# PSYCHOLOGICAL WELL-BEING AND HEALTH-RELATED QUALITY OF LIFE FOLLOWING VENTRICULAR TACHYCARDIA ABLATION, A PROSPECTIVE STUDY

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## Abstract

Ventricular tachycardia (VT) is a debilitating and potentially fatal cardiac arrhythmia. Implantable cardioverter defibrillators (ICD) are first-line therapy for treatment of VT. However, ICD shocks can have a profound impact on psychological well-being and health-related quality of life (HRQoL). Catheter ablation of VT is a novel procedure intended to reduce VT recurrence, medication use, and ICD shocks. To-date, there is a paucity of research examining psychological well-being and HRQoL in ICD recipients undergoing VT ablation.

This case-control prospective study aimed to 1) examine predictors of post-traumatic stress disorder (PTSD) symptoms, and symptoms of anxiety, and depression in ICD recipients following VT ablation and 2) evaluate whether VT ablation is associated with greater improvement in HRQoL, and symptoms of anxiety, depression, and PTSD. Hypothesis 1 assessed whether higher optimism, self-efficacy, and positive health expectations at baseline predict improvement in symptoms of PTSD, anxiety, and depression at six-month follow-up. Hypothesis 2 tested whether HRQoL, depression, anxiety, and PTSD symptoms improve more over six-month follow-up in ICD recipients who underwent VT ablation as compared to ICD recipients who did not. Measures of PTSD, anxiety, depression, and HRQoL were administered at baseline and follow-up. Measures of optimism, positive health expectations, and self-efficacy were administered at baseline. Hierarchical regression analyses were employed to assess the hypotheses.

Results of Hypothesis 1 showed that higher self-efficacy at baseline predicts improvement in symptoms of anxiety and PTSD at follow-up, over and above group membership. Contrary to hypothesis, optimism and positive health expectations did not predict improvement in psychological well-being. Contrary to Hypothesis 2, between-group differences

were not detected on HRQoL, symptoms of anxiety, depression, or PTSD symptoms. However, ICD participants who underwent VT ablation showed improvement in mental health HRQoL and symptoms of PTSD, while control participants showed improvement in domains of anxiety and PTSD.

These findings lend support to the protective function of self-efficacy, particularly with respect to anxiety-based outcomes. HRQoL benefits of VT ablation were not detected, although the pattern of within group improvements hint at potential benefits related to anxiety and trauma symptoms.

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Ventricular tachycardia (VT) is a debilitating and potentially fatal cardiac arrhythmia. In patients with structural heart disease, the majority of sustained VTs originate in the scar tissue of the heart which might be congenital or caused by a prior myocardial infarction (MI; Al-Khatib et al., 2018; Aliot et al., 2009). Presence of a myocardial scar is more likely to be associated with poor tolerance of VT, devolvement of the arrhythmia into ventricular fibrillation, and sudden death (Peachey et al., 2014). Thus, individuals with structural heart disease can be a particularly vulnerable population of cardiac patients whose health and psychological functioning may be profoundly affected by the burden of malignant arrhythmias.

The implantable cardioverter defibrillator (ICD) is the first line of treatment for patients at risk for sudden cardiac death and for most patients with structural heart disease and sustained VT (Russo et al., 2013). The ICD restores normal heart function upon detecting an abnormal heart rhythm. It does so by delivering precisely timed pulses, antitachycardia pacing (ATP), or an electrical shock to the heart muscle. Crucially, while the ICD can effectively terminate the malignant arrhythmia it does not prevent VT from recurring (De Ponti, 2011; Liang, Santangeli, & Callans, 2015). Studies have shown benefits of the ICD on longevity (Buxton et al., 1999; Moss et al., 2002). Despite its life saving benefits, ICD therapy, specifically shocks, is associated with increased morbidity. The psychological impact of having an ICD and of receiving shocks has also been studied extensively. Many ICD recipients experience fear, anxiety, and diminished quality of life in relation to shock therapy (Epstein et al., 2008; Redhead, Turkington, Rao, Tynan, & Bourke, 2010), often likened to being kicked by a horse in the chest (Ahmad, Bloomstein, Roelke, Bernstein, & Parsonnet, 2000; Burke, Hallas, Clark-Carter, White, & Connelly, 2003). It can be anxiety-inducing and frigthening as shocks are typically painful, unpredictable, and uncontrollable (Porterfield, Porterfield, Bray, & Sugalski, 1991). ICD

recpients who receive shocks have generally been found to report higher anxiety levels that those who have not received shocks (Carroll & Hamilton, 2005; Herrmann et al., 1997; Luderitz, Jung, Deister, Marneros, & Manz, 1993; Magyar-Russell et al., 2011; Redhead et al., 2010). The prevalence of anxiety and depression disorders is approximately 20% in ICD recipients irrespective of whether they received shocks or not (Magyar-Russell et al., 2011). Moreover, surviving a cardiac arrest or receiving ICD shocks has been recognized as a possible traumatic stressor and even meets Criterion A in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) for post-traumatic stress disorder (PTSD; Ladwig et al., 2008). A recent systematic review argues that acute cardiac events also meet Criterion A in the DSM-5 (American Psychiatric Association, 2013). ICD recipients live with a constant and internal reminder of the precariousness of their health. It is thus not surprising that this group of patients may be prone to experiencing trauma symptoms (Hamner, Hunt, Gee, Garrell, & Monroe, 1999) with prevalence rates of PTSD ranging from 7.6 to 30% irrespective of shocks (Vilchinsky, Ginzburg, Fait, & Foa, 2017). In this population, PTSD can be enduring and impact well-being over extended time (Kapa et al., 2010). PTSD has serious implications as it has been associated with more anxiety, depression, and cardiac symptoms as well as increased mortality risk independent of disease severity, anxiety, and depression (Ladwig et al., 2008).

Health-related quality of life (HRQoL) has also been assessed in ICD recipients compared to VT patients treated with antiarrhythmic therapy alone. Findings vary with some studies reporting better HRQoL in ICD recipients (Irvine et al., 2002) with others observing no differences or similar trends between groups (Noyes et al., 2007; Passman et al., 2007; Schron et al., 2002). ICD shock, especially more than five shocks, has more consistently been shown to be associated with emotional distress and poorer HRQoL, physical and mental well-being (Carroll

& Hamilton, 2005; Irvine et al., 2002; Mark et al., 2008; Noyes et al., 2009; Passman et al., 2007; Schron et al., 2002). ICD shocks have also been associated with increased mortality, although this may be a function of deteriorating or advanced cardiac disease rather than shocks per se (Peachey et al., 2014; Wilkoff et al., 2016). In summary, although the ICD can be life-saving, it does not prevent VT recurrence and its therapies can have a profound impact on psychological well-being.

Antiarrhythmic medications are utilized as a form of suppressive therapy in adjunct to the ICD or as a stand-alone intervention. Escalated medical treatment (i.e., revision and increase in the use of antiarrhythmics) is often used when there is recurrence of VT. However, despite successes in reducing VT occurrence and shocks, the use of amiodarone, a potent antiarrhythmic, has been associated with adverse side-effects (Al-Khatib et al., 2018; Connolly et al., 2006) and decreased HRQoL (Schron et al., 2002). Thus, side-effects of medication and drawbacks of the ICD prompted the development of innovative approaches with fewer negative effects.

Catheter ablation of VT is one such novel and moderately invasive procedure that can reduce VT recurrence, medication use, and ICD shocks (Liang et al., 2015). This procedure involves delivering radiofrequency energy from the catheter to the heart tissue, creating a burn, which can disrupt the malignant VT. The advancement of technology and the understanding of VT etiology make it particularly appealing as it is generally safe and efficacious (Liang et al., 2015; Viana-Tejedor et al., 2010). There is a consensus amongst experts that VT ablation is recommended when there is VT recurrence, multiple shocks due to sustained VT, or VT storms that are not managed by reprogramming the ICD or by administering antiarrhythmic medications (Aliot et al., 2009; Dagres et al., 2012; Peachey et al., 2014; Zeppenfeld, 2012). Prophylactic VT ablation in unshocked ICD patients has also demonstrated benefit (Kuck, 2009; Kuck et al.,

2010; Reddy et al., 2007). Thus, in patients with scar-related VT, VT ablation is frequently utilized in conjunction with an ICD and/or antiarrhythmic drug treatment (Aliot et al., 2009). Randomized controlled trials (RCT) of VT ablation have reported a lower composite primary outcome of death, VT storms, appropriate ICD shocks and ICD therapy overall (Kuck et al., 2010; Reddy et al., 2007; Sapp et al., 2016).

There is, however, paucity of research examining HRQoL and psychological factors in ICD recipients undergoing VT ablation. Only a few studies examined HRQoL and, to the best of our knowledge, none has thoroughly examined constructs of PTSD, depression, and anxiety, nor the potential protective factors such as self-efficacy or optimism. Studies comparing HRQoL between ICD patients treated by VT ablation versus medication alone have not typically found between-group differences (Gula et al., 2018; Kuck et al., 2010). However benefits within the ablation group have been detected, which suggest improvement in HRQoL after a successful ablation but not an unsuccessful one (Strickberger et al., 1997), as well as improvement in some specific domains of HRQoL (Gula et al., 2018; Kuck et al., 2010). Confidence in these findings is limited by several factors including low sample size, lack of control group, and advancements in ICD technology and VT ablations since study publication (Strickberger et al., 1997). Additionally, low response rates to the HRQoL questionnaire and recruitment of participants who experienced a first episode of stable VT rather than a more serious event such as cardiac arrest or shocks might make it more difficult to detect benefits of the ablation (Kuck et al., 2010). Lastly, smaller sample size and attrition rates can compromise confidence in the above findings (Gula et al., 2018). Taken together, findings from these studies are inconclusive but provide some suggestion for the benefit of ablation therapy on HRQoL in this cardiac population.

With regard to psychological outcomes, a secondary aim of a recent RCT (Ventricular Tachycardia Ablation versus Escalated Antiarrhythmic Drug Therapy in Ischaemic Heart Disease – VANISH; Gula et al., 2018; Sapp et al., 2016) substudy was to assess symptoms of anxiety and depression. Results (that were published well after the present study was underway) did not observe changes over time (Gula et al., 2018). While this is an important RCT to consider it did not assess PTSD or the composite scores of physical and mental health HRQoL. Further, trauma symptoms are understudied although a case report suggested that an ICD patient who received numerous shocks and met criteria for PTSD showed improvement in trauma symptoms following VT ablation (Maryniak et al., 2006).

Thus, while psychological outcomes and HRQoL have been studied in ICD patients, there is a paucity of such data regarding ICD patients undergoing a VT ablation. Moreover, while factors such as ICD shocks and the associated impact upon psychological well-being have been studied, resilience factors are also important to examine in this group of patients. Factors such as optimism, health expectations, and self-efficacy can have a role in buffering or mitigating the stress of ICD therapy in a group of patients experiencing high VT burden. Optimism and health expectations can help enhance patients' ability to experience better health outcomes (Sears et al., 2004). They can do so by facilitating healthy behavioural practices, such as adherence and exercise, and providing a sense of coping and some sense of control over the unpredictability of shocks (Sears et al., 2004). Similarly, coping self-efficacy can affect well-being through beliefs in one's ability to exercise the behaviours needed to manage a given stressful situation such as arrhythmia events or ICD therapy. Having some sense of control in a largely uncrontrollable situation can help enhance one's agency and well-being (Bandura, 1997). With the growing rate of VT ablation procedures in ICD recipients, it is imperative to explore the

psychological correlates in this population as a way of optimizing patient care. The objectives of this dissertation were two-fold: 1) to examine psychological predictors of anxiety, depression, and PTSD outcomes in ICD patients undergoing VT ablation therapy, and 2) to explore whether VT ablation predicts HRQoL outcome. Background literature and the rationale for these objectives are reviewed below.

**Literature review of VT interventions and study variables**

To-date, research in ICD patients has primarily focused on assessing classical domains of psychosocial functioning such as PTSD, depression, anxiety, and HRQoL. Much of this research has focused on the psychological and HRQoL effects of ICD shocks. It is important, therefore, to review and draw upon some of this literature, as well as review the ICD device and the VT ablation procedure, when generating hypotheses for the present study especially as catheter ablation of VT is meant to ameliorate VT burden.

**The ICD: an overview.** Since the first implant in 1980, the ICD has evolved to become the first line of treatment for patients at risk for, or who had received, life-threatening arrhythmias. Initially large and heavy, the ICD required a thoracotomy for implantation and was associated with morbidity and mortality and frequent inappropriate shocks (van Welsenes et al., 2011). Current devices are significantly smaller and implanted subcutaneously. The ICD comprises a pulse generator and leads which serve to monitor heart function, capture data, and store and deliver ICD therapy in the form of ATP or shocks. Therapies are deemed appropriate when they are delivered in response to a sustained ventricular arrhythmia, either VT or ventricular fibrillation. Conversely, they are deemed inappropriate when their delivery is caused by something other than a ventricular arrhythmia, for example a supraventricular rhythm or dislodgement of an ICD lead (Wilkoff et al., 2016). Third-generation ICDs have an improved

ability to discriminate between VTs and supraventricular tachycardias thereby reducing incidence of inappropriate shocks (Wilkoff et al., 2016). The ICD can also be programmed in such a way as to minimize the occurrence of shocks while appropriately treating the tachycardia. Specifically, it can be programmed into zones where detection of the parameters for the arrhythmia are defined as well as the sequence of therapies to be delivered. For example, algorithms can allow VTs to self-terminate without requiring ICD therapy thus reducing inappropriate therapy, or deliver bursts of ATP prior to delivering a shock (Wilkoff et al., 2016). Secondary prevention ICDs are implanted in patients who survived one or more cardiac arrests or had sustained VTs. Primary prevention ICDs are implanted in individuals at risk for, but who have not experienced, a cardiac arrest or sustained ventricular arrhythmia (Russo et al., 2013). Large-scale clinical trials supported the use of the ICD in secondary prevention and demonstrated significant (The Antiarrhythmics versus Implantable Cardioverter Defibrillators [AVID] Investigators, 1997) and non-significant (Connolly et al., 2000) reductions in mortality as compared to patients on pharmacological therapy alone (e.g., amiodarone therapy). Implantation of the ICD for primary prevention also gained support through large scale trials which showed a reduction in mortality in ICD recipients (Buxton et al., 1999; Moss et al., 2002). Taken together, the goal of the ICD is to extend life, however morbidity plays a prominent role and ICD therapies are associated with adverse outcomes. While ICD shocks can be painful and distressing whereas ATP therapies are typically not, both therapies can be associated with emotional distress, syncope, and palpitations (Wilkoff et al., 2016).

**Catheter ablation for ventricular tachycardia: an overview.** Most patients with VT associated with structural heart disease have a standard indication for ICD therapy as a mode of treatment (Al-Khatib et al., 2018; Aliot et al., 2009). A consensus statement by the European

Heart Rhythm Association and the Heart Rhythm Society recommends VT ablation when antiarrhythmic therapy fails to prevent recurrent VT in ICD recipients (Aliot et al., 2009). Even when the targeted VTs are successfully ablated the ICD remains an important intervention because of the elevated risk for VT recurrence (Aliot et al., 2009; Al-Khatib et al., 2018). Ablation of VT can reduce appropriate ICD shocks in patients with ischemic cardiomyopathy (Reddy et al., 2007) and early ablation has been suggested to provide significant VT free survival after one year and good arrhythmia control (Frankel et al., 2011).

Catheter ablation of VT is a moderately invasive procedure, performed by a trained electrophysiologist, a cardiologist with a specialisation in heart rhythm disorders and the electrical system of the heart. During an electrophysiology study, which typically precedes the ablation, an assessment of VT morphologies is conducted in order to identify areas in the heart where the abnormal heart rhythm originates. During the actual ablation procedure, mapping strategies help identify target areas to be ablated. These areas can range in complexity and may be small and narrow allowing discrete application of radio-frequency energy or broad, requiring larger areas of the tissue to be ablated (Aliot et al., 2009). Various mapping techniques are utilized but perhaps the most common are activation and substrate mapping or a combination of the two. When VT is inducible and hemodynamically tolerated, activation mapping is typically used to identify the re-entry circuits and channels and ablate the VT (Aliot et al., 2009; Kumar et al., 2016). When VT is not inducible or there is haemodynamic instability substrate mapping, performed during sinus or paced rhythm, helps identify areas of low voltage consistent with the scar (i.e., VT substrate) which are then ablated (Aliot et al., 2009; Kumar et al., 2016). Since the ICD can sense electrical stimulation and the current, it must be reprogrammed prior to the ablation so that it prevents delivery of ATP (Aliot et al., 2009).

In order to curtail the pain, anxiety, and awareness related to mapping and ablation, varying degrees of sedation or analgesia are administered and may range from minimal to deep sedation or general anaesthesia (Aliot et al., 2009). Because VT ablation is often performed in individuals with advanced heart disease, it can be associated with complications, which occur intraoperatively in about 11% of patients (Yu et al., 2015). Ablation endpoints used to determine success include: 1) non-inducibility of clinical (spontaneous) VT, 2) modification of the induced VT cycle length, and 3) non-inducibility of any VT (Aliot et al., 2009).

Several large RCTs provide support for the use of ablation over escalated anti-arrhythmic therapy in patients with ischemic heart disease, namely a reduction in incidence of shocks and survival which is free from occurrence of VT in the ablation groups (Kuck et al., 2010; Reddy et al., 2007; Sapp et al., 2016). A recent large RCT reported that, as compared to individuals on escalated antiarrhythmic therapy, ablation patients had a lower composite primary outcome of death, VT storms, or appropriate shocks (Sapp et al., 2016). This lent support for the use of VT ablation over escalated antiarrhythmic therapy for purposes of reducing VT in ICD patients with ischemic heart disease. However, the authors emphasized that these patients are a high risk group in which more than half continued to have recurrent VT and over a quarter died despite treatment (Sapp et al., 2016). Another seminal study (Reddy et al., 2007) reported that at two-year follow-up, prophylactic ablation reduced incidence of ICD therapy in secondary prevention ICD recipients (12% vs. 33% in the ablation and control group, respectively). ICD storm occurrences were significantly fewer in ablation patients (6%) compared with control patients (19%). Patients in the ablation group had a 65% reduction in the risk of receiving ICD therapy during the two year follow-up and a 73% chance reduction of receiving shocks. The third seminal RCT examined prophylactic ablation in secondary prevention ICD recipients (Kuck et al., 2010).

Patients were randomized to receive catheter ablation followed by an ICD implant (intervention group) or to receive an ICD implant alone (control group). After two years of follow-up, survival free from VT favoured catheter ablation (hazard ratio: 0.61) and a reduction in the incidence of ICD shocks by 43% (Kuck et al., 2010). Lastly, a small study included 32 ICD recipients with a history of electrical storms (three or more distinct episodes of sustained ventricular arrhythmia within 24 hours which trigger ICD treatment) who underwent VT ablation (Deneke et al., 2011). Ablation successfully suppressed VT with 31% of patients with recurrence of sustained ventricular arrhythmias and 6% with recurrence of electrical storms. Given the positive effects of these studies on arrhythmia outcomes, it is reasonable to hypothesize positive effects of VT ablation on the psychological functioning of ICD patients.

**Outcome measures**

Outcome variables in this study included PTSD, anxiety and depression, and HRQoL. Each is reviewed below to better situate study hypotheses.

**Posttraumatic stress disorder.** A diagnosis of a life-threatening illness can satisfy the criterion for a traumatic stressor according to the Diagnostic and Statistical Manual of Mental Disorders 4$^{th}$ Ed. (DSM-IV-TR; American Psychiatric Association, 2000), the accepted version at the time this study was designed. Since then, the DSM-5 (American Psychiatric Association, 2013) has been published with revised PTSD criteria. Criterion A in DSM-5 stipulates that "a life-threatening illness or debilitating medical condition is not necessarily considered a traumatic event. Medical incidents that qualify as traumatic events involve sudden, catastrophic events (e.g., waking during surgery, anaphylactic shock)" (American Psychiatric Association, 2013, p. 274). While this brings into question whether a life-threatening event meets Criterion A, a recent systematic review of cardiac-induced PTSD argues that, based on data, acute cardiac events meet

the more stringent Criterion A outlined in the DSM-5 (Vilchinsky et al., 2017). Although many cardiac patients might not qualify to meet the PTSD diagnosis as per DSM-5, they can be preoccupied with fear of death and experience avoidance, intrusions, negative alterations in mood and cognition, and changes in arousal. These symptoms might be subsyndromal when assessed by DSM-5 but can, nonetheless, impact well-being and cause significant emotional and psychological distress. Since the DSM-IV-TR publication, there has been growing recognition that medical stressors share many characteristics with other traumatic stressors such as assault or armed combat, including perceived or actual threat to one's life, a feeling of helplessness and extreme fear (Mundy & Baum, 2004). However, unlike trauma arising from an external stressor, those originating with medical illness have a number of distinguishing attributes. Namely, the stressor can be internal, persistent, and the life threatening event may have already occurred and/or there may be threat of future events (Buckely, Green, & Schnurr, 2004). Importantly, in medical populations PTSD is not only of clinical significance but has associated medical implications and complications. For example, PTSD has been associated with poor adherence to treatment regimen (Shemesh et al., 2001; Stoll et al., 2000), increased mortality rates (Vilchinsky et al., 2017), poor HRQoL (Ouimette et al., 2004), and higher cardiovascular disease adverse event rates (Gradus et al., 2015). Strikingly, in a sample of ICD recipients presenting with PTSD the absolute mortality risk was more than double compared to those without PTSD symptoms (Ladwig et al., 2008).

