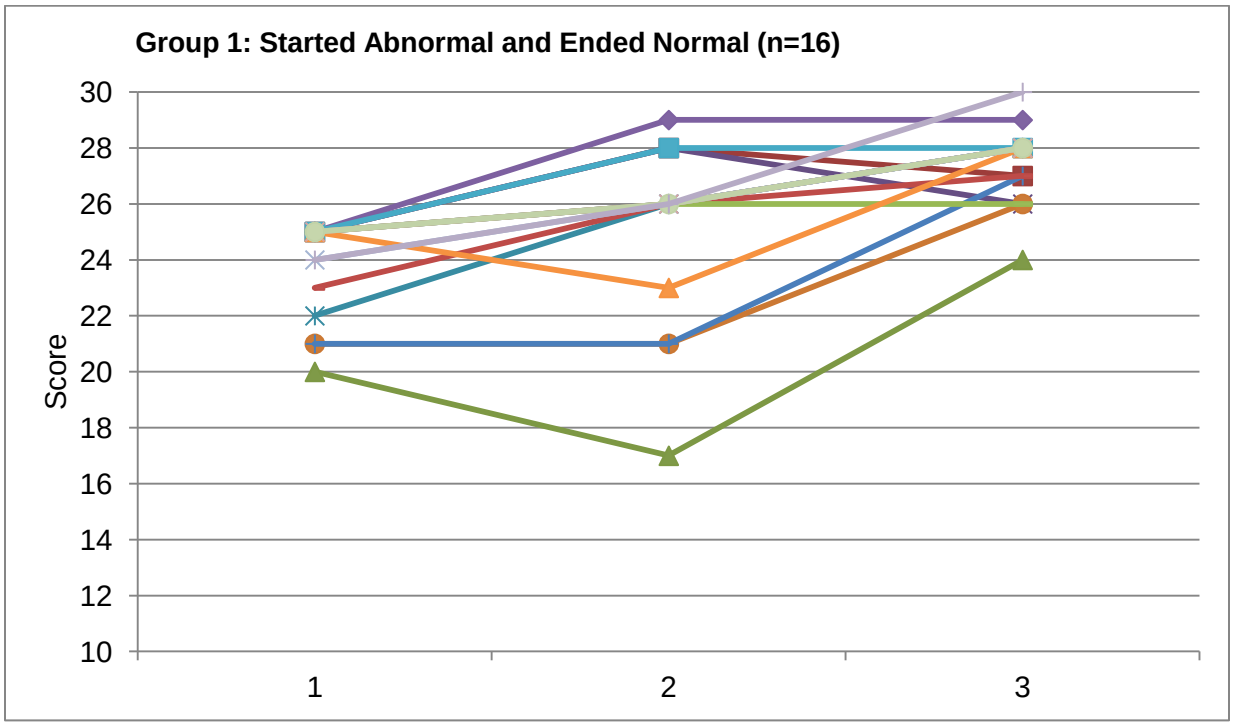
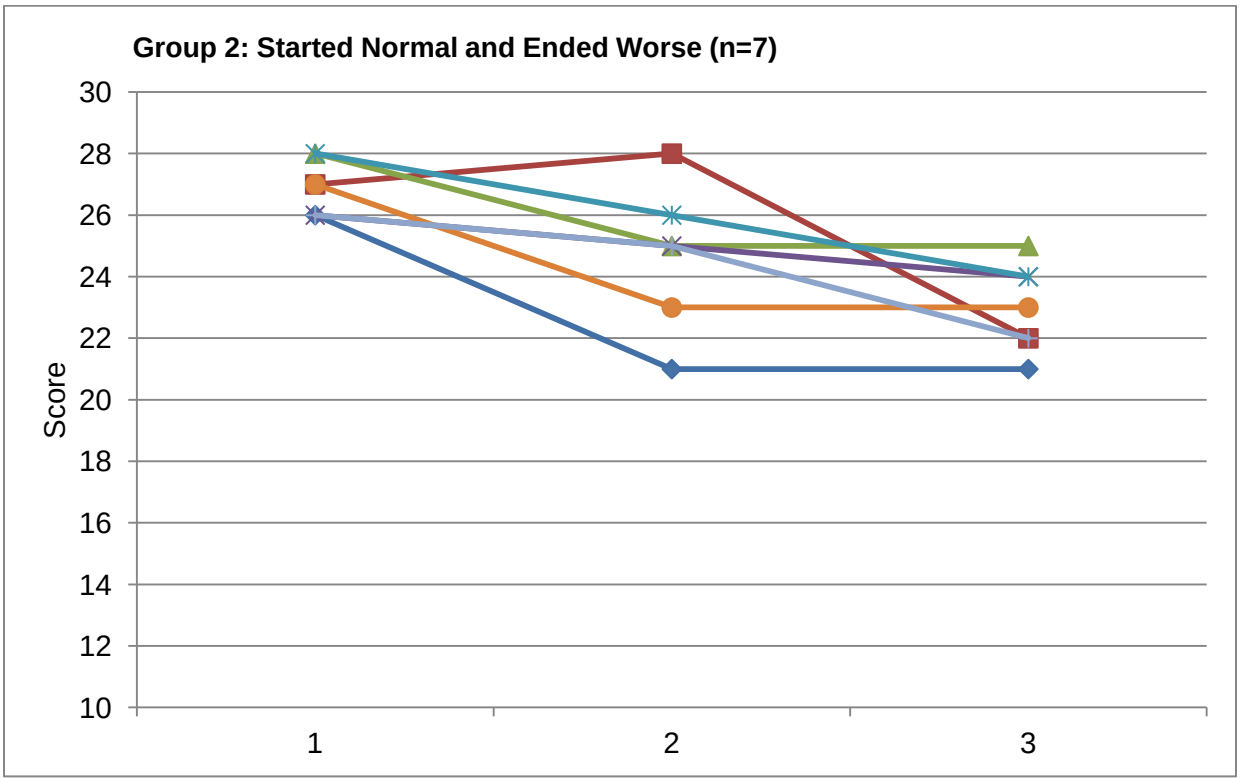
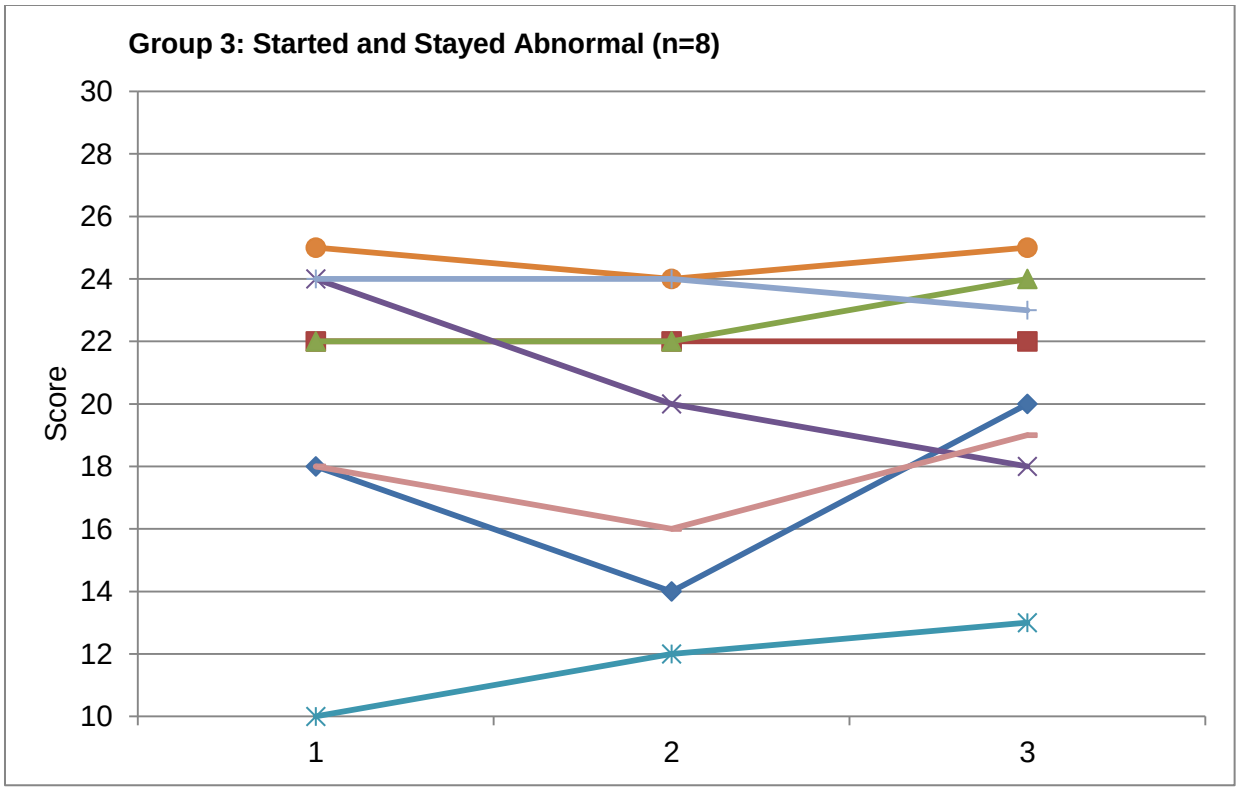


Figure 6. Each Charted MoCA Score by Group (n=40)






Group 3: Started and Stayed Abnormal (n=8)
Score
30
28
26
24
22
20
18
16
14
12
10
1
2
3

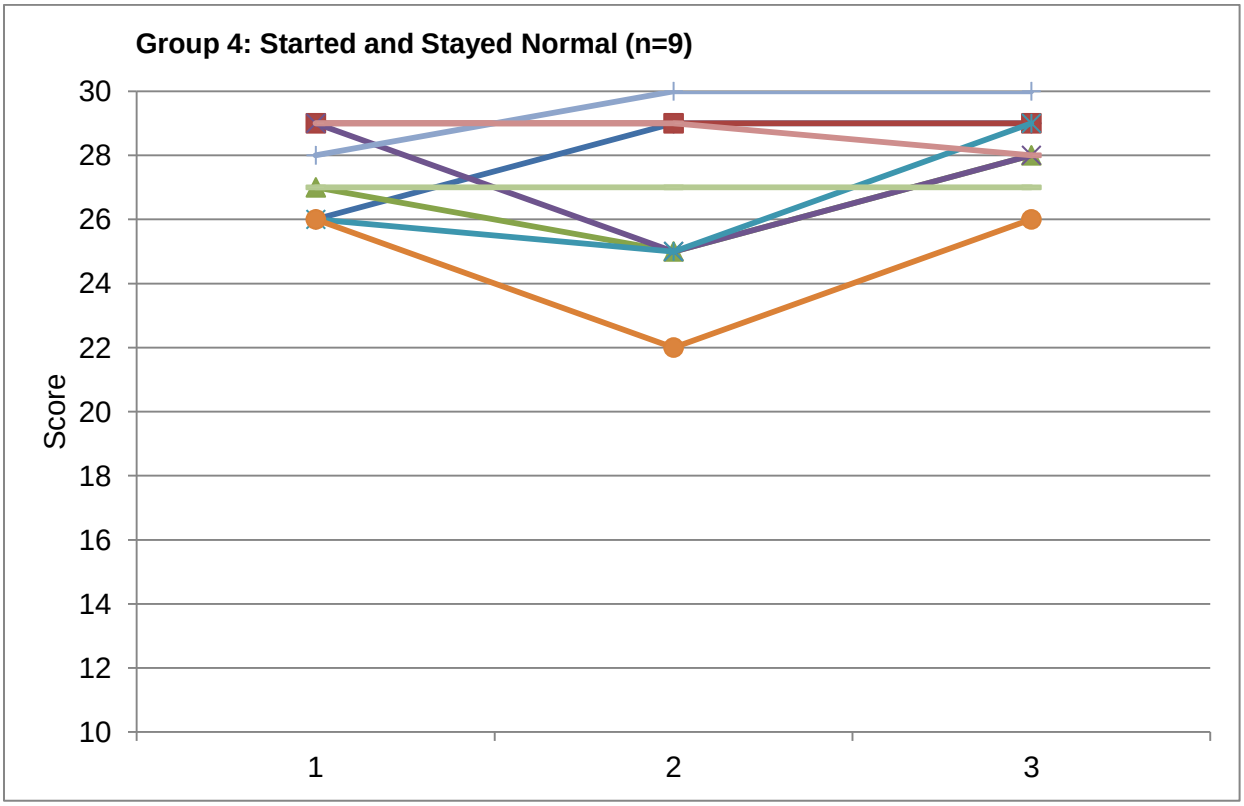

Group 4: Started and Stayed Normal (n=9)
Score
30
28
26
24
22
20
18
16
14
12
10
1
2
3

Figure 7. TMT A and TMT B Seconds Compared

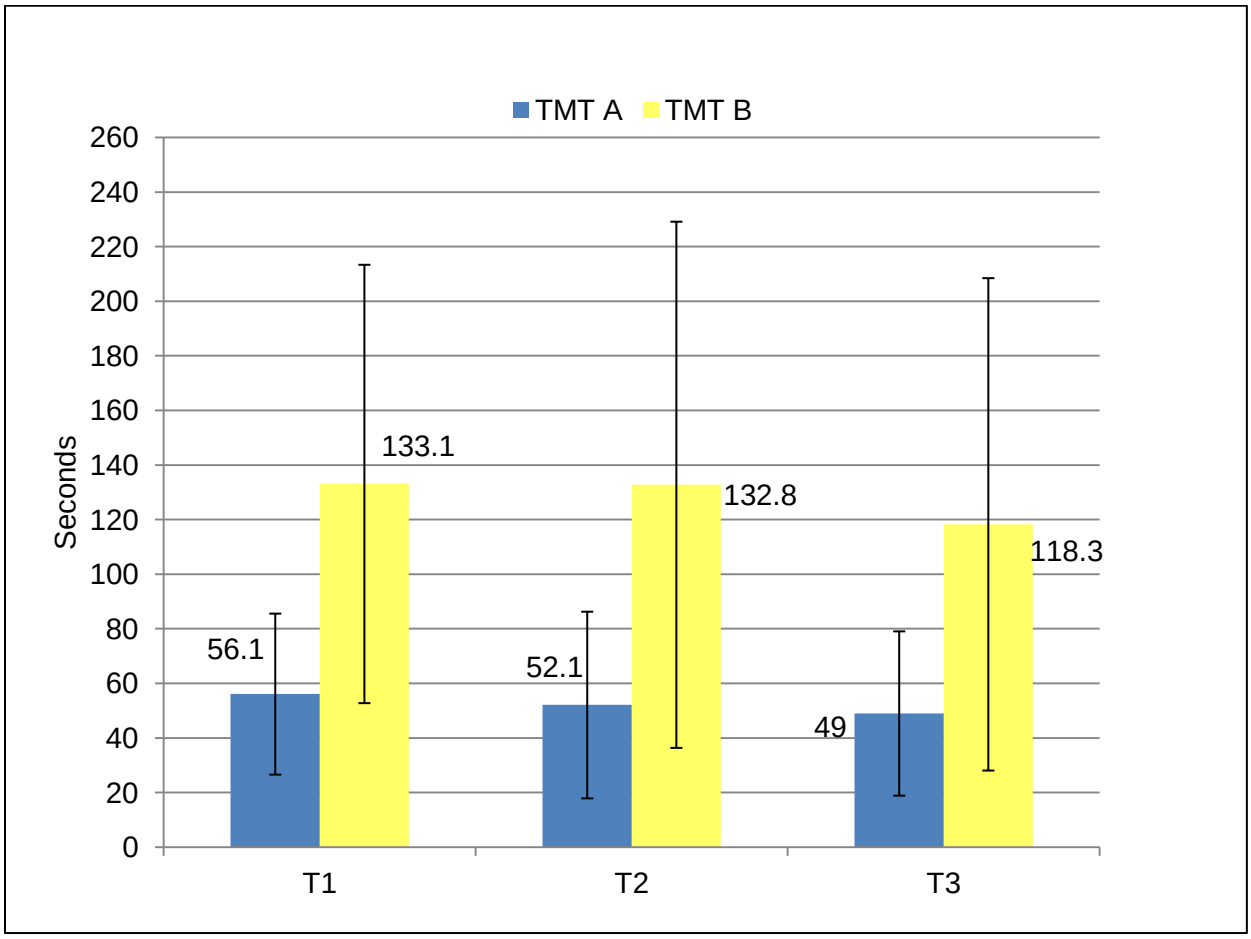


Figure 8. TMT B/A Ratio Mean Over Time

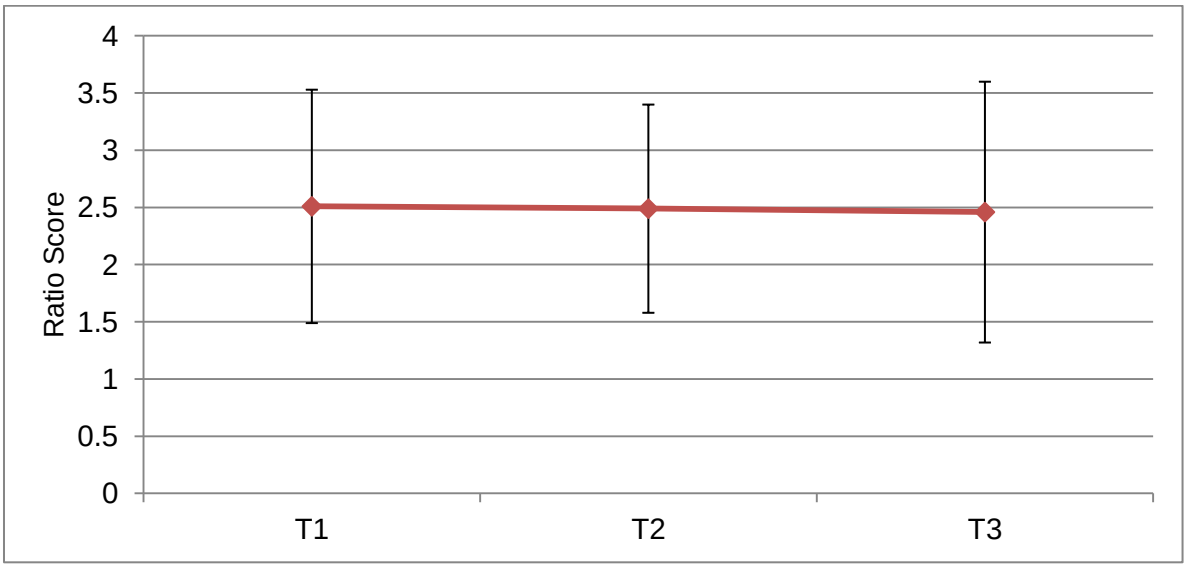


Figure 9. Normal Cognition Scores (n = 40)

