

Changes in Anxiety and Self-Care Practices in Heart Failure Patients after Wireless Implantable Hemodynamic Monitor Implants

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February, 2018

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Background: Heart Failure (HF) is a chronic cardiac disease that places a significant burden on patients through reduced functioning, unpleasant symptoms, and extensive disease management routines. Wireless implantable hemodynamic monitors (W-IHMs) are a novel technology that assists healthcare providers in tailoring medication regimens to slow disease progression and reduce symptom expression. Initial research indicates that this device improves patient outcomes, but no mechanism has yet been determined. The purpose of this study was to determine if changes in patient experiences of anxiety and their self-care routines after receiving these devices may provide information about mechanisms involved in improved patient outcomes.

Methods: Nineteen HF patients who received an W-IHM implant completed a packet of surveys pre-implant and at one-month post-implant including the Cardiac Anxiety Questionnaire (CAQ) and Self Care of Heart Failure Index version 6.2 (SCHFI v6.2), as well as an initial demographic questionnaire. These data were used to examine changes in patient heart-focused anxiety and disease management routines after receiving a W-IHMs device.

Results: Results indicated that patients do experience a significant reduction in heart focused anxiety, and particularly a reduction in fear related to their HF. Patients also reported an increase in self-care behaviors. However, the reduction in heart focused anxiety was not significantly related to the increase in self-care behavior, and changes in both anxiety and self-care behaviors were not related to any demographic variables.

Discussion: Patients with HF who receive a W-IHM device experience a reduction in heart focused anxiety, as well as an increase in self-care behaviors related to HF disease management. It is possible that the increase in self-care behaviors is partially responsible for the improved outcomes for HF patients receiving a W-IHM device, but this data indicated that the increase in self-care behaviors may not be a result of reduced heart-focused anxiety. Implications for further research are discussed.

CHANGES IN ANXIETY AND SELF-CARE PRACTICES IN HEART FAILURE PATIENTS
AFTER WIRELESS IMPLANTABLE HEMODYNAMIC MONITOR IMPLANTS

A Thesis Presented to
The Faculty of the Department of Psychology
East Carolina University

In Partial Fulfillment
of the Requirement for the Degree
Master of Arts in Psychology

by
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February, 2018

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CHAPTER I: INTRODUCTION

Cardiovascular disease (CVD) encompasses all disease states of the heart and blood vessels, and is associated with significant mortality and morbidity. Mortality estimates were more than 17.3 million worldwide in 2013, including 801,000 in the United States (US) alone (American Heart Association, 2017). Due to increases in life expectancy, as well as an aging population in the US, costs of care for chronic disease states like CVD contribute significantly to rapidly increasing healthcare costs. Heart failure (HF) is a chronic and progressive type of CVD that contributes to increasing cardiovascular disease mortality rates (more than 65,000 deaths per year) and costs while progressively decreasing Quality of Life (QoL) for HF patients (American Heart Association, 2016; Nieminen et al., 2015).

In HF patients, the heart's ability to supply necessary oxygen and nutrition to the rest of the body through the blood is reduced as the heart muscle tissue grows less flexible and weaker. Symptoms of HF can dramatically reduce patient ability to perform normal life functions, as HF patients frequently endorse shortness of breath, chest pain, and sleep loss, and these symptoms progress along with the progression of the disease state (Nordgren & Sörensen, 2003; Zambroski, Moser, Bhat, & Ziegler, 2005).

In addition to reduced physical abilities, side effects from HF treatments and concerns about future health status can have negative psychological effects (Jeon, Kraus, Jowsey, & Glasgow, 2010; Vrobel, 1989). Patients living with HF may have comorbid major depression (19%) and clinical anxiety (13%), which have measurable effects on patient QoL (Celano, Villegas, Albanese, & Huffman, 2016). A specific type of anxiety, heart-focused anxiety (HFA), can affect QoL and outcomes for HF patients, especially for patients requiring active HF management technology including implantable cardio-defibrillators (ICDs) (Bunz et al. 2016).

Another critical part of improved patient outcomes is patient engagement in HF management. Daily SCP by HF patients are critical to achieving better physical functionality or maintaining existing functionality, reducing rehospitalization, improving mortality, and enhancing QoL (Britz & Dunn, 2010; Buck et al., 2015; Grady, 2008).

A new, passive technology, wireless implantable hemodynamic monitors (W-IHMs), has recently been approved to improve the monitoring of HF patients. This technology provides more timely information to cardiac care providers, who can in turn better tailor treatment plans for HF patients. Though research exists examining HFA and SCP in a variety of CVD patients, the research is not yet developed on HF patient experience living with W-IHM technology due to its novelty.

CHAPTER II: LITERATURE REVIEW

Cardiovascular Disease

There are several primary types of CVD. The most common type of CVD, affecting more than 15 million people in the US, is coronary artery disease (CAD), also referred to as coronary heart disease, which is a primary contributor to all other forms of heart disease (American Heart Association, 2016). Significant contributors to CVD related mortality are Myocardial infarction (MI), often referred to more colloquially as a “heart attack”, sudden cardiac arrest (SCA), and HF. Myocardial infarctions affect more than 600,000 persons in the US annually (American Heart Association, 2016). An MI occurs when an artery blockage deprives the heart of blood, causing cell death. If the blockage is in a main artery, this quickly leads to enough cellular death to cause the heart to stop beating. Commonly confused with MI, SCA is the abrupt cessation in the operation of the heart due to a problem in the heart’s electrical system, and occurs in more than 300,000 people in the US annually (American Heart Association, 2016). While MI and SCA can be interrelated, SCA can occur without any blockage in the arterial system of the heart.

While MI and SCA pose a serious health risk to individuals, and are more publicly well known, the acute nature of these types of CVD may only require short term health care solutions or limited, targeted treatments. Conversely, HF is a chronic and potentially debilitating disease state which affects more than 5.5 million US adults, and prevalence is increasing with the aging of the population, with an estimated 8 million adult HF cases by 2030 (American Heart Association, 2016).

Heart failure. The development of heart failure, the progressive weakening and stiffening of the heart muscular tissue, has many possible contributing factors that include both

modifiable and nonmodifiable factors. Lifestyle choices that may contribute to the development of HF include lack of exercise, tobacco use, and diets high in salt, fats, and cholesterol (American Heart Association, 2017). Drug and alcohol use may also contribute to the development and progression of HF (Skotzko, Vranceanu, Krueger, & Freudenberger, 2009; Slim, Thomas, Parish, & Mansi, 2012). Finally, age itself is a risk factor, as the aging related degradation of the body reduces cardiovascular functionality (Strait & Lakatta, 2012). Symptomology of HF includes shortness of breath in routine tasks, difficulty breathing at repose, water retention (edema), and fatigue.