For cardiac patients, the above-mentioned attributes are particularly poignant as cardiac events can be life threatening and patients have no control over when the event will occur. As such, the cardiac event can be potentially traumatic (Vilchinsky et al., 2017). Adding further to the inherent burden of illness are worries about recurrence, complications, treatment and its side

effects, and the impact the illness might have on one's life (Fait et al., 2018). For ICD recipients more specifically, the stressor can be an acute event or chronic in nature. For example, ICD shocks which occur acutely have been recognized as meeting criteria for a traumatic stressor (Hamner et al., 1999). Conversely, the surgical scar can serve as a constant reminder of one's precarious health and the potential of future shocks (Sears, Hauf, Kirian, Hazelton, & Conti, 2011). The ICD device itself can also continually remind the patient of his/her underlying cardiac disease (von Känel, Baumert, Kolb, Cho, & Ladwig, 2011). Together, these raise the point that patients with cardiac arrhythmias might be at particular risk of PTSD. Thereby, they seriously challenge one's ability to take control over their disease. Perceived loss of control and helplessness have been identified as important risk factors for PTSD development (Hari et al., 2010; von Känel et al., 2011). Similarly, more shocks during follow-up have been suggested to predict greater PTSD at follow-up (von Känel et al., 2011). In a sample of seriously ill patients such as those in the present study, the burden of VT is significant, numerous unpredictable shocks are likely to occur, and this can in turn impact trauma levels.

Studies have examined prevalence rates of PTSD more broadly as well as in cardiac populations. A recent systematic review of cardiac-induced PTSD across different cardiac disease populations reported that prevalence rates range from 0 to 38% (Vilchinsky et al., 2017). More specifically, prevalence rates of PTSD range from 0% to 16% in MI patients (Tedstone & Tarrier, 2003) and from 15-38% in patients following a cardiac-arrest (Gamper et al., 2004; Ladwig et al., 1999; Vilchinsky et al., 2017). The wide range of PTSD prevalence in both populations may be influenced by several characteristics of the studies upon which these rates were established. Namely, there exists great variance in: 1) study design (e.g., case-control, retrospective, longitudinal, RCT); 2) length of time from index event until the assessment of

PTSD where studies capturing symptoms closer to the index event tended to report higher prevalence rates; 3) type of PTSD self-report measure used as well as little consensus on optimal measures and cut-off scores for classifying PTSD; 4) use of self-report measures versus clinical interviews, where self-report measures typically yielded higher prevalence rates irrespective of when the PTSD assessment was conducted; 5) sample size of studies which can compromise power; 6) gender distribution with largely male samples; and 7) response and attrition rates (Tedstone & Tarrier, 2003; Vilchinsky et al., 2017). It is hard to make sense of studies examining the change in PTSD over time as many of the studies suffer from high attrition rates thereby undermining interpretation of the results observed. More broadly, use of heterogeneous samples within and between studies is particularly problematic in establishing prevalence rates in cardiac populations (Vilchinsky et al., 2017). Some studies combine patients who experienced a first cardiac episode with those who experienced repeated events while other studies combine patients with different diagnoses (Vilchinsky et al., 2017). Thus, there is a vastly different lived experience among these patients and therefore different degrees of exposure to stressors. Given that the studies of PTSD prevalence rates themselves vary in the nature and severity of cardiac diseases represented in the samples, it might not be surprising that prevalence rates across studies vary widely. For example, prevalence rates of PTSD appear to differ between samples of MI survivors and samples of cardiac arrest survivors (Vilchinsky et al., 2017). It is possible that the lower rates observed in MI patients might be because the general MI population is heterogeneous in terms of severity of the heart attack. Conversely, higher prevalence rates observed in cardiac arrest survivors might reflect the severity of the life-threatening event they endured. Indeed, in cardiac arrest patients, high prevalence rates were detected even when more rigorous diagnostic

methods were employed, such as a diagnostic interview, underscoring the profound impact of surviving a life-threatening arrhythmia (Vilchinsky et al., 2017).

In the ICD population, prevalence rates of PTSD are generally consistent with those reported in the cardiac arrest population. A systematic review reported that in ICD recipients, the prevalence of PTSD ranges from 8% to as high as 30% (Vilchinsky et al., 2017). Here too, factors similar to ones outlined above might contribute to the wide range of prevalence rates, including: higher rates when self-report measures are used; the use of varying measures and inconsistent cut-off scores for classifying PTSD; length of time between the assessment of PTSD and index event; the nature of the index event (e.g., ICD implantation or shock, where the experience of shocks might impact differently on trauma symptoms); and variability in study design where cross-sectional studies with smaller sample sizes tended to report somewhat higher prevalence rates (Vilchinsky et al., 2017). In these cross-sectional studies there is also some ambiguity as to when PTSD was assessed in relation to the ICD implant or discharge. Moreover, although indication for ICD implant has not been associated with PTSD, studies often contain few participants meeting criteria for PTSD, thus compromising statistical power to confidently assess the influence of ICD indication on prevalence rates (Habibović, van den Broek, Van der Voort, Alings, & Denollet, 2012; Lang et al., 2014). Taken together, the methodological differences amongst studies assessing prevalence rates of PTSD in ICD recipients make it difficult to confidently judge the robustness of prevalence rates reported across studies.

Studies of ICD recipients have also examined whether PTSD is a relatively short-lived or enduring phenomenon. Rates of PTSD typically decrease over time, with 21% of patients reporting symptoms within 2 months of ICD implantation and 12% and 13% reporting symptoms at six- and 12-month follow-ups, respectively (Kapa et al., 2010). Nonetheless, there is some

suggestion that chronic levels of PTSD can present a clinically significant phenomenon in ICD recipients. Rates have been reported to increase and persist from baseline (approximately two years after implant) to follow-up (approximately 5.5 years post implant) with approximately 19% of patients meeting criteria for PTSD at both time points (von Känel et al., 2011). Together, these studies suggest that PTSD can be an enduring problem for some patients in this population. This is understandable given the frequently persistent VT burden, the risk of repeated shocks, and knowing that one's medical illness is chronic. Interestingly, one case-report of an ICD recipient presenting with signs of acute stress disorder and PTSD re-assessed these symptoms after the individual underwent a successful VT ablation procedure (Maryniak et al., 2006). Following the ablation symptoms of PTSD were significantly diminished (Maryniak et al., 2006), suggesting that mitigating the arrhythmia helps mitigate the stress-related symptoms.

In summary, PTSD has become a recognized phenomenon in medical populations. Prevalence rates, while varying widely, appear to be significant in the ICD population and to persist over a long period of time. Because PTSD is associated with adverse outcomes it is important to better understand factors or interventions that could help reduce the burden. It is reasonable to expect that reducing the risk of malignant arrhythmias and ICD shocks by intervening with VT ablation therapy might favourably impact PTSD in this population. The present study aimed to determine if undergoing ablation therapy to reduce VT burden is associated with a reduction in PTSD symptoms.

**Depression and anxiety.** Although some ICD recipients deem the device to be a "safety net," the perceived VT burden may be high, and fear and dread of potential ICD shocks are often reported. It is thus not surprising that anxiety and depression are common in ICD patients (Ladwig et al., 2014). Together, they can impact adjustment to the device and well-being.

Learned helplessness and the associated lack of control over the occurrence of shocks have been proposed as a mechanism for the manifestation of depressive symptoms (Sears, Todaro, Lewis, Sotile, & Conti, 1999). Faced with the possibility of unpredictable and abrupt shocks, the perceived lack of control may amplify feelings of hopelessness and negative beliefs about one's current and future health (Sears et al., 1999). This can, in turn, compromise psychological well-being of ICD patients who experience repeated shock therapies. Anxiety is often related to ICD-specific concerns such as fear of shocks, their intensity and unpredictable nature, fear of device malfunction, and death (Gallagher et al., 1997; Pauli, Wiedemann, Dengler, Blaumann-Benninghoff, & Kühlkamp, 1999). Patients may come to anticipate and fear, or even dread, the next shock. These negative and catastrophic thoughts can elevate anxiety (Irvine et al., 2010; Sears et al., 1999). Thus, the potentially life-saving therapy of the ICD can also play an important role in the development and maintenance of depressive and anxiety symptoms. Beyond the clinical implications, both anxiety and depression carry medical repercussion as they have been associated with increased major cardiac events, increased readmission rates, and mortality (Berg, Herning, Svendsen, Christensen, & Thygesen, 2016; Ladwig et al., 2014).

Varying prevalence rates of depression and anxiety have been reported across different studies of ICD recipients. While the precise reason for such wide ranges is difficult to identify, there are several possible contributing factors which will be reviewed below. An early review reported prevalence rates of depressive symptoms to range from 24 to 33% following the ICD implant (Sears et al., 1999). Clinically diagnosable levels of anxiety were reported in 13-38% of ICD patients (Sears et al., 1999). The wide ranges in this study were likely impacted by several characteristics of the included studies: studies were often cross-sectional in design and contained small sample sizes (range: 8-104 patients); studies utilized different self-report measures to

assess symptoms of anxiety and depression; and varied significantly with respect to when symptomatology was assessed relative to the ICD implant (Sears et al., 1999).

A more recent systematic review reported that, when assessed by a validated diagnostic interview, between 11% and 28% and between 11% and 26% of ICD patients have a depressive and anxiety disorder, respectively (Magyar-Russell et al., 2011). The three studies upon which these prevalence rates were based comprised relatively small samples ($N$ = 35-90) raising the question of generalizability. Higher prevalence rates were reported in cross-sectional studies of predominantly secondary prevention ICD recipients and when symptoms were assessed twelve or more months post-implant. Higher rates, thus, likely reflect the impact of shocks or the prolonged burden of living with malignant arrhythmia on psychological wellbeing. Lowest rates were captured when the mean assessment time was two days post implant likely not capturing the impact of experiencing shocks or living with the ICD device. These prevalence rate ranges become wider still when elevated levels of depression and anxiety are assessed by way of self-report measures. Elevated symptoms of depression were reported to be as low as 5% and as high as 41%, while elevated symptoms of anxiety were reported to range from 8 to 63% (Magyar-Russell et al., 2011). Beyond the variability in prevalence rates due to mode of assessment (i.e., clinical interview versus self-report), types of self-report measures used varied widely. While the same measure in different studies often yielded similar prevalence rates, this was certainly not always the case. This raises the question of the measures' sensitivity to detecting symptoms in the ICD population. Moreover, rates of depression and anxiety varied when reported pre-ICD implant as compared to shortly after implant, or longer than a year post-implant. However, no discernable pattern could be detected as wide prevalence rate ranges for both were reported at all time points. One possible explanation however may be that many of the studies assessing

symptoms at 12 or more months following implant were cross-sectional in design. They often captured symptoms anywhere from 12 to 75 months post implant in largely secondary prevention ICD recipients. The farther away from time of implant that the symptoms are assessed, the greater the likelihood that patients might require device upgrade, lead changes, pocket revisions, and experience more VT burden/shocks. Another potential contributor to the wide ranges reported may be that some of the longitudinal studies did not account for attirition rates. More broadly, studies encompassed in this review were published between 1996 and 2009, combining older and newer generations of ICDs. Earlier implants were more invasive and patients often received more inappropriate shocks. As a broader caveat, many symptoms of anxiety and depression, such as shortness of breath or lack of energy, may overlap with cardiac symptoms. Thus, there may be over or under reporting of mental health symptoms impacting the range of prevalence rates (Magyar-Russell et al., 2011).

The above findings highlight the burden of depression and anxiety in the ICD population. Conversely, an older meta-analysis found no differences in mood symptoms between ventricular arrhythmia patients treated with an ICD and those treated with medication alone (Burke et al., 2003). Similarly, no differences were detected on anxiety and depression between pre- and post-ICD implant (Burke et al., 2003). The discrepancy in findings may have been influenced by the fact that the 20 studies included in the meta-analysis were published in the early to late 1990s with one study published in 1989 and one in 2000. The data would have been collected much earlier suggesting that studies included first generation ICDs which likely would not have provided much psychological benefit over antiarrhythmic therapy. Older models of the ICD required an invasive thoracotomy and carried with them a greater likelihood of shocks. These burdens of illness could have impacted mood symptoms. The meta-analysis also included few

studies (e.g., one to six) per variable of interest likely compromising the ability to detect differences between groups. Due to the above outlined methodological confounds it is challenging to draw firm conclusions with respect to anxiety and depression in these comparison groups.

Shock is the most salient feature that distinguishes ICD treatment from all other cardiac therapies. Increased levels of anxiety have been observed in patients experiencing any shock (Carroll & Hamilton, 2005), ≥5 shocks (Herrmann et al., 1997; Irvine et al., 2002; Luderitz et al., 1993), and shock storms (Redhead et al., 2010). A correlation between the increased number of shocks and depression has been reported (Dougherty, 1995). However, discrepant findings from earlier studies indicated no difference in depression symptoms between shocked versus no-shock groups (Bilge et al., 2006; Burke et al., 2003). Notably, the older meta-analysis which found no differences between patients who received ICD shocks and those who did not, compared patients who received no shocks versus at least one shock and excluded studies which compared shock frequencies (e.g., 0-4 shocks versus >5; Burke et al., 2003). Studies that did not take into account the frequency of ICD shocks received, might have undermined the sensitivity to detect an increased burden of shocks on symptoms of depression and anxiety. Generally, small to moderate differences are reported across studies of higher anxiety scores in patients who experience shocks as compared to those who do not (Magyar-Russell et al., 2011). Negligible to moderate differences are also reported between shocked and non-shocked patients on meeting criteria for clinically elevated or diagnosable levels of depression (Magyar-Russell et al., 2011). This suggests that shocks, especially frequent shocks, might add to the VT and psychological burden in ICD patients. As with the above discussed prevalence rate ranges, several factors might impact the discrepant findings related to shocks. Older studies appear to show greater

association between shocks and anxiety. This is perhaps not surprising given that patients would more likely have been secondary ICD recipients, had invasive thoracotomy procedures, and increased incidence of shocks both appropriate and inappropriate. Measures and cut off levels used for diagnosing mood symptoms vary among studies and might provide inconsistent findings. While variance exists in how shocks impact anxiety and depression, their effect can be profound. Even if diagnosable levels of anxiety and depression are not reached, the experience of shocks can impact psychological health at sub-clinical levels. Thus assessing the impact of shock burden in this population is important.

There is a paucity of studies examining depression and anxiety in ICD patients undergoing a VT ablation procedure. As noted previously, only one recent RCT of ICD recipients randomized to escalated antiarrhythmic treatment or ablation therapy assessed HRQoL, depression and anxiety as a secondary outcome (Gula et al., 2018; Sapp et al., 2016). At baseline, three, six, 12-months and annual follow-ups, patients completed the Medical Outcomes Study Questionnaire (SF-36), ICD Concerns questionnaire (ICDS), Hospital Anxiety and Depression Scale (HADS), and EuroQoL (EQ-5D) questionnaires. Of the patients enrolled in the main VANISH trial ($N = 259$), 237 completed the above HRQoL questionnaires at baseline. At the six- and 12- month follow-ups, 195 and 175, respectively, completed the HADS. No between- or within-group differences were observed on the outcome measures of anxiety and depression over time (Gula et al., 2018). The limitation of this VANISH substudy was that both subgroups had subclinical scores on depression at baseline. It is possible that the floor effect may have been operating which made it difficult to detect between-group differences. No other baseline differences were observed. When looking at trends within further subgroups of this study, anxiety improved from baseline to six-months in escalated therapy patients who did not

receive shocks but worsened in escalated therapy patients who received shocks. This study is important as it is the only RCT of cardiac ablation therapy in ICD recipients to measure psychological outcomes. However, confidence in the results is undermined by several factors. Response and attrition rates related to the anxiety and depression questionnaire might impact confidence in the results particularly at the 12-month follow-up. Analyses utilized participants who completed the baseline questionnaire and at least one other follow-up questionnaire. As such, it is likely that the longitudinal analyses comprised slightly different samples of participants across the various time points. Furthermore, the authors indicated that most participants received a shock prior to randomisation. However, it is unclear whether the ablation participants, who completed the questionnaires, had greater VT burden or greater number of shocks at baseline as compared to the control group. This was not controlled for in the linear mixed-effects modelling for the outcome measures. It also appears that participants randomized to the ablation group experienced fewer shocks during the follow-up period as compared to the control group. However, it is unclear whether this was a significant difference. While this study has important strengths such as the RCT design, large sample size, and use of validated psychological measures, the factors outlined above might compromise the confidence in findings related to anxiety and depression outcomes.

While the range of anxiety and depression symptoms varies, data suggests that the prevalence rate for both is high at approximately 20% (Magyar-Russell et al., 2011). Moreover, the life-saving shock therapy delivered by the ICD is associated with anxiety and depression particularly when repeated shocks are experienced. Since the VT ablation procedure aims to reduce arrhythmia and shock burden it is reasonable to hypothesize that it can, through reduction of shock burden, ameliorate symptoms of anxiety and depression in this population of ICD

recipients. This study aimed to assess whether undergoing a VT ablation is associated with a reduction in symptoms of anxiety and depression.

**Health-related quality of life.** The World Health Organization defines health as "a state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity" (World Health Organization, 2014). It is this definition upon which the term HRQoL relies as well as the assessment of physical, mental, and social functioning (Moons, Budts, & De Geest, 2006). Quality of life (QoL) refers to the satisfaction with life (Moons et al., 2006), whereas health status is the "impact of disease on patient function as reported by the patient" (Rumsfeld, 2002, p. 5). Although these terms are often used interchangeably, they are distinct. Thus, HRQoL is the QoL consequences of health status (Healthy People 2020).

Across large RCTs which examined HRQoL in ICD recipients versus those treated with medication alone results have been inconsistent. One seminal RCT reported significant improvement in HRQoL in ICD recipients but not in the medication group (Irvine et al., 2002). Conversely, other studies reported benefits to longevity but not HRQoL (Noyes et al., 2007) or similar trends in HRQoL between the two groups (Passman et al., 2007; Schron et al., 2002). Another RCT concluded that while improved psychological HRQoL is observed at three and 12-months post implant, as compared to those on medication alone, benefits are no longer detectable at 30-months follow-up (Mark et al., 2008). The varied findings might be explained by differences in several characteristics of the studies. These RCTs varied in the patient populations recruited (e.g., heart failure patients, primary versus secondary ICD recipients), whether they statistically assessed health of patients during the follow-up period (e.g., measuring development and impact of congestive heart failure), the types of measures administered (e.g., health utility index, health status, or heart failure-specific questionnaire), attrition rates, and years of data

collection (i.e., inherently differentiating between recipients of older generation ICDs as opposed to newer more sophisticated models).

There is more consistency with respect to findings of the impact of ICD shocks on HRQoL. Specifically, differences are often not observed until ICD shocks are experienced and accounted for. Studies which show improvement in HRQoL point out that these benefits are not observed in patients who received five or more shocks (Irvine et al., 2002). Similarly, experiencing one or more shocks (Passman et al., 2007; Schron et al., 2002) as well as three or more (Schron et al., 2002) is associated with a decrease in HRQoL. Clinically noticeable effects are more apparent when patients receive five or more shocks (Passman et al., 2007) highlighting the uniquely taxing nature of this stressor particularly when it is repetitive. Emphasizing the above, a recent systematic review concluded that an association exists between reduced HRQoL and the number and recency of shocks but that the nature of this association is unclear (Tomzik, Koltermann, Zabel, Willich, & Reinhold, 2015). The authors concluded that repeated shocks might impact the individual's perception of his/her health in a negative way or that patients who are sicker, and thus have a lower HRQoL, might be more affected by shocks (Tomzik et al., 2015). Taking together this body of research suggests that ICD therapies and specifically shocks can significantly impact an individual's well-being. As VT ablation aims to reduce shock incidence it is important to consider if VT ablation similarly has a positive effect on patients' HRQoL.

