ABSTRACT

Rebecca L. Harrell, FEAR OF RECCURENCE IN ATRIAL FIBRILLATION PATIENTS: DEVELOPMENT OF THE ECU FEAR OF RECURRENCE SCALE (Under the Direction of Dr. Samuel Sears)
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Atrial fibrillation (AF) is characterized by a rapid and irregular heartbeat that results from abnormal impulse generation from the upper chambers of the heart, the atria. A disorganized heartbeat obstructs the ability of the heart to adequately pump blood through the heart and to other vital organs. Because of this, individuals with AF are at increased risk of adverse health effects including stroke, premature death, and heart failure. Advances in medicine have allowed for treatment developments that target arrhythmic substrate dysfunction and decrease the risk of adverse events. While some AF patients respond effectively to anti-arrhythmic medications, others may require additional interventions to decrease the burden of AF.

Given the increased burden among patients who present with sustained AF recurrence rate following intervention, it is plausible that many patients experience significant fear or anxiety related to AF recurrence. The phenomenon of fear of recurrence (FOR) is well-researched in cancer survivors and is often associated with significant psychological and behavioral consequences. The role of FOR among AF patients, however, has not yet been studied despite notable psychological concerns in this population.

The present study aimed to determine the overall prevalence and impact of FOR among AF patients through the development of a valid, reliable measure to assess this construct. At the East Carolina Heart Institute (ECHI), 51 patients were recruited to complete the ECU Fear of Recurrence Scale, the Cardiac Anxiety Questionnaire, the ECU Behavioral and Lifestyle Assessment for Atrial Fibrillation, the Fear about Exercise Questionnaire, and the Generalized

Anxiety Disorder and Patient Health Questionnaire screeners. Descriptive analyses revealed that the mean age of the sample was 69.71 (*SD = 10.12)* with 49% identifying as women and the majority identifying their racial/ethnic background as non-Hispanic White (80.4%). Medical and psychological co-morbid conditions were common across the study sample, and health care utilization was high. Major findings of the present study included a) an acceptable degree of reliability (α = .92) and construct validity for the new measure b) notable prevalence of recurrence fears across the sample c) moderate-high relationships between FOR, cardiac-specific anxiety, and fears about experience and d) evidence of a predictive relationship between AF-specific fears and exercise-related fears. The findings in the present study provide promising evidence for conceptualization and existence of FOR among AF populations and offer a foundation for continuing to address nuance in the patient experience. This measure can likely help to continue to identify patients struggling with adjustment to this condition and aid in future development of targeted interventions to address AF-specific fears.

FEAR OF RECURRENCE IN ATRIAL FIBRILLATION PATIENTS: DEVELOPMENT OF THE ECU FEAR OF RECURRENCE SCALE

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Chapter 1: Literature Review

Atrial Fibrillation

Atrial fibrillation (AF) is the most common type of heart arrhythmia that impacts roughly 3.5 million people worldwide and is expected to increase to 12.1 million by 2030 in the United States alone (Colilla et al., 2013). In a normal functioning heart, electrical signals that begin in the sinoatrial (SA) node in the heart and travel to the upper (atria) and lower (ventricles) chambers of the heart, initiate contraction of the atria and yield synchronic electrical conduction across the atria and ventricles. The electrical signals followed by contraction produce a steady heartbeat and allow blood to flow to and from the heart effectively. In patients with AF, however, disorganized and rapid electrical signals cause the lower (ventricles) and upper chambers (atria) of the heart to beat in a nonsynchronous fashion – restricting blood flow from the atria to the ventricles and resulting in irregular and often rapid heartbeat (Wang et al., 2018). This poses significant risk as irregular blood flow can cause the blood to pool and form a clot (thrombus) in the left atrial appendage. A thromboembolism can then occur in which the blood clot breaks loose and travels to the brain, causing ischemic stroke and increasing likelihood of premature death (Wang et al., 2018). Compared to healthy individuals, AF patients are as much as 4-6 times more likely to have a stroke, and this risk escalates with increasing age (Benjamin et al., 2017; Centers for Disease Control and Prevention, 2020). AF is more commonly identified in men than women at a 2:1 ratio before the age of 75, and women demonstrate elevated rates of adverse events, including stroke and premature death (Dagres et al., 2007; Frasure-Smith, 2009; Ladwig et al., 2020; Patel et al., 2013; Pothineni & Vallurupalli, 2018). A similar relationship is

recognized among Black and Brown patients who also exhibit greater risk for adverse events, as well as higher reported symptom burden and incidence (Nanda & Kabra, 2019).

The types of atrial fibrillation are classified as paroxysmal AF, persistent AF, and permanent AF. Patients who demonstrate paroxysmal AF presentation experience less frequent episodes of irregular heart rhythm that terminate spontaneously (i.e., described as "on/off") and normally do not last longer than 7 days. These patients are generally responsive to initial treatment measures, albeit the unpredictable nature of symptoms often increases psychological distress and fear among paroxysmal AF patients. Patients with persistent AF experience rapid, irregular heartbeat for longer than a week and will likely need additional treatment interventions to sustain normal rhythm. Permanent AF is classified as chronic dysrhythmias that cannot or have been decided to not be fully corrected with additional medical interventions (Nesheiwat & Jagtap, 2020). Patients with more burdensome symptomatic AF presentations often have undergone several additional AF treatments and have a lower probability of sustaining regular rhythm in the long term. Among all AF classifications, approximately 39% report never experiencing any distinguishable symptoms of atrial fibrillation (i.e., palpitations, shortness of breath, chest pressure, and extreme fatigue) (Freeman et al., 2015). Nonetheless, roughly 61% of patients do report experiencing symptoms, and 16% find them to be disabling (Freeman et al., 2015). Symptom recognition and appraisal across AF patients is subjective and influenced by patient ability to recognize and correctly classify symptoms, potentially driving high volume of asymptomatic patients.

Treatment of Atrial Fibrillation

First-line treatment for AF patients involves placement on rate control medications (i.e., beta blockers, calcium channel blockers, etc.) and anticoagulant medications (i.e., blood thinners

including novel oral anticoagulants [NOACs] and Warfarin) that attempt to reduce rate and risk of stroke. Anti-arrhythmic medications may also be prescribed to prevent occurrence of abnormal rhythm. Continued AF incidence may prompt the need for additional intervention, often an ablation procedure. Recent research has prompted the elevation of catheter ablation to consideration as a front line treatment due to encouraging results of earlier ablation strategies (Andrade, et al, 2021; Chen et al., 2022; Turagam et al., 2021; Wazni et al., 2021). Ablation intervention is common and can be completed either surgically or non-invasively via catheter and involves deliberately creating scarred heart tissue around the pulmonary vein (PV)-left atrium (LA) junction in the heart to block disorganized, irregular electrical signals that prompt irregular heartbeat (Kirchhof et al., 2016; Mujovic et al., 2017). During the procedure, the tip of the catheter is navigated to the PV-LA tissue in the heart and will emit either hot energy (referred to as a radiofrequency ablation) or cold energy signals (cryoablation) to ablate the tissue (Kirchhof et al., 2016; Mujovic et al., 2017), effectively targeting the electrical substrate for AF.

Although risks of the procedure are generally minimal, it is not absent of potential dangers. Catheter ablations of AF can require longer catheter manipulation time, increased delivery of lesions and greater anticoagulation – underscoring why AF catheter ablations are associated with higher overall risk compared to more conservative pharmacological treatments (Carrado & Zorzi, 2017). Identified complications of AF catheter ablations include vascular access issues, periprocedural stroke, cardiac perforation, nerve injury, pulmonary vein stenosis, and atrioesophageal fistula though many are rare and generally do not lead to premature death (Carrado & Zorzi, 2017; Han et al., 2017; Noseworthy et al., 2015). While some studies have indicated a decline in post-ablation complications, women who undergo ablation procedures seem to be higher risk for development of complications (Carrado & Zorzi, 2017).

Coupled with possibility for complications, a catheter ablation procedure demonstrates a 1-year success rate of only 52%, and AF symptom recurrence is common (Calkins et al., 2018). Despite this, however, catheter ablation procedures have consistently proved to be superior to anti-arhythmic medications in decreasing AF recurrence, with efficacy rates of up to 80% over time following multiple ablation procedures (Ariyaratnam et al., 2020). Some studies have also shown that patient quality of life significantly increases post-ablation and remains so up to 12-month following the procedure (Biviano et al., 2017; Poole & Wilber, 2019; Wynn et al., 2015). Significant reductions in post-ablation hospitalizations and need for anti-arrhythmic use have also been reported in the literature, with some studies finding as much as a 56% reduction in overall cardiovascular hospitalizations among post-ablation patients with paroxysmal AF, persistent AF, and long-standing persistent AF (Guo et al., 2019; Poole & Wilber, 2019). Despite this, while in the CABANA clinical trial, Packer and colleagues (2019) found significant differences in AF recurrence, no differences in adverse outcomes were found including overall mortality, stroke, bleeding, and cardiac arrest when comparing AF patient's post-ablation and AF patients on antiarrhythmic drug therapy. Notable differences in overall patient quality of life were however reported. Possible benefits of secondary treatments for AF exist on a system level as well, with reductions in health care consumption post-ablation helping to decrease cost associated with AF care (Poole & Wilber, 2019).

The balance between possible adverse outcomes versus health gains illustrates the evaluative risk-benefit analysis AF patients may have when selecting treatment options and making decisions to move forward with secondary treatment avenues. Understandably so, many patients are apprehensive and often hesitate about these treatments. Though not explicit in the literature, it is possible that AF patients who agree to common secondary treatments (e.g.,

catheter ablation, cardioversions, etc.) represent a unique subset of AF patients. Among this population, increased AF burden, worry, and diminished quality of life pre-treatment are likely significant drivers for the decision and may outweigh apprehension associated with procedural risks. Patient expectations for significant symptom relief and the prospect of being "AF-free," as depicted in the literature, is often not met. As such, patients who undergo multiple additional secondary treatment procedures may be at increased risk for adverse psychological and behavioral outcomes. Catheter ablation, compared to medical therapy only, has not shown to have better primary endpoints specific to patient death rates, occurrence of disabling stroke, bleeding complications and cardiac arrest (Packer et al., 2019). Knowing this, it is hypothesized that AF patients who pursue both pharmacological and procedural treatments, with the expectation of symptom relief, likely are fearful of prospect of symptoms returning and further impact of patient quality of life.

