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Abstract

Atrial fibrillation (AFib) is a common cardiac arrhythmia associated with increased risk for comorbid health conditions. Advancements in consumer technology have enabled patients to monitor hearth rhythm independently, yet, much remains unknown about patient outcomes related to the use of these smart device platforms (SDP). The aim of this study was to examine the iatrogenic and/or remedial effects of SDP use on patient reported outcomes of illness uncertainty, cardiac anxiety, body vigilance, AFib symptoms, symptom burden, and healthcare utilization. The sample included 130 AFib participants (65 in SDP group) recruited through ResearchMatch, American Heart Association support forum, and other online AFib communities. Despite being of younger age, participants in the SDP group reported more medical risk factors associated with AFib. Results partially supported the iatrogenic effect, as participants with SDP reported greater cardiac anxiety and healthcare utilization relative to those without, even after accounting for covariates of age and medical risk factors. These findings should be interpreted with caution, as the global pandemic may have impacted the results obtained.

Keywords: atrial fibrillation, smart device platforms, remote patient monitoring, ECG, illness uncertainty, anxiety, healthcare utilization, Apple Watch, Kardia

Contents

The Impact of Consumer Directed Remote Patient Monitoring Devices on Illness Uncertainty and Anxiety in Patients with Atrial Fibrillation

Atrial fibrillation (AFib) is a heart condition characterized by disorganized electrical signals that cause the cardiac atria and ventricles to desynchronize, resulting in irregular heart rate. AFib is classified by duration and severity in five categories. *First diagnosed* reflects the initial detection of AFib. *Paroxysmal* is the most common type of AFib (January et al., 2014), marked by the sudden onset of arrhythmic episodes with spontaneous recovery to sinus rhythm within seven days. Arrhythmias in *persistent* AFib are sustained for seven days or more, whereas *long-standing* AFib reflects the perpetuation of arrhythmic episodes for one year. *Permanent* AFib is assigned when no further attempts to restore normal sinus rhythm will be made, though symptom management may be warranted (Kirchhof et al., 2016).

At an estimated prevalence of 2.5% – 3.2% of the population (Chugh et al., 2014), AFib is considered as the most common type of cardiac arrhythmia, affecting as many as 2.7 million Americans (Centers for Disease Control and Prevention, 2017) and 33.5 million individuals worldwide (Chugh et al., 2014). Approximately 1% of the population is reported to have undiagnosed AFib (Jonas et al., 2018). Increasing age is a strong predictor of AFib, with prevalence rates rising from <0.2% in adults younger than 55 to 8 – 9% in adults 65 and older, and 17.8% among those 85 and older (Go et al., 2001; Heeringa et al., 2006). Owing to the growing aging population, the number of AFib patients is expected to rise to 12 million Americans by 2050 (Lloyd-Jones et al., 2010).

The impact of AFib on physical health is significant, posing a great strain on personal functioning and the healthcare system as a whole. AFib is a major cause of

cardiomyopathy, heart failure, stroke, sudden death, and unexpected hospitalizations (Miyasaka et al., 2007; Wolf et al., 1991). Moreover, the mortality rate of co-occurring medical disorders is elevated by 200% (Kang et al., 2004). Increased risk of stroke has been observed across permanent, persistent, and paroxysmal classifications of AFib (Link et al., 2017). In fact, AFib confers a 5-fold risk of stroke (Stewart et al., 2002), accounting for approximately 14 – 24% of ischemic stroke cases (Jonas et al., 2018). Ischemic strokes secondary to AFib produce greater fatalities and disabilities relative to those resulting from arterial disease (Lin et al., 1996). A CHA_2-DS_2-VASc score $\geq$2, calculated based on history of congestive heart failure, hypertension, age, diabetes, stroke, vascular disease, and sex, is typically used to estimate the probability for stroke (Lip et al., 2010) and eligibility for anticoagulant therapy (Fitzmaurice et al., 2014). Age is also strongly associated with thromboembolic events, with 1.5% increase of risk per decade (Culebras et al., 2014). The cumulative health complications combined with rising prevalence rates of AFib constitute a sizable financial burden on the healthcare system. An annual estimate of seven billion dollars is directed towards AFib in the US alone (Coyne et al., 2006). Hospital admissions for AFib total more than 1 million each year (Tanigawa et al., 1991), reflecting a 66% increase in the past two decades (Friberg et al., 2003).

AFib detection and treatment is complicated by the large proportion of patients that do not present with symptoms. Approximately 40% of patients are asymptomatic or have silent AFib (Granger et al., 2011). Patients who do experience symptoms often report dizziness, palpitations, dyspnea, and chest discomfort in varying degrees of frequency and severity (Kannel et al., 1998). Recurrence of both symptomatic and

asymptomatic AFib is common within the same patient (Hindricks et al., 2005; Kirchhof et al., 2009). Despite the dearth of symptoms experienced, silent AFib is as precarious, if not more so, than symptomatic AFib. In a longitudinal community cohort study, 25% of newly diagnosed residents were asymptomatic and were three times more likely to experience an ischemic stroke prior to diagnosis (Miyasaka et al., 2007). Siontis and colleagues (2016) found that asymptomatic AFib was associated with elevated risk for cardiovascular and all-cause mortality relative to patients with typical AFib symptoms, even after controlling for age and CHA_2-DS_2-VASc score.

Subclinical AFib is marked by the presence of atrial high rate episodes (AHRE) that occur without corresponding symptoms. Patients with AHRE present with higher rates of stroke when compared to the general population but lower rates compared to patients with clinical AFib matched with similar CHA_2-DS_2-VASc scores (Healey et al., 2012). The duration of AHRE associated with thromboembolic risk remains unclear. Asymptomatic AHRE >5 minutes have been associated with a higher incidence of silent ischemic brain lesions (Benezet-Mazuecos et al., 2014a), stroke, and systemic embolism (Glotzer et al., 2003; Glotzer et al., 2009; Healey et al., 2012). The TRENDS (A prospective Study of the Clinical Significance of Atrial Arrhythmias Detected by Implanted Device Diagnostics) study reported that AHRE totaling or exceeding 5.5 hours a day doubled the risk for a thromboembolic event (Glotzer et al., 2009). ASSERT (Asymptomatic Atrial Fibrillation and Stroke Evaluation in Pacemaker Patients and the Atrial Fibrillation Reduction Atrial Pacing Trial) demonstrated a 2.5-fold increased stroke risk among hypertensive patients with AHRE lasting longer than 6 minutes (Healey et al., 2012), though a recent reanalysis of ASSERT showed that

thromboembolic risks were only evident for episodes >24 hours. Additional research is needed to quantify the duration of AHRE required to derive benefit from initiating anticoagulation treatment in this subclinical population.

Uncertainty in AFib

The experience of patients in this disease population is laden with uncertainties. Symptoms of AFib, such as fatigue, are often non-specific and occur intermittently, posing a barrier to accurate and timely detection. As many AFib patients are older adults, it is often difficult to determine whether symptoms are indicative of AFib or a normal aging process (McCabe, Rhudy, Chamerlain, & DeVon, 2016). The risk status for co-occurring health conditions and all-cause mortality further complicates prognosis and patients' decisions regarding treatment options. Patients may face uncertainty in selecting the optimal symptom management plan, as medications often have adverse side effect profiles and are not recommended for long-term use (Fuster & Mearns, 2010). Uncertainties, faced by both patients and caregivers, may also stem from deficient knowledge or misunderstanding of the cause, meaning, and occurrence of AFib episodes, as well as appropriate coping responses (Dalteg et al., 2014; Taylor et al., 2018).

Problematically, subjective reports of arrhythmias are often discrepant with objective measures. The positive predictive value of AFib symptoms is estimated to range between <10% and 52% (Atarashi et al., 2008; Barsky et al., 1994; Mehall et al., 2007). Patients with a history of AFib may report arrhythmias during normal sinus rhythm. False positive AFib episodes, or reported arrhythmias that occur during normal sinus rhythm, account for 31 - 34 % of patient reports when compared to objective measures obtained from electrocardiographic monitoring systems (ECG; Bhandari et al.,

1992; Mehall et al., 2007). Furthermore, successful restoration of normal sinus rhythm following treatment does not necessarily reduce subjective reports of AFib symptoms (Fuster & Mearns, 2010). In a study following AFib patients who received ablation treatment, one-third of participants reported symptoms that did not correspond to ECG recordings (Björkenheim et al., 2016). Asymptomatic arrhythmias are also common among patients who are nonresponsive to treatment. Among patients with a history of paroxysmal AFib, asymptomatic episodes occurred 12.1 times more frequently than symptomatic AFib, a ratio significantly higher than patients with supraventricular tachycardia (Page, Wilkinson, Clair, McCarthy, Pritchett, 1994). In recent years, advancing technologies have provided an avenue to resolve the uncertainties surrounding the occurrence of arrhythmias.

Remote Patient Monitoring

AFib has typically been classified by the presence of cardiac arrhythmias (e.g., irregular R-R intervals coupled with the absence of identifiable P waves; January et al., 2014) screened by 12-lead ECG in hospital or clinic settings, or continuous home ECG devices, such as the 24-hour Holter monitor. These instruments, however, provide relatively brief recordings that may not detect intermittent, asymptomatic, or subclinical AFib. The development of long-term ECG monitors has enabled patients to document AFib episodes that would typically have gone undetected.

Two of the most common continuous ECG systems are the implantable cardioverter-defibrillator (ICD) and the implantable loop recorder (ILR). The ICD is an implantable unit programmed to detect ventricular arrhythmias and deliver electrical impulses to the heart to facilitate sinus rhythm (Magyar-Russell et al., 2011). Wireless

features allow for data transmission to providers, which enable continuous monitoring of patient vitals and ICD re-programing. The ILR is a single lead ECG monitoring device that is also implanted subcutaneously. It detects AFib using algorithms that measure R-wave variability (Bumgarner et al., 2018). The clinical utility of these implantable devices has been demonstrated in studies citing increased AFib-detection in stroke patients relative to conventional strategies (Sanna, 2018) and prevention of fatalities resulting from myocardial infarction (DiMarco, 2003). Despite the apparent benefits, accessibility to these technologies is limited. The devices are only made available to patients with known heart conditions. Moreover, the systems do not provide feedback to patients, which may cause a degree of uncertainty and anxiety regarding equipment reliability and patients' health status (Skov et al., 2015).

Consumer Smart Device Platforms (SDP)

The latest innovations of heart monitoring systems are non-invasive and provide continuous long-term ECG with interpretable results available to consumers on smart device platforms (SDP). These consumer-directed devices record cardiac physiological data supracutaneously in real time, typically using single-lead ECG technology, and alert patients to arrhythmias corresponding to AFib. Data are stored in a web portal or mobile application for patient self-monitoring and are transmissible to health care providers to aid in guiding decisions regarding diagnosis and treatment. Public espousal of mobile health care technologies has proliferated in the past decade. Sales of wrist worn smart devices have grown exponentially, yielding a 20% growth between 2019 and 2020 (Strategy Analytics, 2020). Apple Inc. maintains the lead in the smartwatch market share, with sales of 7.6 million units worldwide in the first quarter of 2020.

Kardiaband was the first U.S. Food and Drug Administration (FDA) approved 1-lead ECG Apple Watch accessory introduced in November 2017 (Husten, 2017). It was made available to consumers for a price of $200. The Kardiaband replaces the Apple Watch band and is compatible with series 1 – 3 Apple Watches. The SmartRhythm system alerts patients to record an ECG when their heart rhythm deviates from the predicted pattern (AliveCor, n.d.). Consumers can record their heart rhythm by placing their thumb on the band's sensor for 30 seconds. During ECG acquisition, the audio recording feature on the Kardia app allows consumers to report co-occurring symptoms. The Kardiaband algorithm interprets the ECG data, rendering five possible results: Normal, Possible atrial fibrillation, Unclassified, Too short, and Unreadable. Data can be transmitted to a cardiac technician for further assessment, with a one-hour response time, for $9, or a board-certified cardiologist for a comprehensive clinical analysis, including interpretation and recommendations, for $19, with results obtained within 24 hours. The Kardiaband ECG algorithm was tested against physician-interpreted Kardiaband recordings as well as 12-lead ECG recordings to measure its precision in detecting AFib (Bumgarner et al., 2018). Of the interpretable results (66%), the Kardiaband algorithm was determined to have 93% sensitivity and 84% specificity in distinguishing arrhythmia from sinus rhythm in AFib patients. Sensitivity increased to 99% at a negligible cost to specificity (83%) when Kardiaband ECG recordings were interpreted by physicians.