Several studies to date have examined HRQoL in VT ablation patients in comparison to those treated with escalated antiarrhythmic therapy as a secondary outcome. While findings remain inconclusive and between-group differences are typically not detected, there is evidence to suggest improvement in HRQoL within the ablation groups. An older prospective study

examined the impact of VT ablation in 21 patients with coronary artery disease (Strickberger et al., 1997). All patients received multiple ICD shocks or ATPs, had a previous MI, and were on anti-arrhythmic medication. Utilizing an ICD-specific HRQoL measure (i.e., The Index of Subjective Concerns for People with ICDs; Vitale & Funk, 1995), significant improvement was reported following a successful ablation but not after an unsuccessful one (Strickberger et al., 1997). Results should be interpreted with caution due to the small sample size and lack of control group. Moreover, the study was published over twenty years ago and advancements have been made in both the ablation procedure and ICD device. Refinement in ICD programming means that fewer people receive shocks and the techniques and invasiveness of the ablation procedure has evolved significantly. A more recent study randomized patients with VT and history of MI to receive an ablation prior to an ICD implant or to receive an ICD alone (Kuck et al., 2010). No between-group differences were found. However, at the 12-month follow-up, ablation patients had higher scores in six of eight SF-36 subscales (physical functioning, role-physical functioning, bodily pain, vitality, role-emotional functioning, mental health). Similarly, at 24 months they had higher scores in seven subscales (same as at 12 months with the addition of general health subscale). Importantly, the response rate to the SF-36 questionnaire was low. Of the total 107 patients recruited ($n$ = 52 ablation, $n$ = 55 control), 94 completed the baseline questionnaire. At 12 months, 54 (57%) of participants, and at 24 months 30 (56%) completed the questionnaire. Thus, it is possible that the small sample size and low response rates compromised the statistical power to detect significant between-group differences. Participants in this study had only experienced a first episode of stable VT after the MI rather than the more serious events of a cardiac arrest, ventricular fibrillation or ICD shocks prior to the ablation. Thus, the psychological impact of VT burden may be very different than in those patients who experienced

these more serious arrhythmia events. This perhaps rendered it more difficult to detect a benefit from the ablation procedure. Lastly, the substudy of the VANISH trial hypothesized that an improvement in HRQoL would be observed in the ablation group by reducing the anxiety associated with the anticipation of arrhythmia symptoms or ICD shocks (Gula et al., 2018). Most patients enrolled received a shock prior to recruitment. Of the 259 patients enrolled in the main VANISH trial, 237 completed the baseline HRQoL questionnaire. At six- and 12-months, 198 and 178 completed questionnaires, respectively. No between-group differences were detected on any of the measures between the ablation and medication only groups. However, within-group analyses indicated that at six-months the ablation group improved on social functioning (not significant at 12-months) and energy/fatigue domains of the SF-36, had a reduction in ICD concerns (significant at 12-months), as well as significant improvement in overall health based on the EQ-5D visual analog scale (not significant at 12-months). While the improvement in social functioning did not reach conventional levels of significance at 12-months, the subscale score is very similar as compared to the score at six-months (68.9 vs. 69.3, respectively), and thus the statistical test might have been undermined by the reduced sample size at 12-months. It is also possible that there was a slightly different assortment of patients in the six- and 12-month analyses contributing to inconsistencies in the statistical results between the two time points. The escalated antiarrhythmic therapy group did not see improvements in HRQoL but did have a reduction in ICD concerns at six-months (not significant at 12-months). The lack of sustained significance suggests that the ICD concerns worsened somewhat from six to 12 months in the medication group. This perhaps implies that with time this group of patients might have a re-emergence of ICD-related concerns. This pattern of effects is somewhat congruent with the observations made related to HRQoL, discussed above, and might hint at better HRQoL and

cognitive effects in the ablation group. These authors go on to suggest that the improvement in energy levels and decreased concerns about ICD shocks may suggest a confidence in the ablation procedure and a reduction in anticipation of further arrhythmia events. This RCT is important to consider in relation to the present study. However, confidence in findings might be affected by study limitations outlined in the discussion of depression and anxiety. In addition, the relatively small sample size could have compromised the ability to detect subtle differences. Lastly, the health status measure (SF-36) utilized as a proxy for HRQoL is an older version which did not provide composite scores; thus, changes in the overall physical and mental well-being did not appear to be assessed.

While HRQoL findings are mixed it appears that ICD recipients who do not receive shocks benefit from better HRQoL as compared to patients treated with medication alone. However, this benefit is not observed in ICD patients who receive shocks. Interventions such as the VT ablation procedure are intended to help reduce the frequency of shocks and VT burden. Given their novelty, it is important to assess whether they lead to improvement in well-being, particularly in this population that is at risk for deterioration of HRQoL. Lastly, studies conducted to-date which assessed HRQoL associated with VT ablation yield ambiguous results. This underscores the need for further investigation and highlights the importance of including HRQoL as an outcome measure when assessing the health effects of VT ablation in this population of ICD patients.

**Predictors of psychological outcomes**

Not all patients demonstrate improved psychological and HRQoL outcomes in association with arrhythmia treatments. Cardiac variables, such as ICD shocks, only explain part of the variance in these outcomes. Studies of ICD recipients suggest that psychological factors

might render some individuals vulnerable to poorer psychological and HRQoL outcomes. It is thus important to address the psychological predictors of PTSD, depression, anxiety and HRQoL. For example, an abstract reporting on drug-refractory atrial fibrillation patients undergoing a catheter ablation noted improvements on measures of anxiety and depression (Irvine, Baker, et al., 2010). While there was a reported high prevalence of elevated anxiety, regression models revealed that the improvement in anxiety and depression following the ablation procedure was associated with an optimistic outlook rather than with the objective success of the ablation. Similarly, low optimism and greater symptom preoccupation at baseline were associated with depression at follow-up (Khaykin et al., 2010). Moreover, it is important to assess predictors of PTSD, as symptoms of PTSD may have implications for treatment adherence and health. Taken together, it is important to assess factors which may mitigate the psychological outcomes in ICD recipients as this population of individuals can be particularly unwell and at risk for deterioration of physical and mental functioning. Independent variables included in this study were measures of optimism, positive health expectations, and self-efficacy. Each is reviewed below to better situate study hypotheses.

**Optimism and positive health expectations.** Positive psychological factors such as optimism and positive health expectations have been shown to predict better health outcomes in cardiac patients (Barefoot et al., 2011; Leedham, Meyerowitz, Muirhead, & Frist, 1995; Scheier & Carver, 1992). Optimism is conceptualized as a personality trait or disposition, reflecting a somewhat generalized tendency to expect that good things, rather than bad outcomes, will happen across different facets of every-day life, and this characteristic can play a role in self-regulation of behaviour (Carver, Scheier, & Segerstrom, 2010; Scheier & Carver, 1985). The construct of positive health expectations has been conceptualized as one's beliefs related to the

likelihood of positive health outcomes (Leedham et al., 1995). Positive expectations have been associated with reduced risk of depression onset and lower levels of depressive symptoms (Kleiman et al., 2017). Optimism and positive health expectations together have been suggested to provide a sense of coping and control for ICD patients when faced with the uncontrollable aspects of their arrhythmia or ICD shocks (Sears et al., 2004).

Generally, research on optimism suggests that it serves an important function in enabling optimists to adapt to a number of different life stressors (Rauch, Defever, Oetting, Graham-Bermann, & Seng, 2013). Low optimism has been associated with unhealthy mental and physical health outcomes (e.g., depression and increased frequency/intensity of somatic complaints; Scheier & Carver, 1992). Conversely, optimistic individuals have been found to be less anxious, less depressed, and have fewer physical symptoms (Zeidner & Hammer, 1992). Individuals reporting greater optimism often employ more adaptive active coping strategies, as opposed to avoidance, which draw upon social support and positive aspects of stressful situations. It is through this mechanism that optimism has been suggested to exert a positive impact upon quality of life and psychological well-being (Carver et al., 2010; Conversano et al., 2010; Rauch et al., 2013). Optimism has also been conceptualized as a potential predictor for problematic responses to trauma (Rauch et al., 2013). In a sample of rescue workers, it was associated with less distress at 12 months but not necessarily to the change in distress over time (Dougall, Hyman, Hayward, McFeeley, & Baum, 2001). Similarly, higher optimism has been related to lower levels of PTSD in a sample of pregnant women (Rauch et al., 2013) and lower levels of depression, anxiety, and PTSD post natural disaster (Carbone & Echols, 2017). A composite of resilience factors, including optimism, has been associated with trauma where greater resilience predicted decreases in PTSD in a sample of cancer survivors (Campo, Wu, Austin, Valdimarsdottir, &

Rini, 2017). Not only has optimism been associated with trauma, but it has also been found to impact general well-being. For example, in a sample of HIV positive men, optimism positively influenced both mental and physical health (Taylor, Kemeny, Reed, Bower, & Gruenewald, 2000). When faced with a traumatic life-threatening disease, optimism can act as a buffer and help the individual cope with the intensely stressful life-threatening events (Taylor et al., 2000). By employing fewer avoidant coping strategies, typically seen in individuals presenting with PTSD, optimistic individuals might have a buffer against traumatic stress (Rauch et al., 2013). This kind of coping can further buffer against hopelessness and thus low mood. For instance, as compared to pessimistic individuals, those who scored higher on optimism were found to have a higher internal locus of control and lower scores on measures of hopelessness, depression, and perceived stress (Scheier & Carver, 1985). When faced with obstacles, optimistic individuals were more likely to feel capable of coping with them and reported being less bothered by physical symptoms (Scheier & Carver, 1985). More specific to cardiac patients, pre-surgical optimism was associated with mental and physical HRQoL but not mortality post heart transplant (Jowsey et al., 2012). Lastly, in a sample of acute coronary syndrome patients, optimism was found to predict better physical health status and reduced risk of depression at 12 months (Ronaldson et al., 2015).

In ICD patients, dispositional optimism has been highlighted as an important construct which can promote the utilization of problem-focused coping strategies (e.g., information seeking) which have been found to be effective in this population (Dunbar, 2005). Optimism has also been proposed as a covariate for better psychological outcomes in ICD patients who receive shocks (Dunbar, 2005). Specifically, higher optimism at implant has been associated with better mental health functioning and social functioning over the short-term follow-up, a finding which

approached significance at long-term follow-up (Sears et al., 2004). An RCT examining a web-based intervention for distress management in first-time ICD recipients reported that higher baseline optimism was associated with lower anxiety and depression at 12-month follow-up after controlling for demographic, psychological, and clinical variables (Habibović et al., 2018). This relationship, however, was no longer significant after baseline anxiety and depression scores were added as covariates to the regression model. Higher baseline optimism was also associated with physical and mental health status at 12-months only the latter of which remained significant when its baseline value was added as a covariate. These authors concluded that optimism is linked to the mental health status and distress scores at the 12-month follow-up but not to the change in distress and health status over time.

Similarly, positive expectations can help predict psychological adjustment in health populations (Carver et al., 1993; Scheier & Carver, 1992; Sears et al., 2004) although there are some discrepant findings (Habibović, Pedersen, Van Den Broek, & Denollet, 2014). Such situation-specific expectations can impact mood even when complications arise. For example, self-reported positive health expectations were associated with positive mood, adjustment to illness, and HRQoL, in heart transplant patients even when complications post surgery and setbacks in health were experienced (Leedham et al., 1995). More specifically, positive health expectations were negatively correlated with mood disturbance. In a study of patients undergoing coronary angiography, positive recovery expectations at baseline were positively associated with long-term survival and functioning after controlling for relevant clinical, psychological, and demographic variables (Barefoot et al., 2011). A similar trend has been observed in ICD recipients, such that high positive health expectations at baseline were associated with better satisfaction with general health at long-term follow up (Sears et al., 2004). This suggests that

individuals with high positive health expectations might view their ICD implant and its value differently than those with low positive health expectations (Sears et al., 2004). Conversely, an RCT aimed at reducing distress in ICD recipients, reported that positive expectations were not related to any of the distress outcomes measured after adjusting for demographic and medical variables (Habibović et al., 2014). However, negative treatment expectations were associated with higher levels of anxiety, depression, and concerns related to the ICD at three-months post implant. Similarly, in a small sample of individuals undergoing cardiac surgery negative illness beliefs predicted a worsening of physical functioning and depressive symptoms three-months post surgery (Juergens, Seekatz, Moosdorf, Petrie, & Rief, 2010). With this in mind, the present study examined optimism and positive expectations as predictors of psychological well-being in our sample of ICD patients and their impact on adapting to arrhythmia treatments.

**Self-efficacy.** Social cognitive theory conceptualizes self-efficacy as a set of specific beliefs in one's own capabilities to perform certain behaviours in order to attain a desired outcome within a distinct realm of functioning (Bandura, 1977, 1997). It further highlights self-efficacy as an important mediator of behaviour change and suggests that the stronger the sense of efficacy the greater the likelihood that a given activity will ultimately be performed successfully (Bandura, 2006). Accordingly, self-efficacy is a cognitive mechanism which helps mediate behaviour, guides participation in activities as well as the effort and persistence in pursuing a given activity despite challenges (Du, Everett, Newton, Salamonson, & Davidson, 2011). Self-efficacy is typically influenced by several sources of information which are related to: 1) past and present successful performances and thus mastery (e.g., which serve as indicators of ability, offer possibility of refining coping skills), 2) observing behaviour of others (e.g., someone who can demonstrate effort and mastery in similar situations), 3) verbal influences (e.g., receiving

positive feedback from experts regarding behaviours), and 4) the person's perception of his/her physiological and emotional state, for example interpreting physiological response to anxiety, such as increased heart rate, as informative about his/her vulnerability to stress and ability to perform given behaviours where those with higher self-efficacy might interpret the physiological response as innocuous rather than as a threat (Bandura, 1977, 1997; Dougherty, Johnston, & Thompson, 2007; Houston Miller & Barr Taylor, 1995). Thus, self-efficacy is a perceived ability to manage personal functioning in a diversity of situations or events. As such, an individual's self-efficacy expectations vary depending on a particular task or situation (Bandura, 1997; Dougherty et al., 2007). Most importantly perhaps, it is important to recognize the role of the individual as an active agent in the management of his/her own condition with the recognition of the central role of self-efficacy to this human agency (Bandura, 1997; Benight & Bandura, 2004). Moreover, self-efficacy beliefs help regulate the way individuals "function through cognitive, motivational, affective and decisional processes" (Benight & Bandura, 2004, p. 1131). These beliefs, in turn, factor into whether the individual thinks in ways that are self-enhancing, what motivates him/her when faced with adversity or difficulties, the degree to which he/she experiences vulnerability to stress and depression, and resilience to adversity. Thus, a person's belief in his/her ability to exercise some control over a situation when faced with stressors helps promote a person's resilience to them.

Indeed, higher self-efficacy has been shown to be positively associated with behavioural and emotional responses in health populations. It is associated with cardiac lifestyle changes (Evon & Burns, 2004; Ha, Hare, Cameron, & Toukhsati, 2018), participation in cardiac rehabilitation (Grace et al., 2002), responses to traumatic situations (Benight et al., 1997), increased adherence to treatment, self-care behaviours and fewer physical and mental health

symptoms. In their review of the role of self-efficacy in posttraumatic recovery, Benight and Bandura (2004) emphasized the enabling and protective function of one's belief in his/her ability to exercise some control over adversity that arises. Self-efficacy is further highlighted as playing a key role in stress reactions and the quality of coping in threatening situations. Studies have examined self-efficacy in relation to trauma, depression, and anxiety and generally report an inverse relationship between these constructs. In a sample of veterans, self-efficacy was a significant predictor of PTSD and depression such that higher self-efficacy was associated with lower severity of symptoms (Blackburn & Owens, 2015). A recent trauma-recovery intervention study aimed at enhancing self-efficacy and reducing PTSD reported changes in coping self-efficacy to be negatively correlated with changes in trauma symptoms (Benight, Shoji, Yeager, Weisman, & Boult, 2018). Similarly, low perceived self-efficacy was a predictor of PTSD following the exposure to violence at the short, medium, and long-term follow-up periods in a sample of assault victims (Johansen, Wahl, Eilertsen, & Weisaeth, 2007).

Emphasizing Bandura's concept, Dougherty et al., (2007) highlighted that when individuals are dealing with chronic illness, self-efficacy can help organize and integrate social, behavioural, and cognitive skills needed to address a variety of health-related situations. Coping with chronic disease and associated challenges requires the knowledge of specific skills, a belief that one can carry them out, and that they will produce desired outcomes (Dougherty et al., 2007). Thus, one's perceived self-efficacy can influence the effort that is expended when faced with obstacles and impact behaviour change and the maintenance of that behaviour. Indeed, self-efficacy is suggested to be negatively associated with depression, anxiety, and helplessness in chronically ill individuals. Higher self-efficacy predicted greater psychological well-being in individuals with Type I and Type II diabetes (Eiser, Riazi, Eiser, Hammersley, & Tooke, 2001)

and lower depression in cancer survivors (Philip, Merluzzi, Zhang, & Heitzmann, 2013). Perceived self-efficacy to manage recovery following a hurricane predicted severity of PTSD in a sample of HIV positive men as well as healthy controls (Benight et al., 1997). Specifically, greater perceived self-efficacy was related to lower emotional distress and symptoms of PTSD and appeared to function in similar ways in both healthy and chronically ill men. In a sample of individuals with substance abuse, higher self-efficacy predicted lower depression and anxiety at follow-up (May, Hunter, Ferrari, Noel, & Jason, 2015). Similarly, higher levels of self-efficacy were correlated with lower psychological distress and better HRQoL in patients who had a MI or congestive heart failure (Joekes & Van Elderen, 2007). Regression analyses of the baseline data showed that higher self-efficacy was related to less anxiety and depression and better HRQoL. Self-efficacy, however, was no longer a significant predictor in the medium term follow-up when the baseline values of the outcome variables were controlled for (Joekes & Van Elderen, 2007). Attrition of patients over the follow-up period may have influenced the results at follow-up. This relationship has been shown to exist in the opposite direction as well where higher symptoms of PTSD and recurrence of illness have been associated with lower self-efficacy (Taylor, Absolom, Snowden, & Eiser, 2012). This highlights the complexity of the relationship between self-efficacy and outcomes as well as the importance of controlling for disease burden factors when examining the relationship between self-efficacy and psychological outcomes. In summary, self-efficacy is an important construct to assess as it can help ameliorate psychological well-being which in turn can promote the sense of increased self-efficacy.

Taking together the aforementioned literature review, one aim of the present study was to examine self-efficacy as a predictor of PTSD, depression, and anxiety in this population. If an individual doubts his/her self-efficacy, his/her ability to cope lessens. Assessing self-efficacy as a

global trait, rather than in relation to a specific situation, has limitations since items on the self-efficacy scale might not be reflective of the situation at hand and as such might have limited explanatory power (Bandura, 2006). Thus, this study adopted a self-efficacy measure specific to managing arrhythmia treatments to test the predictive validity of this construct. If we consider an unpredictable event such as cardiac arrhythmias, it is reasonable to postulate that lower self-efficacy could lead to more distress. Benight and Bandura (2004) highlighted the impact of a sense of inefficacy to manage demands and exert control over ruminations on successful adaptation to adverse events. Much in the same way, if we consider that some patients feel incapable of having agency and confidence in their actions related to their arrhythmia and the associated treatments, it is reasonable to postulate that lower self-efficacy might be associated with greater distress.

**Control variables**

It is important to control for certain variables that can confound the interpretation of the results (Shaughnessy, Zechmeister, & Zechmeister, 2012). The present study aimed to control for the following cardiac variables: functional status as measured by the New York Heart Association (NYHA), left ventricular ejection fraction (LVEF), presence of ablation procedure, and occurrence of shocks. It also planned to use general life stress as a control variable. All of the control variables are discussed below.

Functional status was measured by the NYHA. The NYHA has been reported to be associated with depressive symptoms. Heart failure patients with NYHA class III and IV had significantly more depressive symptoms than patients with class I and II (Rohyans & Pressler, 2009). In this study, the most endorsed depressive symptom was feeling of tiredness or fatigue. NYHA could also be associated with self-efficacy. For example, limited activity and severity of

symptoms could undermine an individual's self-efficacy to perform given behaviours and his/her belief in being able to manage his/her behaviour in different situations. Similarly, as done in past research, this study planned to control for LVEF, a global measure of cardiac functioning. LVEF has been associated with HRQoL outcomes (Sears et al., 2004).

Shock from the ICD device has been shown to reduce HRQoL (Irvine et al., 2002) and has been associated with increased anxiety in ICD recipients (Bilge et al., 2006). In light of their unpredictable and uncontrollable nature, the experience of shocks may fulfill the criteria of a traumatic stressor for some individuals (Hamner et al., 1999) and thus be associated with an increased risk for PTSD. Research also suggests that patients can develop negative appraisals about the meaning and consequences of ICD shocks, viewing them as indicative of a deteriorating cardiac condition (Sears & Conti, 2002; Sears et al., 1999). Thus, in this study, the experience of ICD shocks could be associated with both the predictor variables (e.g. influence an individual's positive expectancies related to his/her arrhythmia treatment, impacting his/her positive outcome expectancies and his/her positive health expectations) and outcome variables (i.e., HRQoL and psychological well-being). Accordingly, the number of ICD shocks was controlled for when testing the predictive effects of the psychological predictors. Similarly, this study controlled for the presence of an ablation procedure. Successful ablation has been associated with improved HRQoL, while this effect was not seen in unsuccessful ablation procedures (Strickberger et al., 1997). Ablation has also been associated with improved outcomes on symptoms of PTSD (Maryniak et al., 2006). Akin to ICD shocks, an individual's understanding of the ablation procedure and his/her assessment of its success might be associated with positive outcome and health expectancies.