Heart failure demographics. Heart failure in the US shows some variance across demographic groups. Per the American Heart Association, lifetime risk of HF for both men and women at age 40 is 1 in 5, although this shifts as men and women age. HF prevalence approaches 1 in 100 after the age of 65 (p. e271). African Americans are more than twice as likely to develop HF as whites (4.6 vs. 2.4 per 1,000 person-years), and age adjusted incidence rates place African American men (9.1 per 1,000 person-years) at a greater risk for HF than African American women, as well as both white men and women (American Heart Association, 2016). Similar data for lifetime risk do not appear to have been collected consistently in the US for other demographics, but some research suggests similar outcomes among Asian HF patients to white HF patients, and poorer outcomes among Hispanic HF patients compared to white HF patients (Vivo, et al., 2014).

Left ventricular ejection fraction. A primary indicator of cardiac performance is the left ventricular ejection fraction (LVEF). The LVEF indicates what percentage of blood in the left ventricle the heart is pumping out to the body at each contraction. Healthy LVEF ranges are from 50-70%, which means that half or more of the total blood volume of the left ventricle is

dispersed to the body with each contraction. Although LVEF may remain in the normal range for HF patients, a reduced LVEF is a common indicator of disease state progression and correlates with increases in HF symptomology. An LVEF of 35% or lower indicates severe cardiomyopathy, and puts patients at serious risk for early mortality in addition to reduced QoL (Yancy et al., 2013). When LVEF is not reduced despite HF, this is referred to as Heart Failure with preserved Ejection Fraction, or HFpEF. Despite the preserved LVEF, this is not an indicator of a less severe disease state, as the higher percentage does not represent the overall decrease in blood filling the left ventricle (Oktay & Shah, 2015).

Types of heart failure. There are two types of HF: systolic and diastolic (Henry, 2003). Systolic HF presents as a reduction in heart contractility, which prevents the efficient pumping of enriched blood to the rest of the body. The heart compensates for early decreases in output efficiency with left ventricular enlargement, but eventually this is insufficient and increases heart stiffness. Systolic dysfunction is typically diagnosed when LVEF drops below 40%, which is referred to as Heart Failure with reduced Ejection Fraction or “HFrEF”. Diastolic HF presents as abnormal left ventricular filling due to HF on the right side of the heart and is more difficult to detect, as LVEF often remains at normal or near-normal levels. Doppler scans may be required to detect diastolic HF in the presence of HF symptoms with preserved LVEF.

Either type of HF may involve a backup of blood and fluid in the body. Visible swelling, referred to as edema, often results - most commonly in the legs and ankles, but it may also happen in other parts of the body. When the patient lies down, this often relieves the swelling, as the reduced gravitational pull allows the retained blood and fluid to disperse throughout the body. However, if fluid collects in the lungs (pulmonary edema), this interferes with normal respiration, and lying down may increase the respiratory difficulty of the patient.

Heart failure severity. The American College of Cardiology established four stages to delineate the progression of HF. Stage A consists of one or more significant risk factors for developing HF. Stage B consists of asymptomatic HF. At this stage, the heart has deviated a measurable degree from healthy size or function, but not to a degree which impacts patient functionality. Stage C is symptomatic, and incorporates the common symptoms of HF already described, and may necessitate the usage of devices such as W-IHMs and ICDs. The final stage is Stage D, at which point patients may need additional device assistance such as a left ventricular assist device, cardiac transplant, or an end-of-life care plan (American Heart Association, 2001).

Additionally, the New York Heart Association (NYHA) has a roughly parallel system of Functional Classification. Class I parallels Stage 1, Class II parallels Stage B, etc. However, the NYHA system structures these classes based on patient reported symptoms, and also includes an additional Class designator of A-D based on clinically determined evidence of structural cardiovascular disease (American Heart Association, 1994).

Heart failure self-care practices. Patients living in Stages C and D (or alternately Class III and IV) of HF have extensive treatment regimens. While patient SCP are necessary at prior stages to halt the progression, it is at this point that SCP become both more difficult and imperative to halt mortality. Self-care practices in managing HF involve monitoring body weight and swelling (particularly in extremities), managing prescription medications (taking the appropriate medications at the indicated intervals), and modifying diet and physical activity routines in alignment with physician recommendations (Suter, Gorski, Hennessey, & Suter, 2012). Due to the serious threat to health invoked by the disease state, a failure to engage

adequately in any of these areas of self-care can lead to a worsening of the disease state, increased doctor visits, rehospitalization, and even death (Bradley et al., 2013).

Summary. Heart failure is a chronic form of CVD with a significant patient burden, both behaviorally and emotionally. Reduced functionality of the heart is measurable both by patient reporting and objective medical testing, and disproportionately affects different groups of people. Most importantly, patient engagement in treatment via consistent practice of recommended self-care habits are critical to improved outcomes.

Heart failure management technology

Previous cardiac technological developments have focused on preventing death by SCA. Pacemakers provide an electrical impulse to regulate the beating of the heart, thereby preventing arrhythmias, while ICDs provide both pacing technology as well the ability to provide a targeted defibrillation, or shock, to terminate arrhythmias or resynchronize the heart (National Institute of Health, n.d.a, b). While these technologies save lives, they do little to address the chronic disease HF underlying and comorbid with the acute threats to patient health and mortality.

Currently there is no established treatment to inhibit or reverse HF progression, and recommendations for management are limited to controlling blood pressure and fluid volumes, typically through diet and medication (Heart Failure Society of America, 2006a, b). One measurement that may have the potential to predict a worsening of HF up to two weeks in advance of patient observable symptoms are changes in pulmonary artery pressure (PAP) (Zile et al., 2008). Pulmonary artery pressure is particularly sensitive to changes in cardiac pressures and volume, and monitoring technology targeted at measuring these changes could improve HF patient SCP through increased interaction with their care providers, while reducing HFA due to perceived daily expert oversight of their disease state.

Wireless implantable hemodynamic monitor. Recently approved by the Food and Drug Administration upon completion of the CHAMPION trial, W-IHM technology is a novel technology for monitoring HF disease states and improving patient QoL and outcomes (Alam et al., 2016). This technology is comprised of two parts: a small, radio-frequency powered, implantable pressure sensor, and a patient operated electronic unit which activates and interacts with the sensor. Under patient direction, the electronic unit acquires a current PAP from the implanted sensor, and then transmits it over telecommunication networks to a secure server accessible only by authorized users, usually cardiac care providers (Raina, 2014).



Figure 1. CardioMEMS™ by St. Jude Medical. Commercial W-IHMs device.

Currently, the only commercially available W-IHM system is CardioMEMS™ by St. Jude Medical, pictured in Figure 1. This technology is indicated for Stage C HF patients, with no LVEF criterion required. Stages A and B of HF do not involve the severity of symptoms found in Stage C, and therefore patients in those stages do not require daily monitoring provided by W-IHMs technology. Alternately, patients in Stage D of HF are at the end state of HF progression and need heart transplants or ventricular assist technology rather than monitoring technology (Saint Jude Medical, 2017).