As a formidable contender in the consumer health technologies, Apple has eliminated the need for the Kardiaband accessory by including a built-in ECG in recent series of Apple Watches (series 4+). On September 12, 2018, Apple introduced the first FDA-cleared commercially available ECG, making cardiac physiological data even more

accessible to the general public (Apple, 2018a). During the Apple Special Event, the Apple Watch series 4 received an endorsement from the president of the American Heart Association, Dr. Ivor Benjamin, who described the ECG functionality as "game changing," with strong clinical implications in the "shared decision making between people and their healthcare providers," (Apple, 2018a). Similar to the SmartRhythm function of the Kardiaband, the irregular rhythm notification feature of the Apple Watch alerts individuals of arrhythmia and prompts for manual recording. ECG recording is enabled by the placement of electrodes in the back and digital crown on the Apple Watch. Consumers are directed to place their finger on the dial for 30 seconds to produce one of three readings: No AF, Possible AF, and Unclassified. The FDA reviewed data from 588 Apple Watch users, approximately half of whom presented with permanent or persistent AFib (Apple Inc., 2018b). Excluding unclassified recordings (10%), the AFib algorithm demonstrated a sensitivity of 98.3% and specificity of 99.6%. Another study examined the diagnostic sensitivity of the irregular rhythm notification feature against a continuous ambulatory cardiac monitor and determined that 78.9% of irregular rhythm notifications from the app corresponded with cardiac monitor detected AFib (Apple Inc., 2018b).

The application of consumer SDP in cardiac monitoring has received wide acclaim for its promising diagnostic utility and undertaking to address issues with discrepant symptom reporting in AFib. SDP are consumer friendly (i.e., easy to use) and produce results in under one minute. They are affordable and non-invasive, thus, minimizing costs, threats to infection, and physical discomforts commonly associated with implantable devices (Lau et al., 2013). Clinically, consumer SDP may improve diagnostic yield of silent and subclinical AFib, both of which confer a higher risk for

stroke and other comorbid health conditions when compared to healthy samples (CITE). A comparison study found that a smart-phone based ECG recording system outperformed a standard cardiac event monitor in identifying arrhythmias and was better received by patients, based on patient satisfaction measures (Macinnes et al., 2018). Early detection of AFib may enable prompt initiation of treatment to attenuate disease progression (Miyazawa et al., 2018). Moreover, the advent of these continuous mobile monitoring systems may potentially resolve patients' uncertainties about the occurrence of arrhythmias. In spite of these possible gains, several unanswered questions remain with interpreting SDP feedback, raising providers' uncertainties for the optimal course of treatment and patients' uncertainties regarding the meaning of results.

The U.S. Preventive Services Task Force concluded that there is insufficient evidence to evaluate the balance of benefit versus harm in screening for AFib with ECG (Curry et al., 2018). The only known guidelines available, from the European Society of Cardiology (ESC), European Heart Rhythm Association (EHRA), and AF-SCREEN, recommend that patients with high risk-status for stroke, or those $\geq$75 years, be considered for systematic ECG screening (Jonas et al., 2018). Among individuals 75 years and older, daily ECG recordings was reported to increase the detection of AFib (Engdahl et al., 2013; Friberg et al., 2012; Kirchhof et al., 2009). Nevertheless, recommendations on the screening frequency of the general population are lacking in the literature. Furthermore, there are no known studies to date providing evidence that AFib screening improves health outcomes.

The discussion of whether older adults benefit from remote technologies is mixed. One study found no significant differences in activation and adherence to application-

based remote monitoring of cardiac implantable electronic devices (CIEDs) across age groups (Tarakji et al., 2018). Yet, a recent study examining ownership and utilization preferences of health information technology noted that older adults (participants >65) were less likely to own smartphones or tablets, and less likely to install health applications (Onyeaka et al., 2021). The authors also found that older adults were less likely to use technology to seek personal medical information, track healthcare costs, communicate with providers, and view test results. When controlling for ownership of smartphone, tablet, and internet use, these relationships remained significant, but were attenuated, suggesting that age differences in health technology use was attributed to technology access (Onyeaka et al., 2021). Other considerations in the adoption of health technologies among older individuals may include interest, education, income, and health status (Crouch & Gordon, 2019; Heart & Kalderon, 2013; Gordon & Hornbrook, 2018). Thus, despite the higher rates of AFib among older adults as well as the potential benefits of remote monitoring, older adults may experience unique barriers to using mobile health technologies.

Uncertainties with SDP

Despite its FDA clearance, a diagnosis of AFib still requires physician interpretation, as precision in SDP ECG falls short of gold standard. Approximately 15 – 33% of ECG recordings are determined to be “unclassified” by automated algorithms (Bumgarner et al., 2018; Koshy et al., 2018). Passive identification of arrhythmias, such as those measured by the irregular rhythm notification, poses a greater challenge to detect in ambulatory populations relative to those at rest, as movement increases noise (Apple Inc., 2018b; Tison et al., 2018). One study reported that the Apple Watch with

Kardiaband rendered episode sensitivity of 97.5% in an ambulatory population compared with an insertable cardiac monitor (Wasserlauf et al., 2019). In spite of this, Kardiaband is no longer on the sales market. These uncertainties may prompt unnecessary worry in patients, leading to additional testing to determine the possible presence of disease (Mandrola, 2018; Sajeev et al., 2019; Wallace, 2019). Confirmatory tests are not without risks. For instance, angiography is associated with a serious harm rate of 1.7% (Noto et al., 1991). Moreover, repeated testing inflates the rate of Type I error, leading to a higher incidence of false positives or misdiagnoses, as well as the potential for overtreatment. The benefits of anticoagulant therapy in consumer SDP-detected AFib patients is unknown (Sajeev et al., 2019; Sanna, 2018). The efficacy of oral anticoagulants in the prevention of stroke has been demonstrated in patients diagnosed with AFib using standard ECG equipment, which typically detect prolonged AFib episodes in paroxysmal or persistent AFib patients (Sanna, 2018). In contrast, long-term remote monitoring devices such as ICD, ILR, and consumer SDP passively detect all instances of AFib and subclinical AFib. Patients screened with consumer SDP, such as the Apple Watch, may differ in demographics and health status (i.e., younger, lower disease classification, lower risk for stroke) relative to the "conventional AFib patient" diagnosed with standard ECG (Mandrola, 2018; Sanna, 2018). Moreover, there is no consensus on the duration of AHRE required to initiate treatment (Mahajan et al., 2018). Initiation of anticoagulant therapy may be harmful, particularly for patients who are not at high risk for stroke, as it has been associated with bleeding (Cameron et al., 2014).

Whereas the technical limitations of SDP will eventually be refined through development, the clinical implications of their application remain understudied in this

burgeoning field. Little is known about the psychological and behavioral impact of SDP detected AFib, with regard to patient reported distress, healthcare utilization, disease awareness, and symptom burden (i.e., symptom duration, severity, and frequency). Patient reported outcomes offer valuable insight to the daily lives of patients and serve as an important indicator of prognosis (Chan et al., 2009; Heidenreich et al., 2006; Mommersteeg et al., 2009).

The widespread adoption of consumer SDP may generate a degree of worry and uncertainty, as consumers may not be equipped with adequate knowledge about the appropriate use of SDP, meaning of results, and optimal course of action (Benezet-Mazuecos et al., 2018). One randomized controlled trial (RCT) reported increased anxiety among primary care patients systematically screened for AFib (Hobbs et al., 2005). Irregular rhythm and ECG feedback from SDP may serve as a constant reminder of the illness, enhancing anxiety, especially if results are interpreted without aid and reassurance from medical providers (Ottenberg et al., 2013; van Hemel, 2009). Results from a qualitative study highlighted a “vicious cycle” in AFib patients, whereby the unpredictability of symptoms prompted ineffective coping strategies such as avoidance and activity reduction (Taylor et al., 2018). Failed attempts to control symptoms elicited increased distress, which in turn triggered or enhanced awareness of AFib symptoms. Indeed, unpredictable events are reported to have a greater negative impact on mood, anxiety, and physiological reactivity than aversive events that are expected (Grupe & Nitschke, 2013; Sarinopoulos et al., 2009). Yet, the available research examining the impact of continuous health monitoring on anxiety is equivocal.

REHEARSE-AF is the only known RCT comparing the psychological outcomes of one-lead ECG Kardia device with routine clinical care in screening patients without a prior diagnosis of AFib (Halcox et al., 2017). Compared to treatment as usual, participants in the SDP condition reported less anxiety about abnormal heart rhythm results, despite increased awareness of risk. The results of this study should be interpreted in light of several caveats. Participants in the SDP arm were only asked to measure their heart rhythm twice weekly. Per study guidelines, all abnormal Kardia ECG traces obtained were automatically transmitted for secondary analysis by a cardiologist (Halcox et al., 2017). As such, the results of this study may not generalize to consumers with continuous and passive monitoring devices or those that are not monitored by healthcare providers.

Studies of other patient samples have examined the effect of continuous monitoring on anxiety and patient distress. Research in maternal health indicates that continuous monitoring of fetal heart rate using an ECG device is both feasible and acceptable to pregnant women (Crawford et al., 2018). Anxiety was assessed before and after monitoring using four validated questionnaires. No change in anxiety was observed in three out of four measures, though significant score reductions were noted on the Pregnancy Specific Anxiety scale. One meta-analysis highlighted the divergent effects of continuous glucose monitoring (CGM) on patients with Type I diabetes (Messer et al., 2018). Illness related distress was exacerbated with continuous monitoring, as the constant feedback from the device seemed to overwhelm aspects of patients' lives, causing great anxiety (Barnard et al., 2014; Pickup et al., 2015; Rashotte et al., 2014). Yet, another theme of the patient experience rested on the security, reassurance, and

independence provided by the CGM devices (Pickup et al., 2015; Ritholz et al., 2014; Wysocki et al., 2016). Continuous monitoring was reported to reduce fears of unexpected hypoglycemia, allowing patients to resume daily activities.

The emotional burden of continuous heart rhythm monitoring with consumer SDP is unknown. Relief and augmentation of AFib-related uncertainties are speculated as two possible outcomes of constant physiological feedback. Continual monitoring of heart rhythm in SDP obviates the need for patients to rely on subjective reporting of symptoms. One qualitative study suggested that AFib patients with greater perceived knowledge endorse greater feelings of control (Taylor et al., 2018). On the other hand, constant alerts of heart rhythm abnormalities may enhance worry and potentially interrupt activities of daily living, particularly if patients are uncertain about the meaning of results or the appropriate course of action.

Healthcare utilization is another factor likely to be altered by the use of consumer SDP. Stress-related hospital visits rise with increasing levels of uncertainty (Mishel et al., 1984). Moreover, ECG screening has been linked to more downstream testing. Patients who received an ECG during an annual medical exam were five times more likely to receive additional cardiac tests, schedule subsequent visits, and obtain procedures than those who were not screened (Bhatia et al., 2017). Continuous patient monitoring systems may increase the need for additional tests among patients first diagnosed with AFib, though alleviate the influx of clinic and hospital visits downstream, as data can be viewed and monitored remotely (Dubner et al., 2012). Indeed, some studies have shown significant reductions in health care utilization among cardiovascular (Brugada, 2006; Burri & Senouf, 2009; Masella et al., 2008; Matlock, 2010), and COPD patients using

remote patient monitoring systems (Dinesen et al., 2012). Other studies found no differences in hospital admissions between patients using continuous monitoring devices and those receiving conventional care (Ong et al., 2016; Pedone et al., 2013). A meta-analysis of RCTs examining health outcomes of heart failure patients found a significant increase in unexpected hospital and emergency department visits in those with cardiac implantable electronic devices (CIED; Klersy et al., 2016). Results from the REHEARSE-AF study found that patients monitored by Kardia device reported that they were less likely to schedule a follow-up visit with their physician for AFib-related concerns relative to those receiving usual care. This study, however, assessed for patients' intended behaviors rather than actual behaviors (Halcox et al., 2017). Plummeting rates of clinic admissions seem to be a plausible outcome of SDP use, though patients may lose the opportunity to voice their concerns, receive reassurance, and obtain important health information from providers (Pedersen et al., 2016; Simmers, 2012). The reduction of in-person contact with medical staff may induce anxiety in some patients.