Lastly, perceived general life stress was planned to be used as a control variable in order to better isolate and illuminate the potentially traumatic and stressful effects of arrhythmia. Life stressors such as family discord, job loss, serious injury to a close relative or friend, and financial difficulties, among others, are realities of everyday life. Such stressors may interfere with psychosocial adjustment in patients with heart disease (Sears et al., 1999). In their allostatic load model, McEwen and Stellar (1993) argue that distress accumulates over multiple stressors and may contribute to the development and experience of posttraumatic stress. An amalgamation of life stressors is associated with a depression and anxiety (Slusarcick, Ursano, Robert, Fullerton, & Dinneen, 1999; Vinokur & Selzer, 1975) and HRQoL (Kreitler, Peleg, & Ehrenfeld, 2007). Similarly, an amalgamation of life stress might have an impact on one's optimistic future outlook and his/her ability to handle daily occurrences. There is an association between life events and lower levels of perceived control (Cairney & Krause, 2008). Thus general life stress is associated with both predictor variables (e.g., self-efficacy) as well as with outcome variables (i.e., psychological well-being).

To summarize, the present study planned to control for NYHA class, LVEF, ICD shocks, ablation, and life stress in the analyses of the hypotheses about the psychological predictors of psychological outcomes.

**Purpose**

Recurrent VT in patients with an ICD has been associated with increased mortality and poorer HRQoL (Irvine et al., 2002; Schron et al., 2002). Moreover, patients who experience appropriate shocks experience increased mortality compared to patients without shocks (Wilkoff et al., 2016). If VT ablation is indeed able to prevent VT recurrence, it is reasonable to

hypothesize that it might have an important role to play in alleviating or at least mitigating the burdensome psychological side effects of the ICD treatment.

Given the inconsistency in psychological outcomes following ablation therapy, it is reasonable to explore whether differences in personality, outlook, and confidence might influence psychological outcomes. Given past research on the influence of these individual difference factors on health adaptation generally, it is important to explore their influence in predicting psychological wellbeing following VT ablation in ICD patients. Accordingly, the first aim of this prospective study was to examine predictors of psychological wellbeing in ICD patients presenting with VT. More specifically, this study aimed to examine whether self-efficacy, optimism, and positive health expectations predict symptoms of PTSD, depression, and anxiety following VT ablation. The second aim was to evaluate whether catheter ablation of VT is associated with greater improvement in HRQoL compared to matched control ICD participants who did not undergo an ablation.

This study employed a case-control design. The experimental group comprised ICD patients, who have previously experienced an ICD ATP and/or shock and who were scheduled to undergo VT ablation. A stipulation was made to recruit ablation patients either shortly before being scheduled for an ablation procedure, or within two months following the ablation procedure. The control group comprised ICD patients with a history of prior ICD shock and/or ATP but without VT ablation. The experimental and control groups were matched on: 1) gender, 2) age (+/- five years), and 3) time since ICD implant (+/- six months, allow for +/-12 month time frame if no suitable match was available). All participants completed a battery of questionnaires at the time of recruitment (baseline) and at a six-month follow-up. Self-report measures assessed HRQoL, psychological functioning (PTSD, depression, anxiety), and cardiac

variables. Cardiac variables were extracted through chart-review (see the Methods and Results sections for additional details). The aim of this study was to provide, heretofore, unexplored insight into the predictors of psychological well-being and HRQoL following catheter ablation.

**Hypotheses**

1. The first set of hypotheses will test whether higher optimism, higher perceived self-efficacy and higher positive health expectations at baseline predict improvement in symptoms of PTSD, depression, and anxiety at six-month follow-up.
2. The second set of hypotheses will test whether HRQoL (global summary measures of health status and psychological well-being, i.e., anxiety, depression, and PTSD) improve more over six-months follow-up in ICD patients undergoing VT ablation compared to ICD patients who do not undergo VT ablation therapy.

## Method

The present study design was an exploratory prospective case-control study. Participants were recruited from Toronto General Hospital (TGH) and St. Michael's Hospital (SMH), both located in Toronto, Ontario. The study was approved by the research ethics board at York University, University Health Network, and SMH and has complied with the ethics protocols established by these three institutions.

### Participants

Two groups of participants were recruited, both of which had documented history of cardiomyopathy/congenital heart disease, an ICD, and a documented history of ICD ATP and/or shock. One group of participants were undergoing an ablation procedure for the treatment of their VT. It was stipulated that these participants would be eligible for recruitment ranging from two weeks prior to their VT ablation up to two months following the ablation. In practice, majority of participants were recruited on the day of their ablation procedure. The second group of participants were matched-control participants who were not undergoing an ablation procedure for the management of VT.

Because one of the aims of this study was to test HRQoL outcomes, it was important to try to recruit age- and sex-matched control patients. Matching criteria were: 1) sex, 2) age (+/- five years), and 3) time since ICD implant (+/-six months or up to +/- 12 months if no suitable match was found within the six-month time frame). For Hypothesis 1 it was decided a priori to include all participants in the analyses regardless of whether they had an appropriate match – control coupling. Ultimately, matching participants on the above outlined criteria proved to be a challenge; thus, the data analyses for Hypothesis 2 also included all participants who were recruited rather than a subset of matched participants. For details regarding the data analysis,

please refer to the section below entitled Data Entry and Statistical Analyses as well as the Results section. Across participants, proficiency in spoken and written English was stipulated as an inclusion criterion.

**Exclusion criteria.** Participants were excluded if they had a history of severe cognitive and/or hearing impairment and/or expressed an unwillingness or inability to participate. Undergoing >1 VT ablation during the study period was added as an exclusion criteria as the study was underway.

**Procedure**

Consistent with institutional ethics approvals, potential participants were identified by the study coordinator or by members of the electrophysiology team (i.e., VT coordinator, nurses, physicians, fellows, or ICD clinic nurses). Recruitment followed one of two procedures: face-to-face recruitment or "remote" recruitment in instances where we were unable to meet the individual while he/she was hospitalized or attending his/her clinic visits. For face-to-face recruitment, the potential participant was introduced to the study by the EP team and was approached by study coordinator either at the time of his/her clinic visit or while he/she was admitted to the cardiology ward for the purposes of a VT ablation procedure. The individual was provided with the Information Letter (Appendix A) which explained the study. If the individual expressed interest in participating in the study after reading the Information Letter, he/she was then provided with the Informed Consent Form (Appendix B and C). At that time, the study was explained in detail and any questions or concerns were addressed. Upon completing informed consent, the Baseline Questionnaire (Appendix D) was provided to the participant along with a stamped, self-addressed envelope which he/she used to mail back the completed questionnaire.

Alternatively, if the participant was hospitalized for several days, he/she often completed the questionnaire while in hospital and a time was arranged for the questionnaire to be picked up.

Remote recruitment occurred if the potential participant was not approached on the day of his/her clinic visit or while he/she was hospitalized due to time constraints or scheduling conflicts. Thus, for remote recruitment potential participants were contacted by telephone initially by a member of his/her EP team (e.g., nurse, fellow). That individual was then asked if he/she would like information about the study and, if so, whether the study coordinator could contact him/her. If he/she expressed interest in the study, the study coordinator mailed out a complete study package including the Information Letter (Appendix A), the Informed Consent form (Appendix B), and the Baseline Questionnaire (Appendix D), as well as a stamped, self-addressed envelope which the individual could use to mail back the questionnaire package. Approximately a week after mailing the package to the individual, the coordinator contacted him/her to review the consent form and answer any questions or concerns.

**Data collection.** Questionnaires assessing psychosocial functioning were administered at recruitment (Baseline Questionnaire – Appendix D) and at six-months follow-up (Follow-Up Questionnaire – Appendix E). The package provided at the time of recruitment included the Information Letter (Appendix A), Consent Form (Appendix B), and Baseline Questionnaire (Appendix D). The package provided at the time of follow-up included a Thank You Letter (Appendix F) and a Follow-up Questionnaire (Appendix E). Each questionnaire package took approximately 30 – 45 minutes to complete. In instances where questionnaires were mailed out, participants were provided with a self-addressed, pre-stamped envelope. A week after mailing the questionnaire, the study coordinator telephoned the participant to assist with any questions or concerns they may have had about the study. At that time, participants were also encouraged to

return the questionnaire at their earliest convenience preferably no later than three weeks after receiving the package. If the participant did not return the questionnaire within the time-frame specified, he/she was contacted with up to three reminder telephone calls. Participants were free to withdraw from the study at any point in time.

In addition to assessing psychosocial functioning, general demographic data (i.e., living situation, level of education) were collected by way of self-report which was built into the questionnaires. Similarly, participants reported on several variables related to their arrhythmia treatment, namely whether or not they had an ablation, if they did have VT ablations how many were deemed successful, the number of ICD shocks they had, whether they experienced phantom shocks, as well as any antiarrhythmic, sleep, or psychotropic medications they were taking.

**Demographic and cardiac measures.** The patient's medical chart was reviewed (paper chart and/or the electronic patient record chart) by a member of our research team in order to extract relevant demographic and cardiac variables. The collection of general medical and cardiovascular information was performed in consultation with the electrophysiologists and electrophysiology fellows. The following variables were extracted: cardiac diagnosis, left ventricular ejection fraction (LVEF) at the time of recruitment, month and year of the ICD implant, reason for ICD implant (primary vs. secondary prevention), number of objectively recorded ICD shocks and ATPs, presence of phantom shocks (i.e., a patient's report of having experienced a shock without objective evidence of having received one), additional ICD procedures (e.g., pulse generator replacement, pocket revision), and prescribed medications. In addition to the above, for ablation patients the following data were extracted related to the VT ablation: presence and date, ablation procedure approach (i.e., substrate, activation), outcome of the ablation (i.e., successful, not successful, partially successful), and complications. These

variables are logged routinely in participants' charts. In order to capture participation rates and characteristics of eligible patients, basic demographic data were logged for patients who were approached. The patient's NYHA was obtained from the participant upon his/her consent to participate.

To maintain confidentiality, participants who consented to participate were assigned a study identification code. No personal data (e.g., names, full dates of birth) were utilized in the questionnaires. Completed questionnaires were stored separately from the consent forms and all paper files were kept within a double-locked cabinet in a locked office. Electronic data files were password protected and stored on an encrypted hospital computer which used a secure server.

**Outcome measures**

**Hospital anxiety and depression scale (HADS).** The HADS (Zigmond & Snaith, 1983) is widely used for measuring symptoms of anxiety and depression among medical inpatients, outpatients, and in the general population (Bjelland, Dahl, Haug, & Neckelmann, 2002). The HADS is a 14-item questionnaire that measures symptoms of anxiety (seven items) and depression (seven items). For each item, the participant is asked to select a response from four possible choices (scored from 0 to 3) that best describes how he/she has been feeling over the past week. The HADS yields anxiety (HADS-A) and depression (HADS-D) subscale scores. In general, the psychometric properties of the HADS are excellent. Internal consistency for HADS-A and HADS-D show Chronbach's alpha coefficients between 0.80-0.93 and between 0.81 and 0.90, respectively (Bjelland et al., 2002; Herrmann, 1997). Concurrent validity of the HADS is very good with strong correlation coefficients (0.62 - 0.73) for HADS-D with other well-validated depression scales (e.g., Beck Depression Inventory, SCL-90 Depression subscale) and strong correlation coefficients (0.49 - 0.81) for HADS-A with well-validated anxiety measures

(e.g., Spielberger State-Trait Anxiety Inventory, SCL-90 Anxiety subscale; Bjelland et al., 2002; Herrmann, 1997). A score of ≥8 on either subscale is suggestive of "caseness," a probable presence of an anxious or depressive state. HADS is reported to be sensitive to changes resulting from disease progression and therapeutic interventions. It takes between 2 and 5 minutes to complete (Snaith, 2003). The HADS-A and HADS-D subscale scores range from 0-21 (used as continuous scores) and were used as outcome measures for both Hypothesis 1 and Hypothesis 2.

**Impact of Event Scale – Revised (IES-R).** The IES-R (Weiss, 2004) was administered to assess symptoms of post-traumatic stress disorder (PTSD). The IES-R is a 22-item self-report measure comprising three subscales: avoidance, intrusion, and hyperarousal. On a 5-point scale (0 = not at all to 4 = extremely), respondents are asked to indicate the degree of distress they experience. Subscale scores are computed as the mean of the responses for the items on a given subscale. Weiss (2004) stipulates that there is no defined "cut-off" score for this measure nor that such a score was envisioned or would be inappropriate as this measure is intended to provide an assessment of symptomatic status over the previous week which arises in response to a traumatic event. However, a guideline score of 1.5 was found to be the optimal threshold for diagnostic significance in a sample of Vietnam veterans seeking treatment for PTSD (Creamer, Bell, & Failla, 2003). This cut-off score was suggested to help provide diagnostic accuracy against another measure of trauma (the PTSD Checklist; PCLC). IES-R demonstrates high internal consistency (alpha = 0.96) and good validity (Creamer et al., 2003). For the purpose of this study, the IES-R administration instructions were altered slightly in order to standardize the nature of the stressor. Participants were asked to complete the questionnaire "with respect to your arrhythmia (i.e., heart rhythm problem) or its treatment (i.e., having an implantable

cardioverter defibrillator or ablation).” The IES-R takes approximately 5 minutes to complete. The total score as well as the subscale scores were used as outcome measures.

**Short Form Health Survey (SF-36).** The SF-36 Health Survey, the short form of the Medical Outcomes Study questionnaire, can be self-administered and takes 5-10 min to complete (Mcdowell, 2006). The SF-36 is a measure of perceived health-status often used as a proxy for HRQoL. It covers eight dimensions of physical and mental health: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and mental health (psychological distress and psychological well-being; Maruish, 2011). The SF-36 also yields two component summary scores: the mental component summary (MCS) and the physical component summary (PCS). The psychometric properties of the SF-36 are excellent. The mean Chronbach’s alpha coefficient for the internal consistency of all scales is 0.84 (Mcdowell, 2006). The SF-36 has also been shown to be sensitive to change in health status over a 12-month time period (Mcdowell, 2006). A license for the SF-36 was purchased and provided the scoring of participant responses. The component summary scores were employed as outcome measures in testing Hypothesis 2.

**Predictor measures**

**The Life Orientation Test (LOT).** The LOT (Scheier & Carver, 1985) is an eight-item questionnaire measuring dispositional optimism. It contains an additional four ‘filler’ items to disguise the purpose of the measure. Participants are asked to complete the questionnaire by answering to what extent they agree with each item (0 = I agree a lot, 1 = I agree a little, 2 = I neither agree nor disagree, 3 = I disagree a little, and 4 = I disagree a lot). Four of the items are worded positively (Items: 1, 4, 5, 11) and four are worded negatively (Items: 3, 8, 9, 12). The LOT yields a total score as well as two factors -- one representing optimism and the other

representing pessimism (Scheier & Carver, 1985). The LOT has good internal consistency (Cronbach's alpha = 0.76), and good stability over time (test-retest reliability for a four-week interval = 0.79; Scheier & Carver, 1985). Scores for positively worded items were reverse coded. All of the items are summed to yield an overall dispositional optimism score (range: 0-32), with higher scores reflecting a more optimistic disposition, and this score was used as a predictor measure in the test of Hypothesis 1.

**Positive Health Expectations (PHE).** The PHE scale (PHE; Leedham et al., 1995) is comprised of seven items. It was derived from a Quality of Life Scale and measures the patient's expectations regarding health outcomes. Specifically, the PHE measures beliefs about the efficacy of the patient's treatment, chances for future health and survival, and the individual's more general feelings about the self and the future. The PHE has good internal validity (Cronbach's alpha = 0.81) as well as good internal reliability. The PHE demonstrates good convergent validity and is positively associated with HRQoL scores (Leedham et al., 1995). It also shows good divergent validity, being negatively associated with mood disturbance scores (POMS), and predictive validity (at six-month follow-up) with physical health measures. Participants responded to each item on a 7-point Likert scale (range: 7 to 49) where higher scores indicated a more positive outlook on health (Leedham et al., 1995).

**Self-Efficacy.** Self-efficacy reflects a specific belief and confidence in one's own ability to manage personal functioning in a diversity of situations. Thus, self-efficacy expectations will vary depending on a particular task (Dougherty et al., 2007) and measures capturing self-efficacy must be specific to the situation being examined (Bandura, 2006). For the present study, the Dougherty and colleagues' (2007) measure of self-efficacy, developed in a sample of ICD recipients, was adapted in order to capture self-efficacy related to "arrhythmia treatments" rather

than to the ICD only. Dougherty et al., (2007) developed two measures – the Self-Efficacy Expectations After ICD Implantation Scale (SE-ICD) and the Outcome Expectations After ICD Implantation Scale (OE-ICD). Only the adapted version of SE-ICD was used for the present analyses (Hypothesis 1). The SE-ICD was originally a 16-item scale where eight items measured self-efficacy expectations and eight items measured behaviours required to manage problems after the ICD implant following a self-efficacy-based intervention. The SE-ICD showed good internal consistency (Cronbach's $\alpha = 0.93$) and was responsive to change over time (Dougherty et al., 2007). The SE-ICD was adapted and revised into two parts: "Managing Arrhythmia Treatments I; MAT I" which captured self-efficacy expectations and "Managing Arrhythmia Treatments II; MAT II" which captured the health-management behaviours. MAT II was only administered at follow-up since participants needed to have the experience of living with an arrhythmia treatment in order to adopt certain behaviours. For Hypothesis 1, MAT I was used as a predictor variable. MAT I comprised six items since two questions were removed (one regarding driving restrictions and one regarding environmental hazards) both of which pertained only to ICD treatment. Thus, MAT I captured self-efficacy expectations which reflected a person's belief in his/her ability to perform a given behaviour. Participants rated their responses on a scale from 0 (not at all confident) to 10 (very confident). The wording by Dougherty et al., (2007) was revised from "cardiac arrest and defibrillator" to read "arrhythmia treatment" so as to reflect the different arrhythmia treatments which participants in this study underwent. A total score was obtained by adding the numerical rating of each response and dividing the sum by the number of items on MAT I.

**Control variables**

**Functional classification (NYHA).** The NYHA developed a system to quantify the degree of functional limitation for patients with heart disease. The NYHA classification assesses physical activity limitations, symptoms of fatigue, palpitations, dyspnea or angina pain upon engagement in ordinary physical activity, and the individual's status at rest. The NYHA is divided into four classes, where Class I denotes no symptoms, Class II denotes mild symptoms with ordinary activities, Class III reflects marked symptoms at less than ordinary activity levels, and Class IV reflects severe limitations even at rest and the inability to perform any activity. The NYHA reflects a subjective assessment by the healthcare provider (Hunt et al., 2005) and can change over time. For the purposes of our analyses, reflecting common usage, the NYHA Functional Class was dichotomized as NYHA Class I and II versus NYHA Class III and IV (Irvine et al., 2002; Rahmawati et al., 2016).

**Left ventricular ejection fraction.** LVEF was obtained from the participants' charts and was recorded as a continuous variable in order to not lose granularity of this cardiovascular function indicator. Every effort was made to capture an LVEF reading at the time of recruitment. However, not every individual had a recent ECHO and thus did not have a recent LVEF recording. As per the advice and clinical practice of the electrophysiology fellow who worked on this study, we allowed for the LVEF to range +/- six months from the time of recruitment. This also coincides with practice in electrophysiology studies (Moss et al., 2005).

**ICD shocks.** The ICD therapy variables (i.e., shock and ATP) were extracted from participant charts. For the purposes of analyses and in line with previous studies, the shock variable was dichotomized into zero to four shocks versus equal to or more than five shocks.

**Life stress.** This Life Stress Scale (LSS) has been adapted from the Holmes and Rahe (1967) Social Readjustment Rating Questionnaire. The scale developed by Holmes and Rahe (1967) comprises a list of life events that demand an adjustment on the part of the individual experiencing a given event. The process of adjustment is considered stressful with some life events inherently more stressful than others. The version used in this study is abbreviated and includes the 14 items rated most inherently stressful on the Holmes and Rahe Social Readjustment Rating Questionnaire. As was planned in the Ontario Health Study (Ontario Health Study, 2018), an additional question regarding the death of a pet is included in the present Life Stress Scale. The final measurement protocol of the Ontario Health Study, however, did not ultimately include the Life Stress Scale. The total score is obtained by summing the number of events endorsed.