CHAMPION trial. Between September 2007 and October 2009, 347 HF patients completed a multi-site, single-blind, parallel, randomized control group, randomized access trial (Abraham et al., 2016). The treatment group ($N = 177$) received a W-IHM device, which they

used to send daily PAP readings to care providers to inform direction of care, while the control group ($N = 170$) also received the W-IHM device but only followed current HF management protocols. During this study, hospital admissions for HF symptoms were reduced in the treatment group by 33% in comparison with the control group. Additionally, in the 13-month period following the completion of the randomized access portion of the study, the former control group initiated the sending of daily PAP readings, which led to a 48% reduction in hospital admission for HF symptoms in that group in comparison to the prior randomized access period. The CHAMPION trial confirmed earlier research that PAP increases were associated with disease state change in advance of other symptomology, and that this relationship was present in patients with both preserved and reduced ejection fraction. These findings in combination with the improved outcome measure of reduced hospitalizations provided the necessary empirical evidence for regulatory approval for the commercial use of W-IHM technology in HF populations.

While the CHAMPION trial provided evidence of the efficacy of W-IHM technology in improving patient outcomes by measure of reduced hospitalization, no research has attempted to assess the patient experience in living with W-IHM technology. Unlike other cardiac technologies, W-IHM technology does not reduce hospitalization as a treatment tool, rather it provides clinicians more accurate and immediate data to adjust treatment regimens - regimens which depend on patient adherence. Additionally, potential improvement in outcomes could also be driven by an overall increase in physician communication, and patient understanding of the connection between SCP and biological markers. Finally, patient comorbid psychological distress may be reduced, potentially affecting outcomes.

Heart Failure and Anxiety

Much research has been conducted on psychological comorbidities in HF patients. Among individuals with CVD, anxiety is associated with poor patient outcomes and increased mortality (De Jong et al., 2011; Ouakinin, 2016). In addition to the wide range of clinical anxiety disorders in the Diagnostic and Statistical Manual – 5th Edition (American Psychiatric Association, 2013), it is possible that HF patients may experience anxiety related specifically to their disease state, which may not correspond to trait anxiety assessed by standard anxiety measures (Eifert, 2000). Research on non-trait anxiety sensitivity centered on somatic perceptions of heart health and performance has shown similar negative influences on patient outcomes as research on HF patients experiencing clinical trait anxiety (Eifert, 1992).

In patients living with HF, the percentage of persons reporting elevated symptoms of anxiety may be as high as 63% (De Jong, Moser, An, & Chung, 2004). This statistic should be concerning, as research has consistently shown that elevated levels of anxiety are an independent predictor for worsened health outcomes (De Jong et al., 2011; Tsuchihashi-Makaya, Kato, Chishaki, Takeshita, & Tsutsui, 2009; Volz et al., 2011). Although not as well studied in HF patients, how anxiety manifests behaviorally has been well studied in the general population and reduced functioning is prominent. Persons reporting high levels of anxiety are more likely to worry excessively and avoid engaging in necessary tasks (Mahoney et al., 2016). Anxiety driven avoidance and worry in HF patients may have a direct effect on patient ability or willingness to engage in necessary SCP, worsening health outcomes.

Heart focused anxiety and heart failure self-care. Symptoms of anxiety have some overlap with symptoms of HF, including increased heart rate, chest pain, and dizziness. However, despite symptom and potential mechanism overlap, meta-analyses and systematic reviews of studies on the relationship between anxiety and cardiac health have found anxiety

disorders are an independent risk factor for the worsening of cardiac disease states (Benninghoven et al., 2006; Roest, Martens, de Jonge, & Denollet, 2010; Vongmany, Hickman, Lewis, Newton, & Phillips, 2016).

Fear of bodily sensations is an anxiety symptom with particular salience in HF patients. This fear of sensations may cause increased sensitivity or attention to cardiac related stimuli, such as chest pain or changes in pulse, which may be referred to as HFA (Carter et al., 1992; Eifert, 1992; Fleet et al., 1998). It is plausible that the avoidance often accompanying anxiety leads to a decline in SCP and worsening outcomes (Murberg, Furze, & Bru, 2004).

Adequately managing HF often involves dramatic changes in patient routines and lifestyles: Doctor visits, possible changes in employment status, and changes in interpersonal relationships combine with disease limitations and the SCP themselves to disrupt former life patterns. These changes and disruptions may evoke psychological distress above and beyond the distress invoked physically and psychologically by the patient's disease. In turn, this psychological distress may provide a serious hindrance to the patient's ability and confidence to adequately follow the SCP regimen provided by their physician (Riegel et al., 2011).

The introduction of HF monitoring technology may reduce anxiety in HF patients; increased interaction with their care providers, better tailoring of treatment, or a general feeling of increased safety due to expert oversight of their disease state are all possible mechanisms. Investigating potential HF patient HFA changes due to the introduction of this new technology would add to the generally limited literature on HFA. Additionally, how both potential changes in HFA as well as the introduction of the new technology affects SCP regimens would begin to address this new behavioral health gap in HF patient literature.

Purpose of Study

The purpose of the current study was to examine changes in HFA and SCP in HF patients after receiving a W-IHM. The aims for this study are:

Aim 1: To determine if HFA and SCP change significantly after W-IHM device implantation.

Hypothesis 1: HFA (Cardiac Anxiety Questionnaire[CAQ]) scores will decrease in HF patients after W-IHM device implantation, relative to baseline levels.

Hypothesis 2: Patient SCP (Self Care of Heart Failure Index v6.2[SchFI v6.2]: Section A) scores will increase in HF patients after W-IHM device implantation relative to baseline levels.

Aim 2: To test a predictive model of demographic, medical, and psychosocial factors for SCP in W-IHM device patients.

Hypothesis 1: Decreases in HFA will predict increases in SCP in HF patients after W-IHM implantation, after controlling for demographic and medical severity factors.

CHAPTER III: RESEARCH METHODS

Procedure

This study employed a repeated-measures, self-report survey design to examine levels of, and changes in, HFA and SCP in HF patients living with W-IHM technology. The complete CAQ was administered to measure HFA. Although only the 10 items from Section A of the SCHFI v6.2 were analyzed for the purposes of this study, the complete SCHFI v6.2 was administered, in addition to four other brief measures of patient disease perceptions and expectations, which were outside the scope and purposes of this study. Participants were surveyed two times: Pre-implant (to establish a baseline) of the W-IHM device, and at one-month post-implant.