SDP use may subjectively or objectively alter the experience of patients' symptoms by initiating changes in cognitive processes. High levels of uncertainty and anxiety have been shown to enhance attention to pain and pain sensitivity (Ploghaus et al., 2001; Sawamoto et al., 2000). In an experimental induction of uncertainty, threat of shock amplified pain reactivity whereas expected shock exposures reduced physiological indicators of arousal (Rhudy & Meagher, 2000). Another study found that participants in the uncertain condition who received low intensity pain stimulation reported greater perceptions of pain than subjects in the certain condition who received high intensity

stimulation (Brown et al., 2008). Uncertainty has also been associated with perceived pain elevations in patients with rheumatoid arthritis (Braden, 1990) and fibromyalgia (Akkasilpa et al., 2000). Similarly, anxious individuals demonstrate biases in interpreting ambiguous interoceptive stimuli as threatening (Richards et al., 2001) and attentional biases in detecting the potential for impending harm (Bar-Haim et al., 2007; Beck & Emery, 1985). For instance, patients diagnosed with panic disorder (PD) report greater awareness of somatic sensations compared to those without PD (Chambless et al., 1984; King et al., 1986), and demonstrate enhanced cardiac acuity relative to individuals with infrequent panic episodes, simple phobias, non-anxious controls, and cardiac patients (Ehlers & Breuer, 1992; 1996; Stalmann et al., 1987). AFib patients may be especially motivated to detect symptoms of autonomic arousal that signify the possible presence of an arrhythmic event, thereby increasing attunement to specific interoceptive sensations. Heart-focused anxiety has been associated with greater vigilance for AFib symptoms as well as increased pain frequency and intensity (Aikens et al., 2001; Fleet & Beitman, 1998; Zvolensky et al., 2003). This is further complicated by studies citing that uncertainty and anxiety enhances heart rate variability (Gerstenfeld et al., 1999; Thayer et al., 2012), which may mimic or exacerbate symptoms of AFib. Compared to nonanxious individuals, patients with PD who perceived a cardiac event exhibited heart rate accelerations (Pauli et al., 1991). It has yet to be determined whether consumer SDP would amplify or attenuate patients' AFib-related uncertainties and worries, thereby altering attentional processes as well as patient perceptions of symptoms. Intuitively, reliance on subjective pathophysiology is unnecessary when continuous objective feedback of cardiac physiology is available, however, the immediate accessibility of

health data may perpetuate symptom preoccupation, likening reception of ECG feedback to a form of safety behavior. Indeed, one case study described the emergence of illness anxiety disorder in an older adult female one year after diagnosis of paroxysmal AFib (Rosman et al., 2020). The patient was found to have new onset health anxieties that were primarily triggered by heart rhythm monitoring with a smart watch; Within a one-year period, the patient had recorded 916 ECG tracings (701 in sinus rhythm, 55 possible AF). The patient was reported to interpret ambiguous/inconclusive data as actual threats, leading to numerous unnecessary clinic and emergency department visits.

In summary, although remote patient monitoring systems may answer questions regarding the occurrence of cardiac arrhythmias, the psychosocial adjustment of patients using SDP remains unknown. No study to date has examined the psychological sequela of continuous, long-term, and passive heart rhythm monitoring in AFib. Yet, additional research is needed to promote a greater understanding of patient reported outcomes in order to develop comprehensive care for this population. The experience of uncertainty among AFib patients using consumer SDP should be understood in the context of a theoretical framework.

Mishel's Midrange Theory of Uncertainty in Illness

Uncertainty is a strong predictor of psychosocial adaptation and disease outcomes (McCormick, 2002). Given that uncertainty is a critical mark of the AFib patient experience, the Uncertainty in Illness model (Mishel, 1988) provides a fitting theoretical framework to guide the aims of this proposed study. The concept is defined as the inability to derive meaning of illness-related events in the absence of sufficient information (Mishel & Braden, 1988). Individuals living with uncertainty lack the

cognitive framework to make sense of their diagnoses, symptoms, prognoses, and treatments. Thus, they may perceive the disease to be unpredictable and uncontrollable (Budner, 1962; Mishel, 1981; Weitz, 1989).

Mishel's midrange theory of uncertainty in illness (1988) outlines three components of the model: 1) antecedents, 2) appraisal, and 3) coping. The antecedents of uncertainty include the stimulus frame, such as symptom patterns or event familiarity. These illness-specific characteristics are influenced by patient factors (e.g., cognitive capacities) as well as the resources available to the patient (e.g., social support, education). The valence of uncertainty is considered neutral until otherwise appraised, as either negative or positive (Mishel, 1990). Appraisals of danger arise when uncertainty indicates the possibility of an adverse outcome such as the diagnosis of a disease, whereas appraisals of opportunity occur when the outcome is evaluated as positive (Mishel, 1990). Uncertainty may also be interpreted as an opportunity under extreme cases, as is the case when a terminal prognosis is presumed and not knowing is preferable to certain threat. Appraisals of uncertainty determine the actions employed to cope with illness-related experiences (Mishel, 1988). In the context of danger, individuals may rely on mobilizing strategies, such as information seeking or reframing, to increase the perception of control and regulate affect (Afifi & Weiner, 2004; Mishel, 1990). In contrast, opportunity appraisals require the persistence of uncertainty in order for positive inferences to be maintained (Mishel, 1990). Under circumstances of prolonged illness uncertainty, such as chronic illnesses, positive adaptations may also be achieved when patients accept uncertainty to be an inherent feature of life (Mishel, 1990).

Represented in the Mishel Uncertainty in Illness scale are four critical factors encompassing illness uncertainty that are relevant to the literature of behavioral sciences. These include ambiguity surrounding the state of disease, complexity concerning treatment, insufficient data regarding prognosis and diagnosis, and unpredictability of the course of illness. With complex diseases, healthcare providers may face clinical or professional uncertainty, defined as challenges in determining diagnosis, prognosis, and appropriate treatment for illnesses (McIntosh, 1974). Research has documented variations in practice across providers prescribing treatments for the same condition under high uncertainty (Jette & Jette, 1997). With regard to AFib, the use of consumer SDP expectedly generate a degree of clinical uncertainty in determining risk status and duration of AHRE required to initiate treatment (Benezet-Mazuecos et al., 2018; Mela, 2018; Sajeev et al., 2019; Sanna, 2018). AFib patients are likely to experience event and temporal uncertainty. Event uncertainty is experienced when the occurrence of a disease-related event is unknown (Monat et al., 1972), such as the occurrence of an arrhythmia or other AFib symptoms. In temporal uncertainty, the timeliness of an inevitable outcome is unknown (Monat et al., 1972), such as when one will experience an AFib episode. Results of an experimental paradigm indicated that event uncertainty was associated with heightened arousal and vigilance, whereas temporal uncertainty predicted the use of avoidance strategies (Monat et al., 1972). Continuous monitoring devices may alleviate event and temporal uncertainties of arrhythmias, however, the occurrence and timing of thromboembolic events remain unknown. The effect of SDP on illness uncertainty is an understudied area, ergo, the coping strategies of consumers are yet to be determined.

Uncertainty has been found to be a strong predictor of psychological distress in patients with arthritis (Nyman & Lützen, 1999; Wiener, 1975), postpolio syndrome (Mullins et al., 1995), and cancer (Neville, 1998). Yet, few studies have examined illness uncertainty among AFib patients, and the bulk of the extant literature has been produced by the same author. Higher rates of illness uncertainty have been documented in patients with AFib than in those with breast cancer, myocardial infarction, and renal disease (Kang, Daly, & Kim, 2004). Factors contributing to illness uncertainty in AFib patients include lower educational attainment and social support, as well as greater perceived illness severity (Kang et al., 2004). Uncertainty in AFib has been associated with greater symptom severity and poorer mental health. Moreover, the relationship between illness uncertainty and mental health was mediated by the appraisal of uncertainty as a danger rather than an opportunity (Kang, 2005). Those who appraised uncertainty as danger are also more likely to subscribe to an internal health locus of control, or belief that health outcomes are determined by one's behavior (Kang, 2009). Kang (2006) also found differential effects of appraisal influenced by mood, whereby depression was positively and negatively associated with danger and opportunity appraisal, respectively. There are no known studies evaluating the impact of consumer SDP on illness uncertainty in AFib patients. As we shift towards increasing reliance on tele-monitoring systems in modern healthcare, it is ever more critical to enhance our understanding of the user experience in order to develop appropriate interventions that address patient needs.

Current Study Rationale

Technological advancements have enabled continuous and remote detection of irregular heart rhythms, thereby reducing event and temporal uncertainties of AFib

(Apple Inc., 2018a; Benezet-Mazuecos et al., 2014; Bumgarner et al., 2018). The application of this new technology has implications in primary prevention, as both symptomatic and asymptomatic AFib confer higher risk for stroke (Glotzer et al., 2003; Glotzer et al., 2009; Healey et al., 2012; Stewart et al., 2002). Although continuous feedback may reduce uncertainties about whether and when an arrhythmia has occurred, it does not allow patients to draw definitive conclusions about the meaning of these events or the appropriate course of treatment (Benezet-Mazuecos et al., 2018; Mahajan et al., 2018). With limited research in this burgeoning field, the psychological outcomes of SDP consumers are yet to be determined. Specifically, it is unclear how SDP feedback will impact patients' illness uncertainty, cardiac anxiety, attention to bodily symptoms, disease burden (i.e., symptom duration, frequency, and severity), and healthcare utilization. The proposed study aimed to elucidate the psychological sequela of consumer SDP engagement. Two possible outcomes have been hypothesized.

With growing support from reputable institutions (e.g., AHA), advocates of consumer-directed healthcare are optimistic for SDP to remedy psychosocial concerns in AFib patients. The current study hypothesized a *remedial effect*, which is based upon evidence supporting that additional information regarding the predictability of symptoms reduces uncertainty in illness (Mishel, 1988). Patients who have historically relied upon their own subjective interpretations of symptoms to detect AFib events may obtain relief from non-invasive monitoring systems that measure their cardiac physiology. Data can be transmitted to providers for analysis and treatment recommendations, circumventing practical limitations of healthcare access and reducing financial burdens associated with frequent visits (Bumgarner et al. 2018; Dubner et al., 2012; Halcox et al., 2017). The

functionality of such devices may increase symptom predictability as well as patients' perceived control over the disease. Exposure has been shown to be an effective behavioral intervention to reduce illness uncertainty (Abramowitz & Arch, 2014; Carleton, 2012). SDP feedback may serve as a type of exposure, potentially correcting erroneous assumptions regarding interoceptive cues, thus diminishing heart-focused anxiety. Taken together, consumer SDP may obviate the need to attend to AFib symptoms, which in turn, enable more accurate perceptions of symptom frequency and severity.

In contrast, a number of skeptics have expressed reluctance to endorse consumer SDP whole-heartedly, noting the possible iatrogenic outcomes (Curry et al., 2018; Benezet-Mazuecos et al., 2018; Mandrola, 2018; Mela, 2018; Rosman, 2020; Sajeev et al., 2019; Sanna, 2018; Wallace, 2019). In the proposed study, an *iatrogenic effect* was also hypothesized, whereby feedback enhances the salience of existing illness-related uncertainties of risk, management, and treatment. Continuous reminders of disease may overwhelm various aspects of patients' life (Skov et al., 2015). Opportunities to address patient concerns and receive reassurance from direct contact with providers may be missed with remote monitoring (Ottenberg et al., 2013; Skov et al., 2015; van Hemel, 2009). Moreover, persisting uncertainties regarding the imminence of AFib events may lead to greater vigilance of symptoms (Rosman et al., 2020). Enhanced cardiac anxiety may elicit safety behaviors, or efforts to prevent the occurrence of feared outcomes (e.g., AFib symptoms) and promote a greater sense of security (Helbig-Lang & Petermann, 2010; Olatunji et al., 2011; White & Barlow, 2002). In AFib patients, these may include excessive cardiac monitoring, clinic visits, and increased contact with healthcare

providers despite the absence of real threats. Previous studies have shown that anxiety and symptom preoccupation have been positively associated with the reported frequency and severity of AFib symptoms (Kang, 2006; Kupper et al., 2013; Ong et al., 2006). Similarly, the iatrogenic hypothesis posits that cardiac anxiety and vigilance for AFib symptoms would be associated with increased disease burden (i.e., symptom duration, frequency, and severity).

Study Aims and Hypotheses

Aim 1

Explore demographics and identify risk profile of patients in the current sample as well as covariates in subsequent analyses.

H1a. It was hypothesized that the majority (>50%) of the overall sample (across both recruitment methods) would be of middle to higher socioeconomic status, as measured by household income and educational attainment.

H1b. It was hypothesized that sex would be related to outcomes of illness uncertainty, cardiac anxiety, symptom preoccupation, AFib symptoms, AFib disease burden, and healthcare utilization.

H1c. It was hypothesized that age would be associated with illness uncertainty, cardiac anxiety, symptom preoccupation, AFib symptoms, disease burden, and healthcare utilization.

Aim 2

Apply Mishel's Uncertainty in Illness model (1988) as a framework to determine the psychosocial adjustment of AFib patients across two conditions: 1) consumer SDP users 2) non-SDP users (control). Determine whether patient reported outcomes of illness

uncertainty, cardiac anxiety, symptom preoccupation, AFib symptoms, disease burden, and healthcare utilization across SDP users and non-users lend support for a remedial or iatrogenic effect.