The Role of Patient Perception and Common Sense Model

To better understand the unique fears experienced by AF patients and their relationship to patient outcomes, it is important to address the contribution of patient perception in symptom reporting, perceived AF burden, and psychological impact. Leventhal's Common Sense Model of Illness (CSM), a widely accepted model used for understanding the influence of patient perception, postulates that how patients label and appraise their symptoms directly impacts both coping strategies and patient outcomes (Leventhal et al., 1997). This theory may be particularly relevant to AF patients given notable differences in symptom recognition and reporting and influence on the pursuit of additional AF treatments beyond anti-arrhythmic medications.

Conceptualization of symptom perception is variable, but generally refers to an individual's ability to acknowledge, understand, and appraise physical sensations appropriately

(Lee & Riegel, 2018). Patients who are able to accurately label AF symptoms generally exhibit less overall symptom burden and psychological distress. A clear issue arises, however, when patients lack understanding of their diagnosis and label their symptoms as "severe" or "dangerous," when such an appraisal is not warranted relative to actual medical risk. These patients will generally report higher levels of psychological distress surrounding their diagnosis and worse health outcomes (Patel et al., 2013). Given this, how a patient conceptualizes their diagnosis and related symptoms influences not only their mental health, but likelihood of pursuing more serious AF treatments beyond general anti-arrhythmic mediations – further highlighting the roles of perception, appraisal, and cognition in the AF patient experience.

Psychological Distress in AF

While some literature supports that symptom perception accounts for significant variance in rates of psychological distress (most notably depression and/or anxiety), prior research strongly indicates AF patients experience high rates of both with some studies reporting as much as 38% of patients meeting criteria for significant depression and 28% meeting criteria for state anxiety (Patel et al., 2013; Polikandrioti et al., 2018; Thrall et al., 2006). While it is plausible that patient disposition and situational factors can influence anxious and depressive symptoms among this population, general psychological distress and disposition do not paint the entire picture for this population. Specifically, given the often unpredictable nature of this arrhythmia (and possibility for recurrence or adverse events in the future) coupled with the need for continual management of care, AF can significantly impact all aspects of a patient's life. AF is associated with personal, clinical, and socioeconomic impacts including lower overall quality of life, and higher rates of psychological distress compared to the general population (Gehi et al 2012; Lioni et al., 2014; McCabe et al., 2011). Research also suggests that patients who experience increased

number of *recurrent* episodes of AF, report greater symptom severity and negative or exacerbated appraisal of symptoms and overall condition, and have higher mortality rates and increased health care consumption (von Eisenhart Rothe et al., 2014; McCabe et al., 2011; Thompson et al., 2014). High rates of psychological distress are also often associated with increased risk for negative health outcomes, development of comorbid conditions, and inability to self-manage care and attend regularly scheduled doctor's visits. Moreover, restricting previously enjoyed activities and accepting the likelihood of having to manage a chronic, lifelong disease can be particularly overwhelming for patients. All of these factors can contribute to unhelpful behavioral responses and overall diminished quality of life. The importance of psychological factors in AF patient experience is further demonstrated in the fact that negative emotions have been more strongly associated with AF symptom scores and higher reporting than the presence of device-detected AF (Sears et al., 2005). In addition, more recently, observational studies using serial assessment of AF patients in a specialty clinic demonstrated that depression and anxiety were the *best* predictors of AF symptom severity and linked to increased costs and elevated healthcare utilization (Thompson, et al., 2014).

While it is clear that psychological distress significantly impacts AF patients, within this population, individual differences and group differences persist. For instance, women living with AF consistently exhibit elevated rates of depression and anxiety, report greater symptom severity and burden, and lower QOL when compared to their male counterparts (Frasure-Smith et al., 2009; Frasure-Smith et al., 2012; Gleason et al., 2019; Patel et al., 2013; von Eisenhart Rothe et al., 2015). With regard to age, patients who are younger (e.g., <60 years old) also report greater health-related stress and higher rates of anxiety and depressive symptoms when evaluated against older patients (Gleason et al., 2019). Similar patterns exist among patients who represent lower

socioeconomic status (and likely diminished access to resources; LaRosa et al., 2020). Taken together, it is evident that women, younger patients, and patients of lower SES exhibit higher psychological impact associated with AF experience, and as such, may be at increased risk of developing AF-specific fears and worries around possibility of recurrence.

While the study of psychological distress among this population is not new, ideas around fear of AF recurrence and potential impact on patient behaviors and outcomes have yet to be explored. Studies focused on cancer patients and cancer survivors provide a solid framework for the theories of fear of disease recurrence. In the cancer literature, patients who are in remission often endorse the co-occurrence of depression and anxiety and fear related to the possibility for relapse. Fear of cancer relapse (coined fear of recurrence) has been associated with more severe cases of anxiety and depressive symptoms among patients (Liu et al., 2018). The link between psychological distress and fear of relapse exists in chronically ill patients. Given what is known about psychological distress in AF patients, fear of recurrence could potentially be a target for AF intervention that health care providers are missing, emphasizing the importance of this work in this population.

Fear of Recurrence Overview

Fear of recurrence (FOR) is a phenomenon prominent in cancer research and refers to patient fear and worry specific to the potential for cancer relapse. Within populations of cancer survivors, roughly 30-70% endorse having moderate to severe levels of recurrence fears that can persist for many years following diagnosis (Hall et al., 2019). Models of FOR propose that patient perception of physical sensations and identification of symptoms often serve as a trigger for elevated fears that can result in increased symptom reports and significant psychological

distress, feelings of hopelessness, and diminished quality of life (Hall et al., 2019; Mehnert et al., 2013).

Behavioral impacts of fear of recurrence can vary greatly with some patients becoming hypervigilant about their health (i.e., elevated, care-seeking behaviors, constantly monitoring symptoms and displaying need to feel in control of their condition), while others become avoidant (i.e., missing routine appointments, nonadherence to medications and treatment regimens) (Hall et al., 2019; Palas et al., 2021). Patients with high levels of FOR have also demonstrated reductions in physical activity and increased alcohol consumption, which are contributory to clinical management in cardiac populations (Hall et al., 2019). Disease severity has also been associated with FOR in cancer patients in that increased disease severity was related to increased fears around possibility for the cancer to return (Palas et al., 2021). FOR cancer models and associated mechanisms parallel models of symptom perception among cardiac populations in which misappraisals of cardiac symptoms have led to increased anxiety and worry, maladaptive coping behaviors (specifically hypervigilance and avoidance), and increased ED visits and hospitalization (Santos et al., 2020). Given AF patients who have been started on anti-arrhythmic medications and/or undergone secondary procedures likely have expectations of remission and may seemingly be in a gray area between active disease and successful treatment, the idea of FOR seemingly translates into this population.

Though research of this phenomenon among AF patients is virtually nonexistent, a pending clinical trial developed by researchers at Columbia University will examine the role of cardiac event reoccurrence among patients with suspected acute coronary syndrome (ACS). The trial involves implementation of an adapted intervention commonly used to reduce FOR among cancer patients through changing emotion-driven responses and interpretation of bodily

sensations (Birk et al., 2020). Specifically, the study will observe whether addressing FOR in an undifferentiated cardiac sample will result in observed changes in medication adherence, physical activity, and patient ideas about the future (Birk et al., 2020). In this study, fear of reoccurrence will be examined as a modifiable mechanism of behavior change – highlighting the potential relationship of FOR and behavior among cardiac patients and the prospective need for development and implementation interventions that target AF FOR and enhance patient outcomes. Although testing of this phenomenon within AF patients has not yet been done, Anthony et al (2022) recently highlighted the concept of FOR as applied to the AF patient experience. The concept was outlined as having several overarching components, including patient fear of exertion (e.g., exercise, sexual intimacy, emotional reactivity), fear of death, fear of stroke (loss of independence, burden on family), and fear of medical consequences (finances, need for additional procedures, and increasing medical severity).

Fear of Recurrence translated to Atrial Fibrillation Patients

Models of recurrence in both cancer research and in previous scales examining psychology in cardiac electrophysiology have analyzed patient fears using a two-factor framework. Specifically, in patients with implantable cardioverter defibrillators (ICDs), patient fear of shock was conceptualized as attitudes and behaviors that contribute to both the antecedent of the shock and the attitudes and behaviors that would follow from shock as a consequence as measured by the Florida Shock Anxiety Scale (Kuhl et al 2006). Our approach to atrial fibrillation echoes this model with a focus on both patient fears around antecedents (e.g., fear of activities or circumstances that could trigger an AF episode), as well as potential consequences (e.g., fear of what may happen if an AF episode occurs) from an attitude and behavioral framework. More clearly, AF FOR can be understood as both cognitions and behaviors related to

the fears around triggering an AF episode and the fear of potentially harmful consequences resulting from the experience of another AF episode. Despite legitimacy of patient fears and the understanding that recurrence is a reality for many patients, patient identified fears around triggering an AF episode may be somewhat exaggerated. This idea is best represented by a recent study examining potential triggers for an arrhythmia. Marcus and colleagues (2021) found that, despite popularized ideas about the potential for caffeine, lack of sleep, exercise, dehydration etc. to potentially trigger an AF episode, only alcohol use was determined to be a reliable trigger. While much of these beliefs are largely false, fears around AF recurrence remain salient to AF patients and significantly contribute to behavioral and lifestyle factors related to AF management that ultimately impact patient quality of life. Knowing this, it is critical that unique fears among this population are clearly defined and established in order to change patient behaviors that improve overall outcomes.

Role of Health Behaviors and Co-morbid Conditions

As evidenced in the vast body of literature on cancer recurrence, fear of recurrence can impact patient health-related behaviors and modifiable behaviors that influence disease progression. Unlike cancer recurrence following remission periods, AF incident can be heavily influenced by patient behavior including adherence to medications, management of co-morbid conditions, exercise, diet, and other lifestyle factors (Sears et al., 2022). Knowing this, it is clear that a key component of successful AF management is adoption of healthy lifestyle behaviors, and this can be significantly hindered by perceived patient fears of the possibly for AF incident to reoccur. Risk factor management is critical for patients utilizing front line prevention therapies and also can impact long-term procedural success for patients who choose to undergo secondary corrective treatments. Specific to patients who undergo ablation procedures, AF recurrence and

patient quality of life have been recognized as key targets of post-ablation care for optimal patient outcomes (Ariyaratnam et al., 2020). Moreover, a recent consensus statement from the American Heart Association emphasized the crucial role lifestyle changes such as weight loss, exercising, and adherence have on positive patient outcomes (Chung et al., 2020).