Power analyses. A priori estimates of required N of participants for sufficient power were computed with G*Power 3.1.9.2 software (Faul, Erdfelder, Buchner, & Lang, 2009). A sample size of $N = 27$ would have provided 80% power to detect a large effect ($d = .5$) with one-tailed correlated t-tests of changes ($\alpha = .05$) in variables of interest from pre-implant to post-implant assessment. A sample size of $N = 27$ would have provided 84% power with a linear multiple regression model (fixed model, r^2 increase; $\alpha = .05$) incorporating the predictor variable of HFA and dependent variable of SCP, while controlling for medical severity (LVEF) and controlling for 2 post-hoc selected demographic covariates. Due to the short time frame between implant and follow-up, as well as the novelty of the technology and the required daily interaction with the technology, large effect sizes were postulated.

Post hoc power analyses of achieved $N = 19$ were also computed with G*Power 3.1.9.2 software (Faul, Erdfelder, Buchner, & Lang, 2009). The achieved sample of $N = 19$ provided 67% power to detect a large effect ($d = .5$) with one-tailed correlated t-tests of changes ($\alpha = .05$)

in variables of interest from pre-implant to post-implant assessment. The achieved sample also provided 66% power with a linear multiple regression model (fixed model, r^2 increase; $\alpha = .05$) incorporating the predictor variable of HFA and dependent variable of SCP, while controlling for medical severity (LVEF), age, and sex.

Participants

The participants in this study were recruited during visits with their normal cardiac care providers by participating nursing staff members. The following constituted the participant inclusion criteria for this study: (1) Cardiac patients with Stage C or D heart failure (2) The acceptance/scheduled implantation of a W-IHM device (3) English speaking (4) 18 years of age or older. Participants who indicated interest to nurse care providers gave written informed consent to participate to research staff. Participants with visual impairments or literacy limitations were offered the option to have the items read to them and their responses recorded by the researcher. All aspects of the study were approved by the East Carolina University (ECU) Institutional Review Board (IRB).

Measures

Demographic variables. A demographic questionnaire developed by the research team captured age, gender, ethnicity, educational status, marital and employment status, and household income level (See Appendix B).

Heart focused anxiety. To facilitate research and patient monitoring of HFA, Eifert and colleagues (2000) developed the Cardiac Anxiety Questionnaire (CAQ), which provides a self-report of patient perception of their disease state and orientation towards activity and healthcare. The CAQ consists of 18 individual items that are grouped into three subscales: Fear, Avoidance, and Heart-Focused Attention, which was derived through factor analysis from a larger pool of 63

items used in a preliminary study. Utilizing a 5-point rating scale, patient judgments of frequencies is indicated by selection of values between 0 (“Never”) and 4 (“Always”).

Fear. The Fear subscale measures patient fear, anxiety, or worry surrounding their disease state through their agreement with related statements such as “When I have chest discomfort, or when my heart is beating fast: ‘I worry that I may have a heart attack’ or ‘I get frightened.’”

Avoidance. The Avoidance subscale measures patient attempts to reduce activities which increase heart rate, which may be perceived as dangerous, through their agreement with related statements such as: “I avoid physical exercise” or “I avoid activities that make my heart beat faster.”

Heart-Focused Attention. The Heart-Focused Attention subscale measures CVD patient attention to cardiac stimuli (e.g. increased heart rate) through their agreement with related statements such as: “Chest pain/discomfort wakes me up at night” or “I pay attention to my heart beat.”

Validity and reliability. Initial validity establishing research of the CAQ was confirmed through significant convergent correlations with the Anxiety Sensitivity Index (ASI) and the Body Sensations Questionnaire (BSQ), as well as the lack of correlation with divergent measures such as Activities of Daily living and Fear of Negative Evaluation (Eifert et al., 2000). However, CAQ measures HFA specifically, while other assessments treat it more generally and in combination with other illnesses and physical functioning. Ongoing research has validated the measure for use among cardiac patients in this study, verified good psychometric properties, and confirmed that HFA is a different concept from depression or other forms of anxiety (see Appendix B for the complete measure and Appendix C for scoring procedures) (Eifert et al.,

2000; van Beek et al., 2012). The three subscales of the CAQ may be scored together for a total score as well as scored separately by summing the total scores on respective individual items and dividing by the number of items (Eifert et al., 2000).

Self-care practices. The SCHFI v6.2 is “a measure of self-care defined as a naturalistic decision-making process involving the choice of behaviors that maintain physiologic stability (maintenance) and the response to symptoms when they occur (management),” and allows practitioners and researchers the ability to assess the degree to which HF patients are engaging in critical SCP (Barbaranelli, Lee, Vellone, & Riegel, 2014; Riegel, Lee, Dickson, & Carlson, 2009; Vellone et al., 2013). The SCHFI v6.2 consists of 22 items utilizing a 4-point (1-4) Likert-style scale. This index is divided into three subsections measuring maintenance, management, and confidence in heart failure patients. For the purposes of this study, Section A (Maintenance) is the subscale of interest. As W-IHM technology is intended to provide a warning of disease state worsening prior to patients’ symptomology, and as these items do not capture prevention based self-care practices, items in section B and section C will not be further discussed.

Section A: Maintenance. The Maintenance subscale is comprised of 10 items of the total measure count of 22 items, with one item being reverse scored. Patients indicate frequency of various SCP listed on the survey such as weighing themselves or engaging in 30 minutes of exercise.

Validity and reliability. Multiple mixed method studies have assessed convergent validity of the SCHFI v6.2, including both cross-sectional and longitudinal studies, with the most recent psychometric testing completed in 2014 (Barbaranelli, Lee, Vellone, & Riegel, 2014; Riegel et al., 2004; Vellone et al., 2013). Subscales are scored separately and standardized on a 0-100 range (See Appendix B for all Section A items and Appendix C for scoring procedures).

Higher scores on Section A indicate higher levels of maintenance-oriented self-care practices in cardiac patients in this study.

Medical severity. Patient medical records were assessed to determine medical diagnosis severity associated with CAQ and SCP responses to control for condition severity factors.

Medical severity was operationalized via the most recent patient LVEF.

Data Analysis

The data analysis for this paper was accomplished using SAS software (SAS, 2017). Copyright © 2017 SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA. Descriptive statistics were employed to provide information on basic demographic characteristics of the population of interest. Correlations between the variables of interest were also computed to examine inter-relationships between variables. These correlations were also used to consider possible co-variables in additional analyses.

To examine aim 1, paired sample t-tests were employed to test variables of CAQ total and subscale means as well as SCHFI v6.2 Section A standardized scale scores. Differences between time 1 and time 2 on these variables were tested.

To examine aim 2, a multiple regression analysis was used to test the hypothesis that changes in CAQ mean scores predict changes in SCHFI v6.2 Section A standardized scores, controlling for selected demographic factors and LVEF for those with HFrEF.

CHAPTER IV: RESULTS

Descriptive Statistics

Demographic descriptive statistics. Nineteen heart failure patients ($N = 19$) were recruited to participate in this study. The mean age of participants was 68.6 years of age with a median of 67.5, and a range of 39-90. Participation was closely split by sex (8 female, 11 males), and by race (9 African American, 10 Caucasian). The majority of participants were married ($N = 11$), and education levels were varied, with the majority ($N = 10$) reporting attending post-secondary education; for more detailed demographic data refer to Table 1.