H2a: It was hypothesized that illness uncertainty (MUIS) would differ across conditions.

H2b: It was hypothesized that cardiac anxiety (CAQ-Total, CAQ-Fear, CAQ-Avoidance, CAQ-Attention) would differ across conditions.

H2c: It was hypothesized that symptom preoccupation (BVS) would differ across conditions.

H2d: It was hypothesized that AFib symptoms (AFSS-Symptoms) would differ across conditions.

H2e: It was hypothesized that disease burden (AFSS-Burden) would differ across conditions.

H2f: It was hypothesized that healthcare utilization (AFSS-HCU) would differ across conditions.

Aim 3

Explore the mechanism underlying SDP engagement and psychological functioning. Specifically, this study sought to examine whether uncertainty in illness mediated the relationship between SDP use and five outcome variables: cardiac anxiety, symptom preoccupation, AFib symptoms, disease burden, and healthcare utilization.

H3a: It was hypothesized that illness uncertainty would mediate the relationship between SDP use and cardiac anxiety, such that SDP use would be associated

with illness uncertainty, which in turn would diminish (remedial hypothesis) or enhance (iatrogenic hypothesis) cardiac anxiety.

H3b: It was hypothesized that illness uncertainty would mediate the relationship between SDP use and symptom preoccupation, such that SDP use would be associated with illness uncertainty, which in turn would diminish (remedial hypothesis) or enhance (iatrogenic hypothesis) symptom preoccupation.

H3c: It was hypothesized that illness uncertainty would mediate the relationship between SDP use and disease burden, such that SDP use would be associated illness uncertainty, which in turn would diminish (remedial hypothesis) or enhance (iatrogenic hypothesis) disease burden.

H3d: It was hypothesized that illness uncertainty would mediate the relationship between SDP use and AFib symptoms, such that SDP use would be associated illness uncertainty, which in turn would diminish (remedial hypothesis) or enhance (iatrogenic hypothesis) AFib symptoms.

H3e: It was hypothesized that illness uncertainty would mediate the relationship between SDP use and healthcare utilization, such that SDP use would be associated with diminished (remedial hypothesis) or enhanced (iatrogenic hypothesis) illness uncertainty, which in turn would diminish (remedial hypothesis) or enhance (iatrogenic hypothesis) healthcare utilization.

Methods

Participants

Participants in the current study were recruited via web-based platforms, including ResearchMatch, American Heart Association support group, and other online AFib communities (i.e., Facebook).

ResearchMatch is a recruitment registry where individuals enlist to participate in clinical research studies by providing health information, such as medical diagnoses. They are then matched to researchers based on medical information provided. Participants were also recruited through the web-based atrial fibrillation community support groups. An advertisement, providing general information about the study, eligibility criteria, and contact information of the principal investigator, was posted and made public on these online forums.

Procedure

AFib patients with consumer smart devices (e.g., Kardiaband, Apple Watch series 4+) were placed in the SDP condition. AFib patients who did not own smart devices were in the non-SDP group. Data collection were monitored to ensure that the number of participants within each condition was fairly equal. Inclusion criteria remained consistent across recruitment methods and condition, with the exception of participants in the SDP condition, who were qualified by their use of consumer smart devices. Participants were eligible to participate if they were at least 18 years of age, proficient in the English language, and received a medical diagnosis of AFib. Though not explicitly specified, the recruitment method and completion of measures also required that participants have Internet access.

Eligible volunteers on ResearchMatch received an e-mail notification from the web-based portal inviting them to participate in a study examining the psychological

correlates of atrial fibrillation, led by a researcher at the University of Missouri – St. Louis. Interested participants notified ResearchMatch of their willingness to participate, at which point, the volunteer's contact information was released to the principal investigator. Participants who indicated interest received an e-mail containing a link to the online survey hosted by Qualtrics.

Participants recruited through online community support groups responded to an advertisement that included a description of the study, eligibility criteria, contact information for the principal investigator, and a direct link to the survey.

The COVID-19 pandemic unexpectedly emerged during data collection of the study. An amendment was submitted to include two additional measures in order to assess the impact of the global health crisis on participants. Results will be described in the exploratory analysis section.

This study was approved by the University of Missouri – St. Louis Institutional Review Board. Subjects provided informed consent through the online portal before participating. The consent also indicated that participants would be eligible to enroll in a raffle drawing to receive one of ten available e-gift cards worth $25 if they completed at least 80% of the survey items. Odds of winning are approximately one in 13.

Materials

Participants completed measures at a single time point. All surveys were administered via an online platform. Subjects were able to access the study through a link that was hosted by Qualtrics. See Appendix A for a compendium of study measures.

Demographics

Demographic information was collected on patients' age, sex, ethnicity, religious affiliation, marital status, educational attainment, employment status, and annual household income.

Medical Status

Participants were asked to report on their AFib status as well as other comorbid medical conditions. AFib-related inquiries included duration of diagnosis, classification of AFib, history of significant medical events (i.e., stroke, myocardial infarction), treatment(s) received, and history of conditions that would indicate an elevated risk status (i.e., diabetes, hypertension, and vascular disease). Patients unable to report on their medical history, due to unwillingness or uncertainty, had the option to indicate, "I am not sure" on any of the items.

Measures

SDP-Use. Participants in the SDP condition were asked to report on their engagement with consumer smart devices. Specifically, subjects indicated the frequency with which they received irregular heart rhythm or SmartRhythm notifications, self-initiated ECG tracings, submitted data for further interpretation, and requested in-person or virtual visits with a healthcare provider following feedback. A composite SDP-use score was generated by totaling the aforementioned items.

Illness Uncertainty. The Mishel Uncertainty in Illness Scale – Community Form (MUIS-C; Mishel, 1997) is a uni-dimensional scale based on the original Mishel Uncertainty in Illness Scale (MUIS-A; Hallberg & Erlandsson, 1991). The original instrument was intended for hospitalized or acutely ill adults, however, the MUIS-C was modified for use with non-hospitalized and chronically ill adults living in the community.

The MUIS-C contains 23 items rated on a 5-point Likert scale, ranging from 1 *Strongly Disagree* to 5 *Strongly Agree*. Total scores ranged from 23 to 115. Items include, "My symptoms continue to change unpredictably," and "My treatment is too complex to figure out." The MUIS-C has demonstrated acceptable to excellent reliability, with scores comparable to the original scale (Mishel & Epstein, 1997). The MUIS-C demonstrated excellent reliability in the current sample, with a Cronbach's alpha score of 0.90.

Cardiac Anxiety. The Cardiac Anxiety Questionnaire (CAQ; Eifert et al., 2000) assesses fear of cardiac-related stimuli and sensations. Respondents are asked to rate the degree to which they experience heart-related concerns on a scale from 0 *Never* to 4 *Always* on 18 items. The CAQ produces a total score and three subscale scores: (a) fear of cardiovascular sensations, (b) avoidance of activities that may elicit symptoms, and (c) attention to cardiac symptoms. Sample items for each subscale include, "If tests come out normal, I still worry about my heart," "I avoid exercise or other physical work," and "I pay attention to my heart beat." The psychometric properties of the total scale and the three subscales have been shown to be adequate with regard to internal consistency and convergent and divergent validity (Eifert et al., 2000). Reliability scores for the current study were $\alpha = 0.74$ for the total CAQ measure, $\alpha = 0.82$ for CAQ-fear, $\alpha = 0.92$ for CAQ-Avoidance, and $\alpha = 0.71$ for CAQ-Attention.

Health Care Utilization, Disease Burden, and AFib symptoms. The Atrial Fibrillation Symptom Severity (AFSS; Dorian et al., 2002; 2013) is a disease-specific measure consisting of 19 items that assess AFib symptoms, healthcare utilization, and disease burden. The AFib symptom subscale assesses the degree to which respondents have been bothered by seven individual AFib symptoms (e.g., palpitations, shortness of

breath, and chest pain). Response options range from 1 *I have not had this symptom in the past 4 weeks* to 5 *A great deal*. Disease burden is derived from the sum of symptom frequency, duration, and severity scores. Items on the healthcare utilization (HCU) scale assess the frequency of AFib related emergency room visits, hospitalizations, and specialist visits. The AFSS has demonstrated acceptable internal consistency for HCU, $\alpha = 0.67$ and good reliability for disease burden, $\alpha = 0.72$ (Dorian et al., 2002)

Symptom Preoccupation. The Body Vigilance Scale (BVS; Schmidt et al., 1997) is an 18-item self-report measure that assesses attentional focus to physiological sensations. BVS items measure the degree of preoccupation, perceived sensitivity to changes in bodily sensations, and duration of attention to sensations on an 11-point Likert-type scale 0 *Not at all like me* to 10 *Extremely like me*. Respondents are also asked to rate the extent of vigilance to 15 bodily sensations, such as numbness, tingling, and upset stomach. The BVS has demonstrated good internal consistency, convergent, and discriminant validity in previous studies (Olatunji et al., 2007; Schmidt et al., 1997). Cronbach's alpha in this study was in acceptable limits, $\alpha = 0.75$.

COVID-19. The COVID-19 measure assessed qualitative data about whether the pandemic impacted participant's responses. It also inquired about changes in health concerns and behaviors, patient's COVID-19 status, and beliefs about the risks for complications.

Impact of Events Scale – Revised. The IES-R (Weiss & Marmar, 1997) is a 22-item scale that measures subjective distress following an adverse event. This scale corresponds to the symptoms of posttraumatic stress disorder. Respondents were asked to indicate the degree to which they were bothered by experiences related to the pandemic

in the past seven days on a scale of 0 *Not at all* to 4 *Extremely*. Examples include, "Any reminders brought back feelings about it." The IES-R produces a total score (ranging 0-88) as well as subscales scores of avoidance, intrusions, and hyperarousal. Subscales scores are obtained by calculating the mean of subscale items, with scores ranging from 0 to 4. Higher scores are indicative of greater pathology. A total score of 33 or more is considered clinically significant. The IES-R has demonstrated good internal consistency, test-retest reliability, and predictive validity in previous samples (Beck et al., 2008; Creamer et al., 2003; Weiss & Marmar, 1997). Cronbach's alpha in the current sample was excellent for the total and subscale scores (IE-Total $\alpha = 0.97$; IE-Intrusion $\alpha = 0.92$; IE-Avoidance $\alpha = 0.90$; IE-Hypervigilance $\alpha = 0.92$).

Results

Data Cleaning

A total of 819 participants electronically provided informed consent and completed the screener items to indicate that they met the inclusion criteria to participate in the study. Of these participants, only 180 completed at least 80% of the scale items (excluding option text responses containing display logic), a minimum requirement of the raffle entry. The minimum number of items to enter the raffle varied upon the condition and time of completion. Those in the SDP condition were presented with an additional questionnaire assessing their SDP-use. Following the COVID-19 pandemic, two additional scales were included in the battery to assess the degree to which the coronavirus may have impacted participants' responses. Thus, the minimum number of items per condition/time is listed as follows: 125 (SDP condition before pandemic), 151 (SDP condition after pandemic), 117 (Non-SDP before pandemic), 143 (Non-SDP after

pandemic). A significant number of participants completed less than 80% of items (*n* = 639). Of note, several hundred entries (400+) were received on the same day, with close time stamps, and near-identical response styles, suggesting the possibility of "bot" responses. Data from the remaining 180 participants were more closely inspected for signs of careless, unusual, or bot-based responses.

Considering the potential for low quality data with web-based data collection, several authors have identified various methods of quality assurance (Buchanan & Scofield, 2018; Mason & Suri, 2012; Stieger & Reips, 2010; Teitcher et al., 2015). One potential method to assess respondent effort is to examine the completion time of a task (Mason & Suri, 2012). Stieger and Reips (2010) developed a Javascript encoded UserActionTracer alongside web-based surveys to screen low effort responses based on various metrics. The authors found that the most common occurrence of low motivation responses was completion of items at a rate faster than the average reading speed. Trauzettel-Klosinski and Dietz (2012) identified that the average reading rate is 987 (*SD* = 118) characters per minute. Readers in the 95th percentile, at two standard deviations above the mean, read at a rate of 1,223 characters per minute. This method was empirically tested for its ability to distinguish between participants assigned to automated, low effort, and high effort conditions (Buchanan & Scofield, 2018). Results indicated that low effort and automated submission times were significantly faster than high effort data. There were four versions of the online survey in the current study: (1) Non-SDP condition before COVID-19 (2) Non-SDP condition after COVID-19 (3) SDP condition before COVID-19 (4) SDP condition after COVID-19. The character counts for each version were divided by 1,223 to calculate the critical reading rate per minute, then

multiplied by 60 to identify the critical reading rate per second for the fastest readers (95th percentile). For example, the character count for those in the Non-SDP condition before COVID-19 was 13,664. Average readers would complete this survey in approximately 831 seconds and the fastest readers would finish at around 670 seconds. Time completion across the sample ranged from 750 to 7,218 seconds. The median completion time of respondents was 1,132 seconds. On average, participants in the SDP condition completed the questionnaire quicker (948 seconds) than those in the Non-SDP condition (1,564 seconds). Based on the reading rate criteria, 51 participants were identified as low motivation or automated "bot" responses (one in SDP condition before COVID-19 and 50 in SDP condition after COVID-19), and were excluded from subsequent analyses. The total sample was 130 participants, with 65 participants in each condition.