Common modifiable behavioral factors associated with AF progression include hypertension, diabetes, obesity, sleep apnea, dyslipidemia, physical inactivity and alcohol and tobacco use (Ariyaratnam et al., 2020). Hypertension has consistently been identified as a primary contributor to AF development with elevated risks as high as 40-50% and comorbid rates of 60-80% (Ariyaratnam et al., 2020; Verdecchia, Angeli & Reboldi, 2018). Unmanaged blood pressure (BP) can generate significant force in the artery walls and contribute to cardiac remodeling and afterload that exacerbate AF (Ariyaratnam et al., 2020; Chung et al., 2020; Lau et al., 2017). Proper management of blood pressure (defined as sustained systolic BP below 130 mm Hg) has been linked to a 40% reduction in AF incidents (Ariyaratnam et al., 2020). Diabetes is also a commonly identified AF risk factor and contributor to disease progression and has been associated with a 37% increase in AF incident risk. Risk is further elevated in individuals who exhibit poorly controlled or unmanaged blood glucose levels (demonstrated by glycosylated hemoglobin between 7.0-8.9% and above 9.0%) (Dublin et al., 2010). Patients with comorbid diabetes also exhibit lower quality of life and increased health care consumption (Echouffo-Tcheugui, 2017). Intensive management of glycemic control can aid in reduced AF recurrence by as much as 30% and has been indicated in post-ablation populations (Chung et al., 2020). Well-managed blood sugar levels have also been linked to decreased need for multiple ablation procedures among AF patients (Chung et al., 2020) – reiterating the importance of risk factor management in disease management.

Obesity and excessive weight gain have been identified as primary contributors to expected increases in AF prevalence in the coming years. Several studies have supported the notion that 5-point increases in body mass index (BMI) elevate AF risk by as much as 29% (Magnussen et al., 2017). Excessive weight gain can enlarge atrial size and cause structural and electrophysiological remodeling, worsening AF progression (Lau et al., 2017). Increased physical activity and weight loss, however, can result in significant reductions in AF burden and improve quality of life as well as capacity for sustained physical exercise (Chung et al., 2020). By contrast, physical inactivity and persistent sedentary behavior increase likelihood of AF incident and can exacerbate negative health outcomes in AF patients and AF patients post-ablation.

Obstructive sleep apnea (OSA) increases risk of AF development and roughly doubles possibility of AF occurrence (Chung et al., 2020) Chronic, poorly managed OSA can result in increases in atrial pressure, atrial enlargement, and prompt inflammation and electrophysiological remodeling in the heart, worsening AF prognoses (Lau et al., 2017). Properly managed OSA can increase positive AF outcomes with continuous use of CPAP machines predicting lower AF recurrence and decreased risk of progression to permanent AF. In post-ablation populations, lower AF recurrence has consistently been associated with appropriate CPAP therapy (Chung et al., 2020). The relationship between dyslipidemia and AF risk and progression is variable in prior literature, however, some studies have suggested that elevated cholesterol levels negatively impact the ability for blood to flow effectively, increasing cardiac afterload and influencing AF risk and progression (Chung et al., 2020).

Finally, smoking cessation and reducing alcohol consumption are crucial influences on AF patient outcomes. Prolonged, excessive alcohol use consisting of three or more drinks per

day has demonstrated 40% increase in potential for AF development and amplified instances of AF progression to more permanent presentations (Ariyaratnam et al., 2020; Voskoboinik et al, 2016). This is most commonly associated with changes in conduction processes, atrial enlargement, and shifts in the autonomic nervous systems control of the heart (Ariyaratnam et al., 2020). Similarly, tobacco use is linked to increase AF risk and progression via oxidative stress and inflammation. Both alcohol consumption and smoking contribute to likelihood of stroke and premature death (Ariyaratnam et al., 2020; Voskoboinik et al, 2016). Knowing this, it is imperative these factors are addressed in risk management care.

As evidenced in the literature, effective treatment of comorbid conditions and modification of lifestyle risk factors can improve AF burden and long-term patient outcomes, and comprehensive management of all identified behavioral risk factors is needed to yield improvements in AF outcomes (Chung et al 2020). Among AF patients who sought out secondary treatments, aggressive physician-directed risk factor management (RFM) demonstrated significant reductions in weight and post-ablation AF recurrence as well as improved blood glucose levels, BP, and adherence to CPAP machine (Ariyaratnam et al., 2020). Moreover, intensive approaches to risk factor modification have not only demonstrated improvements in AF outcomes among pre- and post-ablation, but also provided support for AF reversal, in that some patients who underwent RFM moved from persistent presentations of AF to paroxysmal. (Ariyaratnam et al., 2020). In essence, positive patient outcomes (i.e., quality of life, reduction in symptoms, decreased burden, etc.) throughout disease management and following secondary treatment procedures are enhanced by proper management of comorbid conditions and behavioral change – both of which are seemingly critical for sustained AF remission.

Health Care Utilization

Adherence to disease management regimens and adoption of behavioral lifestyle changes can reduce AF burden and need for emergency or elevated care-seeking behaviors. Secondary corrective treatments, such as catheter ablation procedures, are also often associated with reductions in overall cost as high as 68.5% and reductions in emergency care costs up to 48.8% following ablation (Kim et al., 2011). Patient perception of disease, fear of recurrence, and associated behavioral factors, however, can significantly influence care-seeking and associated costs. Patients often experience elevated rates of fear and anxiety associated with the prospect of AF episodes reoccurring (as seen in the FOR cancer literature). While for some patients, this could result in adoption of positive preventative behaviors, for others this could result in avoidance or withdrawal from previously enjoyed activities. Often this is associated with limited physical activity and increased sedentary behavior (associated with the need to reduce chances of triggering an AF episode). These maladaptive coping strategies and failure to properly manage AF can lead to health complications and adverse outcomes, increasing the potential need for emergency care and contribution to health care costs. Given the likely relationship between fear of recurrence, behavioral factors, and health care costs, emphasis should be placed on addressing fear of future AF episodes as well as intensive risk factor modification encouragement throughout AF care.

The Current Study

Gaining a better understanding of the mechanisms that contribute to sustained AF remission and better patient outcomes is critical for enhancing patient care and quality of life. Moreover, improving patient outcomes can impact health care burden – highlighting potential benefits of this research at both the individual and system level. Given the proposed similarity of

patient experience among cancer survivors and AF patients (especially those in possible *remission*), it was hypothesized that FoR could be a significant contributor to patient outcomes. As such, the goal of this study was to design, test, and validate a new measure for AF-specific FOR that could aid in establishing the role of FOR on patient behavior and outcomes.

Chapter 2: Method

Study Aims

The purpose of the current study was to evaluate a new measure of fear of recurrence (FoR) among a US sample of AF patients. The measure was created with expert consensus from two cardiologists, two cardiovascular nurses, a cardiac psychologist, and multiple graduate students in the cardiac psychology lab. Reliability and validity of the measure was examined, as well as feasibility and clinical utility in an AF patient clinic. The potential relationship of FoR on patient risk behaviors was determined with the ultimate goal of developing targeted cardiac and AF patient interventions in the future. Specific aims of the study are detailed below.

Aim 1: This study aimed to determine inter-item reliability of the measure and evaluate factor structure to establish reliability and validity of the measure.

Aim 2: This study aimed to determine convergent and divergent validity of the measure using the Cardiac Anxiety Questionnaire and Fear About Exercise Questionnaire.

Aim 3: This study aimed to determine the predictive relationship between FoR and patient risk behavior (e.g., physical inactivity, smoking, alcohol use, unhealthy diet, etc.) using the East Carolina Behavioral Risk Factor and Lifestyle Assessment.

Procedure

Participants

A total of 51 AF patients were recruited for participation in the study in the AF clinic at ECHI. Eligible patients were residents of the United States, English proficient, at least 18 years of age, and had a documented AF diagnosis as confirmed by their EP cardiologist or cardiac nurse.

An initial target sample size of 100 participants was determined using GPower 3.2 for an 80% chance of detecting a medium effect size. This power analysis was calculated to also provide a sufficient number of participants to conduct an exploratory factor analysis (EFA) and regression analyses for proposed relationships.

Study Recruitment

The study was approved by the Institutional Review Board. Prior to recruitment, a review of patient electronic health records (EHRs) was conducted to determine eligibility for the study. Eligible patients were approached and informed of the study at their regularly scheduled appointment at the ECHI cardiology clinic by the NP or EP cardiologist on staff or via phone prior to their appointment to determine interest. If interested during their clinic visit, a study team member met with the patient at the end of their scheduled appointment to give a brief description of the study and participant expectations, review the informed consent document, and address any questions from the patient.

Following completion of the informed consent process, the patients were asked to complete a series of questionnaires including the newly developed measure, the East Carolina Fear of AF Recurrence Scale (ECFoR-AF), the ECU Behavioral Risk Factor and Lifestyle Assessment (patient-report), the Cardiac Anxiety Questionnaire (CAQ), and the Fear about Exercise questionnaire. The Patient Health Questionnaire (PHQ-2) and the Generalized Anxiety Disorder Questionnaire (GAD-2) were also given to participants to account for brief assessment of anxiety and depressive symptoms. Given that these questionnaires were brief, the research portion of the visit took no more than 15-20 minutes to complete. Patients were not asked to come back into the clinic for research purposes after the initial visit. A medical record review was conducted by a research team member to obtain patient demographics, medical information,

medical comorbidities, and surgical and procedural history. There was no incentive provided for participation in the study.

Measures and Information from Medical Record Review

Demographics

Demographic information extracted from patient EHR included patient age, sex, marital/relationship status, race/ethnicity, employment status if available, education level if available and type of health insurance on file. Type of health insurance, education level, and employment status were also collected as a relative measure of patient socioeconomic status.

Medical Information

Medical information extracted from patient EHR included AF type (e.g., paroxysmal, persistent or permanent), and presence of specific medical comorbidities including congestive heart failure (CHF), coronary artery disease (CAD), hypertension (HTN), chronic lung disease, diabetes, chronic kidney disease, history of stroke/TIA, and history of myocardial infarction (MI). In addition, AF treatment history including medications and surgical and procedural history was also extracted from EHR.

Information obtained from patient records was used to determine a Charlson Comorbidity Index (CCI), which is a score used to predict 10-year survival in patients with multiple comorbid conditions (Charlson et al., 1987). Obtaining a CCI helped to give a better estimate of medical severity and presence of comorbid conditions for each participant.