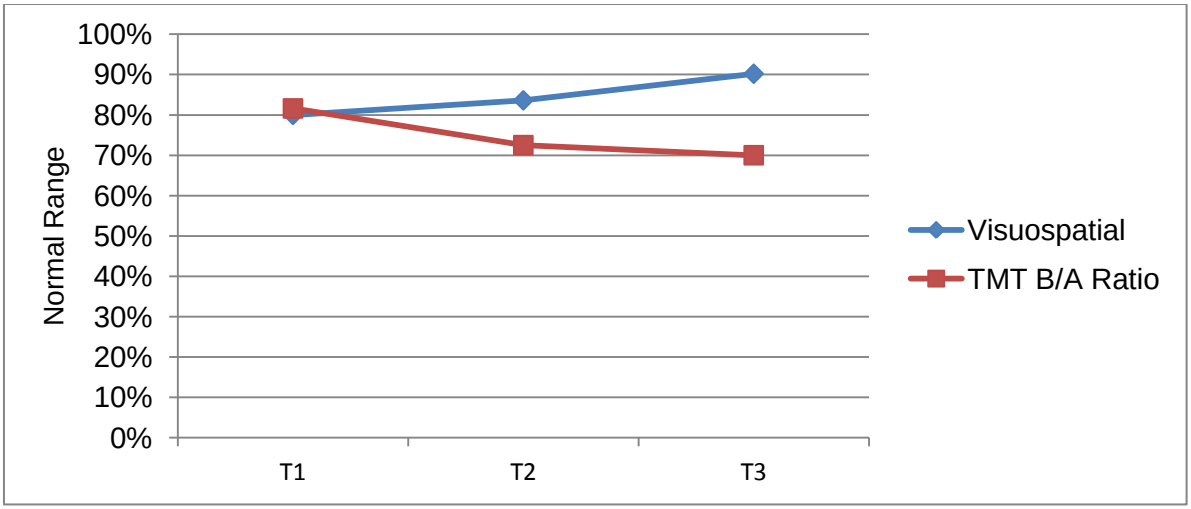
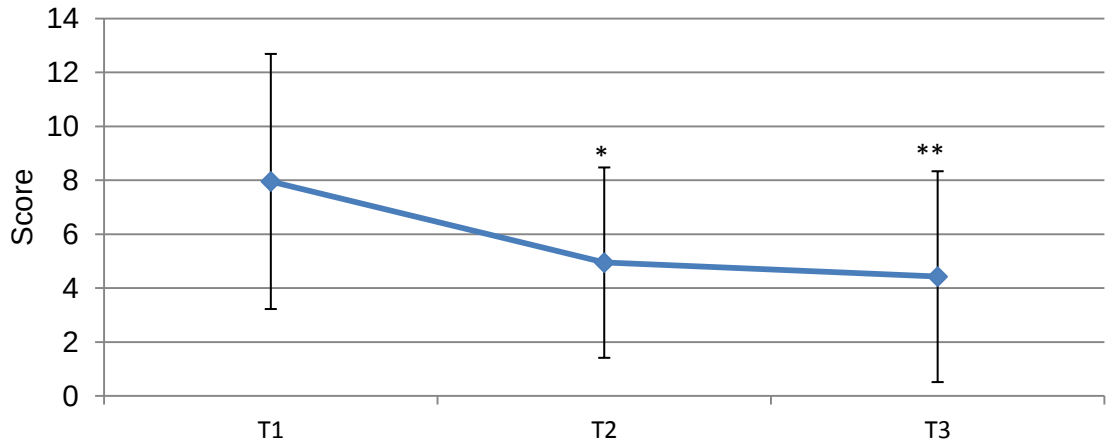
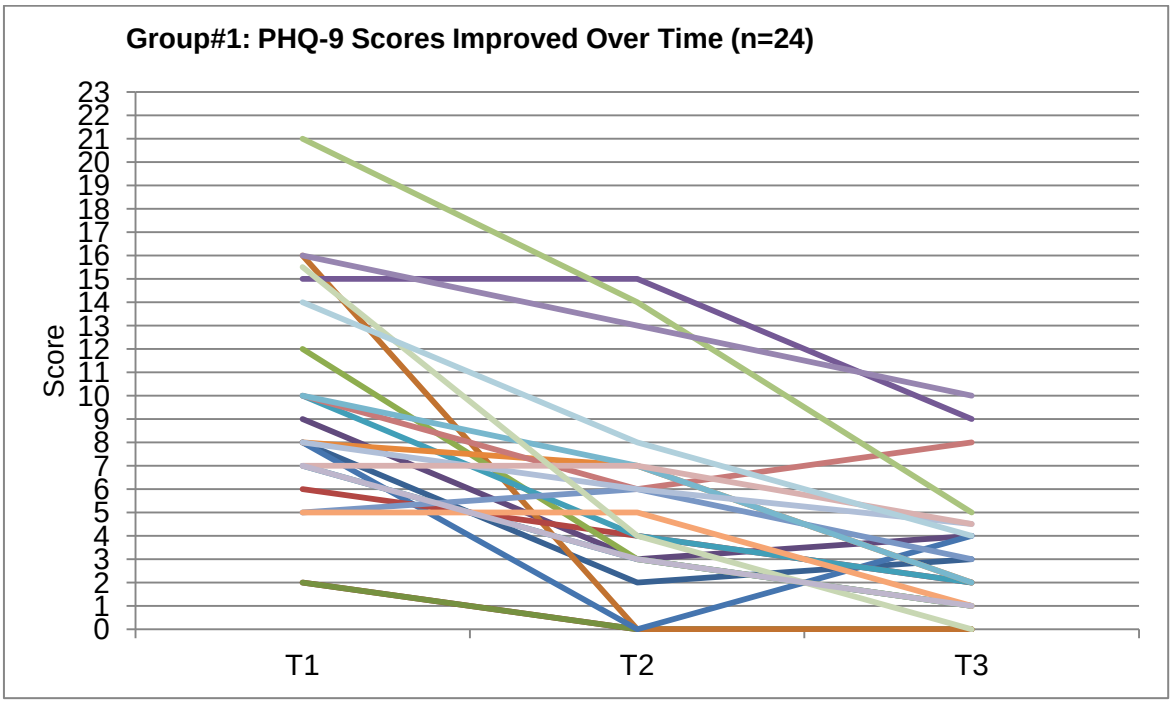


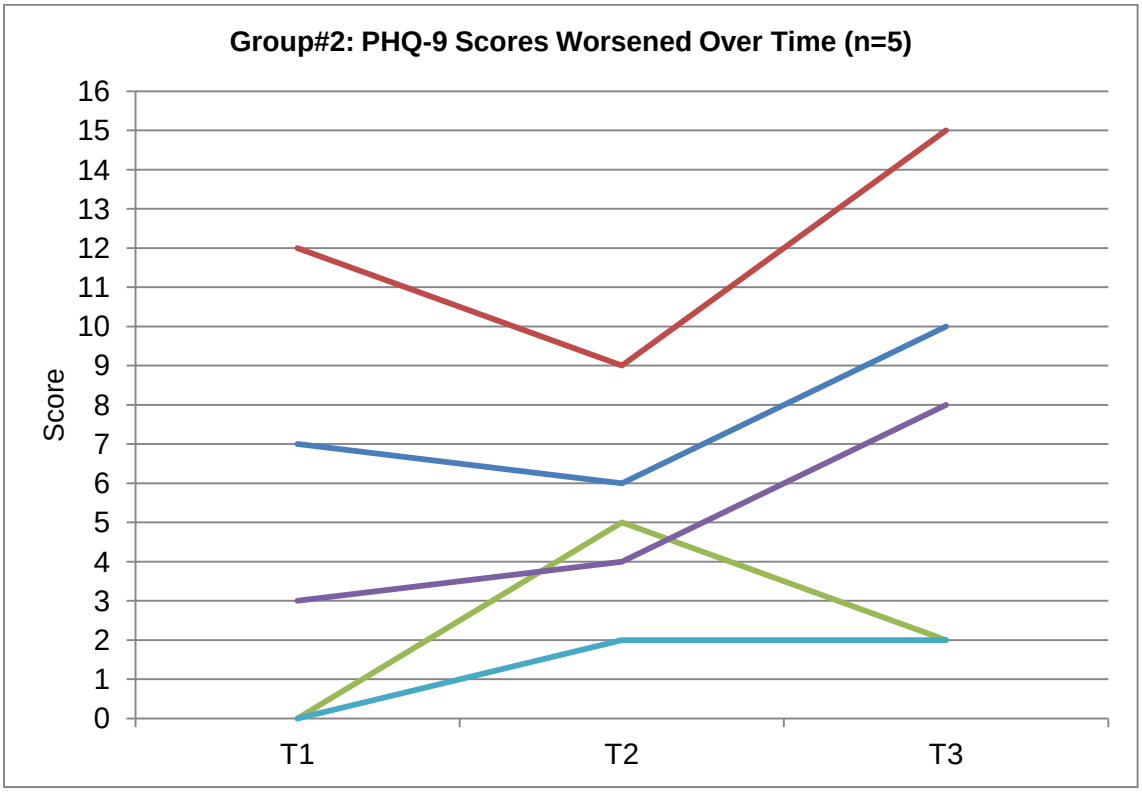
Figure 10. PHQ-9 Mean Over Time



*p<0.001 compared to PHQ-9 T1
**p<0.001 compared to PHQ-9 T1

Figure 11. Change in PHQ-9 Scores over Time by Group (n = 40)





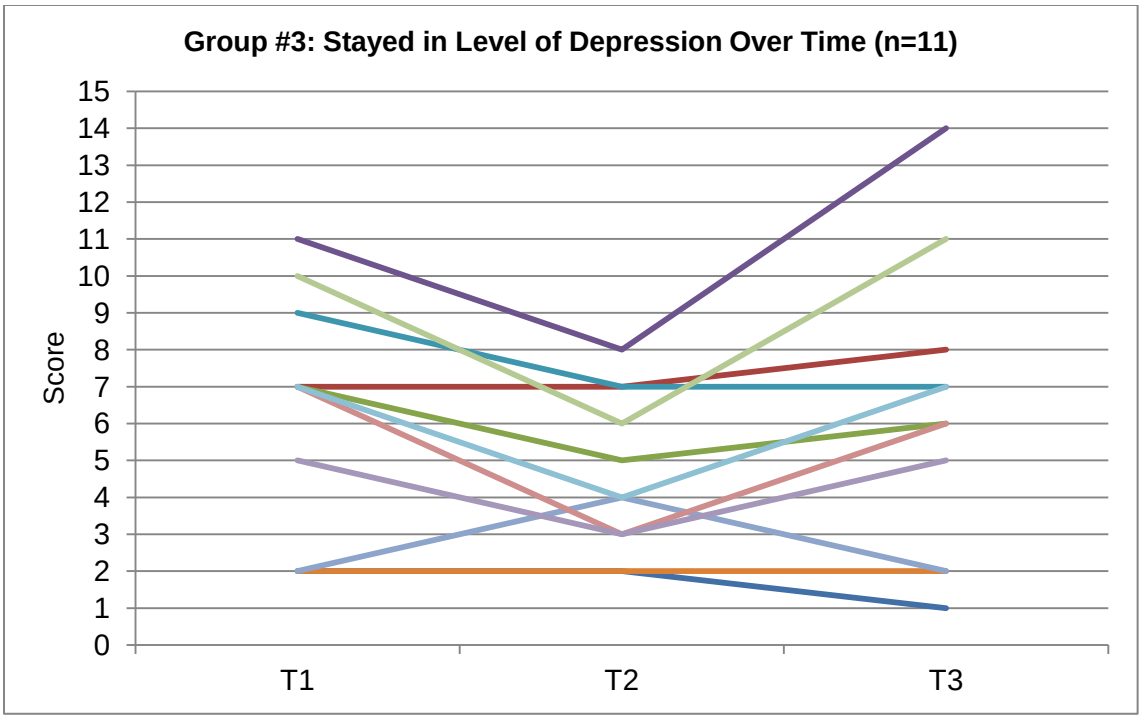
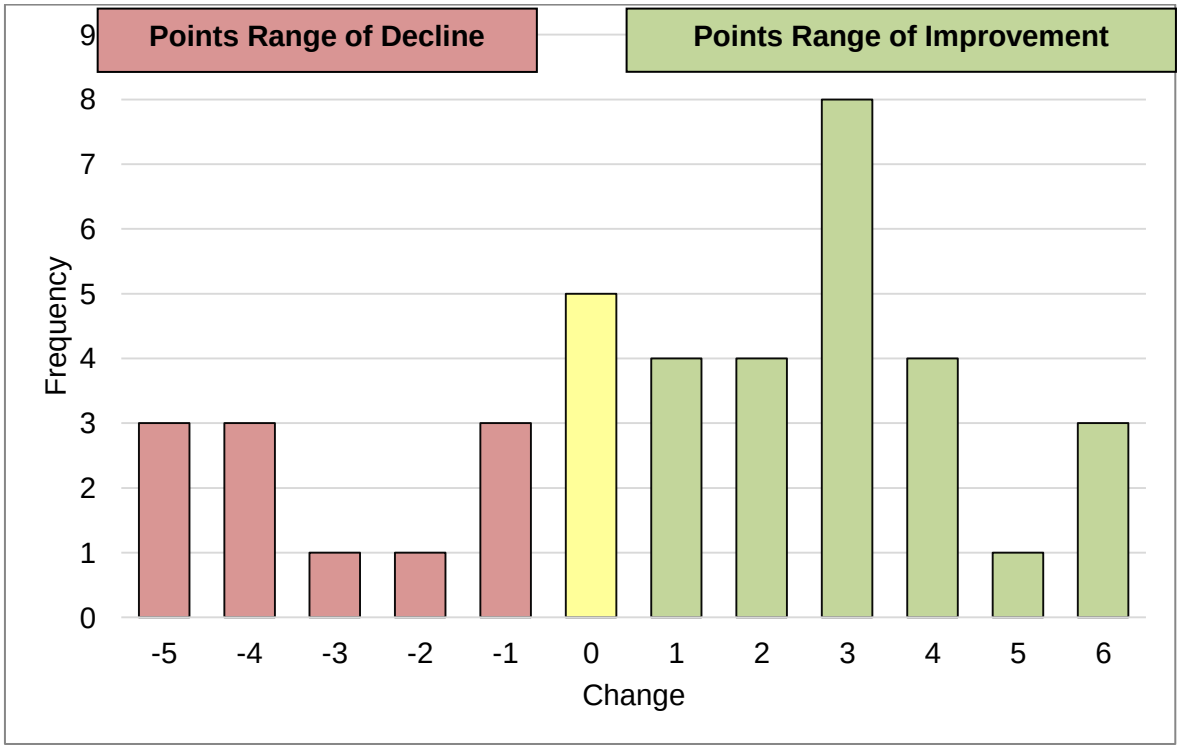


Figure 12. Numerical Change of MoCA Scores from T1 to T3 (n = 40)



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Chapter 6

Discussion

Discussion

Study Sample

The average age of this sample was 73.77 ±11.28 years, which is slightly younger than that of heart failure (HF) patients described in the Acute Decompensated Heart Failure National Registry (ADHERE), whose age averaged 75.3 years (Fonarow & Corday, 2004). A majority of participants were male (71.7%), and most participants were married (66%). Hospital length of stay (LOS) ranged from one day to 43 days, with an average of 8.23 ± 7.12 days. The LOS of the sample is higher by almost four days compared to reported national averages for HF patients (Fonarow & Corday, 2004). This supports our experience that those HF patients who were discharged quickly did not have time to enter the study, whereas those who were in the hospital an extended period of time were more available for study recruitment. Another likely explanation affecting recruitment is that HF patients in this sample may have been more ill than those who experienced earlier discharge. More than half of patients in this sample (64.8%) were discharged home, and seven (13%) went home with the assistance of home health services. These statistics are similar to those in the ADHERE report, in which investigators found that 60% of participants were discharged home and 15% required home health services.

All patients discharged from the hospital to home are expected to perform self-care behaviors and complete activities outlined in their discharge plan. At the time of discharge, the hospital system's Nurse Navigator program was available to all HF patients who lived in San Diego County. The Nurse Navigator screened patients at high risk for readmission based on comorbidity of illness and the LACE (LOS, acuity of admission, co-morbidities, and emergency room visits) score, and then invited eligible patients to have home visits where further education could be provided. A sample of the HF education provided is included in the Appendix. However, only 13 participants (24.5%) who qualified for the Nurse Navigator program actually received a Nurse Navigator. Some participants refused (n = 5), but most participants did not receive a timely referral to the Nurse Navigator program and thus did not have the opportunity to

enroll. Of the 18 participants who did not qualify for the Nurse Navigator Program, four participants (7.4%) were discharged to hospice. Fourteen (25.9%) had a do not resuscitate order during the hospitalization.

Only three participants (5.6%) in the current study received palliative care. Palliative care referrals in HF are often low (Adler, Goldfinger, Kalman, Park, & Meier, 2009; Goodlin, 2009). Some experts suggest palliative care should be part of comprehensive HF care at all stages of HF (Goodlin, 2009). Others suggest the in-hospital use of risk scores for readmission and mortality to identify HF patients that may benefit from outpatient palliative care interventions (Rogers et al., 2017). However, according to 2013 HF guidelines, palliative care consultation should be considered for all hospitalized HF patients (Yancy et al., 2013). One explanation for low referrals to palliative care in the context of advanced HF is provider uncertainty (Adler et al., 2009; Allen et al., 2012). In acute decompensated heart failure (ADHF), it is a challenge to determine whether or not patients are likely to improve or slowly decline over time and this makes the prognosis often feel unpredictable (Goodlin, 2009). This creates uncertainty regarding the best time for clinicians to make palliative care referrals (Adler et al., 2009). A recent study showed outpatient follow-up of a palliative care program in HF can decrease depression and anxiety in patients, and increase spiritual well-being at six months (Rogers et al., 2017). Future studies are needed to support the best timing for advanced care planning, and effectiveness of palliative care interventions, including symptom management and medications (Goodlin, 2009; Yancy et al., 2013).