Table 1
Descriptive demographic statistics

	African-American	Caucasian	Married	High-school and below	College and above
Male	5	6	7	8	3
Female	4	4	4	1	7
Married	5	6			
High-school and below	4	4			
College and above	5	6			

Study variable descriptive statistics. Study variables were drawn from the CAQ and the SCHFI v6.2 Section A. Table 2 shows the descriptive statistics for the study variables. Participant mean reported HFA scores pre-implant as captured by total CAQ score was 2.097, while at follow-up the mean level was 1.778, for a total change of -0.30, $t(18) = 2.63$, $p = 0.008$, $d = .68$, with 13 out of 19 participants reporting a reduction in total HFA. Analyses of CAQ subscales of *Fear*, *Avoidance*, and *Heart Focused Attention* showed significant reduction in *Fear*; participant mean reported *Fear* scores pre-implant was 2.26, while at follow-up the mean level was 1.79, for a total change of -0.47, $t(18) = 2.91$, $p = 0.009$, $d = 0.67$, with 13 out of 19 participants reporting a reduction in *Fear*. Reductions on CAQ subscales of *Avoidance*, $t(18) =$

0.36, $p = 0.7$, $d = .08$, and *Heart Focused Attention*, $t(18) = 1.44$, $p = 0.16$, $d = .33$, were not significant.

Participant mean reported SCP level as captured by total SCHFI v6.2 Section A score was 74.29 at baseline, while at follow-up the mean score was 78.59, for a total change of 4.31, $t(18) = 1.64$, $p = 0.12$, $d = 0.38$, with 10 out of 19 participants reporting an increase in SCP.

Participant mean medical severity as measured by most recent LVEF was 34%, with a range of 20%-70%. Three participants presented HFpEF (LVEF = 65%, 65%, 70%), which does not indicate a healthier heart in a sample of persons diagnosed with HF (Oktay & Shah, 2015). To correct for these outliers in the data and adequately represent the health of participant pool, these EF percentages were removed from consideration.

Table 2
Pre-Post Changes in Study Variables

Variable	Mean	SD	<i>p</i>	<i>d</i>
CAQPre	2.13	0.68		
CAQPost	1.79	0.70		
CAQChange	-0.30	0.54	0.008	0.68
CAQFearPre	2.26	0.80		
CAQFearPost	1.79	0.77		
CAQFearChange	-0.47	0.70	0.009	0.67
CAQAvoidancePre	2.38	1.04		
CAQAvoidancePost	2.28	1.04		
CAQAvoidanceChange	-0.10	1.17	0.70	0.08
CAQHFAPre	1.70	1.02		
CAQHFAPost	1.45	0.97		
CAQHFACHange	-0.37	0.71	0.16	0.33
SCHFIPre	74.29	14.25		
SCHFIPost	78.59	12.83		
SCHFICChange	4.31	11.43	0.12	0.38

Correlational and Comparative Analyses of Variables

Demographic variables correlations and comparisons. Correlational and comparative analyses of study variables were conducted, beginning with inter-demographic correlations to assess for control variables for regression analysis. Women were more likely to have completed some college or more (87.5%) than were men (27.3%), $\chi^2(1, N = 19) = 6.738, p = .009$. No other demographic variables were significantly related with each other or approached significance.

Demographic variables correlated with study variables. Correlational analyses of demographic variables with study variables were conducted with Pearson correlations to determine what demographic variables to include in the regression model. Notably, none of the change scores were significantly correlated with demographic variables. Age was significantly, negatively correlated with the pre-implant total CAQ score ($r = -.52, p = 0.02$), and approached significance with the follow-up total CAQ score ($r = -.38, p = 0.10$), and the pre-implant *Fear* subscale score ($r = -.42, p = 0.07$). African-American patients had significantly higher follow-up total CAQ scores ($M = 2.14, SD = .53$) than did Caucasian patients, ($M = 1.48, SD = .71$), $r_{pb} = -.48, p = 0.037$). African-American patients also had higher follow-up scores on the *Fear* subscale ($M = 2.11, SD = .53$) than did Caucasian participants ($M = 1.50, SD = .86$), but this difference fell short of statistical significance, $r_{pb} = -.41, p = 0.08$. Female participants had significantly higher follow-up scores on the SCHFI v6.2 Section ($M = 85.8, SD = 7.07$) than did male participants ($M = 73.33, SD = 13.74$), $r_{pb} = -.49, p = .03$, indicating higher levels of SCP at follow-up.

Study variable correlations. Correlational analyses of study variables were conducted on study variables. The CAQ subscale of *Fear* was included in these analyses due to the significant reduction in the subscale from pre-implant to follow-up. Participant total CAQ scores

pre-implant and at follow-up were significantly, positively correlated ($r = .7, p < .001$), as were participant *Fear* subscale scores pre-implant and at follow-up ($r = .6, p = .006$). Participant total CAQ scores pre-implant and at follow-up were significantly, positively correlated with *Fear* subscale scores pre-implant ($r = .84, p < .001$; $r = .54, p = .02$), and participant total CAQ scores pre-implant and at follow-up were significantly, positively correlated with *Fear* subscale scores at follow-up ($r = .72, p < .001$; $r = .85, p < .001$).

Change scores in measures were computed by subtracting scores at baseline assessment (pre-implant) from scores at follow-up (post-implant). Participant total CAQ scores at follow-up were significantly, positively correlated with changes in CAQ scores ($r = .72, p < .001$; $r = .85, p < .001$), and change scores for the CAQ were significantly, positively correlated with change scores on the *Fear* subscale ($r = .62, p = .005$). Participant *Fear* subscale scores pre-implant were significantly, negatively correlated with *Fear* subscale change scores ($r = -.49, p = 0.04$; higher *Fear* pre-implant was correlated with greater reductions in *Fear*), and a correlation between participant *Fear* subscale scores at follow-up and *Fear* change scores approached positive significance ($r = .4, p = .09$). A correlation between participant EF and changes in CAQ scores ($r = -.39, p = .10$) and changes in *Fear* subscale scores ($r = -0.43, p = .07$) approached significance, with reductions in total CAQ and *Fear* showing a correlation with higher EF levels.

Participant SCHFI v6.2 Section A scores pre-implant were significantly, positively correlated with scores at follow-up ($r = .65, p = .003$), and significantly, negatively correlated with score change ($r = -0.52, p = 0.02$), with increases in SCP correlated with lower pre-implant scores. There were no other significant correlations involving SCHFI scores, including correlations with patient medical severity.