Preliminary Analyses

All analyses were conducted with SPSS Version 27. Data were screened for missing values. Additionally, relevant assumptions of tests were examined, with adjustments made, prior to proceeding with proposed analyses.

A missing value analysis was conducted to identify potential patterns for missing data. Little MCAR's test revealed non-significant results for MUIS ($\chi^2(175) = 148.47$, $p = 0.93$), CAQ ($\chi^2(114) = 97.31$, $p = 0.87$), AFSS ($\chi^2(103) = 124.80$, $p = 0.07$), and BVS ($\chi^2(172) = 138.09$, $p = 0.97$). Missing values analysis for SDP-use measure was only completed for subjects in the SDP condition, and results were also non-significant, $\chi^2(27) = 37.23$, $p = 0.09$. These findings indicate that data were missing completely at random. Expectation maximization (EM) produced values for missing items from the same scale

or subscale, which were imputed to minimize its effect on subsequent tests. Scale and subscale scores were generated according to developer scoring instructions.

Assumptions of all relevant statistical tests were examined prior to hypothesis testing. All study variables followed normal distribution as indicated by skewness and kurtosis values falling between -1.0 and +1.0, with the exception of SDP-use scores, which demonstrated a skewness of 0.02 and kurtosis of -1.18. Square root transformation of the variable increased the kurtosis value to acceptable limits (Skewness = -0.41, Kurtosis = -0.83). Descriptive statistics and zero order correlations for all variables are reported in Tables 1 and 2. In preparation for ANCOVA, the interaction between condition and covariates were examined in the univariate model. Results were non-significant, indicating homogeneity of regression. Collinearity diagnostic tests showed that Tolerance and Variance Inflation Factors were within acceptable limits, revealing no issues with multicollinearity. Visual inspection of scatterplots was used assess linearity. Levene's test revealed non-significant results, indicating equality of error variances.

Standardized Z-scores were saved on each of the nine continuous variables to determine univariate outliers. Using a cutoff score of $\pm$ 2.5 (Meyers, Gamst, & Guarino, 2013), a total of seven univariate outliers were identified. Specifically, two outliers were identified on the BVS, three outliers on the AFSS-HCU subscale, one outlier on the AFSS-Burden subscale, and one outlier on the CAQ-Attention subscale. After consideration, these cases were retained as the purpose of this study is to conduct an exploratory analysis in a novel area, of which population means have yet to be determined. Analyses were examined with and without the inclusion of univariate outliers with no changes in outcome.

A priori Power Analyses

A set of power calculations were conducted to estimate the required sample size for this study. In order to determine the adequate sample size needed, a power analysis was conducted using G*Power 3.1 (Faul et al., 2014). The second aim of this study was tested with ANCOVA. Parameters for a priori power analysis included Cohen's *f* conventions for a medium effect size of 0.25, $p < 0.05$, and power of 80%. Based on these assumptions, the desired sample size was determined to be 128 participants. To determine the sample size required for the third aim, a power analysis was performed for multiple linear regression, using a medium effect size ($f^2 = .15$) at 80% power and an alpha of 0.05. Results indicated that the desired sample size for this test was 68 participants.

Descriptive statistics

Demographics

A total of 130 participants were included in the analyses, with 65 in the SDP condition and 65 in the control condition. All demographic data are reported in Table 3. Participants' ages ranged between 21 and 90 years, with a mean age of 59.18 (*SD* = 17.18). Approximately 43% of sample was female, 57% was male, and no participants identified as a sex other than male or female. A majority of the sample self-identified as White/Caucasian (88%), with a subset of participants identifying as racial or ethnic minorities, such as Black/African American (4%), Asian (3%), Latinx (1.5%), American Indian/Alaska Native (1.5%), or Other (1.5%). With regard to marital status, most participants reported being married (72%), with the remainder reporting single status (18%), separated (>1%), divorced (7%), or widowed (3%).

Three quarters of participants reported obtaining a college degree (8% Associates degree; 46% Bachelor's degree; 29% Post-graduate degree). Approximately 14% completed some college or attended a vocational/trade school. A minority of subjects reported obtaining a high school diploma or GED (4%). The sample was evenly split between those retired (46%) and those employed (48%), in both part time (9%) and full-time positions (39%). Approximately 2% of participants were on disability, with a small subset of subjects in unpaid positions such as homemaker (2%), student (>1%), or unemployed (>1%). Data on annual household income indicated that many of the participants made over $75,000 (48%), 8% earned $60,001 - $75,000, 22% earned $45,001 - $60,000, 10% earned $30,001 - $45,000, and 12% earned less than $30,000. Over one-half the sample identified as Christian (31% Roman Catholic; 26% Protestant Christian), 26% reported no religious affiliation, 6% identified as Jewish, >1% were Muslim, and 9% selected 'Other' as their religious affiliation.

Medical History

All health information is reported in Table 4. The sample was diverse with regard to their atrial fibrillation classification, with more than half reporting paroxysmal AFib (56%), 27% with persistent AFib, 13% with permanent AFib, and 5% reporting unknown status. Patients initially learned about their diagnosis through their cardiologist (41%), primary care physician (22%), or remote monitoring device (13%). A subset of participants reported learning about their diagnosis during a visit to the emergency department or urgent care (14%). The median number of years since diagnosis was five (22% diagnosed in the past year; 35% diagnosed in the past three years; 54% diagnosed in the past 7 years). Approximately 40% of the sample reported living with atrial

fibrillation for ten or more years. Disease classification was examined for differences across age, race, and sex. Demographic variables were not found to be associated with disease classification.

Patients were also assessed for medical comorbidities, significant health events, and heart-related procedures. Overall, 79% of the sample reported at least one medical comorbidity. Specifically, 58% reported hypertension, 45% reported hyperlipidemia, 43% reported obesity, and 25% reported diabetes. One-quarter of participants reported an incidence of cerebrovascular accident/stroke (19%) or myocardial infarction (6%). More than half of participants underwent surgery (55%), with 35% receiving balloon angioplasty, 35% receiving cardiac catheterization, 19% receiving stent placement, and 12% receiving coronary artery bypass graft (CABG). Patients also underwent minimally invasive procedures for implantable cardioverter defibrillator (ICD; 18%), and implantable loop recorder (ILR; 18%). A composite medical risk score was calculated by totaling the count of comorbidities (i.e., diabetes) and procedures (i.e., stent). Medical risk was examined for differences across age, race, sex, and disease classification. A significant relationship was observed with regard to age, $r(104) = -.28$, $p < .01$, and AFib classification $F(2, 103) = 10.48$, $p < .001$, $\eta^2 = 0.17$. Younger respondents reported a greater number of medical risk factors. Moreover, medical risk was significantly higher for patients with persistent ($M = 4.60$, $SD = 3.04$) and permanent AFib ($M = 4.71$, $SD = 3.75$) when compared to those with paroxysmal AFib ($M = 2.23$, $SD = 2.09$). Medical risk did not differ between persistent and permanent AFib. No other demographics were found to be associated with medical risk.

Patients reported being fairly knowledgeable about their condition (95%; *n* = 124), though a minority of subjects indicated having insufficient understanding (5%; *n* = 5). Three quarters of participants reported being very reassured (77%; *n* = 91), 18% felt moderately assured (*n* = 21), and 5% were not at all reassured by their doctor's diagnosis (*n* = 6). A majority of participants reported symptomatic atrial fibrillation (67 %; *n* = 87). Of those who were symptomatic, 34% reported low interference with daily activities (*n* = 26), 31% reported moderate (*n* = 24), and 35% indicated high interference with daily activities (*n* = 27).

SDP-Use

The type of heart-monitoring device and frequency of use were examined among participants in the SDP condition (*n* = 65). Most patients reported using Kardia device/band (46.2%) or Apple Watch (series 4+) products (52%). Less than one percent of the sample reported using the heart monitoring program on a Fit Bit watch. Participants were asked to report on the frequency that they were device-prompted to record ECG traces (i.e., irregular heart rhythm or SmartRhythm notifications). Two-fifths of participants indicated that they have never been prompted (40%), 20% reported being prompted once or twice, 22% reported being prompted monthly, 11% were prompted weekly, and 8% of participants were prompted several times a week. Participants were also asked to report on the frequency at which they self-initiated ECG recordings to screen for arrhythmia. Results indicate that nearly one quarter of participants recorded ECG traces several times a week (26%), 23% recorded weekly, 26% recorded monthly, and 20% have recorded once or twice in their lifetime. Approximately 5% of participants have never used the ECG function of their smart device. ECG recordings typically

produce one of three outputs. On average, participants reported receiving 'Possible AF' result 30% of time (*SD* = 24.04), 'Normal' ECG tracings 36% of the time (*SD* = 27.37), and 'Unclassified' results 20% of the time (*SD* = 21.42).

Among participants who have used the ECG function on their smart devices, a majority indicated that they trusted the results obtained (82%). After obtaining results, 85% of participants have transmitted the data to a cardiologist, physician, or cardiac technician for further analysis. On average, participants transmitted ECG data 44% of the time (*SD* = 35.72). Moreover, approximately 92% of participants reported scheduling a visit with a provider at least once following recordings. Typically, participants scheduled an in-person/virtual appointment 52% of the time after receiving feedback from their smart device (*SD* = 36.10).

Demographic and Medical Differences between Groups. Data were analyzed to determine whether there were significant differences in characteristics across participants in the SDP and Non-SDP groups. As stated, there were an equal number of participants in each group (*N* = 130). The groups did not differ with respect to sex, ethnicity, income, or marital status. Significant differences were found with age, $F(1, 104) = 64.39$, $p < .01$, $d = 1.60$, education, $\chi^2 = 14.79$, $p < .05$, $\Phi = 0.32$, employment status, $\chi^2 = 49.90$, $p < .001$, $\Phi = 0.62$, and religion, $\chi^2 = 26.70$, $p < .001$, $\Phi = 0.46$ across conditions. Specifically, participants in the SDP group were younger than those in the Non-SDP group ($M_{SDP} = 48.40$, $SD = 16.40$; $M_{Non\text{-}SDP} = 69.56$, $SD = 10.13$). Relatedly, those in the SDP condition had disproportionately higher number of participants reporting full-time employment ($n = 43$, expected count = 25.5), whereas those in the Non-SDP group had a greater proportion of participants who were retired ($n = 46$,

expected count = 30). Participants in the SDP condition also had more participants with Bachelor's degrees (*n* = 38, expected count = 30), compared to those in the Non-SDP group. Lastly, more subjects in the SDP group identified as Catholic (n = 32, expected count = 19.8). In contrast, the Non-SDP condition had disproportionately more participants who did not report any religious affiliation (*n* = 22, expected count = 17.1).

Data were analyzed to evaluate between group differences in medical morbidities, significant health events, and heart-related surgeries. The groups did not differ with respect to AFib classification, hypertension, obesity, hyperlipidemia, catheterization, or incidence of stroke. Rather, significant differences were found with regard to diabetes, $\chi^2 = 15.85$, $p < .001$, $\Phi = 0.35$, myocardial infarction, $\chi^2 = 4.80$, $p < .05$, $\Phi = 0.19$, stent placement, $\chi^2 = 11.96$, $p < .01$, $\Phi = 0.31$, ICD, $\chi^2 = 18.42$, $p < .001$, $\Phi = 0.38$, ILR, $\chi^2 = 9.19$, $p < .01$, $\Phi = 0.27$, CABG, $\chi^2 = 16.22$, $p < .001$, $\Phi = 0.36$, and balloon angioplasty, $\chi^2 = 14.48$, $p < .001$, $\Phi = 0.34$, across groups. Specifically, participants in the SDP condition were more likely to endorse a medical history of diabetes (*n* = 26, expected count = 16.3), myocardial infarction (*n* = 7, expected count = 4), stent placement (*n* = 20, expected count = 12.4), ICD (*n* = 21, expected count = 11.7), ILR (*n* = 18, expected count = 11.4), CABG (*n* = 15, expected count = 7.7), and angioplasty (*n* = 16, expected count = 8.7).

Analyses of Study Aims

Research Aim 1. Explore demographics and identify risk profile of patients in the current sample as well as covariates in subsequent analyses.