The East Carolina Fear of AF Recurrence Scale (ECFoR-AF)

The 14-item FOR scale is a newly developed scale to assess specific fears and fear of future AF episodes among a population of atrial fibrillation patients. This questionnaire is separated by fears specific to antecedents (6 questions) and consequences (6 questions) of

experiencing an AF episode. Responses to each item are measured on a scale from 0-4, with 4 indicating a greater magnitude of each specific fear. Responses of each item are then added to calculate a total score. Overall subjective AF fear of recurrence is also assessed, and a patient feedback question is included. Measures of internal consistency were not conducted prior to this study as this is a newly developed scale. This measure was modeled after the Florida Shock Anxiety Scale (FSAS), a reliable and validated measure developed to assess ICD-specific fears and shock-related anxiety among patients with implantable cardioverter defibrillators (ICDs), with fears separated into specific to shock antecedents and consequences (Ford et al., 2012).

The ECU Behavioral Risk Factor and Lifestyle Assessment

This 15-item questionnaire was developed to provide a comprehensive assessment of AF symptoms, the American Heart Association's (AHA's) Life's Simple 7, and associated AF specific behavioral risk factors. This questionnaire includes assessment of blood pressure, physical activity, blood sugar, smoking and alcohol use, cholesterol, diet habits, body mass index (BMI), sleep apnea, AF type and symptom presence, and health care use (Anthony et al., 2022). Item responses are scored on a scale of 0-2 with 2 indicating riskier lifestyle behaviors. While most of this measure allots three response choices for each item, diet is assessed using five response choices specific to consumption of fruits/vegetables, fish, whole grains, sodium intake, and sugar-sweetened beverages. Total scores are calculated by summing the items, and higher overall total scores are indicative of greater lifestyle burden.

Cardiac Anxiety Questionnaire (CAQ)

The CAQ is an 18-item questionnaire composed of three subscales measuring fear of cardiac symptoms, avoidance behaviors related to cardiac-specific fears, and degree of cardiac sensation monitoring (Eifert et al., 2000). These three subscales were developed to provide

assessment of overall cardiac-specific anxiety. The CAQ has shown high internal consistency with a reported alpha of 0.83. Similarly, high internal consistency is also reflected in the three identified subscales (cardiac-specific fears, $\alpha = 0.83$; avoidance behaviors, $\alpha = 0.82$; cardiac monitoring, $\alpha = 0.69$) (Eifert et al., 2000).

Fear About Exercise Questionnaire

The Fear About Exercise Questionnaire is a brief, 5-item questionnaire developed to measure patient fears related to exercise and physical exertion (Farris et al., 2019). Items aim to assess the belief that something might occur physically during exercise, inability to breath properly during physical exertion, triggering a cardiac event, low exercise confidence, and associated exercise avoidance behaviors. Items responses fall on a 5-point Likert scale ranging from “strongly agree” to “strongly disagree.” This scale was developed for use in a population of patients undergoing cardiopulmonary rehabilitation, and measures of internal consistency are present remain unknown (Farris et al., 2019). However, significant associations were found between fear of exertion and worse patient outcomes.

The Patient Health Questionnaire (PHQ-2)

The PHQ-2 is a brief, valid, 2-item screening tool for depressive symptoms specifically assessment of anhedonia (e.g., lack of pleasure in previously enjoyable activities) and depressed mood (Kroenke et al., 2003). This measure was dereived from the 9-item PHQ to provide a shortened scale for use in clinical settings or as a component of larger health questionnaires. Patients are asked to indicate how often they have experienced either of these two symptoms in the last two-week period, scoring each item on a scale of 0-3 and ranging from “not at all” to “nearly every day.” The PHQ-2 total score is obtained by summing the scores of the two items, and a score of 3 or greater is indicative of possible major depressive disorder. The PHQ-2 has

demonstrated good internal consistency with a Cronbach's alpha of 0.77 (as compared to 0.85 for the PHQ-9) (Maroufizadeh et al., 2019).

Generalized Anxiety Disorder Questionnaire (GAD-2)

The GAD-2 is a brief, 2-item screening tool used for assessment of generalized anxiety disorder. Similar to the PHQ-2, this measure was developed from a longer, 7-item scale to facilitate ease of use in clinical settings (Kroenke et al., 2007). Patients are asked to indicate how often in the past two weeks they have felt nervous/anxious and been unable to manage the worry, with responses ranging from "not at all" (0) to "nearly every day" (3). A total score is generated by summing responses to the two items, and a score of 3 points is used as a cut-off for identification of possible GAD and need for continued diagnostic evaluation. This measure has demonstrated good reliability ($\alpha = .77$) and validity as well as exhibited high correlations with GAD-7 total scores ($r = 0.94$, $p < 0.01$; Ahn et al., 2019; Hughes et al., 2018).

Data Analysis

SPSS statistical software program was employed for all data analyses.

Statistical Analyses

Descriptive statistics were calculated for all study variables which provided information about sample demographics and medical information (e.g., age, sex, race, SES, comorbidities, health care use etc.), as well as means and standard deviations for total scores on questionnaires. Total scores on the FOR scale were analyzed as a continuous variable, with lower scores reflecting fewer patient fears and higher scores indicating increased AF-specific fears. Similarly, total scores for all other questionnaires were examined as continuous variables, excluding the GAD-2 and PHQ-2, which provided a clear cut-off score and were examined as categorical, dichotomous variables.

Aim 1: To determine reliability of the FOR measure, Cronbach's alpha was calculated, and an alpha value of 0.70 or more was considered acceptable reliability. In order to comprehensively examine construct validity of the measure, an exploratory factor analysis (EFA) was conducted, and items were expected to load onto a single factor – FOR.

Aim 2: Convergent validity was examined by conducting a Pearson correlational analysis between total CAQ scores and total FOR scores. A high correlation coefficient was considered indicative of acceptable convergent validity of the measure. Similarly, divergent validity was examined by conducting a Pearson correlational analysis between total Fear About Exercise scores and total FOR scores. A low correlation coefficient between these two measures was considered to be indicative of acceptable divergent validity.

Aim 3: Regression analyses were used to determine whether the independent variables (e.g., total score on FoR items) predict patient behavior (e.g., total score on behavioral and lifestyle risk factor score and Fear About Exercise measures). Total scores on the FOR scale were analyzed as a continuous variable, with lower scores reflecting fewer patient fears and higher scores indicating increased AF-specific fears. Similarly, total scores for both dependent variables were analyzed as continuous variables, with lower scores reflecting less risk behaviors and fear around physical exertion and higher scores indicating increased engagement in risk behaviors and greater fear of physical exertion. Correlation coefficients were examined to determine amount of variance in lifestyle risk behavior and fear of exercise accounted for by patient FoR. Regression analyses were employed to examine which items on the ECU Behavioral Risk Factor and Lifestyle Assessment were most predicted by FoR total scores.

Chapter 3: Results

Sample Demographics

The study sample consisted of a total of 51 participants recruited from the cardiology clinic at the East Carolina Heart Institute (ECHI). All patients who participated in the study had a diagnosis of AF confirmed by their provider. Descriptive statistics for categorical demographic characteristics of the sample are provided in Table 1 below. Age of the sample ranged from 43 to 97 years of age, with a mean of 69.71 (*SD = 10.12*). Just under half of the sample identified as female and the majority of participants identified their race/ethnicity to be non-Hispanic/Latino White. All of the participants in the present study had some form of documented insurance with the largest portion of the sample having primary coverage provided by Medicare/Medicaid. Most were married and presently retired. Unfortunately, educational attainment for the majority of participants remained unknown with an overwhelming portion of the sample having no indication of educational status present in medical record.

Health Care Utilization

Health care utilization was determined by extraction of emergent medical visits and hospitalizations in the previous year prior to enrollment in the study. Approximately 49% of the sample had at least one documented emergency department (ED) visit in the year prior to enrollment date, with an overall average of 1.12 (*SD = 1.94*) ED visits. The majority of the sample had at least one documented hospital admission, with average AF-related hospitalizations at .61 (*SD = 1.09*), CVD-related hospitalizations at .37 (*SD = 1.04*), non-CVD related admissions at .35 (*SD = .66*), and total hospital admissions averaging 1.33 (*SD = 2.01*) in the last year. Descriptive statistics for categorical medical variables are provided in Table 2 below.

Medications

With regard to medication management, most of the study sample was prescribed an anticoagulant medication (most commonly a novel oral anticoagulant [NOAC] over Warfarin) and beta blocker, with less than half of the sample taking an anti-arrhythmic medication and calcium channel blocker. Approximately a fourth of the sample was prescribed an SSRI, with several participants also on benzodiazepines or other psychotropic medications. Over a third of participants exhibited a history of atrial ablation procedures, averaging .43 (*SD = .61*). Among those who demonstrated a history of ablation, 84% had undergone a single ablation with the remaining participants having undergone two or more.

Medical and Psychological Comorbidities

Comorbid conditions were prevalent across the study sample – with *every* participant having at least one documented comorbidity in addition to AF. The most common comorbid conditions among the study sample included hypertension, coronary artery disease, congestive heart failure, diabetes, followed by chronic kidney disease and chronic lung disease. Over a fourth of the study sample had experienced at least one myocardial infarction prior to enrollment, and just under a fourth had a documented occurrence of stroke/TIA.

Psychological comorbid conditions were also extracted from medical records, and it was determined that approximately a third of the sample had a documented history of depression and 25.5% had a prior anxiety disorder diagnosis.

Beyond existing comorbidities, a Charlson Comorbidity Index (CCI) was calculated for each participant. This index is utilized to predict risk of ten-year mortality for patients with various medical comorbidities. Among the study sample, the average CCI was 5.35 (*SD = 2.56*), indicative of severe comorbidity and congruent with an estimated 20% chance of ten-year

survival (Charlson et al., 1987; Radovanovic et al., 2014). Descriptive statistics for these variables are also provided in Table 2 below.