**Data entry and statistical analyses**

Questionnaire data were entered manually into a database created in SPSS version 21.0 (IBM Corp. Released 2012). Data entry was double checked for accuracy by the study coordinator and a research assistant. Questionnaire scoring syntax statements were created in SPSS for all questionnaires except for the SF-36 for which a scoring license was purchased. All statistical analyses were performed using SPSS version 21.0.

Descriptive statistics (e.g., means and standard deviations, and Pearson correlation coefficients within groups) were first performed. To examine Hypothesis 1, namely psychological predictors of anxiety, depression, and PTSD, hierarchical regression analyses were conducted to examine the predictive validity of the independent variables. The baseline value of the given dependent variable was entered in the first model, followed by control variables in the second model, and finally psychological predictor variables in the third model. By controlling for

the baseline value of a given dependent variable in the first model, these analyses assessed residualized change scores. For further details please refer to the Results section below.

Hypothesis 2 examined the HRQoL comparison between ICD recipients who underwent an ablation procedure and those who did not. Initially, it was planned to utilize analysis of covariance (ANCOVA) to test the comparison between the two groups over time on outcome variables, covarying for the baseline value of SF-36. It was planned to repeat the ANCOVA for each of the dependent variables (HADS, IES-R), covarying for their respective baseline value, to examine if there was greater improvement on symptoms at follow-up in the ablation therapy group. As mentioned previously, it was proposed to run the ANCOVA on participants who were matched on sex, age, and time since ICD implant. However, as the study unfolded it became apparent that the number of ablation procedures performed at the recruitment sites was lower than anticipated and it also became progressively more challenging to find appropriate control participants. In consultation with a statistician, it was decided to perform regression analyses instead. This was done as a way to retain valuable data from those individuals who completed the questionnaires but may not have had a match or whose matching participant was missing some questionnaire data. For further details on the regression models for Hypothesis 2, please refer to the Results section.

# Results

## Data screening

Data cleaning of the electronic database was performed prior to conducting statistical analysis. Any missing data or inconsistencies were verified against hospital paper and electronic charts and completed questionnaires. If the data were available, corrections were made in the electronic database.

Similarly, missing data on questionnaires was inspected. At the baseline time-point the number of individual missing items on a given questionnaire ranged from 1.6% (e.g., $n = 1$ on IES-R) to 6.6% (e.g., $n = 4$ on HADS). At the six-month follow-up the number of individual missing items on a given questionnaire ranged from 14.8% (e.g., $n = 9$ on SF-36) to 19.7% (e.g., $n = 12$ on IES-R). Missing data were handled in two ways. The SF-36 questionnaire was scored electronically by way of QualityMetric scoring software. This scoring system handled missing data by way of QualityMetric's Missing Score Estimator (Maruish, 2011). With this algorithm, the Physical Component Summary (PCS) and the Mental Component Summary (MCS) scores can be calculated when seven scale scores are available and the Physical Functioning Scale or the Mental Health Scale are not missing for the PCS and MCS, respectively. With respect to the remainder of the questionnaires, data were screened and determined to be missing at random as evaluated by Little's Missing Completely At Random Test (Tabachnick & Fidell, 2007). Thus, missing data were imputed by calculating means from the available data points and the missing values were replaced prior to analysis (Tabachnick & Fidell, 2007; von Känel et al., 2011). A conservative approach of imputing data was adopted, namely data were imputed only if at least 80% of items were completed. Missing values were not imputed for data related to ICD function

(i.e., ICD therapy) or for other control variables (e.g., functional status) in order to preserve internal validity.

Hierarchical regression analyses were performed in order to test both hypotheses. Regression diagnostics examining assumptions of normality, linearity, and homoscedasticity between the predicted dependent variable scores and the errors of the prediction were performed for all models (Tabachnick & Fidell, 2007). Inspection of the histograms of standardized residuals of the regressions and the normal probability plot of residuals suggested that the residuals were approximately normally distributed. Standardized residuals were plotted by predicted values. Across the optimal linear combination of the predictors, the residuals were approximately linear and homoscedastic. Outliers were assessed by way of standardized residuals, Cook's Distance, and Centered Leverage Value and no observation was excessively influential thus none was removed from the analyses. Independence of errors was assessed by the Durbin-Watson statistic and all were well within the 1-3 range and suggested that the data was not autocorrelated. The Variance Inflation Factor for each predictor was well below 5 and did not suggest a problem with multicollinearity.

**Participants**

**Patient accrual.** Of 885 individuals who were screened for the study, 92 were eligible and approached for study participation. Nineteen individuals declined participation due to not feeling well ($n$ = 6), lack of interest ($n$ = 12), and participating in another study ($n$ = 1). Another three eligible patients could not be reached. Nine additional patients were excluded for the following reasons: cognitive difficulties/deafness ($n$ = 2), ultimately did not undergo an ablation procedure ($n$ = 1), underwent heart transplant shortly after being approached for this study ($n$ = 1), during the data cleaning process it was discovered that an individual consented and

completed questionnaires but was incorrectly recruited (*n* = 1), incorrect packages were sent for completion (i.e., a baseline questionnaire was mailed rather than a follow-up questionnaire; *n* = 2), and underwent subsequent ablation procedures between their baseline and follow-up questionnaires (*n* = 2). Relating to the last-stated reason, since the completed follow-up questionnaires may have reflected the participants' experience related to subsequent VT ablations rather than the index ablation for which they were recruited, a rule was developed to exclude the follow-up data from analyses. Thus, as the study evolved, this was instituted as an exclusion rule. Of the 31 individuals not recruited or excluded from the analysis, 26 (83.9%) were male and 17 (54.8%) were in the ablation group.

Of the 61 individuals enrolled to participate, 50 completed all of the questionnaires at follow-up, whereas 11 completed only some or none of the questionnaires at follow-up. Partial or non-completion of follow-up questionnaires was due to heart transplant (*n* = 1), loss to follow-up (*n* = 6), choosing not to answer specific scales on the questionnaire (*n* = 2), and death (*n* = 2; see Figure 1).

**Sample characteristics at baseline**

Demographic and medical characteristics of study participants are presented in Table 1. Participants ranged in age from 23 to 86 years, with a mean age of 63.66 years (*SD* = 14.34). The majority of participants were male (*n* = 56, 91.8%), living with a family member or roommate (*n* = 52, 85.2%), and had completed greater than a high school education (*n* = 45; 73.8%).

With respect to cardiac diagnosis, 54.1% (*n* = 33) of participants were diagnosed with ischaemic cardiomyopathy, 39.3% (*n* = 24) were diagnosed with non-ischaemic cardiomyopathy, and 6.6% (*n* = 4) had congenital heart disease. Assessment of functional capacity by way of the NYHA indicated that 82% (*n* = 50) of participants could perform all activities of daily living

with minimal or no cardiovascular symptoms (NYHA I or II), and 16.4% ($n$ = 10) were markedly affected by their cardiac disease (NYHA III or IV). NYHA class was missing for one participant. With respect to medications, Class II antiarrhythmic beta-adrenergic blockers ($n$ = 53, 88.3%) were most commonly used. Use of psychotropic medication, anxiolytic or mood, was present in 13.3% ($n$ = 8) of participants.

About half of the participants ($n$ = 32, 52.5%) had an ICD implanted for secondary prevention. Forty-one percent of patients had previously had one or two ICD shocks, 33% had more than four shocks, and about 10% had only ATP. Approximately half of the participants underwent an ablation procedure for their ventricular arrhythmia ($n$ = 34, 55.7%). Of these individuals, 32.4% ($n$ = 11) had an ablation by way of the activation approach, 58.8% ($n$ = 20) had the substrate approach, while 8.8% ($n$ = 3) had a combined approach. Seventy-nine percent of the ablations were deemed to be successful ($n$ = 27).

Differences on demographic and clinical variables between participants who completed all of the questionnaires (i.e., "Completers") and those who were missing at least some questionnaires (i.e., "Non-completers") were tested by way of independent samples t-tests and chi-square tests. Completers and non-completers did not differ on age, $t(59) = .20$, $p = .84$, level of education, $\chi^2(5) = 4.26$, $p = .51$, living situation, $\chi^2(3) = 1.20$, $p = .75$, NYHA, $\chi^2(1) = .56$, $p = .46$), cardiac diagnosis, $\chi^2(2) = .16$, $p = .92$, indication for ICD implant, $\chi^2(1) = .57$, $p = .45$, number of ICD shocks, $\chi^2(3) = .24$, $p = .95$, group membership, $\chi^2(1) = .58$, $p = .45$, ablation approach, $\chi^2(2) = 1.24$, $p = .54$, or the outcome of the ablation procedure, $\chi^2(2) = 2.85$, $p = .24$. There were no differences between groups on any of the medications consumed whether antiarrhythmic or psychotropic.

Table 2 presents the descriptive statistics displaying baseline means, standard deviations, ranges and reliability estimates for outcome and predictor variables utilized in this study. Reliability estimates suggest that most scales had high internal consistency (Cronbach's $\alpha$ = .83 - .95) with HADS-Depression showing moderate internal consistency (Cronbach's $\alpha$ = .76). Testing for equality of means on the predictor and outcome variables by way of an independent samples t-test yielded no significant differences between completers and non-completers on any of the outcome or predictor measures, HADS-A, $t(56) = 1.02$, $p = .31$; HADS-D, $t(56) = .44$, $p = .66$; IES-R Total, $t(58) = .63$, $p = .53$; IES-R Intrusion, $t(58) = .86$, $p = .39$; IES-R Avoidance, $t(58) = .16$, $p = .87$; IES-R Hyperarousal, $t(58) = .73$, $p = .47$; LOT, $t(58) = .15$, $p = .88$; PHE, $t(58) = .07$, $p = .95$; MAT I, $t(58) = -.68$, $p = .50$; MCS, $t(58) = -.94$, $p = .35$; PCS, $t(58) = .02$, $p = .98$.

**Pairwise sample effect approach to analyses**

Due to the small sample size, a consideration was made whether to employ pairwise or listwise sample effects when performing regression analyses to test Hypothesis 1 and 2. Several steps were taken to make an informed decision. Firstly, both pairwise and listwise sample effects were performed and the given regression results were similar. Moreover, since more participants completed baseline than follow-up questionnaires, any important potential baseline differences were examined to determine if differences existed between those participants who completed all questionnaires at follow-up and those who completed only some questionnaires. No differences were detected on demographic or clinical variables or on baseline measures (please refer to the discussion above). Given that no appreciable differences were detected, it was decided to proceed with pairwise sample tests. Importantly, in light of the small sample size, this approach to handling data allowed for the optimal use of data which were available and was thus likely to

minimize Type II error. As a result, all the regression tables that are displayed also indicate the sample size for each comparison or regression.

**Univariate testing of predictive value of psychotropic medication prescription**

Prior to running regression analyses, an exploratory univariate analysis was conducted to assess whether prescription of psychotropic medications had predictive value and as such whether medication use should be included in the regression models as a control variable. Medication data was obtained through chart review. Regressions were performed by entering the baseline value of the respective dependent variable (e.g., HADS-A baseline) in the first step and psychotropic medication in the second step. Not surprisingly, the baseline scores of the dependent variables predicted a significant amount of variance for each respective dependent variable, however psychotropic medication did not help explain a further significant proportion of the variance in predicting HADS-Anxiety, $\Delta R^2 = .01$, $F[1, 45] = 1.38$, $p = .25$, HADS-Depression, $\Delta R^2 = .002$, $F[1, 45] = .33$, $p = .57$, IES-R Total, $\Delta R^2 = .003$, $F[1, 46] = 2.05$, $p = .57$, IES-R Intrusion, $\Delta R^2 = .03$, $F[1, 46] = 2.82$, $p = .10$, IES-R Avoidance, $\Delta R^2 = .00$, $F[1, 46] = .00$, $p = .99$, or on IES-R Hyperarousal, $\Delta R^2 = .01$, $F[1, 46] = .49$, $p = .49$. Consequently, psychotropic medications were not included in the regression models.

**Hypothesis 1: Psychological predictors of anxiety, depression, and PTSD**

**Descriptive statistics.** Table 3 displays means, standard deviations, and ranges for baseline and follow-up outcome and predictor measures for participants who completed a given questionnaire at both time points. As pairwise sample effects were employed, the table also captures the sample size included when calculating these descriptors for each measure.

Scores were compared with published norms or relevant literature to examine whether they were clinically elevated. Also, in order to examine differences between baseline and follow-

up, paired sample t-tests were conducted for each measure and are displayed in Table 3. With respect to anxiety and depression, Snaith (2003) outlined guidelines for interpreting HADS-A and HADS-D scores and defined caseness as score of ≥8 on either scale. The proportion of those who scored above the cut-off on HADS-A were 36.7% and 24.4% on HADS-D. Neither the mean HADS-A nor HADS-D scores in the current sample reached the level of caseness. The baseline scores were comparable with a similar sample of ICD patients in an earlier RCT (Irvine, Stanley, et al., 2010) and a group of ICD recipients with congenital heart disease (Ingles, Sarina, Kasparian, & Semsarian, 2013). Overall, improvements in anxiety were noted over the follow-up period (see Table 3). With respect to PTSD, the current sample of participants had comparable scores to ICD participants enrolled in an RCT (Irvine et al., 2010). Improvement over time was observed for IES-R Total and the Intrusion and Hyperarousal subscales (see Table 3).

Correlations between independent measures, control variables, and outcome measures are presented in Table 4. Initially, NYHA, LVEF, group, shocks, and life stress were planned to be used as control variables. Due to the small sample size, control variables were reviewed in order to assess which might be removed. Upon reviewing the data, it became apparent that the two measures of functional status were candidates for removal; NYHA was retained as it is symptom based and was, in this study, more strongly related to the outcome measures than LVEF. Moreover, most recent LVEF measurements were not available for each patient, whereas NYHA was obtained upon recruitment. Thus, NYHA was deemed a more appropriate measure to retain. Life stress was similarly removed as it correlated very poorly with predictor measures (e.g., LOT $r = .01$, $p = .95$) as well as the control measures (e.g., shocks $r = -.09$, $p = .46$). Beyond the aforementioned measures, age was included in the regression analyses as it was correlated to both the predictor measures as well as anxiety and intrusion symptoms of trauma.

**Regression summaries**

Hypothesis 1 assessed whether higher optimism, positive health expectations, and self-efficacy at baseline would predict improvement in symptoms of depression, anxiety, and PTSD at follow-up. Hierarchical regression analysis was adopted in order to test the predictive validity of psychological predictors. Baseline values of the given dependent variable were entered in the first step, control variables (i.e., group, shocks, age, NYHA) were entered in the second step, and the predictor variables were entered in the third step (i.e., LOT, PHE, and MAT I).

**Prediction of anxiety and depression symptoms at follow-up.** Tables 5 and 6 summarize the results of the regression models examining anxiety and depression outcomes. For anxiety, Models 1 and 2 explained a significant proportion of variance although Model 3, which included the psychological predictors, did not. Model 1, as would be expected, indicated that baseline HADS-A significantly predicted anxiety at follow-up (unstandardized $B = .74$), accounting for 72.6% of the variance, $F(1,47) = 126.48$, $p < .001$, where individuals with higher baseline anxiety scores showed higher anxiety at follow-up. Including control variables in Model 2 indicated that functional status (unstandardized $B = 2.63$) explained a significant proportion of variance, 5.3%, $F(4, 43) = 2.61$, $p = 0.048$, over and above baseline HADS-A. Individuals with poorer NYHA functional status experienced less improvement in anxiety at follow-up. In the third model psychological predictors were examined. While this model did not reach conventional levels of significance, $\Delta R^2 = 0.026$, $F(3, 40) = 1.78$, $p = 0.167$, it is possible that it would have with a larger sample size, thus, a brief overview is warranted. This model suggests a trend where those participants with higher perceived self-efficacy at baseline experienced an improvement in symptoms of anxiety at follow-up (unstandardized $B = -.52$) over and above other predictors.

With respect to depression, not surprisingly, Model 1 explained a significant proportion of variance, 62.9%, F(1,47) = 105.78, $p < .001$. Here, individuals with higher baseline depression scores showed less improvement in depression at follow-up (unstandardized $B = .90$) relative to baseline although overall depressive symptoms appear to have remained relatively stable over time. Models which included control variables, $\Delta R^2 = 0.028$, $F(4, 43) = 1.07$, $p = 0.384$, and psychological predictors, $\Delta R^2 = 0.023$, $F(3, 40) = 1.20$, $p = 0.322$, did not add explanatory value.

**Prediction of PTSD symptoms at follow-up.** Tables 7 – 10 summarize the results of the regression analyses examining symptoms of PTSD at follow-up. When investigating the overall PTSD score (Table 7), Models 1 and 3 explained a significant proportion of variance while Model 2 explained a borderline significant amount of variance. In Model 1, as expected, greater PTSD at baseline was a significant predictor of deteriorating PTSD levels at follow-up (unstandardized $B = .62$), accounting for 56.4% of the variance, $F(1,47) = 60.87$, $p < .001$. Model 3 which included psychological variables explained an additional 7.2% of variance, $F(3, 40) = 3.32$, $p = 0.029$, where greater perceived self-efficacy at baseline (unstandardized $B = -.12$) was an independent predictor of improved PTSD levels at follow-up, over and above other predictors. Baseline levels of PTSD and functional status remained significant predictors of PTSD levels at follow-up.

Examining symptoms of PTSD by way of individual domains showed that when looking at symptoms of intrusion all three models accounted for a significant amount of variance (Table 8). Model 2 accounted for an additional 9.6% of the variance, $F(4, 43) = 2.69$, $p = .044$, where functional status emerged as an independent predictor (unstandardized $B = .51$) over and above baseline level of intrusion. Model 3, which included psychological predictors, explained another 13.2% of the variance, $F(3, 40) = 7.04$, $p < .001$. Perceived self-efficacy at baseline emerged as

an independent predictor over and above other predictor variables where greater self-efficacy at baseline predicted an improvement in symptoms of intrusion at follow-up (unstandardized $B$ = -.16). Interestingly, the model suggested that higher positive health expectations at baseline predicted less improvement in levels of intrusion at follow-up. Notably, the unit of change is small and suggests that for every one unit difference in positive health expectations there is less improvement in symptoms of intrusion by .02 (unstandardized $B$ = .02). This finding is counter to the hypothesis being tested. This raises the question of whether individuals who have greater positive expectations might be more disappointed when these expectations are not met. Importantly, however, as the unstandardized beta is so small the presence of a Type I error cannot be ruled out. Baseline levels of intrusion and functional status remained significant predictors in Model 3.

Unlike for symptoms of intrusion, the two models with control and psychological variables did not explain a significant proportion of the variance in avoidance symptoms at follow-up (Table 9). Not surprisingly, only Model 1 which included baseline levels of avoidance accounted for a significant proportion of variance, 23.6%, $F(1, 47) = 14.54$, $p < .001$, in symptoms of avoidance at follow-up.

Lastly, Models 1 and 3 explained a significant proportion of the variance in symptoms of hyperarousal while Model 2 explained a borderline significant amount of variance (Table 10). Model 2 saw functional status (unstandardized $B$ = .53) as an independent predictor over and above baseline levels of hyperarousal. Model 3 accounted for an additional 8.00% of the variance, $F(3, 40) = 3.58$, $p = .022$, where greater perceived self-efficacy at baseline (unstandardized $B$ = -.14) predicted improved symptoms of hyperarousal at follow-up over and above other predictor variables.

To summarize, perceived self-efficacy emerged as a significant predictor of improved symptoms of anxiety, overall PTSD as well as symptoms of intrusion and hyperarousal. However, contrary to hypothesis, higher optimism at baseline did not help predict improvement in symptoms of anxiety, depression, or PTSD. Similarly, higher positive health expectations at baseline did not help predict improvements in these domains. Indeed, higher positive health expectations were found to predict a small worsening of symptoms of intrusion at follow-up. Simply examining changes of the dependent measures between baseline and follow-up, the current sample of participants showed improvement on symptoms of anxiety, overall PTSD as well as symptoms of intrusion and hyperarousal.

**Hypothesis 2: HRQoL and psychological well-being in ablation and control groups**

**Descriptive statistics per group of all recruited participants.** Table 11 presents demographic, cardiovascular, and pharmacologic characteristics of all recruited participants based upon whether they underwent an ablation or not. Independent samples t-tests and chi-square tests were utilized to test differences on these variables between the two groups. Ablation and control participants did not differ on age, $t(59) = .38$, $p = .71$, level of education, $\chi^2(5) = 2.12$, $p = .83$, living situation, $\chi^2(3) = 3.53$, $p = .32$, cardiac diagnosis, $\chi^2(2) = 3.52$, $p = .17$, or number of ICD shocks, $\chi^2(1) = 2.45$, $p = .12$. For purposes of statistical analyses, ICD data were collapsed into two groups: zero to four shocks and five or more shocks. Zero to four shocks was received by 58.8% of ablation and 77.8% of control participants. Five or more shocks were received by 41.2% of ablation and 22.2% of control participants. Differences were detected on NYHA, $\chi^2(1) = 5.94$, $p = .02$, and indication for ICD implant, $\chi^2(1) = 5.73$, $p = .02$. With respect to medication use, differences were noted on use of Class III antiarrhythmics, $\chi^2(2) = 18.70$, $p < .001$, but not on other types of medication.