Labs. The ADHERE database has the most recent published lab value ranges for hospitalized patients in ADHF, and thus, it was used to compare to our sample. All labs at T1 had some degree of abnormality. Blood urea nitrogen (BUN) and creatinine were abnormal in 46 (86.8%) and 35 (66%) of participants, respectively (Table 2, Chapter 5). Overall, 27 (50%) of study participants had acute renal failure, which is more than double the rate of 15% reported in the ADHERE database (Fonarow & Corday, 2004). Together, these abnormalities reflect the

severity of illness and multiple comorbidities of advanced HF inpatients in this sample. A recent study showed that persistent BUN levels greater than 21 mg/dl in the hospital were associated with an increased risk of cardiovascular death (Jujo et al., 2017). Acute renal failure is a predictor of long term poor outcomes for HF patients (Han & Ryu, 2011). Chronic kidney failure can cause anemia, which is linked to readmissions and mortality in HF (Tang & Katz, 2006). Low albumin is also linked to lower survival in HF patients (Liu et al., 2012).

Comorbidities. Compared to the ADHERE database, the sample in the current study had a higher incidence of multiple comorbidities, including: hypertension (73% versus 79.6%), diabetes (44% versus 48.1%), dyslipidemia (36% versus 53.7%), myocardial infarction (MI) (31% versus 41.3%), coronary artery disease (57% versus 87%), and double the presence of atrial fibrillation (31% versus 64.8%). In previous studies, between 15 and 50% of advanced HF patients were reported to have atrial fibrillation, which was associated with poorer outcomes compared to similar HF patients with atrial fibrillation (Piccini & Allen, 2017; Trulock, Narayan, & Piccini, 2014; Yancy et al., 2013). The reason we had more atrial fibrillation compared to the ADHERE report was likely due to changes in coding practices (i.e. use of International Classification of Disease (ICD)-9 coding in AHDERE compared to use of ICD-10, as in the current sample). Compared to the ADHERE database, characteristics of participants in this study were somewhat different. More participants in this study were in stage III HF (44% versus 79.2%) and fewer participants were in stage IV HF (32% versus 18.9%). However, the percentages of HF patients with reduced ejection fraction (EF) and preserved EF were almost equal in both ADHERE and this study (46% and 54% respectively in ADHERE and 45.3% and 54.7% in the current study) (Fonarow & Corday, 2004). Compared to ADHERE, this study sample had more ischemic HF (defined by ischemic heart disease, coronary angioplasty, and coronary artery bypass surgery) and more atrial fibrillation, but less end stage IV HF and fewer female participants. Perhaps this sample had more ischemic heart disease because survival rates have improved overtime (Benjamin et al., 2018). Since ADHERE's report described

hospitalized HF patients, survival has improved for adults who develop HF after an MI (Benjamin et al., 2018). The findings of this study may not be generalizable to females or those with end stage IV HF.

Medications. With few exceptions, two guideline-based medications, angiotensin-converting-enzyme inhibitors (ACE-I) and beta blockers should be prescribed for HF patients to decrease mortality (Yancy et al., 2013). Both the ADHERE database and the sample in the study had less than perfect adherence to HF guidelines (54% versus 24.5%) and (62% versus 69.8%), respectively. The ADHERE authors note guideline exceptions of low blood pressure and kidney disease for ACEI-I and low heart rate for beta blockers (Fonarow & Corday, 2004; Yancy et al., 2013). As noted previously, participants in the current study had higher than expected rates of kidney disease; further, we did not collect blood pressure or heart rate data. Nonetheless, the low numbers discharged on an ACE-I or Angiotensin II receptor blockers (ARBs) (24.5% reported in Table 5, Chapter 5) suggest that at least some study participants may not have been on guideline therapy at discharge.

When HF patients are admitted to the hospital, they are at risk for hospital readmission within 30 days (Fonarow, 2007; Hajduk, Kiefe, Person, Gore, & Saczynski, 2013). In this sample, 16 (30.2%) experienced at least one hospital readmission in less than 30 days (planned and unplanned). Three of these participants and nine others, a total of 12 participants (22.6%), entered the study during a 30-day unplanned hospital readmission visit. Of the planned readmissions, six came back for a Cardiomems device and two for non-cardiac related surgery. Once in the study, 9 (17%) had an unplanned 30-day readmission. This is below the national average of 21.7% (Pressler, Subramanian, et al., 2010; Sterling et al., 2018). Additionally, 20.8% of study participants had one or more visits to the emergency department within 30 days. This sample, like most HF patients, demonstrated a chronic high use of the hospital system (Fonarow, 2007; Hajduk et al., 2013). As expected by the therapy, those who had a Cardiomems device prior to entry into the current study did not have a 30-day readmission

(Ayyadurai et al., 2019; Heywood et al., 2017). Technology advances help providers treat HF overload symptoms as early as possible and reduce readmissions (Heywood et al., 2017).

In this sample the top reason for readmission was ADHF, which is often characterized by symptoms of fluid overload (Table 4, Chapter 5). If the patient is on appropriate guideline therapies, the cause of fluid overload may be due to HF disease progression, or it may be from poor self-care behaviors (Yancy et al., 2013). The HF guidelines recommend patient education as the best approach to improve self-care behaviors (Yancy et al., 2013). However, HF patients who have failed self-care at home may have cognitive impairment (CI). Previous researchers have hypothesized that unrecognized CI in the outpatient setting may be contributing to ADHF readmissions (Pressler, Kim, Riley, Ronis, & Gradus-Pizlo, 2010). This possibility is also supported by a recent report, in which investigators found mild CI was associated positively with both death and 30-day hospital readmission in HF patients (Huynh et al., 2016) They found patients with CI were more likely to be readmitted for an exacerbation of HF (67%) than those without CI (41%) (Huynh et al., 2016). Cognitive impairment effects the patient's ability to perform self-care behaviors, including recognizing symptoms to report to providers and adhering to the prescribed medications regimens (Cameron et al., 2010; Hawkins et al., 2012; Levin et al., 2014).

Inadequate self-care that causes hospital readmission for symptoms of fluid overload may be linked to unrecognized CI (O'Connor et al., 2016). An individual's history of self-care should be considered when developing patient specific interventions to avoid readmissions (O'Connor et al., 2016; Yancy et al., 2013). If the patient is ready and able to learn, it is important to deliver personalized education to the patient to help gaps in self-care behaviors (Yancy et al., 2013). Patients' ability to perform self-care behaviors has been shown to be compromised when executive function is impaired, particularly medication adherence (Alosco et al., 2014).

Poor self-care behaviors are also related to other variables including depression and anxiety (Hwang, Moser, & Dracup, 2014). Higher depression and anxiety, higher New York Heart Association (NYHA) class, and lower levels of patient reported perceived control in the outpatient setting was related to poor self-care, despite high knowledge of HF (Hwang et al., 2014). In this study, at T1, 18 participants (34%) had moderate to severe depressive symptoms and 27 participants (50.9%) had anxiety symptoms. Cognitive impairment, depression and anxiety can interfere with good self-care behaviors. These three conditions should be routinely assessed in HF patients.

In addition to inadequate self-care, multiple other factors have been associated with 30-day readmissions in HF patients. These include: more severe HF, cardiorespiratory failure and shock during the index hospital stay, hypertension, valvular and coronary artery disease, cardiac arrhythmias, vascular disease, diabetes, kidney disease that compromises renal function, chronic obstructive pulmonary disease, asthma and pneumonia, pulmonary hypertension, fibrosis of the lung, liver and biliary disease, hematologic disorders, low sodium, fluid and electrolyte disorder, protein–calorie malnutrition, hypothyroidism, cancer, urinary track disorders, skin ulcer, gastrointestinal disorder, peptic ulcer, depression, dementia, psychoses and major psychiatric disorders, a history of refusing health services, nonadherence, or missed appointments, a history of cocaine use, other drugs, and alcohol abuse, the number of recent prior hospital admissions, a prior diagnosis of HF, delirium, functional limitations, and B-type natriuretic peptide (BNP) (O'Connor et al., 2016). Thus, further study is needed regarding the role of CI in the complex and dynamic context of HF and psychosocial characteristics.

Lastly, 17 participants (31.5%) died during the study. These findings are in line with other recent reports of mortality in HF patients. Mortality over a two year time frame following hospital discharge has been reported as high as 50% (Lam et al., 2019). In a recent study, HF sufferers who were readmitted in the latter half of the month following hospital discharge were more likely to die from non-HF related reasons (Lam et al., 2019). In our study, we found a similar modest

trend. Of the 16 participants (30.2%) who experienced a 30-day readmission, nine participants had an unplanned (56.3%) readmission. Of those, four participants (44%) died by the end of the study. The two who were readmitted in the first half of the month were readmitted for reasons related to their ADHF; the two who were readmitted in the latter half of the month were readmitted for other reasons. Cause of death was not collected in this study. Further research would be useful to consider the timing and causes of HF readmissions.

AIM #1: Characterize patterns of cognition and depressive symptoms in HF patients at three time points: after 48 hours of hospital admission (T1), within seven days of hospital discharge (T2), and 30 days post discharge (T3).

The cognitive status and depressive symptoms of study participants changed in various ways from the time of inpatient care (T1) to the period of 30 days post-discharge (T3). For most patients, cognition levels improved by T3. Overall, the amount of CI decreased from 60% (n = 24) at T1 to 40% (n = 16) at T3 on the Montreal Cognitive Assessment instrument (MoCA) (Figure 2, Chapter 5). This finding at T3 of 40% CI in stable HF outpatients is consistent with other studies in which investigators reported ranges of CI from 25 to 50% in similar HF outpatients (Cameron et al., 2010; Harkness, Demers, Heckman, & McKelvie, 2011; Pressler, 2008; Riegel & Lee, 2012). The trend observed in this study of higher rates of CI in the hospital (60% at T1) compared to outpatient suggests that cognition may improve following hospitalization. This is supported by other studies that followed patients for less than one year (Hajduk et al., 2013; Kindermann et al., 2012).

In Germany, Kindermann et al. (2012), studied 20 ADHF patients and matched them with two control groups: stable HF patients and healthy controls. Those with ADHF had greater CI in the domains of memory, perceptual speed and executive control than stable HF patients (Kindermann et al., 2012) . As ADHF patients recovered, their scores became no different than the stable outpatient group by three weeks after discharge (Kindermann et al., 2012). All cognition testing was performed in the Intensive Care Unit (ICU).

Our study differed from Kindermann et al (2012) in several ways, which may account for the noted differences between the two. First, our study demonstrated patients on a medical-surgical ward had impairment. We assessed cognition with global cognition assessment tools, while Kindermann et al (2012) used specific domain assessments of memory, executive control, processing speed, and intelligence. We excluded only those with known dementia versus excluding those with confounding comorbidities like acute or chronic renal issues (Kindermann et al., 2012). Because renal failure is a common comorbidity in the context of ADHF, participants in the Kindermann study were likely healthier than those in the current study.

When cognition is studied for more than a year, its longer term trajectory is a progressively declining one (Hajduk et al., 2013). In the longest study mentioned in Hjelm et al.'s review, progressive decline was reported for a Swedish cohort of 80 year olds with five tests in 11 years (2011). It is suggested that cognition remains stable or improves following ADHF whereas over longer periods cognitive function tends to decline (Hajduk et al., 2013). Thus, the trends revealed in this study offer information needed for clinicians to choose appropriate educational strategies and discharge plans in the hospital to support a patient's CI at home.

Cognition patterns from inpatient to 30 days post discharge. Four patterns of MoCA scores emerged over time (Figure 6, Chapter 5). These four trends and their related factors are new to the body of literature for HF patients. In some patients, CI improved by T3 (Group 1). Compared to the other groups, Group1 experienced a lower rate of 30-day readmissions (p=.047) (Table 7, Chapter 5). This could suggest that improvement in cognition may be clinically significant in influencing hospital readmissions. Group 1 was also associated with improvement in the specific domain of executive function at T3, measured by lower TMT B/A ratios (p=.029) and lower TMT B at T3 (p=.018) (Table 7, Chapter 5). This reinforces the conclusion that improvement in executive function can occur following hospitalization (Figure 4, Chapter 5).

Variables related to Group 1 give insight regarding why global cognition improved in this group. First, at T1, Group 1 was associated with better attention (measured by lower TMT A seconds) (p=.041). Also, at T1, everyone who was in Group 1 had mild CI (MoCA scores of 18-25), not moderate or severe CI (<18) (Figure 6, Chapter 5). This supports the conclusion that HF patients who improve cognitively following a hospitalization may have been more cognitively intact in the hospital. Clinically, this trend is important to discharge planning. When the MoCA is used in ADHF patients and they are found to have CI, supportive measures such as educating caregivers, or providing home health should be evaluated to ensure discharge orders are followed (Davis et al., 2012; Koelling, Johnson, Cody, & Aaronson, 2005; Yancy et al., 2013). When mild CI is present at T1, supportive measures may not be needed beyond 30 days because cognition may return to normal (Kindermann et al., 2012). However, if moderate or severe CI is found at T1, cognition will likely not be normal at 30 days and long-term supportive measures for self-care should be explored for those patients. In both cases, the patient's cognition should be reassessed at 30 days.

Another key finding was that the affectionate support subdomain of MOS-SSS was associated with Group 1 assignment (p=.038; Table 7, Chapter 5). Participants with high scores in the affectionate support subdomain reported they had someone who showed them love and affection, someone to love and make them feel wanted, and someone who hugged them (Sherbourne & Stewart, 1991). The relationship between physical touch and health outcomes has been researched extensively in infant development (Field, 2010) and was recently studied across the lifespan of adults (Gliga, Farroni, & Cascio, 2019). Modes of touch may show physiological benefits, such as decreased heart rate, blood pressure and cortisol levels, increased oxytocin, increased attentiveness, and enhanced immune function, and psychological benefits, such as decreased depression (Field, 2010; Gliga et al., 2019). Overall, in this study social support scores were not associated with Group 1 assignment, but the affectionate

support sub domain finding infers aspects of perceived social support are related to improved cognition.

Understanding what potential modifiable variables improve CI is just as important as understanding what contributes to declining CI overall. The exact causes of CI can be complex. There are multiple factors in the hospital that are known to lower cognition, including sleep disruption, medication changes, pain, stress and anxiety (Krumholz, 2013). Secondary acute issues can cause CI and are treated simultaneously as the patient recovers from ADHF in the hospital. A comorbidity positively associated with Group 1 was presence of pneumonia at T1 (p=.029); although, only three participants (5.6%) in the sample had pneumonia in the hospital (Table 6, chapter 5). Pneumonia in older adults can cause CI in the hospital and has been linked to an increased risk for dementia after discharge (Shah et al., 2013). In our sample those who had pneumonia and CI at T1 improved at T3 by four to six points. Pneumonia could have contributed to the CI at T1 for those patients. All those with pneumonia improved at T3. Compared to previous studies of pneumonia, our findings may be attributable to the limited sample size and specific HF population (Shah et al. 2013).

A similar, surprising comorbidity associated with cognitive improvement from T1 to T3 was the presence of liver disease (p=.030). Typically, most patients with severe liver impairment have cognitive decline (Collie, 2005). The data regarding presence/absence of liver disease was collected to calculate the Charleston's Comorbidity Index (CCI). Three patients, two with mild and one with severe liver disease, met the CCI criteria. Understanding how each comorbid condition contributes to the improvement or decline of cognition is complicated and needs further exploration. Some investigators have suggested that treating comorbidities associated with CI will improve its symptoms and may reverse the condition itself (Zuccala et al., 2005). Acute decompensated HF patients often have multiple comorbidities (Table 5, Chapter 5) and in this sample averaged 10.9 ± 3.9 comorbidities. With the exception of depression and anxiety, the stability of each remaining comorbid condition was not collected.

In some patients, CI became worse over the first 30 days after hospital discharge (Group 2). In those whose cognition declined, CI was associated with increased depressive symptoms at T2 ($p = .047$). Most participants showed improvement in PHQ-9 scores at T2 ($p = .000044$); however, in contrast, Group 2 participants' cognition worsened. Depressive symptoms have been shown to be independently associated with CI, specifically, deficient executive function (Cameron et al., 2010). Beyond depressive symptoms, a depression diagnosis is believed to interact and change cognitive function (Leto & Feola, 2014). This can be explained by neuro hormonal levels and reduced cerebral blood flow (Sohani & Samaan, 2012). Prolonged exposure to neuro hormones such as cortisol or pro-inflammatory cytokines (i.e., IL-6, TNF-α, C-reactive protein) are related to sustained depression, worse CI, and anatomical brain changes (Sohani & Samaan, 2012; Vogels et al., 2007; Woo, Macey, Fonarow, Hamilton, & Harper, 2003). Reduced cerebral blood flow, measured by transcranial Doppler, was associated with depression and CI defined as poorer attention, executive function, language, and motor function (Alosco et al., 2013). The data from the current study showed depressive symptoms had decreased by T3. At this time point, the stable HF patient is expected to have lower cortisol levels and potentially improved cerebral blood flow following recovery from a volume overloaded exacerbated state (Leto & Feola, 2014; Sohani & Samaan, 2012). The current study supports the interdependent relationship of HF, CI and depressive symptoms. Additionally, it suggests the beneficial trend that recovery of executive function is linked to depressive symptom resolution at 30 days. As HF and depression stabilize, executive function is more likely to improve (Diamond, 2013).

Managing and stabilizing comorbidities after hospitalization remains important (Hajduk et al., 2013). Recovery from the stress of a hospital experience can take time (Inouye et al., 2006). In this study, those whose CI declined were more likely to have advanced NYHA class (i.e., III or IV) at baseline ($p = .033$) as well as increased volume overload on hepatojugular reflex assessment at 30 days ($p = .041$). Additionally, for individuals in Group 2, positive associations

of declining CI with baseline presence of a cancer diagnosis (p = .030) and occurrence of cardiogenic shock during hospital admission (p=.008) were observed. The association of these severe conditions with declining CI at 30 days emphasizes the seriousness of multifactoral illness trajectories. Not only are those with advanced NYHA class experiencing a decline in CI following hospital discharge, they frequently remain depressed, in volume overload, and subject to simultaneous therapies for other life-threatening diagnoses.