Table 1

Sample Demographic Characteristics

Demographic variable	#	%
Sex		
Men	26	51.0
Women	25	49.0
Race		
White/Caucasian	41	80.4
Black/African American	8	15.7
Hispanic/Latino/a	1	2.0
Asian	1	2.0
Marital/relationship status		
Single	6	11.8
Married	30	58.8
Divorced	7	13.7
Widowed	8	15.7
Insurance		
Veteran Affairs	2	3.9
Medicare/Medicaid	26	51.0
Private	23	45.1
Education level		
Unknown	43	84.3
Less than high school	1	2.0
High school graduate	2	3.9
Some college	1	2.0
Bachelor’s degree	3	5.9
Graduate or professional degree	1	2.0
Employment status		
Unknown	11	21.6
Full-time employment	13	25.5
Part-time employment	1	2.0
Disabled	3	5.9
Retired	22	43.1
Unemployed	1	2.0

Table 2

Sample Medical Characteristics

Medical variable	#	%
Medication Management		
Anticoagulant	42	82.4
NOAC	35	68.6
Warfarin	7	13.7
Beta-blocker	36	70.6
Calcium Channel Blocker	10	19.6
Anti-arrhythmic	15	29.4
SSRI	10	19.6
Benzodiazepine	6	11.8
Other Psychotropic Medication	6	11.8
Atrial Ablation History		
No	32	62.7
Yes	19	37.3
Comorbidities		
Congestive Heart Failure	28	54.9
Hypertension	48	94.1
Coronary Artery Disease	29	56.9
Chronic Lung Disease	15	29.4
Myocardial Infarction	15	29.4
Stroke/TIA	12	23.5
Diabetes	22	43.1
Chronic Kidney Disease	17	33.3
Depression	17	33.3
Anxiety	13	25.5
Health Care Utilization		
≥ 1 Emergency Visits	25	49.0
≥ 1 AF-related Hospitalizations	18	35.3
≥ 1 CVD-related Hospitalizations	10	19.6
≥ 1 Non-CVD Hospitalizations	13	25.5
≥ 1 Total Hospitalizations	30	58.8

Descriptive Statistics for Study Variables

Lifestyle Characteristics

The ECU Behavioral and Lifestyle Risk Assessment System provided supplementary understanding around both patient risk behaviors and AF symptom experience among the study sample. Total scores on the assessment averaged 10.01 (*SD = 3.40*) and ranged from 5-19 points with the majority of the sample having a risk factor score of greater than 9 points. Across the items, the most commonly endorsed risk factors included poor dietary habits, high blood pressure, elevated BMI, and high blood sugar.

Paroxysmal AF was the most commonly endorsed AF type with prevalence in over half of the sample. The most commonly reported AF-related symptoms included fatigue, followed by shortness of breath (SOB), palpitations, and less frequently, chest pain. Remarkably, the large majority of patients in the study sample indicated no present tobacco or alcohol use and endorsed cholesterol levels to be within no to low-risk ranges. Moreover, most participants indicated at least some physical activity engagement throughout the week. Descriptive statistics for items on this measure are provided in Table 3 below.

Table 3

ECU Behavioral and Lifestyle Risk Assessment System: Patient Reported Risk Factors

Behavioral and Risk Factor Variables	#	%
Risk Factors		
Blood Pressure		
<120/80	18	35.3
120-139/80-89 or treated to goal	17	33.3
≥140/90	16	31.4
Physical Activity		
≥150 or 75min/wk moderate/vigorous	22	43.1
1-149 or 1-74min/wk	18	35.3
No physical activity	11	21.6
Blood Sugar		
<100 mg/dl	15	29.4

100-125 mg/dl or treated to goal	18	35.3
≥126 mg/dl	18	35.3
Smoking		
Never or quit >12mo. ago	43	84.3
Former or quit < 12mo. ago	0	0.0
Current	8	15.7
Cholesterol		
<200 mg/dL	44	86.3
200-239 mg/dL or treated to goal	5	9.8
≥240 mg/dL	2	3.9
Diet		
4-5 dietary components met	8	15.7
2-3 dietary components met	21	41.2
0-1 dietary components met	22	43.1
BMI		
<25	12	23.5
25-29.9	11	21.6
≥30	28	54.9
Alcohol Use		
No alcohol consumption	37	72.5
2-7 drinks/wk	12	23.5
8-21 drinks/wk	2	3.9
Sleep Apnea		
No	34	66.7
Dx and CPAP adherent	11	21.6
Dx and non-adherence to CPAP	6	11.8
ED Visits		
None	27	52.9
1-2	19	37.3
3+	5	9.8
Palpitations		
No	29	56.9
Mild to moderate	20	29.2
Frequent and severe	2	3.9
Chest Pain		
No	40	78.4
Mild to moderate	10	19.6
Frequent and severe	1	2.0
Fatigue		
No	12	23.5
Mild to moderate	21	41.2
Tired often	18	35.3
Breathlessness		
No SOB	16	31.4
SOB in moderate/vigorous activity	18	35.3
SOB in light activity	17	33.3

AF Type		
Paroxysmal	30	58.8
Persistent	11	21.6
Permanent	9	17.6

General Cardiac and Exercise Fears

The Cardiac Anxiety Questionnaire (CAQ) and the Fear About Exercise (FAE) Questionnaire were primarily utilized for testing of concurrent validity with the newly developed measure of the present study, the ECU Fear of Recurrence Scale. However, items on these assessments provided additional valuable information about patient general cardiac-specific worry and fears around physical exertion. Total scores on the CAQ ranged from 2-57 and averaged 22.67 (*SD = 12.09*), indicating some elevated presence of cardiac-specific anxiety among the sample population. Although no clear cut-off score has been established, in recent studies, cut-off scores of 24 (Mourad et al., 2016) have been utilized to determine clinically significant cardiac-specific anxiety. Among the present population, 45.1% scored above this cut-off. The most commonly endorsed items on the CAQ included the following: "I pay attention to my heart beat," "I take it easy as much as possible," "I can feel my heart beating in my chest," "I check my pulse," "If I have chest discomfort or my heart is beating fast, I like to be checked out by a doctor," and "If I have chest discomfort or my heart is beating fast, I tell my family or friends."

Total scores on the FAE questionnaire ranged from 5-25 with a mean score of 12.64 (*SD = 5.60*), demonstrating presence of exertion-related fears among the study sample. The most highly endorsed items included, "I believe that something might suddenly happen physically during exercise" and "I stop or slow down exercise due to bodily sensations." Although continuous ratings are utilized in the present analyses, previous studies have valued responses of

>1 for questionnaire items as positive endorsement of the identified fear (Farris et al., 2019). If examined in this way, 60.8% of the study sample demonstrated clinically relevant fears around exertion and exercise activities.

Psychological Screening Results

To determine presence of dispositional depressive and anxiety symptoms, participants also completed the PHQ-2 and the GAD-2. Both assessments provide a clear cut-off score of 3 for detecting clinically significant depressive and anxiety symptoms. Average scores on the PHQ-2 were determined to be 1.04 (*SD = 1.59*) with 13.7% of the study sample meeting clinical cut-off. Average scores on the GAD-2 yielded similar results with mean score of 1.04 (*SD = 1.57*) and 15.7% of the sample meeting clinical cut-off.

Fear of AF Recurrence

The East Carolina Fear of Recurrence Scale yielded total scores on the measure that ranged from 0-44 with an average overall score of 11.78 (*SD = 11.78*) and median score of 8.00. The most commonly endorsed items on the measure included: “I am afraid that another AF episode will be more serious than previous episodes,” “I try to control the chances of experiencing an AF episode as much as possible,” “I worry that AF recurrence would require an ablation procedure or additional medical procedures,” and “I worry that AF recurrence will take a toll on my family and friends.” Given potential spread of the data based on high *SD* values obtained for the measure, suspicion of a non-normally distributed sample population arose. Kurtosis and skewness values were determined to be within normal limits for the measure with kurtosis found to be .03 and skewness found to be .94. Additional tests of normality were also conducted in later regression analyses, and Q-Q plotting, test for residuals, and tests of homoscedasticity supported assumption of normal distribution.

Importantly, the scores on the single item examining overall fear of AF recurrence indicated by patients averaged 3.58 (*SD = 2.72)* out of a range of 1-10 scale. The embedded feedback item on the scale indicated that the majority of the sample (58%) found the scale items to be highly reflective of the patient fears (e.g., as indicated by response of "quite a bit [4]" or "a great deal [5]" on this item) and overall patient concerns. In accounting for individuals who indicated that the scale was "somewhat" reflective of patient experience, this number increases to 72.5% of study sample. Descriptive statistics for the measure are provided below in Table 4.

Table 4

Fear of Recurrence

Items endorsed with scores ≥2 or a frequency of ≥"sometimes"	#	%
Scale Items		
1. "I worry that exercising will trigger an AF episode."	9	17.6
2. "I experience unwanted thoughts about the possibility of having another AF episode."	16	31.4
3. "I am afraid sexual activity will cause an AF episode."	2	3.9
4. "I try to control the chances of experiencing an AF episode as much as possible."	21	41.2
5. "I miss out on activities I used to enjoy to minimize risk of AF."	15	23.5
6. "I worry that other medical problems will cause another AF episode."	14	27.4
7. "I worry that AF recurrence would require an ablation procedure or additional medical procedures."	20	39.2
8. "It bothers me that having another AF episode will make me feel I don't have control over my life."	18	35.3
9. "I am afraid that another AF episode will be more serious than previous episodes."	22	43.1
10. "I worry that AF recurrence will take a toll on my family and friends."	20	39.2
11. "I am afraid that having another AF episode may cause me to die early/prematurely."	18	35.3
12. "I am afraid that having another AF episode will impact my ability to do things I enjoy."	19	37.3

Analysis of Study Aims

Aim 1. To better establish inter-item reliability and construct validity of the newly developed measure, Cronbach's alpha was calculated, and a subsequent exploratory factor analysis (EFA) was conducted. The FOR scale consisted of 12 items as overall fear and feedback items were excluded from reliability and validity testing. Reliability tests yielded high internal consistency (α = .92), indicating an acceptable degree of interrelationship among the items on the scale.

The small sample size of the study provided some initial concern around eligibility for factor structure evaluation of the measure. However, in order to determine if the data sample was adequate for factor analysis, a Kaiser-Meyer-Olkin (KMO) sampling adequacy test was conducted, and a value of .87 was yielded, indicating sample adequacy for evaluation of factor structure. An EFA was conducted, and test of sphericity demonstrated significance and provided evidence of presence of significant factor loading. Each of the 12 scale items loaded onto a single factor, and this was further confirmed with generation of scree plot and inspection of Eigen values. A confirmatory factor analysis in which items were purposefully loaded onto one factor was then conducted to verify factor structure of the measure. These findings support construct validity of the present measure and denote congruence between scale items and the patient experience of fear of AF recurrence. Factor loading and eigen values are provided in Table 5 below.