Table 3
Correlations of study variables

	CAQ Pre	CAQ Post	CAQ Change	Fear Pre	Fear Post	Fear Change	SCHFI Pre	SCHFI Post	SCHFI Change
CAQ Pre		$r = 0.70$ $p < 0.001^*$	$r = -0.36$ $p = 0.13$	$r = 0.84$ $p < 0.001^*$	$r = 0.72$ $p < 0.001^*$	$r = -0.17$ $p = 0.49$	$r = -0.10$ $p = 0.69$	$r = 0.11$ $p = 0.63$	$r = 0.25$ $p = 0.29$
CAQ Post	$r = 0.70$ $p < 0.001^*$		$r = 0.40$ $p = 0.09$	$r = 0.53$ $p = 0.02$	$r = 0.86$ $p < 0.001^*$	$r = 0.33$ $p = 0.17$	$r = -0.009$ $p = 0.97$	$r = 0.31$ $p = 0.20$	$r = 0.35$ $p = 0.14$
CAQ Change	$r = -0.36$ $p = 0.13$	$r = 0.40$ $p = 0.09$		$r = -0.33$ $p = 0.17$	$r = 0.22$ $p = 0.37$	$r = 0.62$ $p = 0.005$	$r = 0.08$ $p = 0.76$	$r = 0.19$ $p = 0.44$	$r = 0.11$ $p = 0.64$
Fear Pre	$r = 0.84$ $p < 0.001^*$	$r = 0.53$ $p = 0.02$	$r = -0.33$ $p = 0.17$		$r = 0.60$ $p = 0.006$	$r = -0.49$ $p = 0.04$	$r = -0.11$ $p = 0.65$	$r = 0.19$ $p = 0.47$	$r = 0.34$ $p = 0.16$
Fear Post	$r = 0.72$ $p < 0.001^*$	$r = 0.86$ $p < 0.001^*$	$r = 0.22$ $p = 0.37$	$r = 0.60$ $p = 0.006$		$r = 0.40$ $p = 0.09$	$r = -0.02$ $p = 1.00$	$r = 0.20$ $p = 0.40$	$r = 0.25$ $p = 0.30$
Fear Change	$r = -0.17$ $p = 0.49$	$r = 0.33$ $p = 0.17$	$r = 0.62$ $p = 0.005$	$r = -0.49$ $p = 0.04$	$r = 0.40$ $p = 0.09$		$r = 0.11$ $p = 0.66$	$r = 0.02$ $p = 0.94$	$r = -0.11$ $p = 0.65$
SCHFI Pre	$r = -0.10$ $p = 0.69$	$r = -0.009$ $p = 0.97$	$r = 0.08$ $p = 0.76$	$r = -0.11$ $p = 0.65$	$r = -0.02$ $p = 1.00$	$r = 0.11$ $p = 0.66$		$r = 0.65$ $p = 0.003$	$r = -0.52$ $p = 0.02$
SCHFI Post	$r = 0.11$ $p = 0.63$	$r = 0.31$ $p = 0.20$	$r = 0.19$ $p = 0.44$	$r = 0.19$ $p = 0.47$	$r = 0.20$ $p = 0.40$	$r = 0.02$ $p = 0.94$	$r = 0.65$ $p = 0.003$		$r = 0.31$ $p = 0.19$
SCHFI Change	$r = 0.25$ $p = 0.29$	$r = 0.35$ $p = 0.14$	$r = 0.11$ $p = 0.64$	$r = 0.34$ $p = 0.16$	$r = 0.25$ $p = 0.30$	$r = -0.11$ $p = 0.65$	$r = -0.52$ $p = 0.02$	$r = 0.31$ $p = 0.19$	

Note. All p values smaller than $p = 0.001$ are reported as $p < 0.001$ and identified with an asterisk.

Predictive Modeling of Changes in Study Variables

To address research aim two, a linear regression analysis was conducted to determine if the predicted reduction in HFA (as measured by total CAQ change scores) was related to increases in SCP (as measured by the SCHFI v6.2, Section A), after controlling for variables of participant age, sex, and medical severity as measured by LVEF. The results of the linear regression were not significant, $F(4, 14) = .84, p = .52$, with an R^2 of .19. A Pearson partial correlation was also performed, and when age, sex, and medical severity were controlled for on the relationship between change scores on the CAQ and SCHFI, the results were also not significant, $pr = .05, p = .85$. Although the low participant sample lacked desirable power for determining significant changes in SCP and significance for the regression analysis, the results of

the regression equation and Pearson partial correlation suggest that modestly increasing the sample size would not increase power enough to provide a significant regression equation.

CHAPTER V: CONCLUSION

Summary of Results and Relevant Implications

The current study investigated HFA and SCP in patients who had received W-IHMs technology to help manage their heart failure, and to analyze the effect of HFA on SCP in this sample. Nineteen participants were recruited by care providers prior to W-IHMs implant and completed the CAQ and SCHFI v6.2 Section A at pre-implant baseline and at one-month follow-up. Reduction in total HFA as measured by the CAQ was significant as was reduction in the *Fear* subscale, with medium to large effects ($d = .68$ and $d = .67$, respectively). Improvements were shown in total SCP as measured by the SCHFI v6.2 with small-to-medium effect ($d = .38$), but the sample lacked sufficient power to provide significance ($p = .12$). Regression analysis of effects of HFA on SCP showed no relationship.

Despite the results of the regression analysis, the descriptive statistics and correlational analyses remain interesting. Due to differences in assessment, the ability to compare this sample to the sample in the CHAMPION randomized control trial (which assessed the effectiveness of W-IHM technology on reducing rehospitalization) was limited. The current sample was an older sample than the CHAMPION trial sample (Abraham, et al., 2016), but remained equitably split within the study in other factors, with one caveat, which was the difference between male and female participant education levels. Although the sample size is small, that women reported higher education levels than men is notable because female college enrollment only surpassed male college enrollment around 1980 (NCES, 2017). The mean age of the female participants in the sample was 65, which based on normal college years places the sample in college between the years of 1970-1974, suggesting the female participants in this sample may be more educated on average than their peers, particularly in this region. Due to the novelty and expense of the W-

IHMs technology, and known correlations between education and lifetime economic outcomes (USBLS, 2017), the higher socioeconomic status of the female participants in the study sample may suggest ways in which this sample was not representative of the more rural and less educated local population. Additionally, it may also provide another point of evidence regarding healthcare access disparities between socioeconomic classes.

While changes in HFA did not predict changes in SCP, both variables moved in predicted directions post-implant with reduced HFA and increased SCP, and the reduction in HFA was primarily driven by a reduction in the *Fear* scale of the CAQ. Furthermore, the medium-to-large effect sizes in total CAQ and *Fear* subscale reductions indicate strong patient responses to the technology. Taken together, these results suggest that the patient experience of this technology includes both greatly increased feelings of safety and some empowerment to better manage their heart failure. As the utilization of W-IHMs technology involves daily monitoring of HF-related biomarkers by care providers, implantees may have increased security regarding their health status, and transmission procedures may act as a daily reminder to engage in other self-care behaviors. Additionally, the process may increase patient understanding of the interactions between self-care, medication, and their disease state.