Hypothesis 1a. It was hypothesized that the majority (>50%) of the overall sample (across both recruitment methods) would be of middle to higher

socioeconomic status, as measured by household income and educational attainment. Descriptive statistics were used to analyze the first hypothesis of the study. As expected, the sample was of middle to higher socioeconomic status, based upon indices of household income and educational attainment. Specifically, 56% of the sample reported an annual household income over $60,000, with 48% earning more than $75,000 per year. According to the United States Census Bureau, the median household income in 2019 was $68,703 (US Census Bureau, 2020). The sample was also fairly well educated. Three quarters of participants reported obtaining a Bachelor's degree or higher, with 29% completing a post graduate degree.

Hypothesis 1b. It was hypothesized that sex would be related to outcomes of illness uncertainty, cardiac anxiety, symptom preoccupation, AFib symptoms, AFib disease burden, and healthcare utilization. Analyses of variance (ANOVA) were completed to assess sex differences in illness uncertainty, AFib symptoms, symptom burden, body vigilance, healthcare utilization, and cardiac anxiety. Contrary to hypotheses, no sex differences were found with regard to MUIS, $F(1, 128) = 0.07$, $p = .79$, AFSS-Symptoms, $F(1, 128) = 0.35$, $p = .55$, AFSS-Burden, $F(1, 128) = 1.67$, $p = 0.20$, BVS, $F(1, 119) = 1.02$, $p = .32$, or HCU, $F(1, 128) = 1.84$, $p = .18$. There were also no sex differences in the total cardiac anxiety measure, $F(1, 128) = 0.30$, $p = .59$, or the subscales of fear, $F(1, 128) = 0.23$, $p = .63$, avoidance, $F(1, 128) = 2.36$, $p = .13$, and attention $F(1, 128) = 0.34$, $p = .56$.

Hypothesis 1c. It was hypothesized that age would be associated with illness uncertainty, cardiac anxiety, symptom preoccupation, AFib symptoms, disease burden, and healthcare utilization. Pearsons correlations were run to examine the

relationships between age and illness uncertainty, AFib symptoms, symptom burden, healthcare utilization, body vigilance, and cardiac anxiety. Age was positively associated with MUIS, $r(104) = .43$, $p < .001$, indicating that older participants reported greater illness uncertainty. Age was negatively associated to CAQ-Total, $r(104) = -.56$, $p < .01$, CAQ-Fear, $r(104) = -.56$, $p < .01$, CAQ-Avoidance $r(104) = -.42$, $p < .01$, CAQ-Attention, $r(104) = -.45$, $p < .01$, AFSS-Symptoms, $r(104) = -.43$, $p < .01$, BVS, $r(98) = -.38$, $p < .01$, and HCU, $r(104) = -.37$, $p < .01$. These results indicate that older participants reported less cardiac anxiety, AFib symptoms, body vigilance, and healthcare utilization. Age was not found to be significantly related to symptom burden.

Research Aim 2. Apply Mishel's Uncertainty in Illness model (1988) as a framework to determine the psychosocial adjustment of AFib patients across two conditions. Determine whether patient reported outcomes of illness uncertainty, cardiac anxiety, symptom preoccupation, AFib symptoms, disease burden, and healthcare utilization across conditions lend support for a remedial or iatrogenic effect.

Hypothesis 2a. It was hypothesized that illness uncertainty (MUIS) would differ across conditions. A one-way ANCOVA was run to examine differences in illness uncertainty between participants with and without SDP, while controlling for age and medical risk factors that were found to be unevenly distributed across groups in earlier analyses. As indicated, a composite score of medical risk was derived from aggregating the total count of medical comorbidities and procedures for each participant. Results did not indicate a significant difference in illness uncertainty between groups after accounting for covariates. Means and standard deviations for all variables are reported in Table 5.

Hypothesis 2b. It was hypothesized that cardiac anxiety (CAQ-Total, CAQ-Fear, CAQ-Avoidance, CAQ-Attention) would differ across conditions. An ANCOVA was conducted to assess for differences in cardiac anxiety and subscales across conditions while controlling for covariates of age and medical risk factors. There was a significant between group difference in CAQ-Total, $F(1, 102) = 18.18$, $p < .001$, $\eta^2 = 0.15$, CAQ-Fear, $F(1, 102) = 15.49$, $p < .001$, $\eta^2 = 0.13$, CAQ-Avoidance, $F(1, 102) = 4.04$, $p < .05$, $\eta^2 = 0.04$, and CAQ-Attention, $F(1, 102) = 13.24$, $p < .001$, $\eta^2 = 0.12$. As seen in Figure 1, participants in the SDP group reported higher cardiac anxiety, cardiac fear, cardiac avoidance, and attention to cardiac symptoms relative to those in the Non-SDP group.

Hypothesis 2c. It was hypothesized that symptom preoccupation (BVS) would differ across conditions. An ANCOVA was run to assess for differences in body vigilance between groups while accounting for covariates of age and medical risk factors. No difference in BVS was found between SDP users and non-users.

Hypothesis 2d. It was hypothesized that AFib symptoms (AFSS-Symptoms) would differ across conditions. An ANCOVA was conducted to examine differences in reported AFib symptoms across groups while controlling for covariates of age and medical risk factors. Results did not indicate a significant difference in AFSS-Symptoms between SDP users and non-users.

Hypothesis 2e. It was hypothesized that disease burden (AFSS-Burden) would differ across conditions. An ANCOVA was run to examine differences in symptom burden across conditions while controlling for covariates of age and medical

risk factors. Results did not indicate a significant difference in AFSS-Burden between SDP users and non-users.

Hypothesis 2f. It was hypothesized that healthcare utilization (AFSS-HCU) would differ across conditions. An ANCOVA was run to examine differences in healthcare utilization across conditions while accounting for covariates of age and medical risk factors. A significant difference was found, $F(1, 102) = 5.85$, $p < .05$, $\eta^2 = 0.05$, with participants in the SDP group reporting higher rates of HCU relative to those in the Non-SDP group.

Research Aim 3. Explore the mechanism underlying SDP engagement and psychological functioning. Examine whether uncertainty in illness mediated the relationship between SDP use and five outcome variables.

Hypotheses 3a-e. It was hypothesized that illness uncertainty would mediate the relationship between SDP use and five outcome variables: 3a) cardiac anxiety, 3b) symptom preoccupation, 3c) disease burden, 3d) AFib symptoms, 3e) healthcare utilization. Mediation analyses were planned to explore the relationships between SDP-use, illness uncertainty, and eight psychological outcomes, using PROCESS macro. No multivariate outliers were identified using Mahalanobis and Cook's distance indicators. As with previous analyses, age and medical risk factors were included as covariates in each mediation model. Mediation analyses were not completed as the assumptions for mediation were not met. Specifically, Path A, which examines the relationship between SDP-use and MUIS was not significant, $B = -0.13$, $SE = 0.26$, 95% CI [-0.65, 0.40], $\beta = -0.08$, $p = .62$. There was no association between SDP engagement and illness uncertainty.

Exploratory Analyses

To date, the outbreak of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), otherwise known as coronavirus disease 2019 (COVID-19) has escalated to a global health crisis. Although respiratory distress is the most common presenting symptom, cardiac complications secondary to COVID-19 have also been documented in patients with and without previous heart conditions (Babapoor-Farrokhran et al., 2020). The risk of these complications is elevated in patients with underlying medical conditions (i.e., cardiovascular conditions, hypertension, type 2 diabetes), many of which co-occur with AFib (Centers for Disease Control and Prevention, 2021). Moreover, irregular heart rhythm has been found to be a symptom in moderate to severe cases of COVID-19. In an international sample of patients from Wuhan China, cardiac arrhythmias were present in 17% of those hospitalized and 44% of ICU admits with COVID-19 (Wang et al., 2020). Thus, contraction of the coronavirus may exacerbate existing symptoms of AFib and other cardiovascular conditions.

On March 2020, an amendment was submitted to IRB to include two additional measures to examine the impact of COVID-19 on patient's experiences (COVID-19 and IES-R). A total of 72 subjects completed the extended battery, 55 of which were in the SDP group. Only 58 participants completed the survey prior to COVID-19, of which 10 were in the SDP group. Given the uneven distribution of participants completing the extended measures in each condition, there was not enough power to detect within group response differences (i.e. SDP condition before and after COVID). Post-hoc analyses were run to examine pre- and post- COVID-19 responses when collapsing across groups.

Comparison of Responses Before and After COVID-19

Several independent t-tests were run to examine differences in mean MUIS, AFSS, CAQ, and BVS scores before and after the emergence of COVID-19. Results indicate that MUIS and AFSS-Burden scores did not differ before and after COVID-19. A significant difference was found in CAQ-Total, $t(128) = -5.16$, $p < .001$, $d = 0.91$, suggesting that subjects participating after the pandemic ($M = 2.10$, $SD = 0.69$) reported higher rates of cardiac anxiety relative to those who completed the study prior to the pandemic ($M = 1.53$, $SD = 0.56$). In examining this effect more closely, all three CAQ subscales were elevated in post-COVID-19 participants (CAQ-Fear, $t(128) = -5.02$, $p < .001$, $M_{pre} = 1.54$, $SD_{pre} = 0.57$, $M_{post} = 2.12$, $SD_{post} = 0.74$, $d = 0.86$; CAQ-Avoidance, $t(128) = -3.09$, $p < 0.01$, $M_{pre} = 1.38$, $SD_{pre} = 0.88$, $M_{post} = 1.89$, $SD_{post} = 0.98$, $d = 0.55$; CAQ-Attention, $t(128) = -5.13$, $p < 0.01$, $M_{pre} = 1.65$ $SD_{pre} = 0.71$, $M_{post} = 2.29$, $SD_{post} = 0.71$, $d = 0.91$). Based on a comparison of BVS scores, $t(119) = -4.46$, $p < .001$, $d = 0.81$, results also indicated that post COVID-19 participants ($M = 23.45$, $SD = 7.64$) reported greater vigilance of general bodily symptoms compared to pre-COVID-19 participants ($M = 17.68$, $SD = 6.29$). A significant difference was observed in AFSS-Symptoms, $t(127) = -3.33$, $p < .01$, $d = 0.57$, with post-COVID-19 participants ($M = 21.10$, $SD = 9.35$) reporting greater AFib symptoms than pre-COVID-19 participants ($M = 16.31$, $SD = 7.01$). A significant difference was also found with HCU, $t(128) = -3.02$, $p < .01$, $d = 0.52$. Participants who completed the study after COVID-19 reported higher rates of health care utilization ($M = 7.26$, $SD = 2.53$) relative to those who completed the study prior to COVID-19 ($M = 6.07$, $SD = 1.98$).

Qualitative data on the COVID-19 Measure

A total of 71 participants completed the COVID-19 measure. Of these cases, approximately 63% of respondents indicated that the pandemic did not impact their responses to the survey, 27% affirmed that survey responses were impacted by COVID-19, and 10% reported being unsure. A majority of respondents reported a fair amount of exposure to COVID-19 news (92%), with subjects initiating consumption more than once a day (25%), once a day (32%), and several times (27%) since learning about the pandemic.

Participants were asked to indicate their COVID-19 status. Approximately 7% of respondents reported contracting the virus (3% of active cases at the time of completion), 67% had never contracted the virus, and 25% were unsure (i.e., had not been tested or were awaiting test results). Approximately 47% of participants reported minimal concerns with contracting or re-contracting the virus, 30% endorsed moderate concerns, and 24% indicated elevated concerns. Participants were also asked whether they knew of someone who had tested positive for COVID-19. More than half of participants had known someone who had contracted COVID-19 (56%), 40% denied knowing anyone who has contracted the virus, and 4% were unsure. Known contacts included a family member (8%), friend (19%), colleague (11%), or a distant party that the patient knew of (7%).

Participants were generally concerned about the impact of COVID-19 on health, with 62% reporting increased health related concerns and 38% endorsing minimal concerns. When asked whether participants believed AFib placed them at an increased risk for COVID-19 complications, 64% reported *Yes*, 21% indicated *No*, and the remainder were uncertain. With regard to attention to physical symptoms, less than one-

half reported no change (45%), 37% reported increased attention, and 18% reported reduced attention to physical symptoms.

One third of the sample reported that their lifestyles were minimally impacted by COVID-19 (32%), 32% reported that they were impacted *A fair amount*, and 35% reported they were impacted *A lot* or *A great deal*. To get a better sense of how patients may have been impacted by the coronavirus, participants were asked whether and how they modified their behavior following COVID-19. Approximately 84% of subjects indicated that they had modified their behavior to some extent. Specifically, participants endorsed the following changes: 9% did not attend work/school, 35% minimized/avoided social contact, 35% increased hand-washing, 35% avoided public places, 36% avoided touching one's face, 31% used disinfectants, 33% wore a face mask, 10% consumed herbal supplements or vitamins, and 18% canceled or avoided travel.