Table 12 presents baseline means, standard deviations, and ranges for outcome variables per group. Testing for equality of means on the outcome variables by way of an independent samples t-test yielded significant differences between the ablation and control groups on the PTSD measure, IES-R Total, $t(58) = -2.71$, $p = .009$; IES-R Intrusion, $t(58) = -2.77$, $p = .008$; IES-R Avoidance, $t(58) = -2.34$, $p = .02$; IES-R Hyperarousal, $t(58) = -2.25$, $p = .03$. Significant between-group differences were not detected on measures of HRQoL or anxiety and depression, MCS, $t(58) = 1.56$, $p = .12$; PCS, $t(58) = -.38$, $p = .70$; HADS-A, $t(56) = -1.15$, $p = .26$; HADS-D, $t(56) = .08$, $p = .94$.

An exploratory regression analysis was performed to examine whether there were any differences on outcome measures between participants whose ablation was deemed to be successful as compared to those whose ablation was deemed unsuccessful. The baseline value of the dependent variable was controlled for in the first step while the grouping variable was entered in the second step. Due to the low number of unsuccessful ablations (n = 5), the two additional participants whose ablations were deemed to be partially successful were recoded as unsuccessful for this analysis. Significant differences were not detected between the successful and unsuccessful ablations on any of the outcome measures: MCS (unstandardized $B = -2.35$, $p = .52$), PCS (unstandardized $B = 1.84$, $p = .59$), HADS-Anxiety (unstandardized $B = 1.08$, $p = .34$), HADS-Depression (unstandardized $B = -1.04$, $p = .30$), IES-R Total (unstandardized $B = .04$, $p = .84$), IES-R Intrusion (unstandardized $B = -.04$, $p = .85$), IES-R Avoidance (unstandardized $B = .16$, $p = .60$), or on IES-R Hyperarousal (unstandardized $B = .21$, $p = .38$).

Likewise, an exploratory regression analysis was performed to assess whether there were any differences on outcome measures between participants who received ICD shocks during the follow-up period as compared to those who did not. Overall, only 7 participants from the study

sample received shocks during the follow-up period. No significant differences were detected. However, as the number of participants who received shocks is very small as compared to those who did not, it is difficult to assess whether any true differences exist.

Tables 13 and 14 present correlations among the predictor and outcome variables within study group. Overall correlations were examined for variables and their relationship to the grouping variable. Shocks ($r$ = .20, $p$ = .12) were not strongly correlated to the grouping variable and were thus not included in the regression model. NYHA was correlated to the grouping variable (e.g., $r$ = .32, $p$ = .01) as well as outcome measures (e.g., PCS; $r$ = .31, $p$ = 03) and was included in the regression.

Table 15 displays means and standard deviations for each group, as well as the within-group comparisons on the psychological measures. An examination of within group differences highlighted areas of improvement for ablation participants over the follow-up period. Ablation participants saw improvements on MCS, $t(28) = -3.35$, $p$ = .002, 95% *CI* [-7.84, -1.89], IES-R Total, $t(27) = 3.05$, $p$ = .005, 95% *CI* [.09, .44], IES-R Intrusion, $t(27) = 3.04$, $p$ = .005, 95% *CI* [.10, .53], and IES-R Hyperarousal, $t(27) = 2.95$, $p$ = .007, 95% *CI* [.10, .53].

Control participants saw improvements between baseline and follow-up on HADS-Anxiety, $t(20) = 2.49$, $p$ = .02, 95% *CI* [.23, 2.54], IES-R Total, $t(20) = 2.20$, $p$ = .04, 95% *CI* [.01, .48], IES-R Intrusion, $t(20) = 2.18$, $p$ = .04, 95% *CI* [.01, .48], and IES-R Hyperarousal, $t(20) = 2.63$, $p$ = .02, 95% *CI* [.07, .58]. They did not, however, see any improvements with respect to HRQoL on either the MCS, $t(21) = -1.51$, $p$ = .15, 95% *CI* [-8.33, 1.32] or PCS, $t(21) = -1.24$, $p$ = .23, 95% *CI* [-5.73, 1.44].

**Regression summaries**

Hypothesis 2 assessed whether global measures of HRQoL, anxiety, depression, and PTSD would improve more over the follow-up period in ICD recipients who underwent an ablation procedure as compared to those who did not. Two types of regression analyses were performed for each dependent variable. To test the original hypothesis, a simple regression with the baseline value of the dependent variable was entered in the first model and the grouping variable (i.e., ablation versus control) was entered in the second model. To account for the variables that were used to recruit participants and potential confounds, a three-step hierarchical regression was performed where baseline values of the given dependent variable were entered in the first model, variables which were used to recruit and match participants (i.e., age, gender, time since ICD implant) and control variables (i.e., NYHA) were entered in the second model, and the grouping variable (i.e., ablation or control) was entered in the third model. Regression analyses of both the simple model and the three-step model are presented below.

**Prediction of HRQoL at follow-up.** Overall, between-group differences were not observed on either the Mental Component Summary (MCS; Table 16 and 17) or on the Physical Component Summary (PCS; Table 18 and 19) when looking at the three-step regression or the simple model. Not surprisingly, the baseline values of MCS and PCS accounted for a significant proportion of the variance across the models. With respect to MCS, no other variable contributed significant explanatory power. Similarly, when examining PCS the addition of control variables, $\Delta R^2 = .064$, $F(4, 44) = 1.74$, $p = .16$, and the grouping variable, $\Delta R^2 = .001$, $F(1, 43) = .06$, $p = .81$, did not help explain additional variance.

**Prediction of anxiety and depression symptoms at follow-up.** As with HRQoL, between-group differences were not observed on symptoms of anxiety (Table 20 and 21) or

depression (Table 22 and 23) over the follow-up period in the three-step model or the simple model. Not surprisingly, baseline levels of anxiety accounted for a significant proportion of variance across models. Gender (unstandardized $B$ = -2.65) and functional status (unstandardized $B$ = 2.31) were significant predictors over and above other predictor variables in Model 2 which explained a significant proportion of variance, $\Delta R^2$ = .074, $F(4, 43) = 4.01$, $p$ = .007. Examining depression, it was only the first model which accounted for a significant proportion of variance, $R^2$ = .629, $F(1, 47) = 105.78$, $p$<.001. Addition of control variables, $\Delta R^2$ = .038, $F(4, 43) = 1.51$, $p$ = .22, or the grouping variable, $\Delta R^2$ = .006, $F(1, 42) = .88$, $p$ = .35, did not help add explanatory power.

**Prediction of PTSD symptoms at follow-up.** Symptoms of trauma are next reviewed with respect to overall symptoms of PTSD as well as specific PTSD domains. The three-step regression as well as the simple model yielded similar results and thus the more complex model findings will be reviewed below. Generally, group differences were not detected across symptoms of PTSD.

With respect to the total IES-R scores (Table 24 and 25), as expected baseline levels of PTSD accounted for a significant proportion of the variance across models. Model 2 accounted for an additional 17% of the variance, $F(4, 43) = 2.38$, $p$ = .13, where age (unstandardized $B$ = .01), gender (unstandardized $B$ = -.79), and functional status (unstandardized $B$ = .31) emerged as independent predictors over and above other predictor variables. Model 3 did not add further explanatory power, $\Delta R^2$ = .007, $F(1, 42) = 1.19$, $p$ = .28. A similar pattern was observed with respect to symptoms of intrusion (Table 26 and 27). Baseline levels of intrusion, as expected, accounted for a significant proportion of the variance across the three models. Model 2 helped account for an additional 18.6% of the variance, $F(4, 43) = 6.87$, $p$ < .001, with age

(unstandardized $B$ = .01), gender (unstandardized $B$ = -.85), and functional status (unstandardized $B$ = .42) emerging as independent predictors over and above other predictor variables. However, the grouping variable did not account for a significant amount of variance. Similarly, and not surprisingly, baseline levels of avoidance (Table 28 and 29) accounted for a significant proportion of variance across the three models. Model 2 was borderline significant, $\Delta R^2$ = .141, $F(4, 43) = 2.43$, $p$ = .06, whereby participants who had their ICDs implanted for a longer period of time showed a borderline significant decrease in symptoms of avoidance (unstandardized $B$ = -.003). Model 3 did not add further explanatory power, $\Delta R^2$ = .033, $F(1, 42) = 2.38$, $p$ = .13, and this was also true for the grouping variable in that model (unstandardized $B$ = .28; $p$ = .13). Lastly, symptoms of hyperarousal (Table 30 and 31) followed a similar pattern as the two aforementioned subscales. As expected, baseline levels of hyperarousal accounted for a significant proportion of the variance across the three models. Model 2 explained an additional 15.2% of the variance, $F(4, 43) = 5.22$, $p$ = .002, with gender (unstandardized $B$ = -.80) and functional status (unstandardized $B$ = .41) emerging as independent predictors over and above other predictor variables, revealing that men changed more than women and that poorer functional status was related to more of an improvement in hyperarousal symptoms. Yet again, group differences were not observed when the grouping variable was entered into the third model.

In summary, contrary to hypothesis, between-group differences were not detected with respect to HRQoL, anxiety, depression, or PTSD symptoms. However, upon examining within-group changes both the ablation and control participants showed improvements in specific domains. Participants with an ICD who underwent an ablation procedure showed improvement in HRQoL specifically on the MCS, overall PTSD symptoms as well as levels of intrusion and

hyperarousal. Improvements in HRQoL were not observed for those ICD recipients who did not undergo an ablation procedure. However, this group did see an improvement in symptoms of anxiety, overall PTSD, and symptoms of intrusion and hyperarousal over the follow-up period.

## Discussion

The first aim of this case-control, prospective, study was to examine whether self-efficacy, optimism, and positive health expectations predict improvement in symptoms of PTSD, anxiety, and depression following VT ablation in ICD recipients. The second aim was to assess whether the VT ablation procedure was associated with greater improvement in HRQoL in patients who underwent the procedure as compared to matched control ICD recipients who did not. To date, only a few studies have examined the psychological and HRQoL effects of VT ablation in ICD recipients (Gula et al., 2018; Kuck et al., 2010; Maryniak et al., 2006; Strickberger et al., 1997). The present study is the first to explore symptoms of PTSD in a larger sample of VT ablation patients, assess individual differences as they predict psychological well-being after VT ablation in ICD recipients, and utilize state-of-the-art psychological measures to assess the aforementioned hypotheses. Moreover, the uniqueness and importance of this study lie in the population of ICD recipients; namely, those who have a long history of cardiac illness and profound and incessant VT burden. Participants who underwent a VT ablation procedure generally had more advanced disease and significant cardiac symptoms. This is the case even when compared to their own matched controls, as ablation patients experienced recurrent sustained VT, VT storms, or recurrent shocks despite antiarrhythmic treatment which is what necessitated the ablation. Thus, this population has had longstanding cognitive, behavioural, and emotional reactions to the stressful cardiac events associated with their VT and arrhythmia treatments. For this reason, the merit of this study, beyond examining whether the VT ablation exerts an impact on HRQoL, is the exploration of individual differences which might impact psychological well-being for this profoundly unwell group of patients.

The chief findings for Hypothesis 1 are that higher perceived self-efficacy at baseline significantly predicted improvement in anxiety-based symptoms (i.e., symptoms of anxiety, overall PTSD, intrusion and hyperarousal) at follow-up over and above group membership and presence of ICD shocks. Contrary to the hypothesis, positive health expectations and optimism at baseline did not predict improvement in symptoms of PTSD, anxiety, or depression. Hypothesis 2 was not supported in that significant between-group differences were not found on measures of HRQoL, anxiety, depression, and PTSD over the study follow-up. Ablation participants, however, showed improvement in mental health HRQoL, overall PTSD, and symptoms of intrusion and hyperarousal. Participants in the control group showed improvement in symptoms of anxiety, overall PTSD, intrusion and hyperarousal. Study findings as they relate to each hypothesis are discussed below.

**Design, recruitment, and sample**

Prior to discussing study findings, it is important to note that the design of this study deviated in several ways from the original proposal. With respect to Hypothesis 1, LVEF and life stress were not included as control variables in the regression analyses. Hypothesis 2 was originally planned to be analysed by way of analysis of covariance. In order to retain valuable data from participants who completed questionnaires but did not have an appropriate match, regression analyses were performed instead.

The recruitment procedure for this study seems to have generated a sample of patients fairly similar to samples recruited in other related studies of ICD and VT ablation patients (Gula et al., 2018; Irvine et al., 2011; Kuck et al., 2010; Sapp et al., 2016; Sears et al., 2004). For example, while the current study had somewhat more male participants as compared to studies of first-time ICD recipients (Irvine et al., 2011; Sears et al., 2004), the gender distribution was

nearly on par with RCTs of VT ablation patients (Gula et al., 2018; Kuck et al., 2010; Sapp et al., 2016). The current sample was similar in age to the above-named studies but somewhat more educated (Irvine et al., 2011; Sears et al., 2004). The current sample displayed poorer functional status compared to first-time ICD recipients (Irvine et al., 2011) but was similar to other studies examining ICD patients undergoing a VT ablation (Gula et al., 2018; Kuck et al., 2010; Sapp et al., 2016). Lastly, the current study is similar to a recent RCT of VT ablation (Gula et al., 2018; Sapp et al., 2016) in that participants who were recruited already had an ICD and had thus been exposed to arrhythmia treatments prior to undergoing a VT ablation. However, it differs in this respect from studies of first-time ICD recipients and an RCT of prophylactic ablation patients (Irvine et al., 2011; Kuck et al., 2010; Sears et al., 2004) as participants in the current study generally lived with an ICD for an extended period of time. They were thus likely to have been exposed to greater arrhythmia burden and repeated arrhythmia treatments. This fortifies the suggestion that this is a profoundly unwell sample of participants who have lived with arrhythmia burden for a prolonged period. Overall, however, the current sample appears to be representative of this population of ICD recipients and those undergoing a VT ablation. As such, the present findings are unlikely to be due to sampling error or bias.

With respect to psychological outcome variables, the only RCT similar in study population was the VANISH trial (Gula et al., 2018). Mean baseline scores of anxiety and depression in the VANISH study were generally similar to those in the present study although ICD participants who did not undergo an ablation in the current study appeared to have lower baseline anxiety as compared to their counterparts in the VANISH trial. This, however, did not appear to impact detection of between-group differences. While the VANISH RCT (Gula et al., 2018) provides some comparison the comparative measures are very limited as that trial utilized

an older version of the HRQoL measure and did not assess symptoms of PTSD. As such the comparison of baseline mean scores of psychological outcomes has been extended to other studies that have used similar measures in ICD recipients or ablation patients. Such a comparison suggests that the present baseline mean scores of depression, anxiety, PTSD, and HRQoL are generally similar to those of other studies of ICD recipients (Irvine et al., 2011; Kapa et al., 2010). As such, the participants in the current study appear to be a representative sample.

**Hypothesis 1**

In line with the study hypothesis, higher perceived self-efficacy at baseline significantly predicted improvement in symptoms of anxiety, overall PTSD, as well as PTSD symptoms of intrusion and hyperarousal at follow-up. Specifically, self-efficacy at baseline was a significant predictor of the above-named outcomes after controlling for baseline values of the respective outcome variable, demographic, and cardiac variables. Importantly, self-efficacy emerged as a significant predictor over-and-above group membership (i.e., VT ablation or control) as well as occurrence of shocks. This suggests that self-efficacy is a protective factor even in individuals who experienced a recent cardiac event, such as recurrent VT or shocks, which necessitated a VT ablation. In this study, the VT ablation procedure itself was not associated with psychological outcomes. While self-efficacy was predictive of anxiety-based measures, contrary to the hypothesis, it was not predictive of depression. Furthermore, and contrary to expectations, optimism and positive health expectations at baseline did not predict improvement in symptoms of PTSD, anxiety, or depression at follow-up.

**Self-efficacy.** Study findings pertaining to self-efficacy are congruent with findings from other studies involving health and non-health populations (Benight et al., 1997; Blackburn & Owens, 2015; Joekes & Van Elderen, 2007; Johansen et al., 2007). The finding that greater self-

efficacy was associated with improved PTSD levels at follow-up fits with the longitudinal findings of Johansen et al. (2007). Their study of predominantly male victims of violence used the IES-R to assess trauma symptoms. Self-efficacy was negatively correlated with total trauma across the follow-up periods and predicted symptoms of PTSD in the short, medium, and long term. Although both studies utilized the IES-R it is difficult to compare mean scores as there is not an agreed upon way of scoring the measure. While the present study scored the IES-R based upon the Weiss (2004) recommendation, and consistent with previous research (Irvine et al., 2011), the Johansen et al. (2007) study did not. Nevertheless, findings remain consistent highlighting the protective nature of self-efficacy as it relates to trauma outcome.

Similarly, results from the present study are in line with the cross-sectional findings of Blackburn and Owens (2015) where hierarchical regression analyses revealed higher self-efficacy to be a predictor of lower PTSD. Blackburn and Owens (2015) also assessed the interaction between self-efficacy and exposure to combat and reported that when exposure to combat was high, as self-efficacy increased, PTSD severity decreased. Although such an interaction was not tested for in the present study, certain parallels might exist. It is not unreasonable to extrapolate to our study the idea that in a sample of patients experiencing high and repetitive VT burden, as self-efficacy increases, symptoms of PTSD lessen. Namely, when faced with repetitive stressors, such as recurrence of shocks, VT storms, or arrhythmia treatments, those individuals who feel that they can control at least some aspect of their cardiac situation might report lower levels of trauma.

Findings are also in line with those of Benight et al. (1997) who studied self-efficacy in a sample of men with HIV ($n$ = 37) and healthy controls ($n$ = 42) following a hurricane. In both studies, strong negative correlations were reported between self-efficacy and trauma as well as

emotional distress. Their results indicate that higher levels of self-efficacy were related to lower emotional distress and lower symptoms of trauma in both groups over and above control variables (e.g., perceived life threat, education, time since hurricane). It appears that perceptions of self-efficacy acted in similar ways in both healthy controls and men with HIV. Notably, using the Symptom Checklist-90-Revised, Benight et al. (1997) assessed general emotional distress including depression and anxiety, among other emotional difficulties such as hostility and interpersonal difficulties. While their results show that greater self-efficacy is related to less general distress, results cannot be entirely extrapolated to the present study as Benight et al. (1997) did not examine depression and anxiety subscales per se. Due to the differences in study design, however, comparisons between the present study and that of (Benight et al., 1997) is tentative at best.

Present findings lend partial support to those of Joekes and Van Elderen (2007) where self-efficacy, anxiety, depression and HRQoL were examined in a sample of MI ($n$ = 41) and congestive heart failure patients (CHF; $n$ = 41). Similar to the present study, an inverse correlation between self-efficacy and anxiety and depression as measured by HADS was observed. Higher self-efficacy was predictive of less anxiety and depression, and better HRQoL on baseline scores. Self-efficacy was no longer predictive of these outcomes when baseline values of outcome variables were controlled for in the longitudinal analysis, suggesting that self-efficacy at baseline did not influence change in outcomes. The reduced sample size at follow-up ($n$ = 67) may have compromised the ability to detect the predictive validity of self-efficacy. An alternative explanation may be that the low baseline mean scores for anxiety and depression produced a floor effect which might have contributed to the lack of significant findings in their longitudinal analysis. In other words, there might have been limitations in how much change

relative to baseline scores was possible. Credence for a floor-effect undermining the analyses in the Joekes and Van Elderen's (2007) study is lent when comparing their mean scores to the means observed in the present study. The present study had comparatively higher mean baseline anxiety and depression scores (5.78 vs. 5.02 and 4.89 vs. 3.91, respectively). This is particularly evident with respect to the depression outcome where both studies captured very low depression scores and failed to find predictive validity of self-efficacy in the longitudinal analyses. Another potential contributor to the lack of longitudinal effects for self-efficacy may be that the follow-up period in the Joekes and Van Elderen (2007) study was too short (i.e., three months) whereas the present study followed patients over a six-month period. If one considers that self-efficacy is in part honed through mastery, observing others, and receiving reinforcement it may be that longer than three months is necessary to foster one's ability to organize and integrate behavioural and cognitive skills needed to address one's health condition in such a way as to impact psychological outcomes.

Contrary to the study hypothesis, self-efficacy was only predictive of anxiety-based measures and not depression. This finding is incongruent with the cross-sectional study by Blackburn and Owens (2015) which reported higher general self-efficacy to be predictive of lower depression symptom severity. However, given the design differences between the Blackburn and Owens (2015) study and this study, it is impossible to draw confident comparisons. Unlike this study, the former study did not examine change in depression over time. The lack of an effect on depression outcome in this study might be explained by a floor effect as the depression scores in the present study rendered it difficult to detect improvements in this domain as discussed above.