Table 5

Exploratory Factor Analysis for East Carolina FOR Scale

Items	Factor 1	% Variance Eigen Values
Scale Items		
1. "I worry that exercising will trigger an AF episode."	.61	55.8
2. "I experience unwanted thoughts about the possibility of having another AF episode."	.77	9.8
3. "I am afraid sexual activity will cause an AF episode."	.48	7.7
4. "I try to control the chances of experiencing an AF episode as much as possible."	.42	6.6
5. "I miss out on activities I used to enjoy to minimize risk of AF."	.48	4.1
6. "I worry that other medical problems will cause another AF episode."	.77	3.6
7. "I worry that AF recurrence would require an ablation procedure or additional medical procedures."	.79	3.3
8. "It bothers me that having another AF episode will make me feel I don't have control over my life."	.86	2.7
9. "I am afraid that another AF episode will be more serious than previous episodes."	.84	2.3
10. "I worry that AF recurrence will take a toll on my family and friends."	.78	1.9
11. "I am afraid that having another AF episode may cause me to die early/prematurely."	.85	1.2
12. "I am afraid that having another AF episode will impact my ability to do things I enjoy."	.85	.9

Aim 2. Pearson correlational analyses were conducted to determined convergent validity of the measure utilizing the CAQ and FAE questionnaires. Assumptions of linearity and normality were confirmed prior to conducting these analyses with generation of scatter plot. Total scores on the FOR scale were found to be highly positively correlated with total scores on the CAQ, $r(49) = .71$, $p = <.001$. The high correlation coefficient across measures supports a

close relationship between the FOR scale and the construct of cardiac anxiety measured by the CAQ.

Similarly, total scores on the FOR scale were also found to be moderate-highly correlated with total scores of the FAE questionnaire, $r(49) = .69$, $p = <.001$. This again supports a close relationship between the construct of FOR and fear around exercise and is in contrast to initial hypotheses made about the relationship between these measures and constructs.

Aim 3. The present study sought to determine the predictive relationship between FOR and patient risk behaviors as measured by the East Carolina Behavioral Risk Factor and Lifestyle Assessment. A simple linear regression was conducted to determine if total scores on the FOR scale were predictive of total scores of behavioral and lifestyle risk factors, $R^2 = .04$, $F(1, 49) = 2.12$, $p = .15$. Contrary to initial hypotheses, no predictive relationship was supported between patient fears of recurrence and behavioral risk factors. Moreover, successive multivariate regression analyses revealed no significant relationship between FOR total scores and individual items on the East Carolina Behavioral Risk Factor and Lifestyle Assessment (e.g., behavioral risk factors, AF symptoms, and AF type).

Subsequent linear regressions were conducted to determine predictiveness of FOR total scores to total scores on FAE questionnaire. Total scores on the FOR scale were found to be predictive of FAE scores, $R^2 = .49$, $F(1, 49) = 46.425$, $p = <.001$, indicating that those who scored higher on the FOR scale (e.g., indicated more frequent or more severe AF-specific fears) also scored higher on the FAE scale and endorsed more frequent and prominent fears around exercise and engagement in exertive activities.

Discussion

The present study sought to develop and test a valid and reliable measure that assesses the construct of FOR specific to an AF patient population. The overall goal of the study was to determine the prevalence of FOR among AF patients and establish behavioral impacts associated with disease-specific outcomes. Based on these aims, it was hypothesized that patients who endorsed greater FOR would exhibit worsened behavioral and lifestyle risk factors. The major findings of the study included a) an acceptable degree of reliability and internal consistency of the newly developed FOR measure, b) an acceptable degree of construct validity of the measure, c) moderate-high relationships of FOR to cardiac-specific anxiety and fears about exercise, and d) confirmation of predictive relationship between AF-specific fears and exercise-specific fears. These findings are discussed in depth below.

Major Study Findings

Testing the ECU Fear of Recurrence Measure

Secondary analyses provided evidence supporting inter-item reliability and construct validity of the ECU Fear of Recurrence Scale. Reliability tests of the measure indicated a high degree of internal consistency across the 12 items (α = .92) on the scale with exclusion of overall fear and patient feedback items. It was determined in early analysis planning that an alpha value of .70 or higher would be utilized as a relative cut-off point for indication of interrelationship of items across the scale, and testing revealed the scale items met this established criterion. These findings support a close relationship and high level of agreement across scale items.

Construct validity of the measure was established by employing EFA testing and examining factor structure of the scale items. Upon conducting an EFA, all 12 scale items loaded onto a single factor, and this was further supported by utilizing confirmatory factor analysis with

one factor loading stipulations. Based on these findings, it can be concluded that all items across the scale attempt to measure the same construct, supporting initial construct validity of the ECU Fear of Recurrence Scale. Taken together, these findings support the reliability and validity of the measure and provided foundation for all remaining analyses. The relationships across items represent key components of FOR including exertion-related fears (e.g., exercise, sexual intimacy, and emotional reactivity), death-related fear, fear of adverse events (e.g., independence/sense of control loss and burden), and fear of medical consequences (e.g., additional procedures and disease progression) and highlight aspects of the AF patient experience without measuring any notably different constructs. With regard to these tests, the measure performed as hoped with the conclusion that this measure accurately captures the experience of specific fears among the AF patient population pending additional testing in larger AF samples.

Convergent and divergent validity tests were also integral to providing supporting evidence for the integrity of the measure. Convergent validity tests attempt to confirm relationship between two seemingly related constructs and provides additional support for validity of the scales attempting to measure those constructs. Conversely, divergent validity tests confirm lack of relationship between two seemingly unrelated constructs. In the present study, the construct of cardiac-specific anxiety as measured by the Cardiac Anxiety Questionnaire (CAQ) was hypothesized to have some relationship to the construct of FOR. This can be attributed to key themes across the CAQ that echo themes measured on the FOR scale including both avoidance behaviors and cardiac-specific fear. As hypothesized, scores on the FOR scale and total scores on the CAQ were highly positively correlated, indicating that individuals who endorsed AF-specific fears on FOR also endorsed cardiac-specific anxiety on the CAQ. The

relationship between these measures may also be influenced by the high level of comorbid conditions present across the sample. Specifically, all of the participants in the study had at least one other cardiac-related comorbid condition, and anxiety and worry around those additional diagnoses is likely reflected on the CAQ responses. While CAQ measures more general cardiac concerns, based on the sample characteristics, this remains a key component of the patient experience for our AF patient sample, too. Altogether, the correlation between these measures supports convergent validity of the ECU Fear of Recurrence Scale and denotes notable cardiac-specific anxiety and worry among the present study sample.

Regarding establishing divergent validity, it was initially hypothesized in the present study that performance on the FOR scale and Fear About Exercise (FAE) questionnaire would not be highly correlated as these scales attempt to measure two distinct constructs with regard to patient fears. However, as results indicated, a moderate-highly correlated relationship was exhibited between participants responses on FOR and FAE scales. This is likely best explained by the overlap of the fear of exertion (e.g., both exercise and sexual intimacy items) component on the FOR scale and overall construct of fear of exertion measured by the FAE questionnaire. Moreover, this finding is likely influenced by presentation of cardiac comorbid conditions across the sample in that fears and patient worries are reflective of the entire patient experience. Fear of exercise, specifically, has been documented across cardiac conditions, after acute cardiac events, and in patients with diabetes and lung disease (Bäck et al., 2013; Bäck et al., 2018; Cigrovski Berkovic et al., 2021; Farris et al., 2019; Sears et al., 2001; Skielboe et al., 2017; Xiang et al., 2022). For this sample, the patient experience is not limited solely to an AF diagnosis, but rather an AF diagnosis in presence of other cardiac comorbidities and other medical concerns. Patient

reported fears on measures not specific to AF are likely reflective of this and cumulative impact of comorbid concerns often experience by our patient population.

Impact of AF Fear of Recurrence

The present study has demonstrated promising results around integrity of the ECU Fear of Recurrence Scale and ability to measure specific fears among an AF patient sample. Because of this, determining predictive ability of FOR on behavioral and lifestyle factors was deemed appropriate. It was initially hypothesized that AF-specific fears would predict engagement in behavioral and lifestyle risk factors and symptom reporting (as measured by the East Carolina Behavioral Risk Factor and Lifestyle Assessment). Specifically, greater endorsement of AF-specific fears was expected to be related to higher scores on risk assessment and greater overall behavioral risk factors. However, FOR was not found to be predictive of overall behavioral risk scores or of components of the behaviors and symptoms comprising the assessment individually (e.g., AF symptom endorsement, diet, obesity, physical activity engagement, smoking and alcohol use, and biometric measures of cardiac risk). These findings are surprising in that FOR in cancer populations has often been associated with increases in alcohol use, maladaptive coping strategies, and greater endorsement of physical symptoms (Hall et al., 2019). Despite this, behavioral concerns across the study sample were not insignificant as *all participants* in the sample endorsed at least one behavioral risk factor across the measure with most of the sample having a risk factor score of 9 or greater (e.g., indicative of endorsement of several items across the measure and presence of behavioral risk concerns).

There are several potential explanations for this finding. First, the most commonly endorsed behavioral concerns included poor dietary habits, elevated BMI, and high blood pressure and blood sugar. As such, endorsement of these items more frequently were likely

driving overall total scores on the behavioral and lifestyle assessment. While a small relationship between these aforementioned factors and AF-related fears may exist, based on what is known of impact of FOR in cancer populations on maladaptive coping strategies, it is expected that specific patient fears would be more closely associated with poorer coping strategies and nonadherence (e.g., lack of PA engagement, alcohol and tobacco use, and exaggerated symptom reporting). While this may help to understand the lack of predictive relationship between FOR and total behavioral risk scores, it fails to explain lack of relationship between FOR and individual items on the scale. Reliance on patient self-report and patient's ability to retrospectively recall behavioral and lifestyle factors may have instead impacted these relationships.