Published literature on the effectiveness of W-IHM technology has focused primarily on rehospitalization and mortality targets and the change to care protocols by information provided by W-IHM usage. While these types of data answer questions of interest to accountants and regulatory agencies, they do not investigate underlying behavioral mechanisms driving improved outcomes and the patient experience of living with the technology. While W-IHM technology allows for proactive changes to self-care regimens via care provider oversight and communication, the patient is still the person responsible for enacting treatment plans. This

study attempted to determine whether or not patients with W-IHMs technology increased their SCP, which is a different question than whether or not the SCPs were different, and in the limited sample the answer is affirmative. This study also attempted to determine if patient HFA was reduced after receiving the W-IHMs technology and if so, would this drive a change in SCP. While the answer in this limited sample was affirmative to the first question, no relationship shown between changes in HFA and SCP leaves an important open question for future investigation. Initial research showed that patients receiving W-IHM technology reported improved QoL (Abaraham et al., 2011), but this initial research lacked specificity regarding the ways QoL was improve. The reduction in patient HFA, specifically the reduction in patient fear of their heart failure, contributes to the literature by showing one specific factor which may contribute to the reported improved QoL.

Limitations

This study was faced with some limitations, including failing to reach the target participant recruitment number, which resulted in underpowered statistics for some analyses. Other limitations can be divided into two limitations of design and limitations of the participant sample. Limitations of design include several threats to internal validity and external validity

Design limitations. The study utilized a within subjects repeated measures design. While a randomized control trial would be a superior design, such a design was not feasible at a single site sample drawing from a low SES population. Recent FDA approval and limited insurance coverage for many potential implantees limits the ability to randomize for an independent, unfunded study. While a repeated measures design increases power for correlational analyses, the lack of a control group, randomized or otherwise, is a threat to internal validity.

Another limitation of the design is the pre-post no control group design, which does not control for maturational threats to internal validity. While medium-to-large effect sizes were shown for changes in HFA, it may be that the psychological effects of a novel technology may wear off over a period of time that exceeds the length of time allowed for the post-implant follow-up; it may also be that differential experiences in the interim provided a history threat to internal validity. One final limitation was potential participant survey fatigue, as the questionnaires were embedded within a larger survey of the patient experience living with a novel HF monitoring technology. To minimize the possibility of this limitation, the CAQ was placed early in the battery of surveys, and the SCHFI v6.2 was placed at the end, as it has a reversed item to check against straight-line answering.

Three potential threats to external validity were present in the study design. The first was the rural, low SES population the sample was drawn from in eastern North Carolina. While this sample may provide generalizability to similar population samples, the findings may differ from urban and/or higher SES populations. However, due to the higher levels of education among female participants, and the cost and novelty of the W-IHM technology, part or all of the study sample may not be reflective of the local population. A second limitation was the setting of survey data collection. Survey data was collected at cardiac care visits, which may have had a social desirability effect on participant responses. The final limitation was the inability to control for multiple treatment interference, which is related to the history threat to internal validity.

Participant limitations. As noted before, participants were drawn from a rural, low SES population with primarily a high-school level education, and low levels of literacy were possible in some participants. Due to age and health problems, eyesight was also an issue for some

participants. Research data collectors in the study provided assistance in either case in the form of reading questions and response options aloud and recording verbal responses. It is possible that this mediation may have some influence on participant responding.

Strengths

While acknowledging the limitations of the study, the study also capitalized on unique opportunities to investigate novel technology use in a unique population. With the support of and coordination with local cardiac care providers, study data was efficiently collected at care visits with minimal participant burden, which likely increased participant interest and minimized potential attrition in a very sick patient pool. This is the first study to look at measures of both emotion and behavior in HF patients living with W-IHM technology.

Future directions

The effect sizes for decreased heart focused fear and increased HF patient SCP in this small, single site sample are a strong signal that a larger research project would be able to more fully explore. Contemporary modern device development and approval must concern itself not only with medical efficacy and economics, but also with the patient experience: how does the patient interact with the device to change SCP, and how does the device contribute to increased QoL? Although a clear answer was not achieved in this study to the first question, the significant, powerful reduction in patient fear of their heart failure after the W-IHMs implant is a meaningful indicator of improved QoL related specifically to the device, freeing HF patients to engage more fully in their daily activities. When participants interacted with researchers, they reported a feeling of security knowing their heart was being monitored by their care providers. The potential depth of qualitative data alongside quantitative data provided by questionnaires like the CAQ could clarify mechanisms identified by the patient participant. While identifying

trends in general patient disease perceptions is valuable in itself, identifying the specific mechanisms behind shifts in disease perception may inform the development of targeted, brief interventions for enhanced initial patient engagement and perception across the timeline of disease management. As this study looked only at reported changes in short follow-ups, longitudinal data may show variance in reduced fear of heart failure over time; information regarding mechanisms may also allow for targeted “booster” sessions with care providers regarding the processes and benefits of W-IHMs technology.

While this study failed to show a significant improvement in patient self-care behaviors, this is most likely due to a lack of power, and it is expected based on effect size that larger studies with adequate samples with additional follow-up periods would show this concrete behavioral interaction between patients and the technology. Again, qualitative investigations into the mechanisms by which this occurs would be helpful for informing targeted, brief interventions by care providers both initially and over time as potential psychological novelty effects fade. Based on this research alone, cardiac care providers may want to include questions taken from the SCHFI v6.2 in regular monitoring calls for patients with W-IHMs technologies, strengthening the association between regular transmission of pulmonary artery pressure data and self-care aspects of heart failure management. As W-IHMs technology is a passive, data collecting and transmitting device, leveraging the combination of data, psychology, care provider expertise, and patient engagement is likely to provide the most improved outcomes for heart failure patients.

Concluding Remarks

HF is a chronic disease state with many challenges for patient and healthcare provider management and W-IHMs are a novel technology to assist in disease management with no prior

research on patient emotional and behavioral experiences in living with the W-IHM technology. The current study findings indicate that HF patients experience significantly lower HFA after receiving the W-IHM technology, and may engage in increased SCP. The significantly lower HFA was driven primarily by reduced patient fear regarding their HF. These findings support the need for further investigation into the HF patient emotional and behavioral experience in living with W-IHMs technology with a focus on mechanisms of behavior change and opportunities for educational and behavioral interventions to improve patient SCP.