In summary, results suggest that the appraisal of one's ability to cope with the stressors of the arrhythmia and its associated treatment play an important role in psychological adjustment following arrhythmia treatments. Those individuals who perceive themselves to be efficacious at baseline show improved psychological function, as compared to their baseline functioning, on anxiety-based measures. Importantly, the presence of a VT ablation did not augment these results. ICD recipients undergoing a VT ablation procedure are a profoundly unwell group of participants. These individuals have typically sustained numerous, and stressful, cardiac events or procedures. Thus, due to the chronic nature of their disease and lack of reprieve from VT symptoms, it is perhaps not surprising that benefits of a VT ablation procedure itself are not easily detected. This group of ICD recipients might be so unwell to begin with that any physical intervention is unable to restore their psychological well-being, particularly within a short follow-up time-frame of six-months, on the psychological variables which were measured in this study. However, it cannot be assumed that no improvements would be observed in other psychological domains which were not assessed in the current study. Encouragingly, however, individual differences and resilience factors such as self-efficacy appear to contribute above and beyond the arrhythmia treatment even in the most unwell ICD recipients. If higher self-efficacy helps individuals organise cognitive, motivational, and affective processes (Benight & Bandura, 2004) these results suggest that even when faced with serious health adversity, agentic individuals are able to regulate how they navigate their arrhythmia and treatments. The specificity of the self-efficacy measure as it relates to arrhythmia management, as opposed to the more general measures of optimism and health expectations, may have contributed to its predictive validity in relation to anxiety-based outcomes. Behaviour and actions are context-specific. As such, assessing self-efficacy in relation to navigating arrhythmia burden may have

allowed for the patterns of strengths and limitations to emerge in relation to psychological outcomes (Bandura, 2006). Importantly, Benight and Bandura (2004) conclude that individuals who believe they can overcome the source of the stressor take an active role in navigating their life circumstances rather than letting the circumstances navigate their life. In line with this, participants may have gained a sense of "mastery" through repeated arrhythmia events, which exposed them to the anxious stimulus and necessitated them to face the stressor head-on. Thus, one possible explanation for the effect of self-efficacy may be that through repeated exposures to the arrhythmia stressor, certain participants may have gained a greater sense of control and how they might deal with the situation should it arise again. In turn, individuals might employ coping strategies which allow them to think in self-enhancing ways that offer some sense of control in a largely unpredictable situation thus reducing distress.

**Optimism and positive health expectations.** Contrary to the study hypothesis, neither optimism nor positive health expectations at baseline were predictive of improvement in symptoms of anxiety, depression, or PTSD over the study follow-up. This finding was somewhat surprising as it relates to optimism given it has previously been proposed as a covariate for better psychological outcomes in ICD recipients (Dunbar, 2005). Current findings are incongruent with those of Sears et al. (2004) who reported high optimism to be associated with better HRQoL (mental health and social functioning) at eight-months follow-up in ICD recipients. While both studies reported similar baseline optimism scores (22.05 vs. 21.5, respectively) several factors may have impacted the discrepant findings. First-time ICD recipients which comprised the Sears et al. (2004) sample would have very different arrhythmia burden as compared to patients who have had numerous arrhythmia interventions, complications, and stressors. This difference in samples possibly impacted the ability to detect a predictive relationship between optimism and

psychological outcomes in the present study. Attrition of patients over follow-up (baseline *n* = 88; eight-months *n* = 42; 14-months *n* = 49) may also have had an impact. Lastly, the Sears et al. (2004) study is unique in its use of median splits (i.e., high vs. low optimism and high vs. low positive health expectations) to assess their hypotheses whereas other studies to be reviewed below did not. Employing this statistical choice may have impacted their findings and as such might have been an anomaly. Moreover, and contrary to findings from the current study, higher optimism has been reported to predict reduced risk of depressive symptoms at 12-months post-acute coronary syndrome after adjusting for baseline depression (Ronaldson et al., 2015). As discussed previously, the relatively small range in depression scores and the minimal change in scores over time might have resulted in a floor effect in the present study, which could have impacted the ability to detect a predictive effect of optimism as it relates to depression.

Conversely, and consistent with the current study, longitudinal studies of first-time ICD recipients (Habibović et al., 2018) and of a different trauma population (Dougall et al., 2001) showed that optimism did not predict the change in overall symptoms of distress when baseline distress was controlled. However, in their analyses of absolute scores, rather than residual change scores, these two studies reported a more optimistic disposition at baseline to be associated with lower distress at follow-up. Together, these findings suggest that while optimism may be related to distress at a given time-point, it is not necessarily related to the way distress changes over time.

Lastly, while not assessing the association between optimism and change in psychological outcome per se, Rauch et al. (2013) reported higher optimism to be related to lower levels of trauma. Methodological differences likely account for discrepant findings. For example, inherent differences in samples may have impacted study outcomes. Childbearing

women from largely urban U.S. centers and from a wide range of socioeconomic strata may have very different experiences with trauma, distress, and optimism as compared to largely older males in a Canadian urban centre. While the range of optimism was fairly wide in the present study, it is possible that the wide range and high sample size allowed Rauch et al. (2013) to detect the predictive validity of optimism. However, the cross-sectional nature of that study precludes confident comparison with the present study.

In summary, while some studies report optimism to be predictive of less distress at follow-up, it is often not associated with the change in distress over time. Carver et al. (2010) argue that while optimism is a fairly stable trait, there are moment-to-moment variations as well as variations over time. Many patients in the current study survived a cardiac arrest, endured an ICD implant and associated therapies, repetitive VT, and VT ablation. It is possible that the inherent variability in optimism taken together with intermittent and yet repetitive nature of the arrhythmia events experienced by this population of ICD patients, rendered it difficult to detect an association between optimism and psychological outcome in this study.

Findings as they relate to PHE are incongruent with those of Sears et al. (2004) where high PHE was associated with better HRQoL outcome. PHE scores were lower in the present study as compared to Sears et al. (2004) (34.47 vs. 43.5, respectively). Thus, perhaps PHE scores were not high enough in the present study to detect an influence on outcome. This explanation seems plausible given the participants in the present study might have had their health expectations negatively impacted by the fact that they had a long history of poor health outcomes. Participants in the Sears et al. (2004) study were getting an ICD for the first time and thus might have had more reason to have more positive health expectations. Of course, methodological inconsistencies between the two studies might also account for the discrepancies

seen on baseline PHE scores. Sears et al. (2004) collected questionnaire data via telephone which may have elicited responses which were deemed to be more socially desirable by the patient. Moreover, in the present study PHE showed small correlations with outcome variables in the predicted direction, however not all correlations were significant. It is unclear what the correlations were between PHE and outcome variables in the Sears et al. (2004) study but if stronger correlation coefficients were present it may have impacted study findings. Issues related to the use of median splits and attrition of patients, discussed above, also remain relevant to the construct of PHE (Sears et al., 2004). It is of course possible that both studies reflect chance findings due to the small sample sizes.

Present findings lend support to the study of ICD recipients which examined treatment expectations as they relate to anxiety and depression at three-months post implant (Habibović et al., 2014). Treatment expectations, both positive and negative, were assessed by an ICD-specific questionnaire which the authors developed. Positive expectations were not associated with anxiety nor depression, while negative expectations were associated with more anxiety and depression after adjusting for demographic and clinical variables. Notably, baseline levels of distress were not controlled. Unlike in the study of Sears et al. (2004) which assessed treatment expectations and its relationship to HRQoL, the present study and that of Habibović et al. (2014) assessed anxiety and depression. This might suggest that health expectations are more intimately related with general mental and physical health rather than specific psychological domains. Difference in measure and construct used may have played a factor in discrepant findings. Moreover, Sears et al. (2004) captured data over a longer period of time (eight and 14 months) raising the possibility that positive expectations may be relevant at a later time point following an arrhythmia treatment.

Lastly, Leedham et al. (1995) suggest that positive health expectations might act as a buffer against low mood in a sample of heart transplant patients. The current study and that of Leedham et al. (1995) utilized the same instrument to assess this construct. Baseline PHE scores were slightly lower in the present study as compared to Leedham et al. (1995) (32.24 vs. 38.5, respectively) with the current study showing a wider range of scores (13-49 vs. 27-49, respectively). Beyond the small sample size ($N = 31$) of the Leedham et al. (1995) study, the correlational nature of their analysis precludes direct comparisons with the present study.

Briefly, a review of the regression analyses suggests that functional status, as measured by the NYHA, emerged as a significant predictor of outcome variables. Moreover, it typically remained significant even when psychological predictors, such as self-efficacy and optimism, were entered into the regression model. This is perhaps not unusual as NYHA is a symptom-based measure which assesses fatigue, light-headedness, and racing heart. As these symptoms are frequently captured by psychological measures, especially anxiety-based measures, there may be overlap between NYHA and these measures. A similar association between greater functional impairment, measured by NYHA, and depression and anxiety has been reported in heart failure patients (Haworth et al., 2005; Lossnitzer et al., 2013; Thomas et al., 2009).

**Hypothesis 2**

Contrary to study hypothesis, HRQoL, anxiety, depression, and PTSD did not improve more during the study follow-up in ICD recipients undergoing a VT ablation procedure as compared to ICD recipients who did not undergo an ablation. Within-group differences, however, showed that participants who underwent a VT ablation exhibited improvement in mental health HRQoL, overall PTSD, and symptoms of intrusion and hyperarousal. Participants

in the control group showed improvement in symptoms of anxiety, overall PTSD, intrusion and hyperarousal.

The lack of between-group differences is consistent with other studies which also failed to detect differences between ICD patients who underwent an ablation as compared to those who did not on measures of HRQoL (Gula et al., 2018; Kuck et al., 2010), depression and anxiety (Gula et al., 2018). The robust RCT study design of those trials fortifies the current finding that the ablation procedure itself does not necessarily improve psychological well-being and HRQoL over follow-up as compared to outcomes in non-ablation patients. The current hypothesis is informed by prior research which has highlighted the detrimental effects of ICD shocks on HRQoL and psychological well-being (Carroll & Hamilton, 2005; Herrmann et al., 1997; Irvine et al., 2002; Luderitz et al., 1993; Magyar-Russell et al., 2011; Maryniak et al., 2006; Passman et al., 2007; Redhead et al., 2010; Schron et al., 2002; von Känel et al., 2011). Thus, hypothesizing that psychological and HRQoL outcomes would improve more over study follow-up in participants who underwent an ablation as compared to those who did not was predicated on the idea that the ablation procedure would reduce the shock burden thereby helping improve these outcomes. The two groups did not differ with respect to shocks at baseline and the shock variable had a weak correlation with the grouping variable. Moreover, few participants received shocks during the follow-up period and the two groups did not differ with respect to shock burden during that period. Thus, it appears that shock burden was not impacted by the ablation procedure possibly helping explain the lack of between-group differences. Perhaps had the follow-up period been longer, there would have been more time to see a difference in shock burden emerge between the two groups, and thereby see a positive effect of ablation therapy on HRQoL and psychological wellbeing.

An alternative explanation for lack of between-group differences may be that, as compared to the control group, participants who underwent a VT ablation were inherently a more unwell group. They exhibited poorer functional status as captured by NYHA Class III/IV and had significantly more ICDs implanted for secondary prevention. The latter indicates that ablation participants had more often experienced life-threatening arrhythmias or survived a cardiac arrest which prompted the ICD implant. Moreover, in order to necessitate a VT ablation, participants have to experience persistent sustained VT, VT storms, or ICD shocks. This too strengthens the argument that ablation participants are a more unwell group. Considering the above, it is possible that any physical intervention, such as a VT ablation, might not be able to ameliorate HRQoL and psychological well-being in this group of ICD recipients experiencing high VT burden, at least within the first six-month post ablation. Importantly, between-group effects were small as indicated by the $R^2$ of the grouping variable in the regression analyses. This suggests that even with a larger sample size significant differences are unlikely to have been detected.

While studies to date have failed to detect between-group differences, within-group improvements detected in the present study align with results of others who have shown psychological and HRQoL improvements after the VT ablation procedure (Gula et al., 2018; Kuck et al., 2010; Maryniak et al., 2006; Strickberger et al., 1997). Some findings illustrate improvements in most domains of HRQoL over a two-year follow-up (Kuck et al., 2010). Others detect improvements only in certain domains of HRQoL (social functioning and energy/fatigue) and ICD-related concerns (Gula et al., 2018) or only after a successful ablation (Strickberger et al., 1997). Results from the current study show that, as compared to baseline, the mean mental health component scores (MCS) of the SF-36 increased by almost 5-points in the ablation group.

Such an improvement was not detected on the physical component summary as these scores remained stable. Previous research has proposed 3-points as a minimally important difference which can be considered socially and clinically significant (Maruish, 2011). Baseline mean scores of both MCS and PCS were in the moderately to severely impaired range as compared to Canadian normative data for the appropriate age range (Hopman et al., 2000). Improvements on MCS suggest a clinically important shift. To achieve such an improvement in the MCS domain, overall health should be rated as "good" at the very least (Maruish, 2011). This suggests that, from the subjective perspective of the ablation participants there may be confidence related to the ablation procedure which in turn impacts MCS. Moreover, as in this study, a single case-report detected improvements in symptoms of PTSD in an ICD recipient following a VT ablation (Maryniak et al., 2006).

These findings suggest that ICD recipients who undergo a VT ablation gain some benefits. One possible explanation for these observed improvements is that ICD recipients who necessitate an ablation are profoundly unwell and might experience elevated psychological distress. This may be the case irrespective of whether they receive ICD shocks. Namely, the stressors may exist as a result of high and repetitive VT burden, repeated exposure to arrhythmia treatments, and survival of a life-threatening event. Burke et al. (2003) point out that poor psychological outcomes in ICD recipients might be due to factors associated with the ventricular arrhythmia, such as having experienced a cardiac arrest, rather than shocks or device itself. Indeed, ablation participants in this study were more likely to have secondary prevention ICDs, suggesting that they would have experienced the burdens highlighted by Burke et al. (2003). Moreover, a recent RCT reported significantly less sustained VT below the ICD detection limit and a trend toward fewer VT storm events following a VT ablation (Sapp et al., 2016).

Unfortunately, the HRQoL substudy which emerged from that RCT did not provide sufficient information to ascertain whether the ablation subgroup who completed HRQoL questionnaires differed in terms of VT storms or shocks from the subgroup who did not undergo an ablation (Gula et al., 2018). Concerns related to the ICD have been also been reported to decrease following a VT ablation over a year-long follow-up (Gula et al., 2018). Taking these observations together, if the VT ablation reduces arrhythmia burden or is able to provide some confidence that the likelihood of further interventions or arrhythmia events are lower, then there might be a favourable impact on HRQoL and psychological outcomes in patients undergoing the procedure. Simply put, this might suggest that there are subtle cognitive benefits, namely a decrease in stress and worry, associated with ablation therapy. It might be that a longer follow-up period is needed to detect the benefits of the ablation on psychological domains and HRQoL and for this change to truly become apparent as compared to their control counterparts.

Lastly, in line with findings from Gula et al. (2018) differences were not detected on measures of anxiety and depression in the ablation group. In that study, anxiety and depression scores remained stable over time precluding detection of within-group changes (Gula et al., 2018). In the current study, low anxiety and depression scores at baseline suggest a floor effect might have undermined the ability to see much improvement in scores and, thus, precluded the detection of within-group changes. Interestingly, ablation participants in the current study showed significantly higher levels of trauma at baseline as compared to the control group. No differences were detected on measures of anxiety, depression, or HRQoL. This might suggest that the trauma measure is more relevant for ablation participants whereas the anxiety measure is more pertinent for control participants when assessing psychological outcomes. This is clinically sound as ablation participants are more likely to have sustained a life-threatening arrhythmia as

well as have experienced more repetitive stressors in the form of VT burden, arrhythmia interventions, and compromised functional status. Notwithstanding the clinical sense of this suggestion, regression to the mean might have impacted the findings. In other words, in most instances, the psychological scores that changed within the ablation versus the control group were also those that had more room to change as compared to baseline scores.

Overall, effect size estimates of within group findings range from small to medium providing some confidence in the improvements observed within the ablation group. However, due to the small sample size in the current study, the relatively brief follow-up period, and the lack of between-group differences, further study is warranted to better understand the HRQoL and psychological benefits of VT ablation therapy in the ablation group.

Due to the paucity of studies examining HRQoL in patients undergoing VT ablation, the above discussion has been slightly extended to consider research examining radiofrequency catheter ablation (RFA) of atrial fibrillation (AF). Studies have demonstrated improvement in AF burden in patients undergoing a RFA as compared to treatment with antiarrhythmic drug therapy (Cosedis Nielsen et al., 2017; Jaïs et al., 2008; Siontis et al., 2016). This is particularly the case when RFA is used as a second-line rhythm control therapy (i.e., following the failure of one or more antiarrhythmic drugs). RFA as a first-line rhythm control therapy (i.e., patients who are anti-arrhythmic drug naïve) has gained support but requires further study (Calkins et al., 2018; Raatikainen et al., 2015). Similar to VT ablation, findings with respect to HRQoL in RFA treatment of AF are less consistent. Results from RCTs examining RFA as a second-line treatment generally demonstrate improvement in HRQoL relative to baseline and better HRQoL as compared to patients treated with medication alone (Jaïs et al., 2008; Wilber et al., 2010). One

of these studies showed more improvement in PCS over one-year follow-up and a trend in MCS improvement in the RFA group (Jaïs et al., 2008) while the other suggested greater improvements in both domains (Wilber et al., 2010). RCTs examining RFA as first-line treatment suggest improvement in both RFA and medication groups, with the ablation group showing a significantly greater improvement (Calkins et al., 2018). Collapsing across RFA as first- or second-line treatment, a recent meta-analysis examined twelve RCTs which compared treatment with RFA to medication alone (Siontis et al., 2016). While RFA led to greater improvements in some areas of HRQoL (i.e., mental component summary, physical functioning, vitality and role emotional) from baseline to three-months follow-up, between-group differences diminished with increasing follow-up and none were detected beyond the nine-month follow-up (Siontis et al., 2016). Lending support to the meta-analysis is a recent RCT which did not detect between-group differences for patients treated with RFA or medication alone (Cosedis Nielsen et al., 2017). Although improvements were observed from baseline to the two-year follow-up and persisted to the five-year follow-up, between-group differences were not detected. Authors explain this as possibly being related to less AF burden in both groups as compared to baseline. Similarly, an on-treatment analysis of an RCT of RFA as first-line treatment of patients with paroxysmal AF detected no between-group (i.e., RFA, medication alone, cross-over groups) differences with all groups showing improvement on PCS and MCS from baseline to one- and two-year follow-up periods (Raatikainen et al., 2015). Overall, while findings remain mixed, there is suggestion of RFA benefit over medication-alone although it appears to be most prominent during a short-term follow-up. Interestingly, it has been proposed that lower AF burden or even a placebo effect associated with the more invasive RFA procedure might account for improved HRQoL of RFA patients in the short term and that AF recurrence or the

diminishing placebo effect might help explain the lack of differences at longer-term follow-up (Siontis et al., 2016). This argument, however, has been disputed by others who detected sustained improvements over a one-year follow-up (Jaïs et al., 2008).

Importantly, it can be challenging to directly compare some of the above findings to the current study as many studies of RFA patients include lower risk, younger, and relatively healthy patients with AF (Calkins et al., 2018; Cosedis Nielsen et al., 2017; Jaïs et al., 2008; Siontis et al., 2016; Wilber et al., 2010). The AF population typically appears to be less unwell based on having LVEF in the mild to normal range (Cosedis Nielsen et al., 2017; Jaïs et al., 2008; Wilber et al., 2010) and often no heart failure symptoms (Siontis et al., 2016). Moreover, AF patients do not sustain the burdensome effects of ICD shocks as VT patients do. In line with the aforementioned, the benefits sometimes observed in AF patients as compared to those treated with medication alone and the lack of such differences in the current study might reflect the nature of the profoundly ill population of VT patients where even a state-of-the-art intervention such as a VT ablation is not able to improve HRQoL. Alternatively, despite the population differences discussed above, the lack of reliable between-group differences in the AF and VT populations might suggest that the ablation procedure does not yield the expected benefits with respect to HRQoL despite the improved rhythm control.

**Limitations of the study**

The present study employed a case-control design which is a limitation when testing between-group differences of novel interventions such as a VT ablation procedure, particularly in the case of Hypothesis 2. Although participants were not randomly assigned to treatment groups, control participants were recruited based on best available data and carefully selected matching criteria. Nonetheless, due to lack of random assignment, the two groups had inherent

differences; one group had arrhythmia-related indications which necessitated an undertaking of a VT ablation while the other group did not. This may have impacted responses on the measures administered as participants had differing experiences with arrhythmia interventions. This may have, in turn, influenced the detection of between-group differences. Importantly, a case-control design was adopted for the current study given the value of advancing knowledge on psychological outcomes in this novel but growing population of cardiac patients. A more robust RCT design was beyond the scope of this dissertation. Notably, however, RCTs examining a similar group of ICD recipients also failed to detect benefits of VT ablation on measures of HRQoL and psychological well-being (Gula et al., 2018; Kuck et al., 2010) lending support to current findings.