The potential predictive relationship of FOR and patient willingness to engage in exercise was further examined by testing relationship of total FOR scores and FAE scores. In contrast to prior findings, it was determined that individuals who endorsed greater FOR and AF-specific fears also endorsed more prominent fears around exercise and engagement in activities resulting in or requiring some level of exertion. This is likely explained by the component of fear of exertion included in the FOR measure and identified correlational relationship between the scores on FOR and FAE measures. AF-specific fears, as outlined in the FOR scale, are tied to potential for adverse events and disease progression that often represent looming concerns for patients that can feel outside of their immediate control. In the presence of these high-stakes situations and related fears, patients' natural inclination often involves attempting to regain sense of control over their life – however this can manifest as maladaptive forms of coping. Patients may engage in self-protective behaviors in order to guard themselves against feelings of medical vulnerability and loss of control – increasing *perceptions* of increased risk avoidance. One way

in which patients may feel some re-established sense of control can be to avoid the activities that they fear may exacerbate disease including avoidance of exercise and exertive activities. One of the most commonly endorsed items on the FOR measure included attempts to control chances of experiencing an AF episode, likely relating to patients fears around exercise endorsed on FAE scale. These findings do mirror that of cancer survivors in that cancer FOR has often been associated with lower PA engagement and overall reductions in activity (Hall et al., 2019).

Study Findings and Relationship to Common Sense Model

To better understand these findings and longer-term impacts for the present sample, it is important to reference the theoretical framework often utilized in chronic disease populations to evaluate the relationship between patient beliefs and illness appraisals to coping strategies and patient outcomes – Leventhal's Common Sense Model of Illness (Leventhal et al., 1997). Key components of Leventhal's model are reflected in some of the highest endorsed items on the FOR scale, most specifically, items that reflect patient beliefs about controllability, consequences, and timeline/disease progression of AF. More than 30% of the sample endorsed items related to experiencing negative cognitions around AF recurrence, attempts to control AF recurrence and feelings of diminished controllability should another AF episode occur, and worry around medical consequences, disease progression, premature death, and family and QOL impact. Across disease groups, in cancer survivors, and in AF groups, less perceived controllability and negative perceptions of consequences and timeline have been associated with less adaptive coping strategies in response to illness, worsened illness outcomes, and greater psychological burden (Breland et al., 2020; Richardson et al., 2016; Taylor et al., 2022).

Although the relationship of FOR in AF to behavioral risk factors (outside of PA avoidance) was unable to be established in the present work, it is plausible, based on AF-specific

fears endorsed by the study sample, that some additional behavioral risk factors and maladaptive coping strategies may be more easily identified in larger AF samples. In cancer survivor populations, for instance, recurrence worry has been associated with behavioral correlates. For some patients, recurrence fears can motivate activation of beneficial health behavior change, or by contrast, recurrence fears can magnify pre-existing beliefs about negative consequences and controllability, leading to behavioral deactivation and avoidance (Durazo & Cameron, 2019). Interestingly, in the cancer literature, patients who view recurrence as conditional upon engagement in unhealthy behaviors (e.g., view behavioral and lifestyle risks as key component of treatment and continued remission), are more motivated to engage in proactive and health-protective behaviors. This highlights the importance of continuing to emphasize behavioral pillar of AF management as integral to AF treatment and warrants continued investigation of the relationship to AF-specific fears.

Study Strengths and Weaknesses

We conceptualized and tested a novel measure of AF-specific fears and FOR among an AF patient sample. Although the concept of general cardiac FOR is being presently tested in non-specific cardiac populations (Birk et al., 2020), cardiac conditions and patient experiences are specific and treatment is highly specialized (Sears et al., 2022), differentiating the patient experience. The present work represents the first study to examine FOR in a differentiated cardiac sample, and more specifically, in a clinical population of AF patients. The tool itself was designed with consideration for models of fear of recurrence in the cancer literature and previous cardiac-specific tools validated for measuring specific patient fears, like the Florida Shock Anxiety Scale (FSAS; Ford et al., 2012).

Components included on the developed measure also represent significant strengths of the overall measure and opportunities for providers to capitalize on quicker assessment of patient fears. Specifically, the patient feedback item embeds opportunity for patients to better relate their experience of AF to identified patient fears (outside of what may be captured by the scale itself). Throughout the study, this provided an opportunity for patient concerns to be expressed and could represent an avenue for patients to continue to identify AF fears in a clinical setting. Moreover, this measure can be a helpful tool for patients to better understand both their condition and impact of an AF diagnosis on their QOL and re-adjustment to life. This is a notable benefit for AF patients as patient health literacy and overall understanding of their condition has represented a significant barrier for patients. This is especially true among those in rural areas and in rural-serving clinic where health literacy and access to facilities/resources to improve coping and response to AF diagnosis and management remain a challenge (Magnani et al., 2021).

Based on patient feedback, the ECU Fear of Recurrence Scale not only adequately reflected the patient experience but allowed for quick and relatively simple assessment of patient fears. On average, patient visits with researchers for the present study were approximately 15-20 minutes including time needed to complete the entire battery of questionnaires. This means that, for the majority of the patient sample, the newly developed scale could be completed in less than 5 minutes and during normal wait times in clinic – supporting feasibility and clinical utility of this measure in AF clinics. With minimal burden on both the patient and the provider, this tool provides an opportunity for assessment of AF-specific fears that can be addressed during regular clinic visits.

Finally, although some aspects of the present study sample lacked diversity, the patient population was comprised of an extensive age range of participants and an almost equal number of male and female patients. The present sample also exhibited some interesting characteristics including high health care utilization (e.g., both hospital admissions and use of emergent services), significant presence of comorbid conditions, and poor projected longevity of the study sample. Although bleak, these aspects of the study sample are consistent with research on rurality and poor health status and are comparable to other rural health care settings in the United States (Cross et al., 2020; Harrington et al., 2020). As such, study findings are likely generalizable to other clinics and AF patient populations – especially across sexes and age and among clinics in rural-serving areas. This is integral for future work in this area as present findings represent a foundation and opportunity for development of interventional studies that address AF-specific fears. Similar to the measure, interventions in the future should also *encompass and account for the entire AF patient experience.*

Study Limitations

Although the present study demonstrates some notable strengths, there are some study limitations that should be considered when interpreting study findings. Firstly, the study sample size was small and represents a significant challenge to interpretation of results. Although small sample size may not dramatically change study findings, the inclusion of more participants especially with regard to testing a newly developed measure would have strengthened efficacy of study findings and enhanced understanding of validity of the measure.

While the sample exhibited diversity in sex/gender identity and participant age, racial/ethnic diversity among the sample was lacking. Specifically, an overwhelming majority of the sample identified their race/ethnicity to be non-Hispanic White with very few participants

identifying as Black, Hispanic/Latino, or Asian and none identifying as American Indian, Alaskan Native, Native Hawaiian or other Pacific Islander. This is important to consider as study results may not reflect AF-specific fears salient to individuals belonging to other marginalized groups. Important components of the AF patient experience may be missing due to lack of racial/ethnic diversity of study sample especially given increased adverse events, symptom burden, AF incidence, and poorer outcomes often reported among Black and Brown patients with AF. (Nanda & Kabra, 2019). Moreover, the majority of individuals involved in measure development identified as non-Hispanic white women (41%), non-Hispanic white men (25%), and Central and South Asian women (16%) and men (16%). As such, the majority of collaborators creating and approving the measure items have similar racial/ethnic background to sample majority. Concerns and fears addressed by measure items may be influenced by racial and cultural background of those involved in measure creation and may not be representative of fears for Black and Brown patients. Larger studies with greater racial/ethnic diversity are needed to better determine applicability of measured fears to broader patient populations.

Some demographic components were unable to be adequately obtained in the medical record review. Specifically, both educational attainment and occupational status were unable to be obtained for significant portions of the study sample as these variables were often inconsistently noted in patient medical records or undocumented in the chart entirely. Both could have provided some insight into health literacy and socioeconomic status of the overall study sample, informing better understanding of sample characteristics and overall generalizability to other AF patients.

Finally, because the present study contained retrospective components in which patients were asked to recall specific behaviors and psychological concerns, data pertaining to

retrospective surveys could be subject to recall bias. Relationships observed in the present study could also have been influenced by other confounding variables not accounted for. Factors such as participant mood on the day the battery was given and influence of social desirability could have influenced the way participants responded, ultimately impacting study findings.

Implications and Future Directions

Despite limited findings around implications of FOR and impacts on overall behavioral and lifestyle concerns, prevalence of FOR among this sample was notable (Total mean score of 11.78 and mean of single item overall fear score of 3.58 on scale 1-10). Variability in patient responding is reflective of the unique AF experience and range of presentations and overall life burden. While continued work in this area could better establish prevalence of FOR among AF patient populations, it is evident that AF-specific fears exist among AF patients, and this notion is supported by patient feedback on the measure. Additional work in this area is also needed to better understand behavioral and psychological correlates. The promising scale metrics, clinical utility, and feasibility of the scale provide an opportunity for continued use in research among AF patient populations and for future use in clinical practice.

Future directions should include an expanded study addressing sample size concerns, and collaboration with additional AF clinic sites may be key to improving both sample size and diversity of the sample. Additional scale metric testing is needed once sample size goals can be met to better establish validity of the measure and predictive relationships to patient behaviors and behavioral correlates. These findings should prompt develop of interventional studies that specifically target FOR among AF patient populations, and the present study helps to lay the foundational work needed to begin to address these concerns.

Study findings highlight important implications for clinical practice, specifically with respect to identification of AF patients most impacted by AF patient fears and those at-risk for difficulty with adjustment to the diagnosis. Identification of these patients early-on following initial diagnosis may help to increase likelihood that patient fears are addressed by providers, address associated maladaptive coping and behavioral concerns, improve patient QOL, and limit disease progression and overall lifestyle burden.

Conclusions

Atrial fibrillation (AF) remains the most commonly identified arrhythmic condition in the United States and worldwide, and the prevalence continues to grow at an exponential rate (Colilla et al., 2013). As this national and global health concern continues to widen, so much our understanding of the AF patient experience. This experience is unique, and presentation remains highly variable, but patients often share many things in common – including the experience of psychological distress and lifestyle concerns following a newfound diagnosis and throughout attempting to navigate and manage disease (Gehi et al 2012; Lioni et al., 2014; McCabe et al., 2011; Patel et al., 2013; Polikandrioti et al., 2018). As such, maintaining a sense of overall QOL presents a challenge for AF patients, and avenues to both maintain and re-establish sense of purposeful living can feel blocked by AF-specific fears. In addition, patient fears can manifest as and contribute to behavioral and lifestyle concerns, negative symptom appraisal, increased health care consumption, and worsening disease progression (von Eisenhart Rothe et al., 2014; McCabe et al., 2011; Thompson et al., 2014). Despite clear high stakes for patients, identification of patient fears and their connection to a patient's ability to return to life remains a challenge and has yet to be studied prior to the current work. The present study attempted to close this gap by increasing our present understanding around specific AF fears and components of FOR not yet

examined in an AF patient population. FOR and specific fears identified and strengthened by the study results help to better understand the impact on patient outcomes and represent clinical relevance as patient ability to adapt to disease is impacted. Future work in this area should include upscaling study size to better establish validity of the measure and FOR impact and developing targeted interventions to address patient fears with longer-term goals of clinical implementation in AF clinics.