Impact of Events Scale – Revised (IES-R)

A total of 44 participants completed the IES-R (M = 37, SD = 22.31). A majority of participants reported elevated scores on the total impact of events scale. Specifically, 59% of subjects produced a score of 33 or greater, which is indicative of clinically significant symptoms of distress. The IES-R also produced the following subscale mean scores: IES-Intrusion M = 1.63, SD = 1.04; IES-Avoidance M = 1.78, SD = 0.99, IES-Hypervigilance M = 1.62, SD = 1.14.

Total IES-R and subscales scores were found to be correlated with COVID-19 status, $t(42) = -5.90$, $p < .001$, $d = 1.78$. Participants who had contracted COVID-19 or were awaiting test results (M = 51.19, SD = 19.52) reported greater symptoms of distress

relative to those who had not (M = 21.46, SD = 12.89). Known contraction in others did not impact IES-R scores.

An unplanned ANOVA was also conducted to explore the relationship between IES-R and patient's reported change in attention to physical symptoms following COVID-19. Results were found to be significant, $F(2, 41) = 8.36$, $p < .01$. Notably, participants reporting less attention and more attention to physical symptoms following COVID-19 endorsed clinically significant distress (IES-R Score $\geq$ 33). Tukey post-hoc analyses revealed that mean IES-Total scores for participants reporting less attention to physical symptoms (M = 54.85, SD = 18.93) was significantly higher than IES-scores for participants reporting no change (M = 24.87, SD = 22.65) and more attention to physical symptoms (M = 35.76, SD = 15.44).

Discussion

With the advent of wearable heart monitoring devices, consumers are now gaining greater access to their personal health information. Although patient autonomy is generally regarded as a favorable outcome of modern technologies, the behavioral and psychological sequelae of smart device platform (SDP) use has yet to be examined. Proponents have argued that wearable heart monitoring devices affords consumers an increased sense of control and assurances regarding the incidence of arrhythmias, which may aid in early intervention and identification of arrhythmias that may otherwise have gone undetected, such as silent AFib or AHRE. Continuous remote heart monitoring systems may also provide feedback about the effectiveness of interventions, such as catheter ablation. Despite these potential benefits, SDP have also garnered concern across members of the scientific community (Mandrola, 2018; Rosman et al., 2020; Sajeev et

al., 2019; Sanna, 2018; Wallace, 2019). For instance, uncertainties may persist with regard to overall health risk and treatment options, particularly for patients who do not represent the “typical” demographic of AFib patients. Continuous feedback may serve as a constant reminder of one’s disease, increasing vigilance to threat cues (Barnard et al., 2014; Pickup et al., 2015; Rashotte et al., 2014). Moreover, anxious consumers may engage in safety behaviors such as frequent checking and unnecessary healthcare utilization as a means mitigate concerns (Rosman et al., 2020). Ultimately, these actions may serve to maintain the pathology of illness anxiety. This study utilized Mishel’s Uncertainty in Illness as a theoretical framework to elucidate the outcomes of SDP use by comparing illness uncertainty, cardiac anxiety, body vigilance, AFib symptoms, symptom burden, and healthcare utilization across AFib patients with and without remote heart monitoring technology.

Overall, the sample was of middle to higher socioeconomic status, as measured by indices of income and educational attainment. The study design required subjects to complete measures online, thereby excluding participants with limited access to a computer, tablet, or reliable internet. The discussion of socioeconomic status would be incomplete without mention of race and ethnicity. Previous research indicates racial disparities across AFib, with greater rates of AFib across non-Latinx White individuals compared to African Americans, Asian-Americans, and Latinx-Americans (Ferdinand & Puckrein, 2015). Despite having a greater number of shared risk factors for stroke and AFib, African Americans have a lower incidence of AFib and a two-fold higher risk for stroke when compared to non-Latinx White individuals (Shen et al., 2010). This may be attributed to a number of factors related to SES, including reduced health literacy, limited

access to health services, and differential delivery of anticoagulant medication (Christian et al., 2003; Gardwood et al., 2010; Meschia et al., 2010; Soliman et al., 2009). Consistent with previous research, the current sample of AFib patients was predominantly White.

Age was associated with illness uncertainty, cardiac anxiety, body vigilance, AFib symptoms, and healthcare utilization. Specifically, older participants reported greater illness uncertainty, and lower rates of cardiac anxiety, body vigilance, AFib symptoms, and healthcare utilization. Previous research indicates that anxiety disorders are generally less common in older adults (Wolitzky-Taylor et al., 2010), however, it was expected that older adults would report greater AFib symptoms and HCU as age has been associated with increasing incidence of AFib and other health complications (Go et al., 2001; Heeringa et al., 2006). Interestingly, younger participants reported greater medical risk factors (i.e., diabetes, heart attack, stent placement) relative to older participants in the current sample. Considering this elevated risk profile, younger participants may report greater cardiac concerns and attention to cardiac symptoms, which would increase AFib symptom count and use of healthcare services. Relatedly, illness uncertainty was inversely associated with medical risk. Individuals with high rates of comorbid medical conditions may be more likely to receive additional care and testing, thereby increasing contact with providers to better understand their chronic conditions and available treatment options.

Participants in the SDP condition were younger and were more likely to hold full-time employment. These findings are consistent with previous research indicating lower ownership of smart devices among older adults (Carroll et al., 2017; Onyeaka et al.,

2021). Despite being younger, participants in the SDP group reported greater risk profile (i.e., diabetes, heart attack, stent placement, balloon angioplasty) than those in the Non-SDP group. It is possible that health complications are emerging earlier in life and/or being detected sooner. In young people (>50 years), AFib can be precipitated by hypertension, hyperthyroidism, and heart disease as well lifestyle factors such as exercise, alcohol, smoking, and diet (Chamberlain et al., 2011; Sankaranarayanan, Kirkwood, Dibb, & Garratt, 2013). Obesity in children and young adults has risen dramatically in recent decades, along with associated adverse health outcomes of diabetes, hyperlipidemia, and cardiovascular disease (Centers for Disease Control and Prevention, n.d.). Overconsumption of alcohol, a practice that is common in young people, increases the risk of AFib by 37% (Djoussé et al., 2004). These findings illustrate the trend of health complications emerging earlier in life due to poor lifestyle patterns. An alternative interpretation of the study results is that younger participants with known health problems may be more motivated to purchase SDP in attempts to monitor and assume greater control of their overall health. Wearable smart devices may also alert consumers to arrythmias that may otherwise have gone undetected, possibly identifying a subset of younger AFib patients. Both age and medical risk were controlled for in subsequent between-group comparisons.

Results partially supported the iatrogenic effect of wearable heart monitoring technology, as evidenced by enhanced cardiac anxiety (fear, avoidance, attention) and healthcare utilization in the SDP group, even after accounting for age and medical risk. Participants in the SDP group reported increased fear, attention, and avoidance of activities that elicit cardiac symptoms. Fear may interact with vigilance for cardiac

symptoms in a positive feedback loop, whereby increased monitoring is employed to mitigate health related concerns though has the unintended effect of enhancing symptoms, thus increasing cause for concern. Despite increased cardiac attention, fear, and avoidance in SDP users, there were no between group differences in body vigilance. The BVS measured vigilance of general bodily symptoms which may not be specific enough to capture attention to symptoms relevant for AFib patients. Interestingly, participants in the SDP condition did not report any more AFib symptoms or symptom burden than those in the control. Symptom inflation may be corrected by SDP, which provides direct feedback about the incidence of arrhythmias. Symptom burden may also be ameliorated by active attempts of SDP users to minimize AFib symptoms by avoiding activities that would typically elicit cardiac symptoms. Avoidance may result from beliefs about the risk of overexertion. Patients with smart devices will likely benefit from additional information regarding the advantages of physical activity from providers and explicit instruction of activities that are contraindicative for their conditions. Moreover, the smart devices can increase engagement by setting specific activity goals for AFib patients, based on provider recommendations, and providing feedback on progress. Relatedly, consumers can set alerts on their watch to notify medication times, thus increasing adherence.

Once consumers record ECG tracings, they are provided with opportunities to engage with healthcare services. In the current sample, a majority of SDP users indicated that they had transmitted data for further analysis at least once, and on average 44% of the time. Moreover, after receiving ECG results, participants reported scheduling a healthcare visit half the time. These results contrast those found in the REHEARSE-AF

study, in which AFib patients monitored by Kardia devices reported that they were less likely to schedule a follow up visit with a physician (Halcox et al., 2017). Notably, when assessing patient's actual rather than intended use of healthcare services, findings were consistent with previous research indicating increased unexpected visits in AFib patients with implantable devices (Klersy, et al, 2016). What remains unknown is the impact of increased HCU. Do these additional visits/contacts ameliorate patient concerns more than they otherwise would if patients did not receive feedback on remote heart monitoring devices? To what extent does increased HCU benefit health outcomes of patients with AFib? These are important considerations of future research.

Contrary to expectations, patients with SDP did not differ in illness uncertainty relative to those without SDP. Moreover, SDP engagement was not associated with illness uncertainty after accounting for age and medical risk factors. Though it is unclear why these findings emerged, the relationship between SDP use and illness uncertainty may not be as linear or clear-cut as it was originally conceptualized to be. For instance, SDP may enhance illness uncertainty in a subset of users but diminish uncertainty for others. Many individuals are prone to mobilize strategies such as information seeking to reduce uncertainties (Afifi & Weiner, 2004). Although, individuals may also deliberately avoid additional information in self-protection, if the state of uncertainty is preferred over certain threat (Mishel, 1990). In this study, participants who endorsed diminished attention to bodily symptoms following the pandemic also reported higher rates of distress. Avoidance of stress-associated cues (i.e., bodily symptoms, COVID-19 news) is a feature of post-traumatic stress (APA, 2013), and participants may be engaging in avoidance as a way to manage their heightened distress. The current study did not

identify potential moderating factors such as pre-existing anxieties and coping strategies (i.e., monitoring and blunting), which may be an avenue of future research.

The results of this study should also be interpreted in light of a number of limitations. First, the study design limits interpretations of causality. The use of heart rhythm monitoring systems may promote or maintain cardiac anxiety, particularly in individuals who are predisposed to anxiety. Indeed, one recent case study illustrated the onset of illness anxiety in a newly diagnosed AFib patient (Rosman et al., 2020). Despite sinus rhythm feedback from smartwatch and assurance from specialists, the patient continued to exhibit heightened concern and perseverated on checking behaviors. The patient excessively recorded ECG tracings and would even assume threat in innocuous feedback results, leading to increased clinic visits and contact with providers (Rosman et al., 2020). In contrast, it is also plausible that features on the smart devices are more appealing to individuals with elevated cardiac anxiety. Due to the cross-sectional design of the study, the direction of causality between cardiac anxiety and SDP use cannot be determined, nor can it be assumed to be one-directional; Individuals with elevated cardiac anxiety may be more inclined to purchase heart monitoring devices, and increasing use of ECG may further enhance heart related concerns in a positive feedback loop. Future research may explore this relationship more closely by examining the temporal sequence of cardiac anxiety before and after SDP use in an experimental within-subjects paradigm. Next, the online collection method confers a degree of risk for low quality data. Conservative screening methods were used to address this issue post-hoc, though this could have been better addressed by implementing a number of screening methods prior to the collection process. Relatedly, the current study employed a relatively small sample

size, which may limit the statistical power and increase the rate of Type II errors. Despite this, the findings of the current study are an entrée to discussions of SDP patient outcomes. Nevertheless, the literature would benefit from a replication of this study with a larger sample size. Lastly, the results of the current study are complicated by the emergence of the global pandemic, COVID-19. A majority of subjects who completed the measures after the pandemic fell in the SDP group. Thus, it is difficult to ascertain whether increased healthcare utilization is a function of SDP use alone, or resulted from increased health-related concerns due to COVID-19, especially when considering that SDP users reported more medical risk factors. Similarly, cardiac anxiety was found to be higher in participants completing study measures after COVID-19, which may explain significant group differences in CAQ total and subscale scores between the SDP and non-SDP groups.