Previous studies of stable HF patients in the outpatient setting have shown associations of CI with other comorbidities, including atrial fibrillation, chronic kidney disease, sleep apnea, prior stoke, and anemia (Bugnicourt, Godefroy, Chillon, Choukroun, & Massy, 2013; Kumar et al., 2011; Pullicino et al., 2008; Thacker et al., 2013). In Group 2, we did not find statistical significance in the association of these comorbidities with CI at T3, which was likely due to small sample size. However, in Aim #3 (which examined variables likely to be associated with global cognition and included a larger sample [n = 53]), we found that those with higher MoCA scores (better cognition) had better anxiety scores (less anxiety) at T1 (p = .005). This is a new finding, as other studies had not found anxiety related to cognition in the inpatient setting.

Some patients had mild CI at T1, sustained abnormal cognition at T3, but did not worsen (Group 3). This pattern of stable CI adds new data and expands on previous findings in HF patients. Prior studies of CI in HF reported outcomes at a single time point and found older age to be a statistically significant factor (Pullicino et al., 2008). A recent study also found older hospitalized HF patients to have CI (Hajduk et al., 2013). Ischemic HF has a relationship to sustained CI over time in the outpatient setting (Festa et al., 2011). In the Festa et al. (2011) report, the investigators found that those with ischemic HF were associated with verbal delayed recall and memory. In the current study, cognition and depressive measurement stopped at 30 days. Perhaps those impaired in Groups 2 and 3 take longer to recover, or perhaps they will not recover. Future studies are needed to follow HF patients with CI after hospital discharge for

longer periods of time. Regardless, this study demonstrates that HF patients need a wide range of supportive care measure through at least the first 30 days after hospital discharge.

Nine participants (22.5%) did not have CI at baseline (Group 4). Additionally, for this group, cognitive status was not associated with reduced readmissions or mortality. This group suggests that not all acutely decompensated HF patients will have CI and calls for the importance of assessing CI for each individual.

Cognitive Sub-Domain Findings. In previous studies of HF patients, the most commonly reported domains associated with CI are executive function, processing speed, and memory (Levin et al., 2014). Two global cognitive assessments used frequently in HF patients are the mini mental state exam (MMSE) and the MoCA; they provide an overall global score and individual 7 domain scores (Athilingam et al., 2011; Gallagher et al., 2013; Harkness et al., 2011). However, regardless of cognition screening tool used on the ADHF patient, previous research had single time point study designs (Cameron et al., 2010; Dodson, Truong, Towle, Kerins, & Chaudhry, 2013; Feola et al., 2013; Huynh et al., 2016; Levin et al., 2014; Sterling et al., 2019; Sterling et al., 2018) Only one study looked at cognition in HF from inpatient to outpatient at 14 ± seven days, when the patient was deemed recovered from ADHF (Kindermann et al., 2012). They did not assess global cognition but rather the three domains, executive function, processing speed, and memory (Kindermann et al., 2012). They found improvement in all three domains from inpatient to outpatient once the patient's HF exacerbation was stabilized (Kindermann et al., 2012). In this study, global cognition was measured inpatient, seven days following discharge, and at 30 days outpatient. To our knowledge, this study is the first to assess global trends in cognition in HF patients from the inpatient setting to the outpatient setting at 30 days following hospitalization.

Of the seven MoCA domains, the visuospatial domain was the only one that demonstrated statistically significant improvement ($p<.001$) over time (Figure 4, Chapter 5). The visuospatial domain assesses for executive function (Nasreddine, June 2009). Improvement in

this domain at 30 days means better capacity for decision making. Memory was the most impaired domain and did not improve (Figure 5, Chapter 5). Thirty-five participants (89.7%) at T1 and 29 participants (72.5%) at T3 could not recall five words they were asked to remember after five minutes. On average at T1, when education occurs in the hospital, participants recalled 2.69 ± 1.52 of the five words. Nine (23.1%) could not remember at least two words after five minutes. Healthcare providers should not expect someone who cannot remember a minimum of two words after five minutes to remember other education they are hearing (Levin et al., 2014). There was no significant change in memory at T3 as seven participants (17.5%) were not able to remember two words. Low memory scores in the hospital negatively impact education retention.

The current standard of care to prepare a HF patient for discharge includes education on disease process, medications, diet, symptoms to watch for, and when to call the doctor (Yancy et al., 2013). Before time and resources are spent educating the HF hospitalized patient, it is important to determine his/her cognitive state. When global cognition or certain domains like memory are impaired, there is a direct effect on the patient's ability to retain information and learn while in the hospital. We recommend objectively evaluating cognition in HF patients before spending significant time teaching at the bedside. Using the MoCA test is reasonable as it takes less than ten minutes to administer.

There are a few options as to who could administer the MoCA in the hospital. One option is to order a cognition evaluation by a speech therapist. Speech therapists are trained in cognitive evaluations and appropriate treatments (Mechler, 2018). Another option is to train the nursing team on cardiac units to administer the MoCA prior to patient education. Out of the three hospital sites where patients were invited to participate, one of them had nurses as full-time patient educators. At this location, it would make sense to train this smaller, specialized nursing team since they are often the primary educators for HF patients. The MoCA test is available on paper and has recently been designed and validated to be completed on a tablet

called the electronic MoCA (eMoCA) (Berg et al., 2018). Although those who administer the eMoCA still need training, scoring would be recorded automatically and transferred to the electronic medical record.

Additional considerations regarding the selection of nurse educators may be warranted when HF patients are found to have advanced impairment (MoCA < 18). The use of advanced practice registered nurses (APRNs), such as Clinical Nurse Specialists (CNS) or Nurse Practitioners (NP) with cardiac expertise may be warranted to assist the nursing team with education strategies and transitional care planning. If caregivers are available to the patient, and assuming their cognition is not impaired, education should be given to them as well (Lacerda, Cirelli, Barros, & Lopes, 2017).

As with patient education, discharge planning strategies may differ depending on the severity of CI. Supportive strategies for self-care should be considered even for mild CI (i.e., MoCA < 26) (i.e. like home health and Nurse Transition programs) (Huynh et al., 2016). Those who have moderate to severe CI (i.e. MoCA < 18) in the hospital may need a plan for more self-care support (i.e. care givers with longer hours or skilled nursing placement) (Huynh et al., 2016). All patients who are have CI in the hospital need cognition reassessment and follow-up after hospital discharge (Levin et al., 2014) . Clinically, if CI is identified in the hospital, routine reassessment should occur 30 days after discharge, with referral to a neuropsychologist if CI persists at that time (Diamond, 2013). Future research should focus on potential interventions to treat CI in HF following hospital discharge.

Executive function was also measured with TMT A and B to provide a more thorough assessment. From enrollment to 30 days after hospital discharge, the mean ratio of TMT B to TMT A trended worse (n = 40). However, the visuospatial domain of the MoCA, which measures executive function, improved (p=0.004) (Figure 9, Chapter 5). Global cognition (the MoCA mean) did not improve (Figure 8, Chapter 5). We purposely chose to use more than one tool to

follow the trajectory of CI in our HF sample because sensitive tools to detect subtle cognitive changes across the seven domains of cognition are not yet available (Sterling et al., 2018).

Executive function is comprised of multiple elements of cognition including: inhibition, self-control, working memory, and cognitive flexibility (Diamond, 2013). These executive functions allow a person to reason, problem solve, and plan (Diamond, 2013). When there is impairment in one element of executive function, the others are often compromised (Diamond, 2013). Clinically, there may be reasons why TMT A improved and TMT B results did not change. It was noted by the PI that the patients often approached TMT B with strategy, reading the pattern out loud and slowing down to not make mistakes, which lengthened the time it took to complete the test. Those that made mistakes did so when they were attempting to draw a line which involved switching back and forth between numbers and letters. Error rates on TMT B are typically related to deficits in working memory and executive function that produce impairment of cognitive flexibility and in some cases attention (Ashendorf et al., 2008).

Addressing related causes to poor executive function is imperative to successful treatment. Known variables that negatively affect executive function include: stress, sadness, loneliness, sleep deprivation and lack of physical fitness (Diamond, 2013). Having even one of these conditions has been associated with impaired executive function (Diamond, 2013). In this sample, the improvement in the visuospatial domain score over time suggests that as an individual's influencing variables resolve, there is the potential for improved executive function. It is likely that ADHF patients in the hospital will experience some of these variables, if not all, simply by being a hospital patient (Inouye et al., 2006; Krumholz, 2013). Following discharge, whether or not these variables resolve or remain determines if executive function improves (Inouye et al., 2006). When there is no improvement, it may be evident of low perfusion, another contributing variable of CI in HF patients. The effect of low perfusion on the brain is supported by imaging evidence that HF patients have significant brain injury on computed tomography (CT) in areas of the brain responsible for autonomic, pain, mood, language, and cognitive

function (Kumar et al., 2011; Woo, Kumar, Macey, Fonarow, & Harper, 2009). However, when blood flow is restored with mechanical circulation support (MCS), CI may be modifiable in some HF patients. In multiple studies with HF patients who receive MCS, significant improvements occur in almost all domains of cognition after one month following surgery (Bhat, Yost, & Mahoney, 2015; Pavol et al., 2018; Petrucci et al., 2012; Petrucci et al., 2006). Future research is needed to understand how findings of CI during and after hospitalization could contribution to decision-making regarding the timing of MCS treatment options.

Another explanation for the worsening trend of TMT B/A ratios over time is that it may be an artifact of the measurement method. Put simply, it may be a consequence of using the ratio, rather than separate scores for TMT A and TMT B. However, a limitation of the ratio is that the two tests are reported as a single metric. If the scores were interpreted separately, discordance between the two tests could be reflected and evaluated. Interpreting A and B scores separately show that some aspects of cognition trend toward improvement, whereas others (i.e. complicated tasks) remain impaired. For this study, we chose the ratio measurement because it has been shown to be the best measure for alternating task performance (Arbuthnott & Frank, 2000). In future analysis, we may be able to compare study outcomes between the methods of scoring the TMT.

Depression symptoms in HF. Despite evidence that depression in individuals with HF is two to three times greater than that of the general population (Rutledge, Reis, Linke, Greenberg, & Mills, 2006), screening for depression is not routine. The finding of higher depression in the hospital (34%; n=18) in this HF sample is consistent with previous findings of 16% to 38% (Rutledge et al., 2006). Yet, only 14 participants (25.9%) were coded as having depression in the hospital and only 11 participants (20.8%) were receiving antidepressants at discharge. This gap shows the importance of routine screening for depression in this population and for a comprehensive discharge plan. Depression scores have been shown to remain elevated post hospitalization in HF patients 11-25% of the time (Holzapfel et al., 2008; Rutledge

et al., 2006). Although depression improved in our sample, five participants (12.5%) continued to have depressive symptoms at T3. Only one of the five participants was on an antidepressant at time of discharge (Table 5, Chapter 6), meaning four remained untreated at T3. Ten percent of our sample did not have a comprehensive care plan to treat their depressive symptoms.

Overall, moderate to severe depression in this sample was low. At T1, only 32.5% (n=13) were in this category, which is lower than the 42% previously reported in the outpatient setting (Russell et al., 2010). This is probably due to the different tools that were used and time frames of depression symptom assessment. The Cardiac Depression Screen asked the patient to recall the prior three months during the assessment, whereas the PHQ-9, used in this study, asked the patient to recall the previous two weeks. A larger time frame would give more opportunity for depressive symptoms to occur thus increasing frequency of report.

Depression trends from inpatient to 30 days post discharge. Three PHQ-9 trends (n = 40) emerged over time. Participants assigned to Group 1 improved their PHQ-9 scores at T3; this was the most frequent trend occurring in 24 Group 1 participants (60%). In Group 1, PHQ-9 scores at T1 ranged from minimal to severe depressive symptoms (Figure 11, Chapter 5). Compared to others, participants assigned to Group 1 had significantly higher global cognition (i.e., higher MoCA scores) at T1 ($p = 0.031$) (Table 10, Chapter 5). Additionally, the subdomain attention improved, as measured by TMT A ($p = .003$), and MoCA attention ($p = .030$) (Table 10, Chapter 5). Membership in Group 1 was also inversely associated with age ($p = .05$) and weight change by T3 ($p = .016$). This indicates that participants who had improved depression were younger than those assigned to other groups. Importantly, the findings regarding weight loss suggest that Group 1 participants may have been euvolemic at T3.

One unique aspect of our study was demonstrating that depressive symptoms in HF patients can improve from inpatient to outpatient settings (Figure 10, Chapter 5). Since the PHQ-9 encompasses depressive symptoms in the preceding two weeks, the improvement trend

in Group 1 suggests that variables in the preceding two weeks leading up hospitalization, and early days of the hospital stay, may contribute to depressive symptoms found in the hospital.

One variable leading up to a hospitalization for ADHF is retention of fluid and weight gain (Chaudhry, Wang, Concato, Gill, & Krumholz, 2007). As the body retains fluid, the renin-angiotensin-aldoserone system system is activated which in turn increases cortisol levels (Rustad, Stern, Hebert, & Musselman, 2013). High cortisol is reported in those with depression diagnosis (Sohani & Samaan, 2012), and can predict cardiac events in chronic HF when there is higher oxidative stress (Yamaji et al., 2009). In addition to the neuro hormonal response, the retained fluid can also impact sleep patterns at home when the excess extracellular fluid goes to the patient's lungs and the patient cannot lay flat without difficulty breathing (Yancy et al., 2013). Excess extracellular fluid in the abdomen can also decrease appetite (Yancy et al., 2013). Along with the increased cortisol levels, reduction of sleep and changes in appetite can affect other neuro hormones that may contribute to depressive symptoms (Krumholz, 2013; Rustad et al., 2013; Sohani & Samaan, 2012).

Heart failure patients are often hospitalized for treatment of fluid overload. Hospital admission creates a challenging environment that can lead to depressive symptoms. Depressogenic variables in the hospital setting include disruptions of sleep, altered circadian rhythms, diet restrictions, new and changing medications that alter mentation and strength, irregular activity or even bedrest can cause deconditioning, as well as, unpredictable schedules and complex decisions that affect one's health (Krumholz, 2013). Acute illness requiring hospitalization, such as ADHF, can be stressful and may represent a life-altering event (Inouye et al., 2006). Stress can increase norepinephrine and cytokine levels, which are associated with depression in HF (York, Hassan, & Sheps, 2009).

Within one week following discharge, it is likely that participants in Group 1 experienced continued improvement in their HF symptoms, along with relief from the hospital environment, and return to the comfort of their home. This may account for Group 1's improvement in

depressive symptoms. Global cognition also improved in Group 1 and this supports that the relationship between depressive symptoms and cognition may be bidirectional.

This bidirectional relationship is further seen in Group 2, in which increased depressive symptoms were associated with lowered cognition in two domains: attention and language. Participants assigned to Group 2 showed decreased attention at T1 by displaying both low MoCA domain scores ($p = .05$) and more errors on TMT A ($p = .018$). Decreased attention continued at T2 with more errors on TMT A ($p = .000076$) (Table 10, Chapter 5). Attention is imperative to effective problem solving, an important part of executive function (Diamond, 2013). Attention is necessary for cognitive tasks (Leto & Feola, 2014). The attention deficits support the conclusion that along with increased depressive symptoms, executive function remained impaired in Group 2. Assignment to Group 2 was associated with lower language scores ($p = .041$). This impairment affects verbal skills, reading and writing (Leto & Feola, 2014). These are necessary skills for expressing oneself, communicating, and interpreting discharge instructions. Health literacy requires language skills to gain access to, understand and use information to promote wellness (Serper et al., 2014). Depressive symptoms are associated with lower health literacy as well (Serper et al., 2014).

Group 2's findings are consistent with those of other reports. Other investigators found that cognitive domains of attention, language, and motor function were associated with depression in HF (Alosco et al., 2013). They concluded that cerebral HF related hypoperfusion exacerbates depressive symptoms and cognitive abilities (Alosco et al., 2013). These findings and those of other investigators (Diamond, 2013), suggest that CI in Group 2 is not likely to improve.

Pullicino and colleagues posited a hypothesis to explain relationships among psychobehavioral variables and HF outcomes (2008). In short, they hypothesized that pathologic conditions associated with HF (i.e., fluid retention, electrolyte disturbance, cardiac medications, and anemia) may interact with depressive symptoms to produce a transient CI,

which they coined as “cardiac encephalopathy” (Pullicino et al., 2008). The association of the variables in the current study with higher PHQ-9 scores, indicate the association with CI (Table 10, Chapter 5), and support aspects of this hypothesis. Particularly, in Group 2, increased ankle circumference (p = .017) (fluid retention), taking a statin medication (p = .033) (cardiac medication), and having liver disease (p = .005) (increasing likelihood of anemia) support aspects of Pullicino et al. (2008) hypothesis. Given the low sample size of Group 2 (n = 5), it is not appropriate to draw conclusions. However in larger studies of other populations of acutely ill patients, there have been associations with increased depressive symptoms and worsening cognition (Stewart, Enders, Mitchell, Felmlee-Devine, & Smith, 2011).

The way ADHF symptoms are measured helps to define the relationship of depressive symptoms to health outcomes. Fluid retention, a symptom of ADHF, is measured in various ways. One way is with lab values (Yancy et al., 2013). In a Italian study with hospitalized ADHF patients, plasma BNP levels were used (Feola et al., 2013). Higher BNP was associated with lower CI when measured by the MMSE (Feola et al., 2013). Plasma BNP was not collected in this study; rather, other direct assessments (i.e. ankle circumference, jugular venous distention, and weight) were collected at all three time points. In clinical practice, these assessments are used to estimate the magnitude of excess extracellular fluid (Yancy et al., 2013). In this study, plasma BNP as a global inflammatory biomarker would have likely supported the physical assessment findings. One benefit of BNP is that as a lab value, it has less variability in collection. It is suggested to be a potential useful biomarker for CI in hospitalized HF patients (Zuccala et al., 2005) and in the general population (Feola et al., 2013).

Research shows participants of Group 2 are at risk for poor outcomes. Measuring the effect of depressive symptoms revealed that for each additional depressive symptom, reported physical symptoms increased by 0.6 in HF patients (Bekelman et al., 2007). Depressive symptoms have been reported as predictors of cardiovascular mortality (Kim, Hwang, Heo, Shin, & Kim, 2019; Sohani & Samaan, 2012), quality of life (AbuRuz, 2018; Kim et al., 2019),

and having increased anxiety (Cirelli, Lacerda, Lopes, de Lima Lopes, & de Barros, 2018; Feola et al., 2013). Experts have suggested that depressive and anxiety symptoms might exacerbate HF symptoms and contribute to worsening functional impairment (Feola et al., 2013). The findings in this study support that hypothesis. Further research is needed to explore interventions to help HF patients with ongoing depressive symptoms.