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Appendix A: Surveys for this Study

East Carolina Fear of AF Recurrence Scale (ECFoR-AF)

The following scale measures fear of recurrence in AF populations. Responses reflect the frequency with which these fears are experienced ranging from "Not at all (0)," "Rarely(1)," "Sometimes(2)," "Often(3)," or "Always(4)." Questions about overall subjective fear of AF recurrence and survey feedback are also included.

		Not at all	Rarely	Sometimes	Often	Always
1.	I worry that exercising will trigger an AF episode.	0	1	2	3	4
2.	I experience unwanted thoughts about the possibility of having another AF episode.	0	1	2	3	4
3.	I am afraid sexual activity will cause an AF episode.	0	1	2	3	4
4.	I try to control the chances of experiencing an AF episode as much as possible.	0	1	2	3	4
5.	I miss out on activities I used to enjoy to minimize risk of AF episode.	0	1	2	3	4
6.	I worry that other medical problems will cause another AF episode.	0	1	2	3	4
7.	I worry that AF recurrence would require an ablation procedure or additional medical procedures.	0	1	2	3	4
8.	It bothers me that having another AF episode will make me feel I don't have control over my life.	0	1	2	3	4
9.	I am afraid that another AF episode will be more serious than previous episodes.	0	1	2	3	4
10.	I worry that AF recurrence will take a toll on my family and friends.	0	1	2	3	4
11.	I am afraid that having another AF episode may cause me to die early/prematurely.	0	1	2	3	4

12.	I am afraid that having another AF episode will impact my ability to do things I enjoy.	0	1	2	3	4
Overall Fear						
	On a scale of 1-10, how fearful are you of AF recurrence? 1=Not fearful at all 10=Extremely fearful	Indicate:				
Feedback		Not at all	A little	Somewhat	Quite a bit	A great deal
	How well do you feel the above questions reflected your concerns about experiencing another AF episode? Not at all, A little, Somewhat, Quite a bit, Great deal.	0	1	2	3	4

Cardiac anxiety Questionnaire

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

		Never	Rarely	Sometimes	Often	Always
1.	I pay attention to my heart beat	0	1	2	3	4
2.	I avoid physical exertion	0	1	2	3	4
3.	My racing heart wakes me up at night	0	1	2	3	4
4.	Chest pain/discomfort wakes me up at night	0	1	2	3	4
5.	I take it easy as much as possible	0	1	2	3	4
6.	I check my pulse	0	1	2	3	4
7.	I avoid exercise or other physical work	0	1	2	3	4
8.	I can feel my heart in my chest	0	1	2	3	4
9.	I avoid activities that make my heart beat faster	0	1	2	3	4
10.	If tests come out normal, I still worry about my heart	0	1	2	3	4
11.	I feel safe being around a hospital, physician or other medical facility	0	1	2	3	4
12.	I avoid activities that make me sweat	0	1	2	3	4
13.	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:

14.	I worry that I may have a heart attack	0	1	2	3	4
15.	I have difficulty concentrating on anything else	0	1	2	3	4
16.	I get frightened	0	1	2	3	4
17.	I like to be checked out by a doctor	0	1	2	3	4
18.	I tell my family or friends	0	1	2	3	4

ECU ATRIAL FIBRILLATION BEHAVIORAL RISK FACTOR ASSESSMENT SYSTEM

PLEASE CHECK THE BOX THAT MOST ACCURATELY DESCRIBES YOURSELF FOR EACH FACTOR BELOW			
BLOOD PRESSURE	SBP<120 and DBP<80 ☐	SBP 120-139 and DBP 80-89 or treated to goal ☐	SBP ≥ 140 and DBP ≥ 90 ☐
PHYSICAL ACTIVITY	≥150 min/wk of moderate* activity or ≥75 min/wk of vigorous** activity or ≥150 min/wk of moderate and vigorous activity ☐	1–149 min/wk of moderate* activity or 1–74 min/wk of vigorous** activity or 1–149 min/wk of moderate and vigorous activity ☐	No physical activity ☐
BLOOD SUGAR	< 100 mg/dl ☐	100 to 125 mg/dl or treated to goal ☐	≥126 mg/dl ☐
SMOKING	Never or quit > 12 months ago ☐	Former smoker and <12 months since quitting ☐	Current smoker ☐
CHOLESTEROL	< 200 mg/dL ☐	200-239 mg/dL or treated to goal ☐	≥ 240 mg/dL ☐
DIET Please select all statements applicable to your diet by placing a checkmark in the corresponding box:	≥ 4.5 cups/day of fruits and vegetables ☐ ≥ two 3.5-oz servings/week of fish ☐ ≥ three 1-oz-equivalent servings/day of fiber-rich whole grains ☐ <1500 mg/day of sodium ☐ ≤450 kcal (36 oz)/week of sugar-sweetened beverages ☐		**TOTAL: _____**
BMI, kg/m2	<25 ☐	25-29.9 ☐	≥ 30 ☐

ALCOHOL	No alcohol consumption ☐	Consumes 2-7 drinks per week ☐	Consumes 8-21 drinks per week ☐
SLEEP APNEA	YES ☐ NO ☐	Do you own a CPAP? YES ☐ NO ☐	Do you use your CPAP daily? YES ☐ NO ☐
ED VISITS IN THE PAST YEAR	None ☐	1-2 ☐	3+ ☐
PALPITATIONS	YES ☐ NO ☐	Mild to moderate palpitations ☐	Frequent and severe palpitations ☐
CHEST PAIN	YES ☐ NO ☐	Mild to moderate chest pain ☐	Frequent and severe chest pain ☐
FATIGUE	No fatigue ☐	Mild to moderate fatigue ☐	Tired often ☐
BREATHLESSNESS	No shortness of breath (SOB) ☐	SOB in moderate/ vigorous activity ☐	SOB in light activity ☐
TYPE OF AF	No AF ☐	Paroxysmal AF (off & on) ☐	Persistent AF (most of the time) ☐ Permanent Persistent AF (always) ☐

* Moderate exercise is defined as a medium amount of effort when you breathe harder than normal, but you are still able to talk (e.g., walking, dancing, gardening)
**Vigorous exercise is defined as a high amount of effort when you are unable to talk without getting short of breath (e.g., running, swimming laps, jumping rope)

Fear About Exercise Questionnaire

I believe that something might suddenly happen physically during exercise.	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
I worry about not being able to breathe properly during exercise.	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
I fear that a cardiac event will occur during exercise.	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
I stop or slow down exercise due to bodily sensations.	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
I avoid exercise when I am alone because it is not safe.	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree

GAD-2

1. Over the last 2 weeks, how often have you been bothered by feeling nervous, anxious or on edge?	Not at all	Several days	More than half the days	Nearly every day
2. Over the last 2 weeks, how often have you been bothered by not being able to stop or control worrying?	Not at all	Several days	More than half the days	Nearly every day

PHQ-2

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

1. Little interest or pleasure in doing things	Not at all	Several days	More than half the days	Nearly every day
2. Feeling down, depressed, or hopeless	Not at all	Several days	More than half the days	Nearly every day

Resources are provided below for patients to seek help if feeling down, depressed, or hopeless.

Appendix B: IRB Approval Letter

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** **rede.ecu.edu/umcirb/**

Notification of Initial Approval: Expedited

From:	Biomedical IRB
To:	Rebecca Harrell
CC:	Samuel Sears
Date:	1/31/2022
Re:	UMCIRB 21-001968 Fear of Recurrence in Atrial Fibrillation Patients

I am pleased to inform you that your Expedited Application was approved. Approval of the study and any consent form(s)occurred on 1/31/2022. The research study is eligible for review under expedited category # 5 and 7. The Chairperson (or designee) deemed this study no more than minimal risk.

As the Principal Investigator you are explicitly responsible for the conduct of all aspects of this study and must adhere to all reporting requirements for the study. Your responsibilities include but are not limited to:

1. Ensuring changes to the approved research (including the UMCIRB approved consent document) are initiated only after UMCIRB review and approval except when necessary to eliminate an apparent immediate hazard to the participant. All changes (e.g. a change in procedure, number of participants, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the UMCIRB before they are implemented;

2. Where informed consent has not been waived by the UMCIRB, ensuring that only valid versions of the UMCIRB approved, date-stamped informed consent document(s) are used for obtaining informed consent (consent documents with the IRB approval date stamp are found under the Documents tab in the ePIRATE study workspace);

3. Promptly reporting to the UMCIRB all unanticipated problems involving risks to participants and others;

4. Submission of a final report application to the UMICRB prior to the expected end date provided in the IRB application in order to document human research activity has ended and to provide a timepoint in which to base document retention; and

5. Submission of an amendment to extend the expected end date if the study is not expected to be completed by that date. The amendment should be submitted 30 days prior to the UMCIRB approved expected end date or as soon as the Investigator is aware that the study will not be completed by that date.

The approval includes the following items:

Name	Description
af6.docx	Surveys and Questionnaires
AFSS.doc	Surveys and Questionnaires
Cardiac Anxiety Questionnaire.docx	Surveys and Questionnaires
East Carolina Fear of AF Recurrence Protocol.docx	Study Protocol or Grant Application
East Carolina Fear of AF Recurrence Scale.docx	Surveys and Questionnaires
ECU AF RISK FACTOR ASSESSMENT.docx	Surveys and Questionnaires
Fear About Exercise Questionnaire.docx	Surveys and Questionnaires
GAD-2.docx	Surveys and Questionnaires
HIPAA alteration or waiver form FoR.pdf	HIPAA Documentation
HIPAA Prep form ECU.pdf	HIPAA Documentation
Merged Informed Consent and HIPAA-FOR.doc	Consent Forms
PHQ-2.docx	Surveys and Questionnaires

For research studies where a waiver or alteration of HIPAA Authorization has been approved, the IRB states that each of the waiver criteria in 45 CFR 164.512(i)(1)(i)(A) and (2)(i) through (v) have been met. Additionally, the elements of PHI to be collected as described in items 1 and 2 of the Application for Waiver of Authorization have been determined to be the minimal necessary for the specified research.

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