Conclusion

This is the first known study to examine the psychological and behavioral outcomes of consumer remote heart monitoring devices in AFib patients. This is an important area of research given the espousal of SDP in an increasingly technology-centric world and acceleration of digital healthcare in modern medicine. Care should be taken not to compromise quality for convenience, especially with the exponential growth of telehealth services which has been an unexpected outcome of the current pandemic. On one hand, telepsychology may enable patients to generalize and practice skills in various domains (i.e., home, school, work). Moreover, patients living in rural areas will have greater access to treatment. On the other hand, telehealth may be a disservice to patients with agoraphobia, robbing them of opportunities to challenge the belief that

home is the only “safe” space, and patients with body dysmorphia, who may turn off their cameras for fear of offending others and would otherwise receive feedback that would contradict these beliefs. To the extent that support and assurance ease distress, the overuse of telepsychology may preclude patients from identifying alternative strategies to manage difficult emotions, thus maintaining pathology. More information is necessary to evaluate the costs and benefits of increased healthcare utilization in the context of cardiac anxiety in AFib patients. Although the findings of this study are confounded by the emergence of COVID-19, it remains that health complications are emerging earlier in life, and with it, a population of younger adults in need of effective psychological and medical care. As we look ahead to the future, it is incumbent on healthcare providers to identify solutions and mobilize technologies responsibly to promote patient care.

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Table 1

Independent and Dependent Variable Descriptive Statistics

Measures	N	Mean	SD	Min	Max	Skewness	Kurtosis
Uncertainty in Illness	130	77.61	14.65	43.0	111.0	0.23	-0.66
Cardiac Anxiety Total	130	1.85	0.69	0.4	3.5	0.32	-0.34
Cardiac Fear	130	1.86	0.73	0.6	3.5	0.56	-0.44
Cardiac Avoidance	130	1.66	0.97	0.0	3.6	-0.03	-0.94
Cardiac Attention	130	2.01	0.78	0.0	3.6	-0.44	-0.04
Body Vigilance	121	20.88	7.60	2.3	45.4	0.29	0.51
Atrial Fibrillation Severity Scale							
AFib Symptoms	130	18.96	8.69	7.0	39.0	0.50	-0.61
Symptom Burden	130	17.09	5.33	3.0	30.0	-0.24	-0.16
Healthcare Utilization	130	6.73	2.37	3.0	15.0	0.87	0.59
SDP Use	65	3.66	1.04	1.4	5.2	-0.41	-0.83

Note. Uncertainty in Illness = MUIS Total Score; Cardiac Anxiety Total = CAQ Total Score; Cardiac Fear = CAQ-Fear Score; Cardiac Avoidance = CAQ-Avoidance Score; Cardiac Attention = CAQ-Attention Score; Body Vigilance = BVS Total score; Atrial Fibrillation Severity Scale = AFSS; AFib Symptoms = AFSS Symptom Score; Symptom Burden = AFSS Burden Score; Healthcare Utilization = AFSS HCU Score; SDP = Smart Device Platform

Table 2

Descriptive Statistics and Correlation Coefficients for Study Variables

Variable	1	2	3	4	5	6	7	8	9
1. BV	-	.099	-.205	-.035	.365**	.570**	-.021	.305*	.003
2. HCU	.377**	-	.107	.159	.124	.054	.235	.009	-.051
3. BURDEN	.340**	.341**	-	.244*	.098	-.009	.167	.071	-.125
4. AF SYMPTOM	.377**	.267*	.364**	-	.568**	.371**	.514**	.447**	-.583**
5. CAQ-TOTAL	.554**	.421**	.243	.607**	-	.736**	.757**	.849**	-.490**
6. CAQ-ATTN	.532**	.293*	.169	.377**	.723**	-	.283*	.464**	-.258*
7. CAQ-AVOID	.391**	.401**	.206	.611**	.809**	.336**	-	.497**	-.425**
8. CAQ-FEAR	.483**	.342**	.217	.488**	.918**	.625**	.581**	-	-.458**
9. MUIS	-.251	-.197	-.299*	-.637**	-.498**	-.303*	-.478**	-.423**	-

Note. Correlations for control (non-SDP group) are presented above the dashes whereas correlations for SDP group are presented below. Key: BV – Body Vigilance Scale; HCU – Atrial Fibrillation Severity Scale Health Care Utilization; BURDEN – Atrial Fibrillation Severity Scale Symptom Burden; CAQ-TOTAL – Cardiac Anxiety Questionnaire Total Score; CAQ-ATTN – Cardiac Anxiety Questionnaire Attention Score; CAQ-AVOID – Cardiac Anxiety Questionnaire Avoidance Score; CAQ-FEAR – Cardiac Anxiety Questionnaire Fear Score; MUIS – Mishel's Uncertainty in Illness Scale Score

* $p < 0.05$; ** $p < 0.01$; ($N = 130$)

Table 3

Demographic Descriptive Statistics by Condition

Demographics	Control (*n* = 65)	SDP group (*n* = 65)
	n (%)	*n* (%)
Sex		
Female	28 (43.1)	28 (43.1)
Male	37 (56.9)	37 (56.9)
Race		
American Indian/Alaska Native	1 (1.5)	1 (1.5)
Asian/Asian American	-	4 (6.2)
Black/African American	1 (1.5)	4 (6.2)
White (non-Latinx)	61 (93.8)	54 (83.1)
Latinx	-	2 (3.1)
Other	2 (3.1)	-
Education		
Less than high school	2 (3.1)	3 (4.6)
High school or GED	11 (16.9)	4 (7.7)
Vocational/Trade school	-	2 (3.1)
Associates Degree	8 (12.3)	2 (3.1)
Bachelor's Degree	22 (33.8)	38 (58.5)
Graduate Degree	22 (33.8)	15 (23.1)
Income		
Less than $15,000	1 (1.5)	2 (3.3)

$15,001 - $30,000	4 (6.2)	8 (13.1)
Demographics	Control (*n* = 65)	SDP group (*n* = 65)
	n (%)	*n* (%)
Income		
$30,001 - $45,000	10 (15.4)	3 (4.9)
$45,001 - $60,000	10 (15.4)	18 (29.5)
$60,001 - $75,000	6 (9.2)	4 (6.6)
Over $75,000	34 (52.3)	26 (42.6)
Employment		
Full-time	8 (12.3)	43 (66.2)
Part-time	4 (6.2)	7 (10.8)
Home-maker	3 (4.6)	-
Unemployed	1 (1.5)	-
Disability	3 (4.6)	-
Retired	46 (70.8)	14 (21.5)
Student	-	1 (1.5)
Marital Status		
Never married/Single	10 (15.4)	13 (20)
Married	45 (69.2)	48 (73.8)
Divorced	7 (10.8)	2 (3.1)
Separated	-	1 (1.5)
Widowed	3 (4.6)	1 (1.5)
Religion		

Jewish	5 (7.7)	3 (4.7)
Demographics	Control (*n* = 65)	SDP group (*n* = 65)
	n (%)	*n* (%)
Religion		
Catholic	8 (12.3)	32 (50)
Protestant Christian	25 (38.5)	9 (14.1)
Muslim	-	1 (1.6)
No affiliation	22 (33.8)	12 (18.8)
Other	5 (7.7)	7 (10.9)

Note. SDP = Smart Device Platform

Table 4

Health Information Descriptive Statistics by Condition

Medical Information	Control (*n* = 65)	SDP group (*n* = 65)
AFib Classification		
Paroxysmal	26 (54.2)	36 (57.1)
Persistent	12 (25.0)	18 (28.6)
Permanent	7 (14.6)	7 (11.1)
Unsure	3 (6.3)	2 (3.2)
Medical Comorbidities/Procedures		
Diabetes	6 (9.5)	26 (56.3)
Hypertension	39 (60.0)	36 (56.3)
Obesity	26 (41.3)	30 (46.2)
Hyperlipidemia	29 (46.0)	30 (46.2)
Heart Attack	1 (1.5)	7 (10.8)
Stroke	8 (12.5)	16 (25.0)
Stent	4 (6.2)	20 (30.8)
CABG	0 (0.0)	15 (23.1)
Balloon Angioplasty	1 (1.5)	15 (24.6)
Cardiac Catheter	17 (28.3)	27 (41.5)
ICD	2 (3.2)	21 (32.3)
ILR	5 (7.7)	18 (27.7)

Note. CABG = Coronary Artery Bypass Grafting; ICD = Implantable Cardioverter Defibrillator;

ILR = Implantable Loop Recorder

Table 5

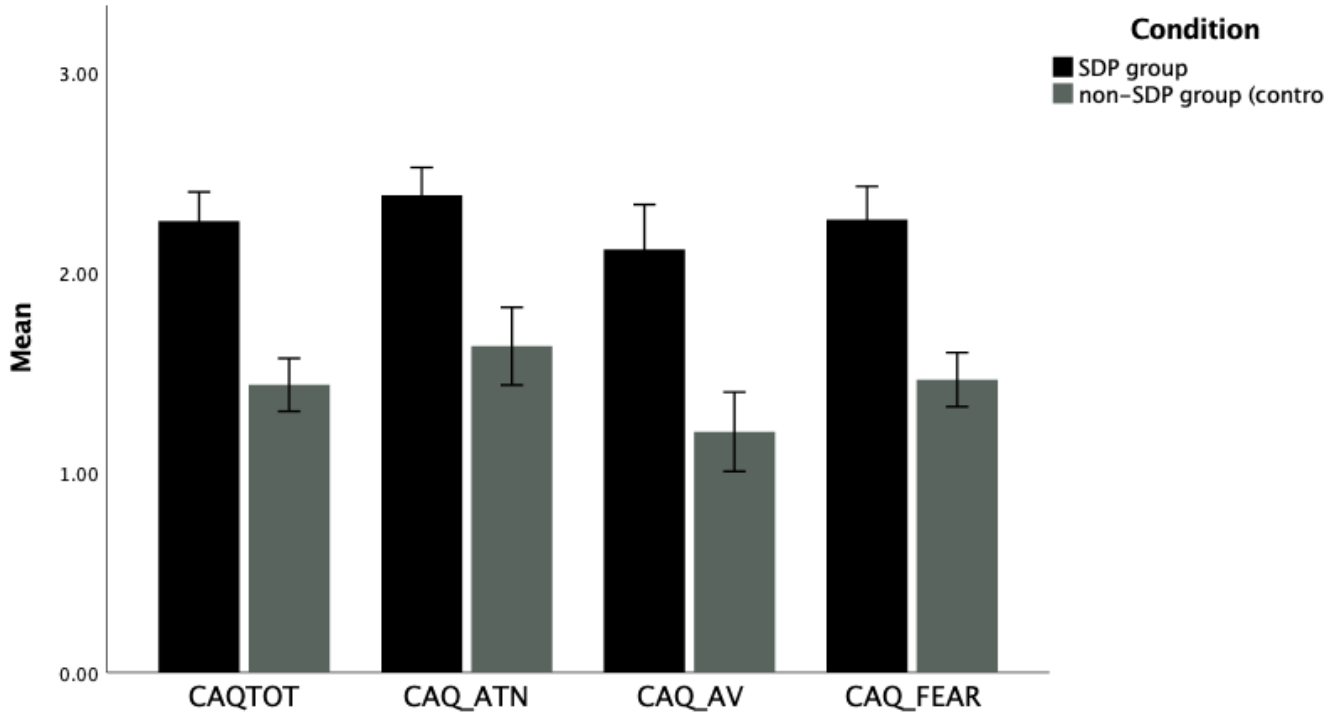
Means and Standard Deviations of Measures

	Control (*n* = 65)		SDP group (*n* = 65)	
Variable	Mean	SD	Mean	SD
Uncertainty in Illness	82.65	15.00	72.57	12.49
Cardiac Anxiety Total	1.44	0.53	2.26	0.59
Cardiac Fear	1.46	0.55	2.26	0.67
Cardiac Avoidance	1.20	0.80	2.11	0.90
Cardiac Attention	1.63	0.78	2.38	0.56
Body Vigilance	18.59	7.38	23.20	7.17
Atrial Fibrillation Severity Scale				
AFib Symptoms	15.40	7.28	22.52	8.57
Symptom Burden	16.88	5.89	17.30	4.74
Healthcare Utilization	5.68	1.86	7.78	2.36
SDP Use	-	-	3.66	1.04

Note. Uncertainty in Illness = MUIS Total Score; Cardiac Anxiety Total = CAQ Total Score; Cardiac Fear = CAQ-Fear Score; Cardiac Avoidance = CAQ-Avoidance Score; Cardiac Attention = CAQ-Attention Score; Body Vigilance = BVS Total score; Atrial Fibrillation Severity Scale = AFSS; AFib Symptoms = AFSS Symptom Score; Symptom Burden = AFSS Burden Score; Healthcare Utilization = AFSS HCU Score; SDP = Smart Device Platform

Figure 1

Cardiac Anxiety across Conditions



Note. Error bars are 95% Confidence Interval.

CAQTOT = Cardiac Anxiety Questionnaire Total Score; CAQ_ATN = Cardiac Anxiety Questionnaire Attention Score; CAQ_AV = Cardiac Anxiety Questionnaire Avoidance Score; CAQ_FEAR = Cardiac Anxiety Questionnaire Fear Score; SDP = Smart Device Platform

n = 65 for each group; N = 130