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Appendix A: IRB Approval



EAST CAROLINA UNIVERSITY
University & Medical Center Institutional Review Board
4N-64 Brody Medical Sciences Building · Mail Stop 682
600 Moye Boulevard · Greenville, NC 27834
Office 252-744-2914 · Fax 252-744-2284
www.ecu.edu/ORIC/irb

Notification of Continuing Review Approval: Expedited

From: Biomedical IRB
To: [Ashley Burch](#)
CC: [Samuel Sears](#)
[Ashley Burch](#)
Date: 3/15/2018
Re: [CR00006771](#)
[UMCIRB 15-002120](#)
Cardiomems Patient Experience

The continuing review of your expedited study was approved. Approval of the study and any consent form(s) is for the period of 3/13/2018 to 3/12/2019. This research study is eligible for review under expedited category #5,7. The Chairperson (or designee) deemed this study no more than minimal risk.

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

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

The approval includes the following items:

Document	Description
Brief Illness Perception Questionnaire (B-IPQ-English).pdf(0.01)	Surveys and Questionnaires
Cardiac Anxiety Questionnaire.pdf(0.01)	Surveys and Questionnaires
Cardiomems Demographic Questionnaire.docx(0.01)	Surveys and Questionnaires
Cardiomems Protocol IRB Amend 1 27 May 2016.docx(0.01)	Study Protocol or Grant Application
Duke Activity Status Index (DASI).pdf(0.01)	Surveys and Questionnaires
Informed Consent Cardiomems 2Aug(0.02)	Consent Forms
Informed Consent Cardiomems Post only 2Aug(0.02)	Consent Forms
Patient Activation Measure (PAM-13).pdf(0.01)	Surveys and Questionnaires
Patient Health Security.docx(0.01)	Surveys and Questionnaires
Self-Care of Heart Failure Index (SCHFI_R6.2_revised_3-09).pdf(0.01)	Surveys and Questionnaires

The Chairperson (or designee) does not have a potential for conflict of interest on this study.

Appendix B: Measures

Cardiomems Demographic Questionnaire

What is your age?

What is your gender?

Male

Female

Other

What is your race/ethnicity?

Black/African
American

White/Caucasian,
not Hispanic

Hispanic/
Latino

Asian/Pacific
Islander

Native
American/
Alaskan
Native

Other

Don't
Know

Prefer
not to
answer

What is your marital status?

Single

Married

Divorced

Widow

What is your level of education?

Grade
School

Some High
School

Some
College

College
Graduate

Graduate
School

Technical
School

Prefer not to
answer

Which category best describes your yearly household income? Include all sources of income for all people living in your home?

\$0 –
9,999

\$10,000 –
19, 999

\$20,000 –
29,999

\$30,000 –
39,999

\$40,000 –
49,999

\$50,000 –
74,999

\$75,000 –
99,999

\$100,000 –
149,999

\$150,000
and
above

Prefer
not to
answer

Cardiac Anxiety Questionnaire

Please rate each item by circling the answer (number) that best applies to you:

	Never	Rarely	Sometimes	Often	Always
I pay attention to my heart beat	0	1	2	3	4
I avoid physical exertion	0	1	2	3	4
My racing heart wakes me up at night	0	1	2	3	4
Chest pain/discomfort wakes me up at night	0	1	2	3	4
I take it easy as much as possible	0	1	2	3	4
I check my pulse	0	1	2	3	4
I avoid exercise or other physical work	0	1	2	3	4
I can feel my heart in my chest	0	1	2	3	4
I avoid activities that make my heart beat faster	0	1	2	3	4
If tests come out normal, I still worry about my heart	0	1	2	3	4
I feel safe being around a hospital, physician or other medical facility	0	1	2	3	4
I avoid activities that make me sweat	0	1	2	3	4
I worry that doctors do not believe my symptoms are real	0	1	2	3	4
When I have chest discomfort or when my heart is beating fast:					
...I worry that I may have a heart attack	0	1	2	3	4
...I have difficulty concentrating on anything else	0	1	2	3	4
...I get frightened	0	1	2	3	4
...I like to be checked out by a doctor	0	1	2	3	4
...I tell my family or friends	0	1	2	3	4

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

Appendix C: Scoring Procedures

Cardiac Anxiety Questionnaire

Each of the 18 items is rated on a 5-point Likert scale as to how frequently the behavior typically occurs with response anchors ranging from 0 (never) to 4 (always). A total score is computed as the mean of the relative frequency ratings for each of the 18 items (i.e., summing all responses to individual items and dividing the sum by 18, the number of total test items). Subscale scores are computed similarly as the mean of the relative frequency ratings for each of the items in each subscale. Using means ensures that the total test score and scores from subscales with different numbers of items can be more directly and easily compared because the range of the total and all subscale scores is the same (0 ± 4). Higher scores indicate greater HFA (Eifert et al., 2000).

Self Care of Heart Failure Index version 6.2

Directions for Use: The time interval used in the directions can be adjusted to reflect your study design. For example, if your follow-up is 3 months, ask patients to “think about how you have been feeling in the last 3 months”. We recommend that no longer than 3 months be used, though, because of issues with recall.

Scoring: Previously we advocated use of a total score but we now strongly recommend that the 3 scales (self-care maintenance, management, and confidence) be used separately. Self-care is best represented by maintenance and management. Confidence is an important process that probably moderates the relationship between self-care and outcomes. This change benefits users because now even asymptomatic patients will have self-care maintenance and confidence scores. Self-care management scores remain appropriate only in persons who have been symptomatic. Specific formulas for calculating scale scores are available in the 2009 article.

Maintenance. To calculate the Maintenance scale scores, each scale score is standardized to a 0 to 100 range. There is one negatively worded item in the maintenance scale (# 8). After reverse-coding that item, standardize the raw score to a 0-100 scale. Note that more than half of the items in this section A should be answered for the scale to be an adequate measure of self-care maintenance.

Management. Score the management scale only if the patient reported having trouble breathing or ankle swelling in the past interval. Otherwise, ignore responses, even if the patient answers the items. Note that the first item (In the past month, have you had trouble breathing or ankle swelling?) is used only for this purpose and not in the scale score. Note that at least 2 of the 4 possible remedies must be answered for the scale to be an adequate measure of self-care management.

Confidence. Self-care confidence scores (Section C) should be standardized as described above. Note that more than half of the items in this section should be answered for the scale to be an adequate measure of self-care confidence.

Retrieved from: http://www.self-careofheartfailureindex.com/?page_id=49

Appendix D

Frequent Abbreviations

CVD – Cardiovascular Disease
CAD – Coronary Artery Disease
CAQ – Cardiac Anxiety Questionnaire
DSM-V – Diagnostic & Statistical Manual – 5th Edition
HF – Heart Failure
HFA – Heart-Focused Anxiety
ICDs – Implantable cardioverter defibrillators
LVEF – Left ventricular ejection fraction
MI – Myocardial Infarction
PAP – Pulmonary Artery Pressure
QoL – Quality of Life
SCA – Sudden Cardiac Arrest
SCHFI v6.2 – Self Care of Heart Failure Index version 6.2
SCP – Self-care practices
W-IHMs – Wireless implantable hemodynamic monitors