Group 3 are those who remained within the same level of depressive symptoms from T1 to T3 (Figure 11, Chapter 5). All participants assigned to Group 3 presented in minimal to mild depressive categories except two participants who reported moderate to severe depressive symptoms (Figure 11, Chapter 5). Assignment to Group 3 (i.e. unchanged depressive symptoms throughout the study) was associated with not being married ($p = .039$) and remaining in volume overload at T3 ($p = .044$) (Table 10, Chapter 5). Not being married and presence of depressive symptoms have been linked to poor cardiac outcomes in coronary heart disease (Compare et al., 2013). Continued volume overload may be associated with disease severity, which is known to be related to depression in HF (Holzapfel et al., 2008; Rutledge et al., 2006). We also found a relationship between Group 3 assignment and surviving septic/systemic inflammatory response syndrome (SIRS) ($p = .02$) and presence of hypo-osmolality and hyponatremia ($p = .014$) at T1 (Table 10, Chapter 5). The relationship between these variables and depressive symptoms are new findings for HF patients. Hyponatremia levels are associated with increased severity of HF disease; sodium levels less than 135 milliequivalents per liter (mEq/L) are associated with increased risk for HF readmission and mortality (Gheorghiade et al., 2007; Klein et al., 2005). Depressive symptoms have also been correlated to NYHA functional class (Cirelli et al., 2018). In the general population, an episode of sepsis did not change the incidence of depressive symptoms (Davydow, Hough, Langa, & Iwashyna, 2013). In fact, the most sensitive factor for post-sepsis depression is pre-sepsis depression (Davydow et al., 2013). In our study, the pre-hospital depression state of the patient was unknown.

Following discharge from the hospital, depression status should be reassessed. When depressive symptoms remain, clinicians should consider psychiatric and pharmacologic treatment (Diez-Quevedo et al., 2013; Rustad et al., 2013). Cognitive behavioral therapy (CBT) over six weeks alone improves depressive and anxiety symptoms in HF patients and in combination with exercise programs has been shown trends toward improvement; however, self-care behaviors and physical functioning measures were not affected (Celano, Villegas, Albanese, Gaggin, & Huffman, 2018). Although selective serotonin reuptake inhibitors (SSRIs) are safe for both depression and anxiety disorders, it is suggested that response to treatment may be limited when onset is after 30 to 40 years of age, the peak diagnoses years for these disorders (Celano et al., 2018). Experts suggest treating these disorders in care collaborations with HF and psychiatry experts as the best approach because to the potentially physiologically distinct nature (Celano et al., 2018). Many variables can affect a HF patient's emotional symptoms. A recent study found different variables (anemia in the outpatient setting and hypothyroidism in the inpatient setting) to have association with major depressive disorder in hospitalized HF (Patel et al., 2018). In our study, five participants (12.5%) at T1 and one remaining participant (2.5%) at T2 and T3 had symptoms consistent with major depressive disorder (PHQ-9 >15). In this study, these comorbidities were not associated with those with major depression likely due to our small sample size. Of note, Patel et al. (2018) used an ICD-10 coding abstraction in their retrospective study to define major depression as oppose to prospective assessment. Their sample may not have included all those depressed, or their comorbidities. Identifying depression is believed to be related to how HF patients present their depressive symptoms during assessment. Interestingly, depression (presence or absence) in HF does not differentiate the presence or absence of somatic depressive symptoms (Holzapfel et al., 2008). Individuals with HF endorse greater cognitive-emotional feelings (i.e. feelings of hopelessness and guilt) than do individuals without HF (Holzapfel et al., 2008). Investigators have suggested that this may be due to the loss of perceived control over one's medical illness

associated with HF, which highlights the importance of individual assessment (Holzapfel et al., 2008). Furthermore, in HF patients, somatic depressive symptoms are independently associated with increased mortality (Hwang, Moser, Pelter, Nesbitt, & Dracup, 2015).

In general, chronic disease is associated with increased risk of depression (Simon, 2001). We found that some chronic conditions, including valve surgery ($p = .032$) and peripheral vascular disease ($p = .038$) were associated with higher levels of depressive symptoms. Conversely, we did not find that acute renal failure ($p =.024$) was associated with increasing depressive symptoms (i.e. assignment to Group 2). Previous research with heart surgery patients showed that patients are at risk for prolonged depressive symptoms after surgery, especially when pain is present (Doering, Chen, McGuire, Bodan, & Irwin, 2014; Tully & Baker, 2012).

Lastly, Group 3 assignment was associated with lower scores in the MoCA naming domain at T3 ($p = .02$). The MoCA's ability to identify impairment in the naming domain has contributed to its reputation as the most sensitive test for mild CI (Tsai et al., 2012). This is supported by our data; 81.8% ($n = 9$) of those in Group 3 had mild CI at T3. Further research is needed to investigate the relationship between depressive symptoms, modifiable comorbidities, and mild CI.

Overall in this study, from T1 to T3, depressive symptoms peaked at T1, dropped at T2 ($p < .001$) and stayed lower at T3 ($p < .001$) (Figure 10, Chapter 10). This improvement is another reason why clinicians should consider waiting to educate patients until they are mentally and emotionally ready to learn. When depressive symptoms are present, a person experiences reduced effort or motivation (Foster et al., 2011). As supported by the Model of Health Learning, motivation and ability are foundational elements to learning and retaining health knowledge (Wolf et al., 2009). Capacity to learn is reduced when CI and depressive symptoms are both present (Davis, Himmelfarb, Szanton, Hayat, & Allen, 2015; Diamond, 2013). The relationship between cognition and depression in HF cannot be overlooked (Wallenborn & Angermann,

2013). In this study, improved depressive symptoms at T3 were associated with improved global cognition, executive function, and attention domains at T1. Participants whose depressive symptoms worsened or continued at T3 exhibited lower executive function, attention, language and naming domains.

The findings of our current study expand knowledge from previous studies of HF patients in outpatient settings. Foster et al. (2011) reported that higher depressive symptom scores and lowered executive function scores explained up to 46% of variance in reduced participation in self-care and social activities. Cameron et al. (2010) also found higher depressive symptoms and higher age explained up to 13% of variance in self-care confidence scores. For HF patients, obtaining and recalling self-care knowledge, self-care confidence, and successful participation in self-care at home are foundational requisites to achieving a successful transition from hospital to home and avoiding hospital readmissions (Figure 3, Chapter 3). Our findings support the relationship of depressive symptoms to lowered executive function and potential for increased adverse outcomes.

AIM #2: Determine if change in fluid volume status at T1 is independently associated with change in cognition status from T1 to T3.

Two variables, change of weight and change of hepatojugular reflex, were associated with the amount of change in MoCA scores at T3 (Table 11, Chapter 5). Weight gain was associated with declining cognition status ($p = .017$). This finding adds to the knowledge of factors which contribute to CI changes; specifically regarding the relationship between fluid overload and CI. Fluid overload is common in ADHF (Chaudhry et al., 2007). When weight increases rapidly, it is a sign of fluid overload that requires immediate treatment (Chaudhry et al., 2007). Fluid accumulation and fluid redistribution both increase cardiac load and congestion in ADHF (Mebazaa, Arrigo, Parissis, & Akiyama, 2016). In volume overload, there is a reported neuro hormonal response that effects CI (Yamaji et al., 2009; York et al., 2009) Additionally, HF patients in fluid overload are at risk for hypoxemia (Jung, Riley, Drozdzewski, & Pressler, 2017).

In a recent study, HF patients were compared to healthy controls and were found to have significantly higher frequency and longer duration of desaturation events, and lower oxygen saturation (Jung et al., 2017). Although our findings are novel and clinically relevant, it is important to note that in this study cognition status was a calculated number (i.e. MoCA T3 subtracted from MoCA T1). The scores changed from -5.0 to +6.0 by T3 (Figure 12, Chapter 5). This was enough to move cognition scores by one MoCA category, (i.e. from mild CI to normal cognition). Most scores did not shift drastically (i.e. from moderate/severe CI to normal CI). Thus, further study is needed to replicate our methods and confirm these findings.

Inadequate perfusion is believed to be a primary cause of CI in HF (Hajduk et al., 2013). Still, mild CI can be detected when the cerebral perfusion pressure and cardiac index remain normal (Athilingam et al., 2011). In this study, in addition to the relationship between weight gain and decreased cognition, participants assigned to Group 2 (i.e. those whose MoCA scores declined from normal at T1 to cognitively impaired at T3 did not improve their hepatojugular reflux scores at T3 ($p = .041$). These findings suggest that when HF patients are in fluid overload, their cognition is worse. Clinicians contend that when HF patients present with weight gain, it is likely that it has been going on at least one week before admission (Chaudhry et al., 2007). In HF patients, altered but unrecognized CI may contribute to lapses in self-care because patients may not recognize or interpret symptoms promptly and, thus, may delay in seeking care. Further research is needed to explore this relationship and ultimately, to test interventions that may help HF patients with CI avoid unnecessary admissions.

Power analysis for multivariate linear regression for eleven variables using G-Power suggests a sample size of 89. We had a small sample size that completed all three time points ($n=40$). This may be why the overall model of estimated change in MoCA scores was not statistically significant. Other investigators have reported that recruitment for HF studies regarding CI is challenging (Hajduk et al., 2013; Pressler, 2008). It is likely that there are other

variables contributing to MoCA change, since our model explained only 22.1% of the variance. Further research is needed to explore other variables.

AIM #3: Identify variables present at T1 that are correlated with cognition at T1 and T3.

In the hospital setting, anxiety disorders and major depressive disorder have been associated with incident HF (Garfield et al., 2014). Heart failure patients have multiple comorbidities and variables that may impact cognition in the hospital and after discharge (Hajduk et al., 2013; Levin et al., 2014). In this study, high anxiety symptoms and greater number of comorbidities negatively affected inpatient cognition scores (Table 12, Chapter 5).

The relationship of anxiety symptoms to cognition in the hospital is a new finding in the literature. Anxiety's relationship to HF and CI has been investigated in two other studies with hospitalized HF patients (Feola et al., 2013; Huynh et al., 2016) and one outpatient study (Vogels et al., 2007). Of the two inpatient studies, neither found a relationship with anxiety and CI in HF patients. Instead of CI, higher anxiety symptoms in the hospital were correlated with higher NYHA class, longer six minute walk tests (Feola et al., 2013) and was an independent predictor of 30-day readmission (Huynh et al., 2016). Measurement of anxiety symptoms with different tools and in varied populations in different counties may have contributed to different findings. In the study in Italy, the Hospital Anxiety and Depression Scale (HADS) (Feola et al., 2013) was used; and in Australia, the Generalized Anxiety Disorder 7 questionnaire (Huynh et al., 2016) measured symptoms in the hospital. In the outpatient setting, investigators in the Netherlands did not find a relationship between anxiety symptoms and cognition using the Symptoms Checklist 90 tool (Vogels et al., 2007). In our study (United States), higher Brief Symptom Inventory- Anxiety (BSI-A) scores (higher anxiety) were associated with worse CI when participants were hospitalized (T1), but not in the outpatient setting (T3). Because participants in our study were older (mean age = 73.77 ± 11.28), our findings are consistent with other reports that hospitalizations increase anxious feelings for older inpatients at large (Inouye

et al., 2006). Anxiety symptoms are known to cause stress and alter cognition even in healthy adults (Diamond, 2013; Robinson, Vytal, Cornwell, & Grillon, 2013).

Participants were asked to recall feelings in the previous two weeks when reporting their anxiety symptoms on the BSI-A. Thus, variables in the outpatient setting prior to admission may have contributed to the inpatient anxiety symptoms for some participants. For example, being unemployed or an active smoker influenced anxiety in HF patients in the outpatient setting (Cirelli et al., 2018). These variables were not collected in this study. However, other research showed history of mental ill-health, diabetes, angina, and NYHA class III and IV were predictors of the diagnosis of anxiety in the outpatient setting (Haworth et al., 2005). Both diabetes (48.1%, n = 26) and NYHA III and IV (98.1%, n=52) were common comorbidities in the current study. Moreover, this study showed a higher CCI was associated with greater anxiety at T1. Having more comorbidities usually means more self-care behaviors are needed (Hajduk et al., 2013; Krumholz, 2013; Riegel. et al., 2009). Prior to admission, when poor self-care happens, greater anxiety, depression, and lower levels of perceived control follow (Hwang et al., 2014). This is despite high recorded HF knowledge, and was associated with worse NYHA (Hwang et al., 2014). Together, anxiety symptoms and CCI explain 22.6% of the variance of MoCA scores at T1 (Table 13, Chapter 5). Further research is needed to understand the impact of treating anxiety symptoms in the hospital.

In the current study, the bidirectional relationship of cognition and CCI is also present at T3. We found that higher cognition at T3, when participants were not in the hospital, was associated with the presence of fewer comorbidities at T1, when they were in the hospital (p=.05) (Table 14, Chapter 5). One explanation for the sustained inverse correlation of cognition and comorbidities scores at both T1 and T3 may be that neither measurement varied greatly as HF patients move from inpatient to outpatient settings. For example, reports suggest the burden of required self-care behaviors increases as the number of comorbidities increase (Hajduk et al., 2013; Krumholz, 2013). Similarly, other investigators have shown that in

outpatient settings cognition remains impaired when patients are at risk for poor self-care behavior (Cameron et al., 2010). MoCA scores consistent with CI, the presence of more comorbidities, and higher NYHA classification explained up to 20% of the variance in self-care management scores (Cameron et al., 2010). Our findings are consistent with this previous report and reinforce the importance of including assessment and treatment of comorbidities in discharge planning for HF patients. Clinicians should consider using the CCI score which is available in most electronic medical records to assess an individual's potential cognition while they are still in the hospital.

In this study, the absence of relationships with cognition and other putative factors (HF severity, presence of sleep apnea, depressive symptoms, perceived social support, and number of medications at discharge) at T1 and T3 may be due to the relative absence of variance within those findings. Within group assignments related to changes in CI over time (Groups 1-4), there were associations of some of these variables with group assignment (Table 7, Chapter 5), but no associations with cognition were significant in the overall sample. The most likely explanation is that we lacked adequate power to detect some relationships, since our power analysis estimated a sample size of 89 to identify seven variables in multivariate linear regression. Another factor may be the highly complex and interrelated processes associated with cognition (Hajduk et al., 2013; Krumholz, 2013).

Aim #4: Identify variables present at T1 that are correlated with likelihood of 30-day all cause readmissions.

Of the seven variables examined in this aim (inpatient MoCA scores, depressive symptoms, anxiety symptoms, medical comorbidities, social support, length of hospital stay, self-care behaviors and receiving the Nurse Navigator program), only medical comorbidities (measured by the CCI) trended towards association when forced entry was used for input into a linear regression model (p=.083). The variable CCI explained 3.4% of the variance of 30-day readmissions. The impact of comorbidities on readmissions is consistent with previous reports.

Other investigators have reported that poor self-care behavior scores are associated with poor cognition (Cameron et al., 2010) and that an individual's ability to transition successfully to outpatient status without readmission within 30 days is dependent on their ability to perform self-care (Naylor et al., 2004; Pressler, Subramanian, et al., 2010; Riegel. et al., 2009). Further, the effects of multiple comorbidities on overall health may play a role in risk of readmission (Hajduk et al., 2013). Those with more illness may face greater self-care burden once they leave the hospital (Kindermann et al., 2012; Krumholz, 2013).

In this study, the impact of comorbidities on 30-day readmissions contributed to less than ten percent of the variance (Table 16, Chapter 5). Variables that contribute to readmissions for HF patients included those who had a history of MI and peripheral vascular disease (Wang et al., 2014). Although not associated with readmissions in this study, we found that a history of MI was associated with abnormal cognition scores at T1 and T3. We also found worsening depressive symptoms at T3 related to peripheral vascular disease. Poor outcomes have been found to be associated with depression, anxiety, or cognition and HF. Depressed middle aged white females have a higher risk of hospitalization for HF (Patel et al., 2018). Anxiety disorder was reported to be associated with development and progression of HF, as well as increased mortality rates (Celano et al., 2018). When depression and anxiety were added to a HF specific readmission risk model, the accuracy improved showing their importance (Amarasingham et al., 2010). Cognitive impairment can go undetected without deliberate assessment and potentially increases patient's risk of readmission (Hajduk et al., 2013; Levin et al., 2014; Sterling et al., 2018). In one study in Italy, mild CI was found to predict 30-day readmission and death in HF (Huynh et al., 2016). In comparison, in a study with 883 ADHF patients at Vanderbilt, numeracy, health literacy, and cognition were not associated with 30-day readmission (Sterling et al., 2018). These varying results between studies indicate that more research is needed to understand the impact of cognition to 30-day readmissions in HF.

In the regression, the other original variables of interest (inpatient cognition, age, presence of sleep apnea, perceived social support, length of hospitalized stay, HF self-care, depressive symptoms, and those with RN follow-up) were not correlated with readmissions. As noted previously, this is likely due to insufficient power to identify relationships in multivariate analyses.

Limitations

The study took place in one hospital system across three sites and was limited to English and Spanish language preferred patients. The study sample was small and mostly male. A larger sample size to increase power and allow for adequate evaluation of more variables, including gender, would have been optimal. Researchers have reported problems with recruitment for ADHF studies focusing on cognition (Arslanian-Engoren et al., 2016). In this study, we experienced similar recruitment problems, including patient refusal from fatigue, lack of interest, or early discharge. The complexity of HF patients leads researchers to control for a multitude of variables within a study and test exhaustion can occur. Although once in the study, subjects did not request breaks and refused them when offered, data on other variables, like health literacy, were not added to the battery of tests collected. Other researchers have reported challenges in studying the HF population (Arslanian-Engoren et al., 2016; Harrison et al., 2016). One reported that men and women gave similar reasons for declining participation in studies involving cognition; they also noted that participation rates of women were smaller than those of men (Harrison et al., 2016). Perhaps the prevalence of depressive symptoms identified in hospitalized HF patients contributes to this reported reluctance to enroll in research studies.

For the current repeated measures study, participant retention proved difficult because the population had high mortality risk and CI. After a year of collecting data, we started to screen potential participants for wellness. If the provider believed they would die in the following month or they were planned to be discharged to hospice care, we did not invite them to participate. This improved our retention of subjects; however, if a participant's status changed

after enrollment and before hospital discharge (i.e. they agreed to hospice care after enrollment), we would reaffirm their willingness to continue in the study. Only three declined the study for this reason.

Retention across three time points was labor intensive. Meeting the patients at their provider follow-up appointment was the best strategy. In hindsight, we underestimated the time required to meet potential participants, screen, consent, and enroll them. Intake sessions took longer to complete when the patient had CI or depression. Other researchers confirm these challenges to retention in HF studies investigating cognition (Arslanian-Engoren et al., 2016).

Summary- Implications for Practice

In the context of HF, the high prevalence of CI in the hospital should lead clinicians to evaluate each patient's ability to retain necessary self-care education. Today, as part of standard routine care, clinicians use many resources to educate hospitalized HF patients. Ultimately, the patient's success at home is dependent on the patient and/or caregiver's ability to learn and follow the discharge care plan. This observation is supported theoretically by the Model of Health Learning (MHL), which suggests that the patient's cognitive state is responsible for the patient's ability to learn. Nonetheless, cognition is rarely assessed in hospitalized HF patients (Hajduk et al., 2013; Levin et al., 2014).

Often, as we found in this study, HF patients demonstrate impairment in how they received and processed information (Rakel & Bulechek, 1990). Readiness to learn is evidenced by the state of having both the willingness and ability to understand (Rakel & Bulechek, 1990; Vanetzian, 1997). Specifically for health information, the skills and ability required to gain access to, understand and use information to promote wellness is called health literacy (Serper et al., 2014; WHO, 2009). Health literacy requires memory, processing speed, problem-solving, attained health knowledge, as well as reading and numeracy skills (Serper et al., 2014). In addition to motivation and health literacy, readiness to learn requires a lack of illness-related learning impairments (Rakel & Bulechek, 1990; Wong et al., 2009). Illness-related impairments

are any factors that cause disruptions in cognitive processes, such as HF, depression, and anxiety found in this sample.

In this study, we showed that higher anxiety scores were directly associated with poorer cognition in the hospital. Clinicians should assess the patient's anxiety and cognitive state in the hospital prior to teaching the patient. If the patient is found to have anxiety then cognition may be impaired and plans to teach the patient in depth should be made for following discharge. Patient learning is likely compromised in the hospital. These variables may interact with depressive symptoms to produce transient CI or "cardiac encephalopathy" (Pullicino et al., 2008). The complex interaction of these conditions may include physical (i.e., decreased blood flow) or cognitive factors (i.e. depressed mood) and in both instances are associated with disruptions in thinking (Levin et al., 2014). The neuro hormonal effect of ADHF, depression, and anxiety contributes to overall CI and cannot be overlooked (Yamaji et al., 2009; York et al., 2009). One unique aspect of our study was assessing the relationship between learning ability, readiness to learn, and cognitive impairment in HF patients. Our findings support the prudence of delaying patient education until the patient recovers from the hospital experience (Davis et al., 2015; Kindermann et al., 2012). Further study is needed to design nursing interventions to assess and address readiness to learn in HF patients.

The clinical management of HF is primarily pharmacologic; however, maximizing patients' quality of life through self-sufficient living, social functioning, and psychosocial welfare is equally important (Hui et al., 2006). Both treatment aims (relieving HF symptoms and improving quality of life) involve daily decisions and actions by the individual. Ultimately, HF patients are expected to master a program of complex, individualized, and dynamic self-care management. Decreased decision-making capability contributes to poor self-care management, poor adherence, and frequent hospitalizations (Bauer, Johnson, & Pozehl, 2011; Hwang et al., 2014).

Treatment of HF requires more than treating the heart alone. We must also treat the brain. It's not just HF, it is mind failure. The body's systems are connected and impairment in one system impacts other symptoms. During treatment, clinicians who treat HF patients must monitor other body systems. For example, acute renal failure occurred in about 50% of the sample in our study. Cognitive impairment was present in 60% of patients at T1. One of the barriers to assessing and treating CI in HF patients is the lack of standardized recommendations for both assessment and treatment. Cognition screening is recommended for all HF patients yet rarely followed (Dodson et al., 2013; Hajduk et al., 2013). Chart review reveals that when cognition is assessed and found impaired in the hospitalized patient, less than half of those impaired have provider documentation on the issue (Dodson et al., 2013). Despite the Heart Failure Society of America (HFSA) guidelines' support of patient education and assessment of cognition (Yancy et al., 2013), a cognitive assessment is not standard of care for a HF patient in the inpatient or outpatient setting. Outside of the routine clinician assessment of orientation and "alert/not alert," cognition status is still not routinely assessed during hospitalization (McDougall, 2017). When CI is diagnosed, it should be addressed in the care plan because of its effect on knowledge retention, complex reasoning, and problem solving (Athilingam et al., 2011; Pressler, 2008). The discharge plan should include a plan to closely follow patients with CI (Davis et al., 2012; Huynh et al., 2016).

To avoid readmissions, those with CI and depressed emotions need extra support while they recover outside the hospital. Even so, as our findings indicate some HF patients remained cognitively impaired at 30 days after hospitalization.

It is important to know what cognitive deficits remain after the patient has stabilized at home. Ongoing cognitive deficits should be addressed in a care plan to promote potential improvement and improve patient's quality of life. Recent literature suggests that mild CI improves with cognitive training (Bier et al., 2015). Cognitive training can be performed as an intervention with a neuropsychologist specialist. There are computerized cognitive training

programs that have been shown to improve some ranges of cognition (Hajduk et al., 2013; Pressler et al., 2011). Additionally, there are promising results that cognition can improve in healthy subjects with brain training games as an intervention (Al-Thaquib et al., 2018). Further research is needed to know if this intervention will be beneficial for HF patients with CI.

Ongoing reassessment of HF patient's depressive symptoms is imperative to ensuring a comprehensive care plan. This study showed over a third of HF patients will likely be depressed in the hospital, but it is also likely their depression will improve once discharged. Understanding the patient's unique variables, and how they may help or hinder recovery, will aid the clinical team to approach the plan of care conversations with the patient (De Vecchis, Manginas, Noutsias, Tschöpe, & Noutsias, 2017). Appropriate treatment of depression is necessary if it does not resolve. Even though HF patient's presentation of somatic symptoms cross over and may be interpreted as symptoms of ADHF, the cognitive-emotional symptoms must be purposefully assessed in addition to suicidal ideation. Ideally, ACC/AHA/HFSA HF guidelines should recommend routinely screening patients for depression across the continuum.

The dynamic relationship among HF, CI, and depressive symptoms should be assessed on a case by case basis. Particularly important is the patient's capability to retain knowledge in the presence of CI. Specific characteristics of CI in an individual should be considered when planning interventions to improve comprehension and retention of information (Bauer et al., 2011). Findings from the current study will inform the design and testing of nursing interventions aimed at incorporating cognitive assessment into standard of care for HF in order to help patients make successful transitions from hospital to home and to prevent repeated hospital readmissions.

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Appendices

University of California, Los Angeles

Screening Eligibility Script

Cognition in Acute Decompensated Heart Failure (COGHF)

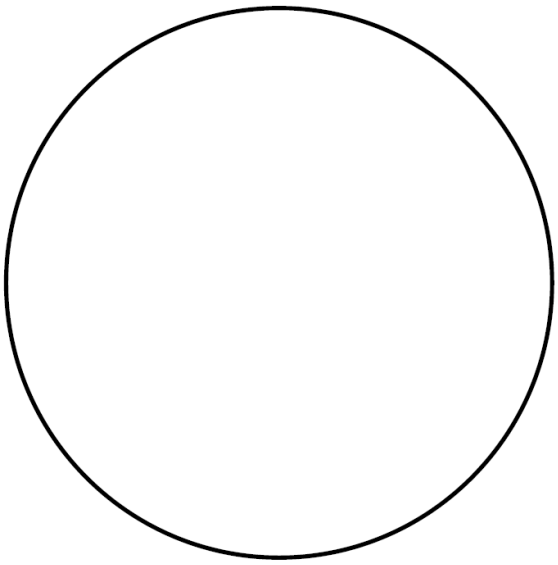
Hello, my name is Kristin Dixon (or delegate -research associate) and I am a doctoral student researcher at the University of California, Los Angeles (UCLA) (delegate identifies themselves affiliate (UCLA/Scripps Employee). I am visiting you today because you have been diagnosed with heart failure and may be eligible to participate in a research study. This is a study to describe what happens to people who have heart failure's ability to think and learn during hospitalization and following discharge; and its effect on readmission rates. Readmission means returning to the hospital within 30 days since your discharge.
Would you like me to continue with the screening? [If no, thank them for their time and do not continue with the screening, if yes, continue]. The screening will take about 10 minutes. I will ask your primary language and ask you to answer a series of questions evaluating reasoning and thinking. The surveys ask you for example about attention and recall. The reason for this screening is to help assure you are eligible to participate. You do not have to answer any questions you do not wish to answer or are uncomfortable answering, and you may stop at any time. Your participation in the screening is voluntary.
Your answers will be confidential. No one will know your answers except for the research team. Would you like to continue with the screening? [If no, thank the person] If yes, continue with the screening:

- **A.** Is English or Spanish your primary language? [If other language than English or Spanish patient not eligible thank participants for their time and explain why. If Yes then proceed.]
- **B.** Now I will ask you to answer a series of questions evaluating reasoning and thinking. Provide the reasoning surveys (Watson Clock-Drawing Test and CAM), [administer and score the two screens following guidelines].

Thank you for answering the screening questions. [It appears you meet the screening eligibility based on your score. Indicate whether the person is eligible, or if not eligible explain why. If either screen is positive, patient not eligible.] Do you have any questions about the screening or the research? I am going to give you this paper about the study and contact numbers [provide hand-out of contact numbers]. If you have questions later about the research screening you may call me about the screening or research. If you have questions about your rights as a research subject or if you wish to voice any problems or concerns you may have about the study to someone other than the researchers, please contact the Office of the Human Research Protection Program at UCLA (310) 825-7122 which is on the hand-out. Do you want to move forward with the consent? Or do you want me to come back later?
Thank you again for your willingness to answer questions [if eligible, complete consent the study information sheet and the HIPAA authorization form or arrange a time and place to administer the consent].

Clock Drawing Test

Patient's name: _____ Date & time: _____



Delirium Assessment:

Confusion Assessment Method	**YES**	**NO**
1. **ACUTE ONSET/FLUCTUATING COURSE** Is there a history of an acute change in mental status with evidence of fluctuation in the degree of symptoms?	___	___
AND 2. **INATTENTION** Does the patient have difficulty focusing attention (e.g., being easily distractible, or failing to focus on the discussion or sustain an effort)?	___	___
AND 3. **DISORGANIZED SPEECH** Is the patient's speech disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching of subjects?	___	___
OR 4. **ALTERED LEVEL OF CONSCIOUSNESS** Is the patient's level of alertness either hyper-alert (e.g., vigilant, overly sensitive to environmental stimuli, easily startles); or hypo-alert (e.g., lethargic, stuporous, drowsy, difficult to arouse)?	___	___

For a positive CAM numbers 1 & 2 BOTH must be present and only one of numbers 3 and/or 4 must be present.

Adapted from: Inouye, S, vanDyck, C, Alessi, C, Balkin, S, Siegal, A, Horwitz, R (1990). Clarifying confusion: The Confusion Assessment Method. A new method for detection of delirium. *Ann Intern Med. 113*: 941-948.

CHECK THE APPROPRIATE BOX:

☐ **POSITIVE** ☐ **NEGATIVE**

****Document findings of the CAM in the EMR neuro nursing narrative. Describe behavior present**

Scripps

IRB NUMBER: IRB-16-6759
IRB APPROVAL DATE: 05/23/2018
IRB EXPIRATION DATE: 05/22/2019

CONSENT TO PARTICIPATE IN RESEARCH

Cognition in Acute Decompensated Heart Failure (COGHF)

Principal Investigator: Kristin W. Dixon RN, MSN, PhD candidate sponsored by Lynn V. Doering, RN, PhD, from the School of Nursing at the University of California, Los Angeles (UCLA)

Sub-Investigators (all Nurses from Scripps Health 858-824-8464)**:** Heidi Arens, Ellen Ashman, Dawn Hutson, Nancy Blakely, Melissa Miller, & Laura Moreau

Research Site(s): Scripps Memorial La Jolla, Scripps Green, & Scripps Memorial Encinitas Hospitals

Sponsor: J. Thomas Heywood, MD, Scripps Health heart failure medical director

Before you start reading about this research, please read the California Experimental Subjects' Bill of Rights, which is page 5 of this form.

You were selected as a possible participant in this study because you have a diagnosis of heart failure and are currently a patient in the hospital. Your participation in this research study is voluntary.

Why is this study being done?
The purpose of the research study is to understand how heart failure patients think and learn while they are in the hospital and when they are home. This information will help your healthcare team provide information in a way that may help keep you out of the hospital in the future.

What will happen if I take part in this research study?
If you volunteer to participate in this study, the researcher will ask you to do the following:

- Read this consent form, ask any questions you have and, if you agree to take part, sign this form and a HIPAA authorization (last two pages of this form) that allows the researchers to gather information from your medical record about your heart failure, history of any mental health issues, your general health, and your care.

- Complete a questionnaire in the hospital that asks questions about your heart failure care, such as, (how often you see your doctor and whether you have a caregiver).

- Complete a screening form that asks questions about how you reason and think; for example, telling the researcher as many words as you can think of that begin with a certain letter of the alphabet. This will be done once in the hospital and twice after you leave the hospital.

- Complete a survey that asks questions about feelings of distress or sadness that you may have. This will be done once in the hospital and twice after you leave the hospital.

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- Have a short physical exam that measures extra fluid you may have, such as weighing you on a scale. This will be done once in the hospital and twice after you leave the hospital.

How long will I be in the research study?
The total time you will be in the study is about one month.

The study staff will meet with you shortly after you are admitted to the hospital to ask if you want to take part in the study and ask you a few questions.

A few days later, when you are feeling better you will meet with the researcher to answer 2 questionnaires, 2 screens, and 2 surveys that will take a total of 30-45 minutes. A physical exam will be done that take 5 min. If you need to rest during this meeting, just ask the study staff.

After you leave the hospital, you will be contacted for follow-up visits with the researcher. At the two follow-up visits, only the 2 screens and 2 surveys will be repeated along with the physical exam. This will take no more than 30 minutes to complete.

These visits may take place at you doctor's office when you return for a follow-up visit or at your home.

Are there any potential risks or discomforts that I can expect from this study?
You may feel uncomfortable about answering questions about your health or lifestyle. You can choose not to answer any questions that you do not like. You may get tired during the visits. Tell the study staff and they will allow you to rest. You may decide not to participate at any time. This will not change how you will be cared for as a patient.

Are there any potential benefits if I participate?
There may be no benefits to you personally, but your participation may help us better understand how to care for heart failure patients at our hospitals.

Will I be paid for participating?
There is no payment for being in the research. There is no cost to you for being in this study.

Will information about me and my participation be kept confidential?
Any information that is collected in this study will remain confidential. It will only be available with your permission or as required by law. Confidentiality will be kept by removing your name from all paperwork and instead using a code for your name. All data is guarded and maintained in a locked secure area. No one other than the researchers will have access to the secure files. Data collected for this study may be shared with other researchers for studies that are unknown at this time. If any data is shared, it will not include names or other personal identifying information.

What are my rights if I take part in this study?
- You can choose if you want to be in this study, and you may stop at any time.

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- Either way this will not change how you will be cared for as a patient.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:**
  If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

  Kristin Dixon, RN, ACNS-BC, PhD (c) principal investigator at (858)-824-8464.
  Lynn Doering, RN, PhD, FAAN, FAHA UCLA professor at (310) 825-4890.
  Tom Heywood, MD, Director, Heart Failure Recovery Program at (858) 554-5588.

- **The Scripps Office for the Protection of Research Subjects:**
  If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please call Scripps at (858) 678-6402 or UCLA (310) 825-7122 or write to:

  Scripps Clinical Research Services
  4275 Campus Point Court, CPB200
  San Diego, California 92121

  UCLA Office of the Human Research Protection Program
  11000 Kinross Avenue, Suite 211, Box 951694
  Los Angeles, CA 90095-1694

FUTURE USE OF DATA

Please check the appropriate box below and initial:

_____ I agree to have my data stored for use in future research by the Principal Investigator, research team, and/or other researchers.

_____ I do not want my data stored for use in future research by the Principal Investigator, research team, and/or other researchers.

Scripps

IRB NUMBER: IRB-16-6759
IRB APPROVAL DATE: 05/23/2018
IRB EXPIRATION DATE: 05/22/2019

I agree to participate.

I have read and understood the explanation of the study. The study has also been explained to me by Kristin Dixon RN MSN or the study staff. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel obligated to take part.

I have read this consent form. I must sign this consent form, and I will be given a signed copy of it to keep.

SIGNATURE OF STUDY PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ 858-824-8464
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

Scripps

IRB NUMBER: IRB-16-6759
IRB APPROVAL DATE: 05/23/2018
IRB EXPIRATION DATE: 05/22/2019

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS*

If I am asked to consent to be a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:

1. *Learn the nature and purpose of the experiment (also called "study" or "clinical trial").*
2. *Receive an explanation of the procedures to be followed in the study, and any drug or device to be used.*
3. *Receive a description of any discomforts and risks that I could experience from the study.*
4. *Receive an explanation of any benefits I might expect from the study.*
5. *Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to me.*
6. *Learn what medical treatment will be made available to me if I should be injured as a result of the study.*
7. *Ask any questions about the study or the procedures involved.*
8. *Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment.*
9. *Receive a copy of the signed and dated consent form.*
10. *Decide to consent or not to consent to a study without feeling forced or obligated.*

If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Scripps Office for the Protection of Research Subjects, which protects volunteers in research studies. I may telephone the Office at ***(858) 678-6402****, 8:00 a.m. to 4:00 p.m. weekdays, or I may write to the Scripps Office for the Protection of Research Subjects, 4275 Campus Point Court, CBP200, San Diego, CA 92121.*

By signing this document, I agree that I have read and received a copy of this Bill of Rights.

_____ _____

Signature of Subject or Legal Representative Date

**California Health & Safety Code, Section 24172*

Scripps

IRB NUMBER: IRB-16-6759
IRB APPROVAL DATE: 05/23/2018
IRB EXPIRATION DATE: 05/22/2019

Authorization to use your Private Health Information

Name of Study: *Cognition in Acute Decompensated Heart Failure (COGHF)*

Principal Investigator: Kristin W. Dixon RN, MSN, PhD candidate

What is private health information?
Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- While you are in the hospital, a chart review will collect your age, gender, medical history, medications, recent hospitalizations and results of any procedures or lab tests.
- 30 days after leaving the hospital, we will collect the date you were discharged, where you were discharged to, the number of days spent in the hospital, and the number of readmissions in the past 30 days.
- Information needed to contact you such as your name, address, and phone number

Who else will see my information?
In addition to the Principal Investigator, this information may be shared with:

- the sponsor of the research study, Lynn V. Doering, RN, PhD, from the School of Nursing at the University of California, Los Angeles (UCLA), the sponsor of the research study, J. Thomas Heywood, MD, Scripps Health heart failure medical director, and members of this research team.
- government agencies, such as the US Food and Drug Administration and agencies like it in other countries, or agencies of the Department of Health and Human Services, and
- Scripps committees that review research to help protect people who join research studies.

Once we have shared your information we cannot be sure that it will stay private. If ***you*** share your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will Scripps use and share my information?
Your information will be used and shared until the research is completed, which we think will be about 5 years after the date you sign this form.

Scripps

IRB NUMBER: IRB-16-6759
IRB APPROVAL DATE: 05/23/2018
IRB EXPIRATION DATE: 05/22/2019

What if I change my mind about sharing my research information?
If you decide not to share your information anymore:

- The sponsor and the research team can continue to use any of the private information that they already have.
- You will no longer be a part of the research study.
- You will still get the same medical care that you've always had at Scripps.
- You must write to the investigator and tell him that you no longer want to share your information. Write to the investigator at:

Scripps Memorial Hospital La Jolla Attn: Kristin Dixon
9888 Genesee Ave.
La Jolla, CA 92037

Do I have the right to see and copy my research information?
You cannot see your research information while the study is going on, unless it is also being used for your health care. Once the study is over, you can ask to see any research information that is in your Medical Record that is kept at Scripps.

If you agree to share your information you should sign this form below. You will be given a copy of this form.

****

I agree to share my information as described in this form

_____
Print your name

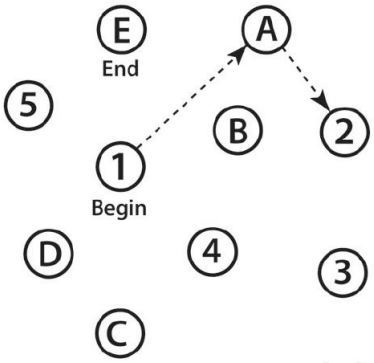
_____ _____
Sign your name Date

If you have questions or concerns about your privacy and the use of your personal medical information, contact the investigator at the telephone number listed in the consent form.

MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE



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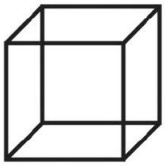


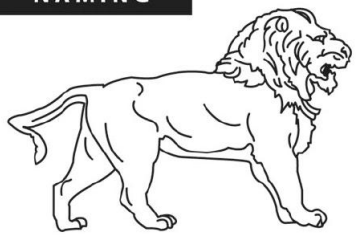
Copy cube [ ]

Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

POINTS ___/5

NAMING



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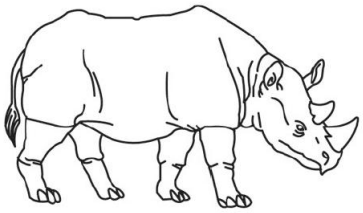

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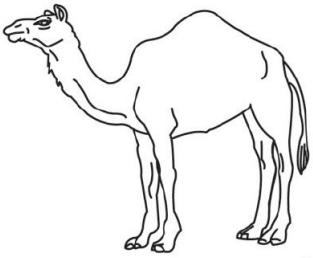


[ ]

___/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4
Subject has to repeat them in the backward order [ ] 7 4 2 ___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors
[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B ___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65
4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt** ___/3

LANGUAGE Repeat : I only know that John is the one to help today. [ ]
The cat always hid under the couch when dogs were in the room. [ ] ___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words) ___/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler ___/2

DELAYED RECALL

	FACE	VELVET	CHURCH	DAISY	RED	
Has to recall words **WITH NO CUE**	[ ]	[ ]	[ ]	[ ]	[ ]	Points for UNCUED recall only
Optional Category cue						
Optional Multiple choice cue						

___/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City ___/6

 www.mocatest.org

Normal ≥26 / 30

TOTAL ___/30
Add 1 point if ≤ 12 yr edu

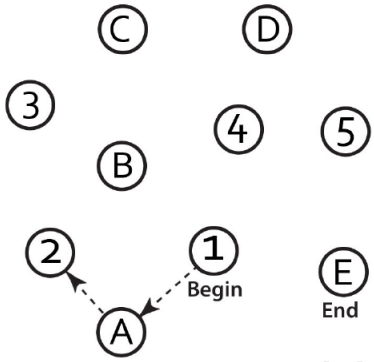
Administered by: _____

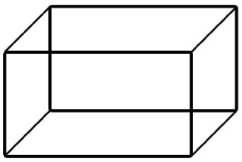
MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.2 Alternative Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS

Copy rectangle





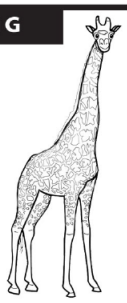
[ ] [ ]

Draw CLOCK (Five past four)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

___/5

NAMING



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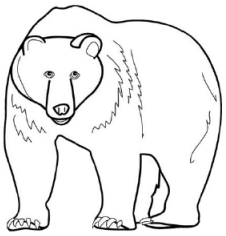

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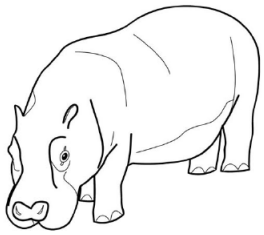

[ ]

___/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	TRUCK	BANANA	VIOLIN	DESK	GREEN
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.).
Subject has to repeat them in the forward order [ ] 3 2 9 6 5
Subject has to repeat them in the backward order [ ] 8 5 2

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors
[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 90 [ ] 83 [ ] 76 [ ] 69 [ ] 62 [ ] 55
4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE

Repeat : A bird can fly into closed windows when it's dark and windy. [ ]
The caring grandmother sent groceries over a week ago. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter S [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION

Similarity between e.g. carrot - potato = vegetable. [ ] diamond - ruby [ ] cannon - rifle

___/2

DELAYED RECALL

	TRUCK	BANANA	VIOLIN	DESK	GREEN
Has to recall words **WITH NO CUE**	[ ]	[ ]	[ ]	[ ]	[ ]
Optional Category cue					
Optional Multiple choice cue					

Points for UNCUED recall only

___/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

Adapted by : Z. Nasreddine MD, N. Phillips PhD, H. Chertkow MD
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Normal ≥ 26 / 30

TOTAL ___/30
Add 1 point if ≤ 12 yr edu

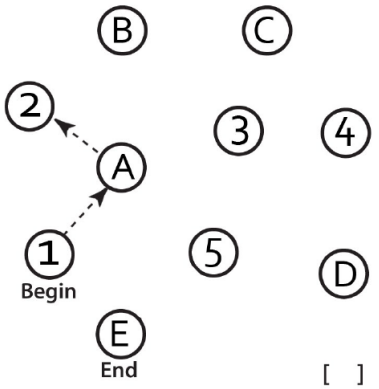
Administered by: _____

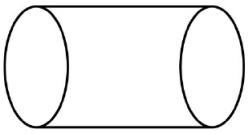
MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.3 Alternative Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS

Copy cylinder





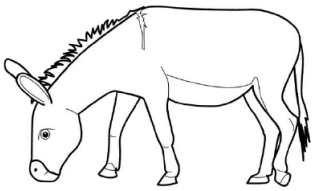
[ ] [ ]

Draw CLOCK (Ten past nine)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

___/5

NAMING



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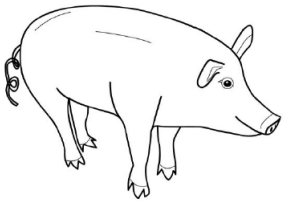

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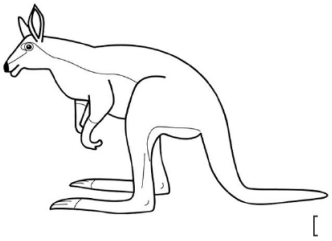

[ ]

___/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	TRAIN	EGG	HAT	CHAIR	BLUE
1st trial					
2nd trial					

No points

ATTENTION Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 5 4 1 8 7
Subject has to repeat them in the backward order [ ] 1 7 4

___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors
[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

___/1

Serial 7 subtraction starting at 80 [ ] 73 [ ] 66 [ ] 59 [ ] 52 [ ] 45
4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

___/3

LANGUAGE Repeat : She heard his lawyer was the one to sue after the accident. [ ]
The little girls who were given too much candy got stomach aches. [ ]

___/2

Fluency / Name maximum number of words in one minute that begin with the letter B [ ] _____ (N ≥ 11 words)

___/1

ABSTRACTION Similarity between e.g. banana - orange = fruit [ ] eye – ear [ ] trumpet – piano

___/2

DELAYED RECALL

	TRAIN	EGG	HAT	CHAIR	BLUE	
Has to recall words **WITH NO CUE**	[ ]	[ ]	[ ]	[ ]	[ ]	Points for UNCUED recall only
Optional Category cue						
Optional Multiple choice cue						

___/5

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

___/6

Adapted by : Z. Nasreddine MD, N. Phillips PhD, H. Chertkow MD
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Normal ≥ 26 / 30

TOTAL ___/30
Add 1 point if ≤ 12 yr edu

Administered by: _____

Trail Making Test (TMT) Parts A & B

Instructions:

Both parts of the Trail Making Test consist of 25 circles distributed over a sheet of paper. In Part A, the circles are numbered 1 – 25, and the patient should draw lines to connect the numbers in ascending order. In Part B, the circles include both numbers (1 – 13) and letters (A – L); as in Part A, the patient draws lines to connect the circles in an ascending pattern, but with the added task of alternating between the numbers and letters (i.e., 1-A-2-B-3-C, etc.). The patient should be instructed to connect the circles as quickly as possible, without lifting the pen or pencil from the paper. Time the patient as he or she connects the "trail." If the patient makes an error, point it out immediately and allow the patient to correct it. Errors affect the patient's score only in that the correction of errors is included in the completion time for the task. It is unnecessary to continue the test if the patient has not completed both parts after five minutes have elapsed.

Step 1: Give the patient a copy of the Trail Making Test Part A worksheet and a pen or pencil.

Step 2: Demonstrate the test to the patient using the sample sheet (Trail Making Part A – *SAMPLE*).

Step 3: Time the patient as he or she follows the “trail” made by the numbers on the test.

Step 4: Record the time.

Step 5: Repeat the procedure for Trail Making Test Part B.

Scoring:

Results for both TMT A and B are reported as the number of seconds required to complete the task; therefore, higher scores reveal greater impairment.

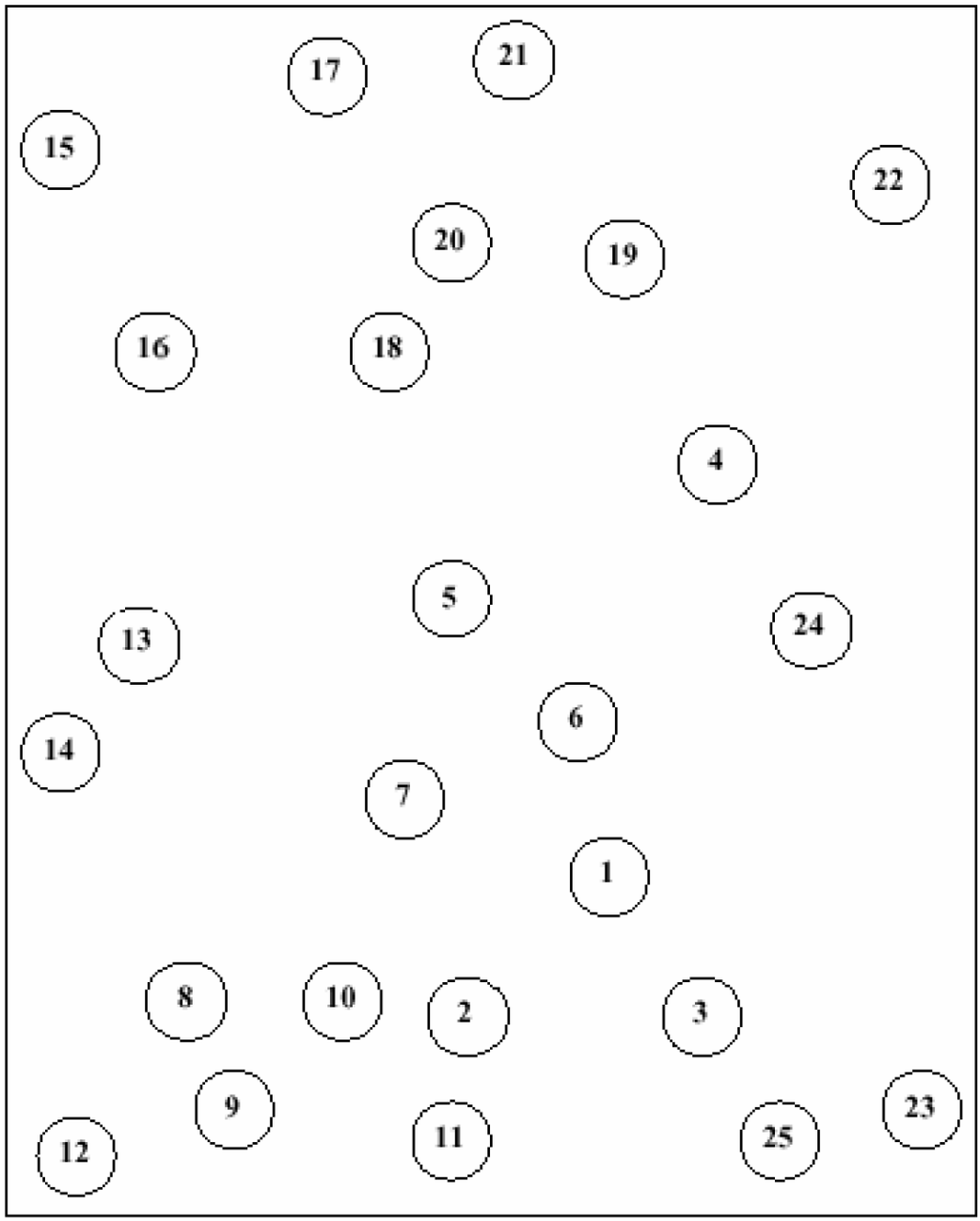
	Average	**Deficient**	**Rule of Thumb**
Trail A	29 seconds	> 78 seconds	Most in 90 seconds
Trail B	75 seconds	> 273 seconds	Most in 3 minutes

Sources:

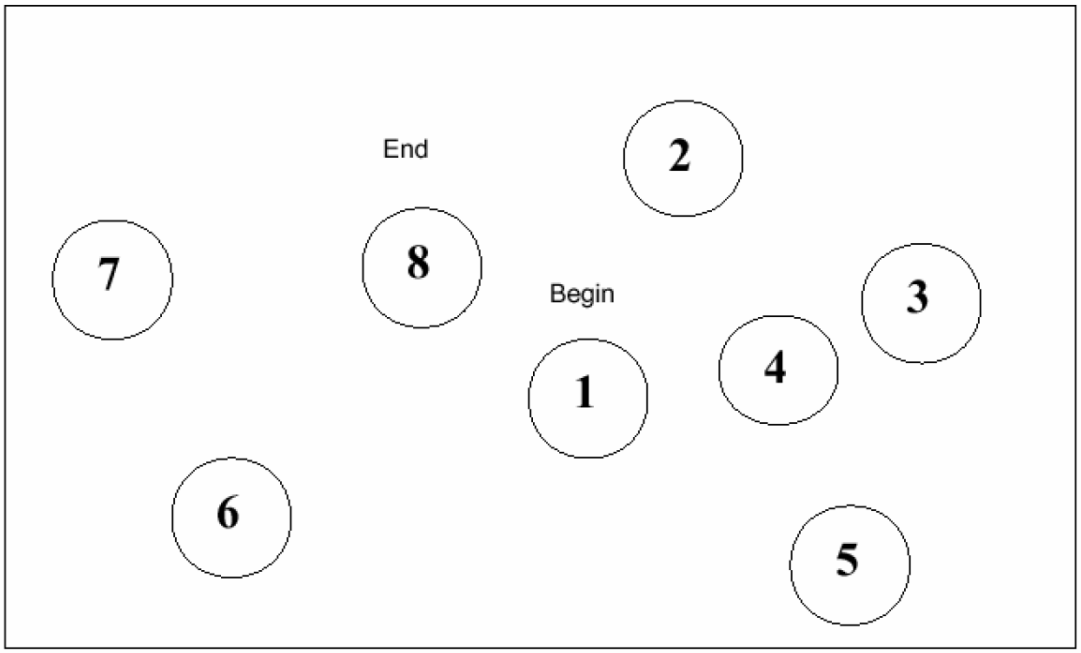
- Corrigan JD, Hinkeldey MS. Relationships between parts A and B of the Trail Making Test. *J Clin Psychol*. 1987;43(4):402–409.
- Gaudino EA, Geisler MW, Squires NK. Construct validity in the Trail Making Test: what makes Part B harder? *J Clin Exp Neuropsychol*. 1995;17(4):529-535.
- Lezak MD, Howieson DB, Loring DW. *Neuropsychological Assessment*. 4th ed. New York: Oxford University Press; 2004.
- Reitan RM. Validity of the Trail Making test as an indicator of organic brain damage. *Percept Mot Skills*. 1958;8:271-276.

Trail Making Test Part A

Patient's Name: _____ Date: _____

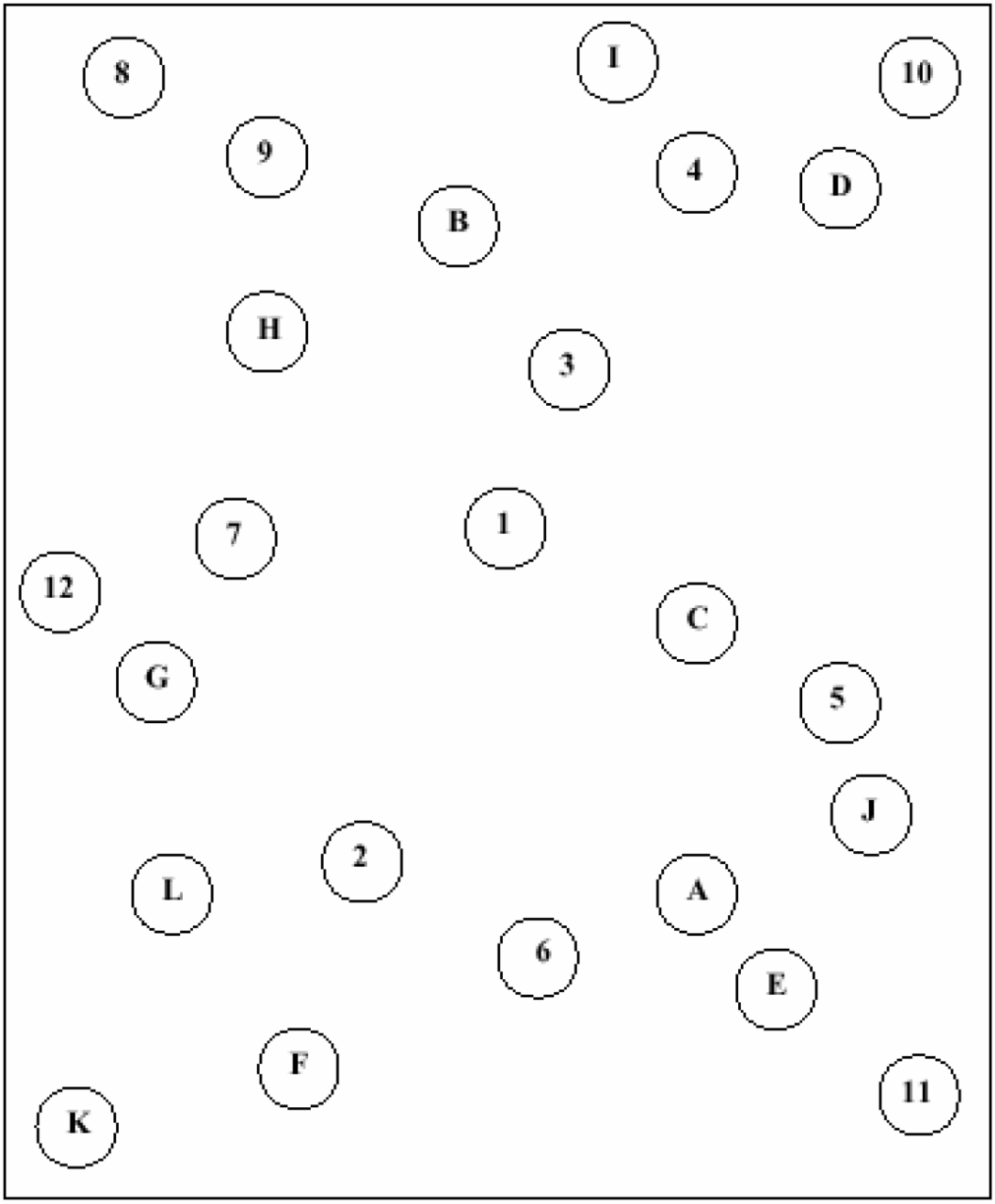


Trail Making Test Part A – *SAMPLE*

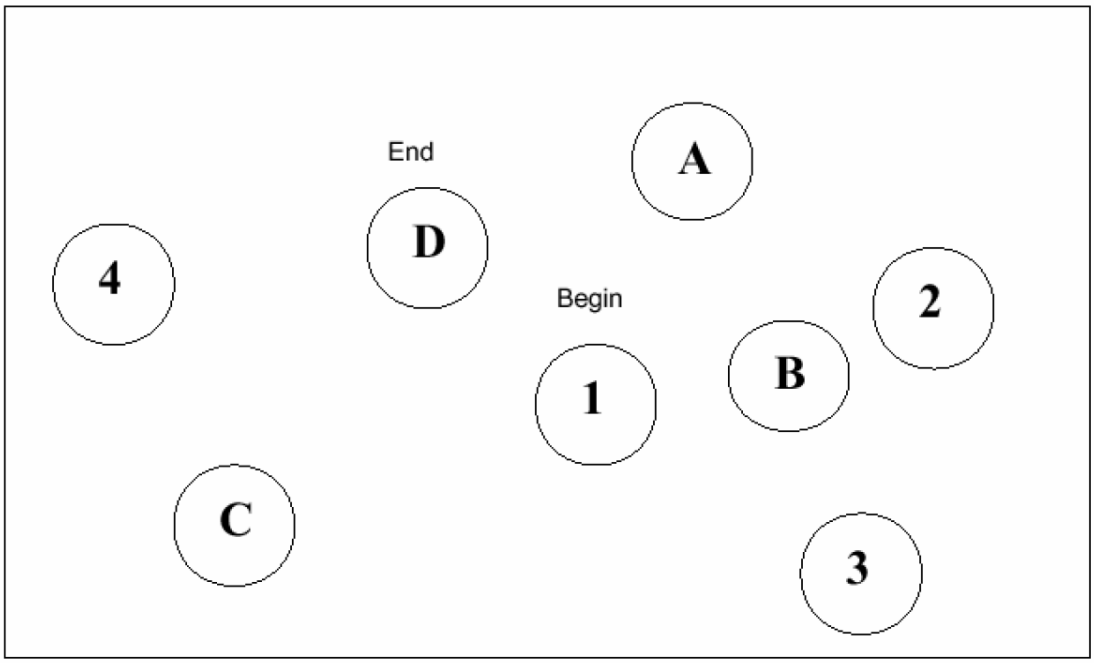


Trail Making Test Part B

Patient's Name: _____ Date: _____



Trail Making Test Part B – *SAMPLE*



PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? *(Use "✔" to indicate your answer)*	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

MOS Social Support Survey

People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it? Circle one number on each line.

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Emotional/informational support					
Someone you can count on to listen to you when you need to talk	1	2	3	4	5
Someone to give you information to help you understand a situation	1	2	3	4	5
Someone to give you good advice about a crisis	1	2	3	4	5
Someone to confide in or talk to about yourself or your problems	1	2	3	4	5
Some whose advice you really want	1	2	3	4	5
Someone to share your most private worries and fears with	1	2	3	4	5
Someone to turn to for suggestions about how to deal with a personal problem	1	2	3	4	5
Someone who understands your problems	1	2	3	4	5
Tangible support					
Someone to help you if you were confined to bed	1	2	3	4	5
Someone to take you to the doctor if you needed it	1	2	3	4	5
Someone to prepare your meals if you were unable to do it yourself	1	2	3	4	5
Someone to help with daily chores if you were sick	1	2	3	4	5
Affectionate support					
Someone who shows you love and affection	1	2	3	4	5
Someone to love and make you feel wanted	1	2	3	4	5
Someone who hugs you	1	2	3	4	5

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Positive social interaction					
Someone to have a good time with	1	2	3	4	5
Someone to get together with for relaxation	1	2	3	4	5
Someone to do something enjoyable with	1	2	3	4	5
Additional item					
Someone to do things with to help you get your mind off things	1	2	3	4	5

Charlson score: http://touchcalc.com/calculators/cci_js - on line calculator [accessed June 13th, 2013]

Charlson Comorbidity Index

(http://www.fpnotebook.com/prevent/Exam/ChrlsnCmrbdtyIndx.htm)

Aka: Charlson Comorbidity Index, Comorbidity-Adjusted Life Expectancy

1. Indication
    1. Assess whether a patient will live long enough to benefit from a specific screening measure or medical intervention
2. Scoring: Comorbidity Component (Apply 1 point to each unless otherwise noted)
    1. Myocardial Infarction
    2. Congestive Heart Failure
    3. Peripheral Vascular Disease
    4. Cerebrovascular Disease
    5. Dementia
    6. COPD
    7. Connective Tissue Disease
    8. Peptic Ulcer Disease
    9. Diabetes Mellitus (1 point uncomplicated, 2 points if end-organ damage)
    10. Moderate to Severe Chronic Kidney Disease (2 points)
    11. Hemiplegia (2 points)
    12. Leukemia (2 points)
    13. Malignant Lymphoma (2 points)
    14. Solid Tumor (2 points, 6 points if metastatic)
    15. Liver Disease (1 point mild, 3 points if moderate to severe)
    16. AIDS (6 points)
3. Scoring: Age
    1. Age <40 years: 0 points
    2. Age 41-50 years: 1 points
    3. Age 51-60 years: 2 points
    4. Age 61-70 years: 3 points
    5. Age 71-80 years: 4 points
4. Interpretation
    1. Calculate Charlson Score or Index (i)
        1. Add Comorbidity score to age score
        2. Total denoted as 'i' below
    2. Calculate Charlson Probablity (10 year mortality)
        1. Calculate Y = e^(i * 0.9)
        2. Calculate Z = 0.983^Y
        3. where Z is the 10 year survival
5. References
    1. Charlson (1987) J Chron Dis 40: 373–83
    2. Gold (1994) J Clin Epidemiol 47: 1245–51

ID#_____

BSI-A

Instructions

Below is a list of problems and complaints that people sometimes have. Read each one carefully, and select one of the numbered descriptors that best describes HOW MUCH DISCOMFORT THAT PROBLEM HAS CAUSED YOU DURING THE PAST 2 WEEKS INCLUDING TODAY. Place that number in the open box to the right of the problem. Do not skip any items, and print your number clearly. If you have any questions please ask the nurse researcher.

Descriptors

0	Not at all
1	A little bit
2	Moderately
3	Quite a bit
4	Extremely

HOW MUCH WERE YOU DISTRESSED BY:

1. Nervousness or shakiness inside……....
2. Suddenly scared for no reason……....
3. Feeling fearful……...
4. Feeling tense and keyed up ……
5. Spells of terror and panic……
6. Feeling so restless you couldn't sit still……..

SELF-CARE OF HEART FAILURE INDEX

All answers are confidential.

Think about how you have been feeling in the last month or since we last spoke as you complete these items.

SECTION A:

Listed below are common instructions given to persons with heart failure. How routinely do you do the following?

	Never or rarely	Sometimes	Frequently	Always or daily
1. Weigh yourself?	1	2	3	4
2. Check your ankles for swelling?	1	2	3	4
3. Try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. Do some physical activity?	1	2	3	4
5. Keep doctor or nurse appointments?	1	2	3	4
6. Eat a low salt diet?	1	2	3	4
7. Exercise for 30 minutes?	1	2	3	4
8. Forget to take one of your medicines?	1	2	3	4
9. Ask for low salt items when eating out or visiting others?	1	2	3	4
10. Use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

SECTION B:

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

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

0) No

1) Yes

11. If you had trouble breathing or ankle swelling in the past month…

(circle **one** number)

	Have not had these	I did not recognize it	Not Quickly	Somewhat Quickly	Quickly	Very Quickly
How quickly did you recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

Listed below are remedies that people with heart failure use. If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies?

(circle **one** number for each remedy)

	Not Likely	Somewhat Likely	Likely	Very Likely
12. Reduce the salt in your diet	1	2	3	4
13. Reduce your fluid intake	1	2	3	4
14. Take an extra water pill	1	2	3	4
15. Call your doctor or nurse for guidance	1	2	3	4

16. Think of a remedy you tried the last time you had trouble breathing or ankle swelling,

(circle **one** number)

	I did not try anything	Not Sure	Somewhat Sure	Sure	Very Sure
How sure were you that the remedy helped or did not help?	0	1	2	3	4

SECTION C:

In general, how confident are you that you can:

	Not Confident	Somewhat Confident	Very Confident	Extremely Confident
17. Keep yourself free of heart failure symptoms?	1	2	3	4
18. Follow the treatment advice you have been given?	1	2	3	4
19. Evaluate the importance of your symptoms?	1	2	3	4
20. Recognize changes in your health if they occur?	1	2	3	4
21. Do something that will relieve your symptoms?	1	2	3	4
22. Evaluate how well a remedy works?	1	2	3	4

Clinical Assessments Form

The clinical assessments will be conducted by a trained clinician according to the following standardized procedures. Perform clinical assessments after the test battery is complete with the patient lying in bed.

1) **Evaluation of ankle edema**

Directions: 1) elevate the head of the bed to 30 degrees; 2) measure each ankle's circumference at seven centimeters (cm) proximal to the midpoint of the medial malleolus with a tension-controlled measuring tape

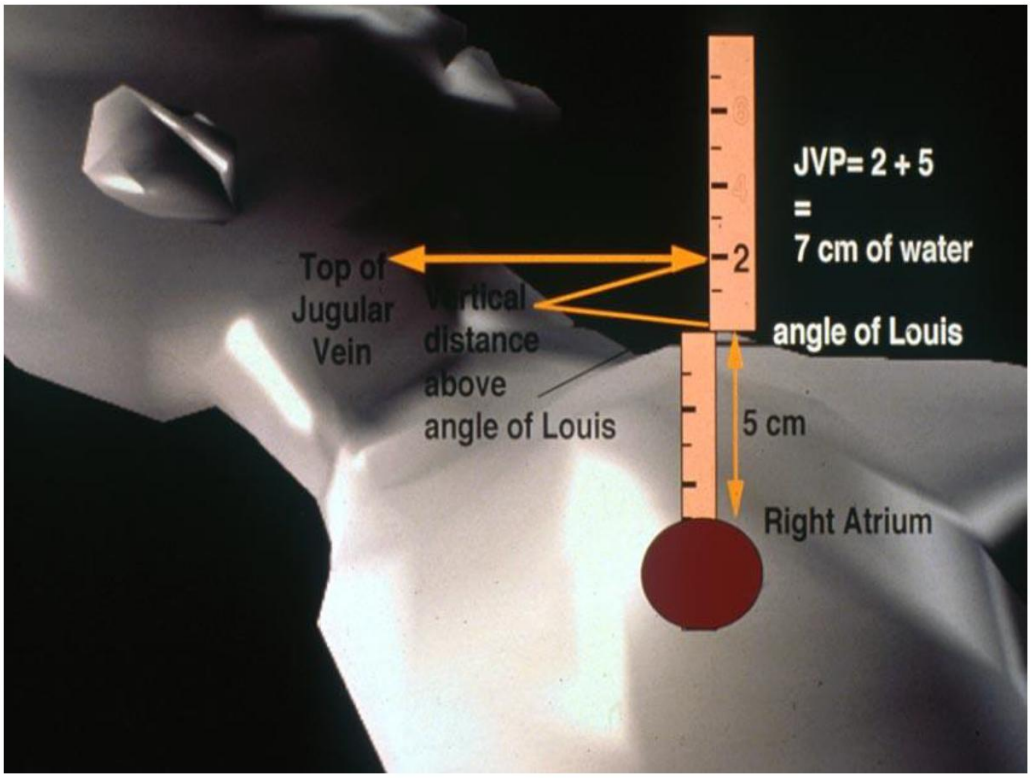
References: (Brodovicz et al., 2009; Mora, Zalavras, Wang, & Thordarson, 2002)

	Time Point #1	**Time Point #2**	**Time Point #3**
Researcher:			
Date & Time:			
Right ankle	_____cm	_____cm	_____cm
Left ankle	_____cm	_____cm	_____cm

2) Evaluation of jugular venous distention (JVD)

Directions: 1) position the patient in a supine position with the head at a 30 degree angle; 2) stand on the right side of the patient; 3) turn the patient's chin away so he/she is looking to the left; 4) identify the jugular vein and shine a light on the neck; 5) identify the supra-sternal notch, a concavity at the top of the manubrium, near the level of the second intercostal space; 6) using cm, mark visually the vertical distance from the top of the jugular vein column to this angle and add five cm.

1. Diagram of how to measure JVD (Heywood, 2008)



References: (Butman, Ewy, Standen, Kern, & Hahn, 1993; Heywood, 2008)

	Time Point #1	Time Point #2	Time Point #3
Researcher:			
Date & Time:			
JVD measurement	_____cm	_____cm	_____cm

3) Evaluation of hepatojugular reflex (HJR)

Directions: 1) While looking at the patient's neck in the 30 degree angle, the clinician will apply gentle pressure to the right upper quadrant of the abdomen for five to ten seconds. 2) Assess the internal jugular (IJ) vein. 3) Is there a sustained increase in IJ vein pulsations of one cm or more that resolves within 15 seconds of the release of pressure.

(Goldberg, 2009; Heywood, 2008; Sochowski, Dubbin, & Naqvi, 1990)

	Time Point #1	**Time Point #2**	**Time Point #3**
Researcher:			
Date & Time:			
HJR reflux	positive / negative	positive / negative	positive / negative

References

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Butman, S. M., Ewy, G. A., Standen, J. R., Kern, K. B., & Hahn, E. (1993). Bedside cardiovascular examination in patients with severe chronic heart failure: importance of rest or inducible jugular venous distension. *J Am Coll Cardiol, 22*(4), 968-974.

Goldberg, C. (2009, 8/16/2008). A Practical Guide to Clinical Medicine. *Cardiovascular Exam.* Retrieved 11/29/2014, 2014, from http://meded.ucsd.edu/clinicalmed/heart.htm

Heywood, J. T. (2008). Examination of the Neck Veins with Audio www.youtube.com.

Mora, S., Zalavras, C. G., Wang, L., & Thordarson, D. B. (2002). The role of pulsatile cold compression in edema resolution following ankle fractures: a randomized clinical trial. *Foot Ankle Int, 23*(11), 999-1002.

Sochowski, R. A., Dubbin, J. D., & Naqvi, S. Z. (1990). Clinical and hemodynamic assessment of the hepatojugular reflux. *Am J Cardiol, 66*(12), 1002-1006.

Study Variables Data Forms

Data for both forms will be collected from the chart and face to face interview.

Inpatient Form- To be collected at the first time point, in the hospital	
Age	years
Gender	M/F
Medical History	list
Medications	list
# Hospitalizations in 30 days	#
EF	% & date
Presence of sleep apnea	yes or no
Medical comorbidities	CCI
NYHA Status	Class
Heart Rhythm	BP, rate and rhythm
Electrolytes (K & Mag)	list
Complete Blood Count	list
Metabolic Panel	list
Outpatient form – To be collected at the third time point, after 30 days from hospital discharge	
# Past day readmissions (chart review)	#
The patient will be asked "How many times did you visit an emergency department/ urgent care, and/or hospital since their hospital discharge at the first testing?"	#
Did you receive the Outpatient Navigator specialized nursing intervention?	yes or no