The small sample size is another study limitation. A priori power analysis was conducted for the hierarchical regression analyses utilized to test the hypotheses. A sample size of 109 participants with complete data would have been required in order to detect a medium effect size, powering the study at 80%, while accounting for control and predictor variables in the regression analyses (Faul, Erdfelder, Buchner, & Lang, 2009; Tabachnick & Fidell, 2007). As recruitment unfolded it became evident that fewer VT ablation procedures were performed at both TGH and SMH than originally anticipated. Moreover, it was profoundly challenging to find and recruit appropriate match control participants. Even when matching criteria were expanded (e.g., matching on time since implant based on +/-12 months rather than +/-six months) the same challenge remained. As a result, the sample size for this study was smaller than planned thus compromising power to detect significant differences. In order to mitigate, at least in part, the limitations of the small sample size control variables were reviewed and two were removed from the regression analyses in Hypothesis 1. The first variable removed was functional status as

measured by LVEF. Every attempt was made to obtain an LVEF within +/-six months of recruitment, as measured by an ECHO, however not every patient had a recent LVEF recording. Since not all participants had a recent LVEF measure and since functional status assessed by NYHA is symptom based and was more strongly related to outcome measures in this study than the LVEF, the latter was deemed to be the more appropriate measure to retain in the regression analyses. Although lack of an objective measure of functional status is a limitation, the LVEF was not highly correlated with psychological outcomes. Thus, it is unlikely that being unable to include it in the analyses undermined confidence in results. The second variable removed was life stress as it correlated poorly with predictor measures and other control measures. The challenge of recruiting large sample sizes is also reflected by the sample sizes of recent RCTs. Since VT ablations are relatively novel they are not performed as frequently as ICD implants, for example, even in major cardiac centres. One recent RCT recruited 259 participants ($n$ = 132 ablation) across 22 different centers over a five-year time span (Sapp et al., 2016). Another RCT recruited 110 participants ($n$ = 54 ablation) across 16 cardiac centers over a four-year period (Kuck et al., 2010). While the sample size was small in the present study relative to these RCT studies, it is important to note that effect size analyses suggest that even with a larger sample in the current study significant differences were not likely to have been detected. Thus, while study design and sample size are limitations, results of recent RCTs and effect size analyses lend credence to the current findings.

Another limitation is the short follow-up period of six-months. A longer follow-up time-frame of two years might have offered insights into further gains or losses. An RCT examining effects of a prophylactic VT ablation detected benefits in HRQoL for ablation patients over a two-year follow-up (Kuck et al., 2010). This raises the possibility that for individuals who

experience high VT burden and subsequently undergo a VT ablation a longer follow-up period might provide insight into longer-term psychological benefits of this procedure, particularly since the effects of the ablation on VT burden could be captured over a longer period. A longer follow-up might also offer the opportunity to assess protective factors such as self-efficacy in the management of arrhythmia and associated treatments. As self-efficacy develops over time through past successful performances, verbal influences, and observing others a longer follow-up would offer a more robust way of testing its effects (Bandura, 1977, 1997; Dougherty et al., 2007; Houston Miller & Barr Taylor, 1995).

**Future directions for research**

Results of the current research highlight the importance of self-efficacy as a resilience factor in relation to symptoms of PTSD and anxiety, over and above the occurrence of shocks or presence of a VT ablation procedure. The suggestion in this study that higher self-efficacy is protective in this patient population is based on an observational design. An RCT aimed at increasing self-efficacy might provide more insight into the value of offering specific psychological interventions for a population living with ongoing unpredictable and life-threatening arrhythmias. Clinically, self-efficacy would be important to bolster in patients experiencing repeated and unpredictable ventricular arrhythmias. Self-efficacy can help enhance a sense of agency and provide cognitive, behavioural, and emotional tools toward coping with an essentially unpredictable illness. A group intervention might build upon those facets which have been shown to promote self-efficacy; namely, providing education about arrhythmia treatments, discussing past successful coping experiences of dealing with the arrhythmia and associated treatments, and correcting misconceptions about physiological and emotional responses (e.g., follow-up discussion with health-care professionals to help re-interpret symptoms and provide

reassurance; Ashford, Edmunds, & French, 2010; Du et al., 2011). A group format would advance this goal since vicarious learning has been identified as an important part of honing self-efficacy (Ashford et al., 2010). Information provided in-hospital as part of usual care is important in terms of providing knowledge about arrhythmia interventions. However, education and intervention post hospitalization is important in terms of building upon and maintaining knowledge and self-efficacy (Dougherty, Thompson, & Lewis, 2005).

While no between-group differences were detected, ablation participants saw improvements in several domains, a finding corroborated by other studies (Gula et al., 2018; Kuck et al., 2010; Strickberger et al., 1997). Future research might focus on replicating these findings in a larger sample so as to investigate whether domains of PTSD, anxiety, and HRQoL improve consistently following an ablation procedure and how such improvements arise. A larger sample would allow for an investigation of how VT ablation impacts VT burden both in the form of shocks (i.e., multiple shocks as well as shock storms) as well as sustained VT (e.g., VT below the ICD detection threshold or VT storms with the delivery of ATP) and, relatedly, how anxiety-based measures change following a VT ablation. While shocks have been identified as major contributors to poor psychological functioning, participants in this study did not differ on shock burden at baseline or follow-up. Psychological factors varied, however, with the ablation participants generally showing poorer function, which might suggest that arrhythmia burden, even in the absence of shocks, might contribute to poor psychological function. Employing a measure such as the Cardiac Anxiety Questionnaire (Eifert et al., 2000), which assesses heart-focused anxiety and fear, avoidance of strenuous activity, and heart-focused attention and checking, might provide insights into how VT ablation impacts arrhythmia burden and associated distress. Moreover, the ablation group showed more PTSD symptoms at baseline

as compared to the control group and exhibited within-group improvements following the ablation. This begs the question of how the ablation procedure relates to and augments symptoms of PTSD in this subgroup. The Enduring Somatic Threat model of PTSD in chronically ill individuals has been put forth by Edmondson (2014). It argues that the acute nature of a life-threatening medical event differs from external/discrete trauma since the threat is internal and enduring and fears are future-oriented. A recent study has lent support to Edmondson's theory and reported an association between cardiac-induced PTSD and fear of disease progression (Fait et al., 2018). Fear of illness progression is a construct particularly important for individuals who are chronically ill and one which has been strongly associated with cardiac-induced PTSD (Fait et al., 2018; Herschbach et al., 2005). As such, it would be informative to assess how the ablation procedure impacts PTSD specifically and whether the within-group improvements which were observed might be related to the ablation procedure helping mitigate the fear of disease progression in this subgroup of ICD patients.

**Conclusions**

Results of Hypothesis 1 show that higher self-efficacy at baseline predicts improvement in symptoms of anxiety and PTSD at follow-up. Self-efficacy emerged as a significant predictor over and above demographic and cardiac factors, as well as shocks and group membership. This offers support to the protective function of self-efficacy in this profoundly unwell group of ICD recipients. Self-efficacy, contrary to the hypothesis, was not predictive of depression. Generally, low mean baseline depression scores were detected in the current study. As such a floor effect may have precluded the detection of improvements in this domain. Similarly, contrary to hypothesis, optimism and positive health-expectations at baseline did not predict improvement in anxiety, depression, or PTSD. As discussed above, this might reflect momentary variations in

optimism (Carver et al., 2010) whereby participant responses to key optimism items, might be impacted by the long and stressful experience of dealing with repetitive VT events. Nonetheless, results as they pertain to self-efficacy and its relationship to anxiety-based psychological symptoms are encouraging. These findings reinforce the importance of individual resilience factors and the role of self-efficacy in ICD recipients who are consistently faced with unpredictable and uncontrollable arrhythmia. Together they suggest that the appraisal of one's ability to cope with and navigate the stressors of illness, of arrhythmia and its treatments play a significant role in the psychological adjustment following arrhythmia treatments.

Results of Hypothesis 2 failed to detect differences between the ablation and control groups on HRQoL, anxiety, depression, or PTSD outcomes. This finding is consistent with past studies, some of which were more robust in study design (Gula et al., 2018; Kuck et al., 2010). Shock burden was similar between groups at baseline as well as during follow-up. This hypothesis was driven by past research which highlights the detrimental effect of shocks on psychological functioning and the notion that ablation therapy would reduce shock occurrence. Thus, it is possible that lack of differences in shocks precluded detection of between-group differences. Alternatively, as individuals undergoing an ablation are profoundly unwell it is possible that any intervention might not be able to yield positive psychological effects at least within a six-month time frame. Encouragingly, however, ICD recipients who underwent a VT ablation showed improvement in mental health HRQoL and symptoms of PTSD. Control participants showed improvement on anxiety and PTSD although ablation participants had significantly worse trauma scores at baseline. This might suggest that trauma measures might be more sensitive to capturing psychological functioning in the ablation group as they have undergone significant and repetitive stressors. While effect size estimates for within-group

changes were small to medium, due to the study's small sample size and lack of between-group differences, results should be interpreted with caution and warrant further investigation.

Even though participants in the present study, particularly those undergoing a VT ablation, are an unwell group, self-efficacy exerted a protective function with respect to anxiety-based outcomes from baseline to follow-up. The belief and confidence in personal ability to deal with a specific situation related to the arrhythmia might represent small wins that allow the individual to "check off" specific manageable tasks which in turn provide a greater sense of control. In this way, the individual might feel more agentic and engaged, less anxious and traumatized, rather than withdrawn. Ablation participants also showed improvement in mental health HRQoL and symptoms of PTSD. Future directions for research include replicating findings in larger samples as well as testing the role of self-efficacy by way of a longitudinal intervention study.

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Table 1

*Baseline characteristics table of demographic and clinical variables for all participants*

| **Variable** | **All recruited participants (n=61)** | **Completers[x] (n=50)** | **Non-completers[z] (n=11)** |
|---|---|---|---|
| Age (years), mean (SD) | 63.66 (14.34) | 63.48 (14.38) | 64.45 (14.77) |
| Male | 91.8 | 92.0 | 90.9 |
| Greater than high school education | 73.8 | 74.0 | 72.7 |
| Living alone | 6.6 | 8.0 | 0 |
| Clinical Variables | | | |
| Cardiac Diagnosis | | | |
| Ischaemic CMP | 54.1 | 54.0 | 54.5 |
| Non-Ischaemic CMP | 39.3 | 40.0 | 36.4 |
| Other | 6.6 | 6.0 | 9.1 |
| NYHA class I & II | 82.0 | 81.6 | 90.9 |
| NYHA class III & IV | 16.4 | 18.4 | 9.1 |
| NYHA unknown | 1.6 | | |
| ICD implantation | | | |
| Primary | 52.5 | 50.0 | 63.6 |
| Secondary | 45.9 | 48.0 | 36.4 |
| Unknown | 1.6 | 2.0 | |
| Medications | | | |
| Psychotropic Medications | 28.3 | 32.0 | 10.0 |
| Antiarrhythmic Medication | | | |
| Class I | 14.7 | 14.0 | 18.2 |
| Class II | 86.9 | 86.0 | 91 |
| Class III | 60.7 | 64.0 | 45.5 |
| Class IV | 6.6 | 8.0 | 0 |
| Class V | 18.0 | 16.0 | 27.3 |
| ICD therapy pre-baseline | | | |
| ATP | 9.8 | 10.0 | 9.1 |
| 1-2 | 41.0 | 40.0 | 45.5 |
| 3-4 | 16.4 | 16.0 | 18.2 |
| More than 4 shocks | 32.8 | 34.0 | 27.3 |
| Underwent VT ablation | 55.7 | 58.0 | 45.5 |
| Ablation Approach | | | |
| Activation | 32.4 | 34.5 | 20.0 |

| | | | |
|---|---|---|---|
| Substrate | 58.8 | 55.2 | 80.0 |
| Activation and Substrate | 8.8 | 10.3 | 0 |
| Ablation outcome | | | |
| Successful | 79.4 | 79.3 | 80.0 |
| Partially successful | 5.9 | 3.4 | 20.0 |
| Unsuccessful | 14.7 | 17.2 | 0 |

*Note*. Data are shown as percentages unless stated otherwise. CMP = Cardiomyopathy; NYHA = New York Heart Association Functional Classification; ICD = Implantable Cardioverter Defibrillator; VT = Ventricular Tachycardia. [x] = completers defined as individuals who completed all questionnaires at follow-up; [z] = non –completers defined as individuals who were missing at least some questionnaires at the follow-up.

Table 2

*Baseline characteristics – psychological variables for all participants*

| Variable | All who completed given measure (n) | M (SD) | Range | α | Completers[x] (n) | M (SD) | Non-completers[z] (n) | M (SD) |
|---|---|---|---|---|---|---|---|---|
| **HADS-A** | 58 | 6.14 (4.97) | 0 – 18 | 0.90 | 48 | 5.83 (4.98) | 10 | 7.60 (4.95) |
| **HADS-D** | 58 | 4.96 (3.50) | 0 – 14 | 0.76 | 48 | 4.86 (3.50) | 10 | 5.40 (3.63) |
| **IES-R-T** | 60 | 0.81 (0.73) | 0 – 2.73 | 0.95 | 49 | .78 (.72) | 11 | .93 (.84) |
| **IES-R-I** | 60 | 0.80 (0.80) | 0 – 2.75 | 0.90 | 49 | .78 (.76) | 11 | .99 (.99) |
| **IES-R-A** | 60 | 0.79 (0.79) | 0 – 2.75 | 0.83 | 49 | .79 (.78) | 11 | .83 (.86) |
| **IES-R-H** | 60 | 0.84 (0.82) | 0 – 3.00 | 0.85 | 49 | .80 (.81) | 11 | 1.0 (.91) |
| **MCS** | 60 | 46.27 (12.13) | 16.68 – 62.80 | | 50 | 46.93 (11.22) | 10 | 42.98 (16.27) |
| **PCS** | 60 | 42.26 (9.31) | 18.37 – 58.05 | | 50 | 42.25 (9.75) | 10 | 42.31 (7.10) |
| **LSS** | 60 | 2.63 (2.25) | 0 – 10 | | 49 | 2.80 (2.36) | 11 | 1.91 (1.51) |
| **LOT** | 60 | 22.05 (7.42) | 5 – 32 | 0.86 | 49 | 21.98 (6.94) | 11 | 22.36 (9.68) |
| **PHE** | 60 | 34.47 (8.91) | 13 – 49 | 0.89 | 49 | 34.43 (8.76) | 11 | 34.64 (9.98) |
| **MAT I** | 60 | 7.52 (1.90) | 3.50 – 10 | 0.87 | 49 | 7.60 (1.84) | 11 | 7.17 (2.23) |

*Note*. *M* = Mean; *SD* = Standard Deviation; HADS = Hospital Anxiety and Depression Scale; IES-R = Impact of Event Scale – Revised; IES-R-T = IES-R Total score; IES-R-I = IES-R Intrusion subscale; IES-R-A = IES-R Avoidance subscale; IES-R-H = IES-R Hyperarousal subscale; MCS = Mental Health Component Summary Score on the SF-36; PCS = Physical Component Summary Score on the SF-36; LSS = Life Stress Scale; LOT = Life Orientation Test; PHE = Positive Health Expectations Scale; MAT I = Managing Arrhythmia Treatments I (Self Efficacy Scale).

[x] = completers defined as individuals who completed all questionnaires at follow-up; [z] = non –completers defined as individuals who were missing at least some questionnaires at the follow-up.

Table 3

*Descriptive statistics for Hypothesis 1 (Inclusive of all participants who completed baseline AND follow-up questionnaires).*

| Variable | *n* | *M* | *SD* | Range | *t* | *p* |
|---|---|---|---|---|---|---|
| **HADS-A** | | | | | | |
| Baseline | 49[a] | 5.78 | 4.94 | 0 – 17 | 3.05 | .004 |
| Follow-up | 49[a] | 4.65 | 4.43 | 0 – 18 | | |
| **HADS-D** | | | | | | |
| Baseline | 49[a] | 4.89 | 3.47 | 0 – 14 | .830 | .411 |
| Follow-up | 49[a] | 4.63 | 3.85 | 0 – 17 | | |
| **IES-R-T** | | | | | | |
| Baseline | 49[a] | 0.79 | 0.72 | 0 – 2.73 | 3.56 | <.001 |
| Follow-up | 49[a] | 0.52 | 0.61 | 0 – 2.23 | | |
| **IES-R-I** | | | | | | |
| Baseline | 49[a] | 0.76 | 0.76 | 0 – 2.63 | 3.76 | <.001 |
| Follow-up | 49[a] | 0.47 | 0.64 | 0 – 2.63 | | |
| **IES-R-A** | | | | | | |
| Baseline | 49[a] | 0.79 | 0.78 | 0 – 2.75 | 1.72 | .092 |
| Follow-up | 49[a] | 0.60 | 0.70 | 0 – 2.38 | | |
| **IES-R-H** | | | | | | |
| Baseline | 49[a] | 0.80 | 0.81 | 0 – 3.00 | 3.99 | <.001 |
| Follow-up | 49[a] | 0.48 | 0.69 | 0 – 2.67 | | |
| **LSS** | 50[b] | 2.80 | 2.24 | 0 – 10 | | |
| **LOT** | 50[b] | 22.06 | 6.89 | 5 – 32 | | |
| **PHE** | 50[b] | 34.24 | 8.77 | 13 – 49 | | |
| **MAT I** | 50[b] | 7.57 | 1.83 | 3.50 – 10 | | |

*Note*. *M* = Mean; *SD* = Standard Deviation; *t* = paired *t*-test comparing Baseline and Follow-up values; HADS = Hospital Anxiety and Depression Scale; IES-R = Impact of Event Scale – Revised; IES-R-T = IES-R Total score; IES-R-I = IES-R Intrusion subscale; IES-R-A = IES-R Avoidance subscale; IES-R-H = IES-R Hyperarousal subscale; LSS = Life Stress Scale; LOT = Life Orientation Test; PHE = Positive Health Expectations Scale; MAT I = Managing Arrhythmia Treatments (Self Efficacy Scale).

[a] = the n reflects 49 participants completed HADS and a different set of 49 participants completed IES-R ; [b] = the n of 50 participants reflects those individuals who completed both baseline and follow-up of HADS or baseline and follow-up of IES-R.

Table 4

*Correlations among predictor, control, and dependent measures*

| Variable (n) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. LOT | -- | .59** 60 | .61** 60 | .30* 60 | .09 60 | -.01 60 | -.03 60 | -.16 60 | -.21 60 | -.19 59 | -.58** 51 | -.45** 51 | -.44** 49 | -.48** 49 | -.25 49 | -.48** 49 |
| 2. PHE | | -- | .54** 60 | .34** 60 | .07 60 | .16 60 | .01 60 | -.00 60 | -.12 60 | -.11 59 | -.30* 51 | -.43** 51 | -.27 49 | -.21 49 | -.22 49 | -.31* 49 |
| 3. MAT I | | | -- | .29* 60 | .19 60 | .18 60 | -.10 60 | -.12 60 | -.08 60 | -.26 59 | -.67** 51 | -.41** 51 | -.65** 49 | -.68** 49 | -.44** 49 | -.66** 49 |
| 4. Age | | | | -- | .49** 61 | .01 61 | -.05 61 | -.04 61 | -.24 61 | -.10 60 | -.30* 52 | -.18 52 | -.27 50 | -.31* 50 | -.15 50 | -.28 50 |
| 5. Gender | | | | | -- | -.13 61 | .10 61 | -.17 61 | -.03 61 | -.19 60 | -.30* 52 | -.19 52 | -.39** 50 | -.43** 50 | -.22 50 | -.41** 50 |
| 6. Time since implant | | | | | | -- | .08 61 | .40** 61 | -.06 61 | -.16 60 | -.07 52 | -.09 52 | -.09 50 | .09 50 | -.21 50 | -.13 50 |
| 7. Group | | | | | | | -- | .20 61 | .00 61 | .32* 60 | .19 52 | -.08 52 | .32* 50 | .29* 50 | .31* 50 | .26 50 |
| 8. Shocks | | | | | | | | -- | -.06 61 | .16 60 | .24 52 | -.09 52 | .20 50 | .30* 50 | .15 50 | .07 50 |
| 9. LVEF | | | | | | | | | -- | -.12 60 | -.03 52 | -.05 52 | -.10 50 | -.06 50 | -.08 50 | -.13 50 |
| 10. NYHA | | | | | | | | | | -- | .45** 51 | .37** 51 | .49** 49 | .46** 49 | .38** 49 | .50** 49 |
| 11. HADS-A | | | | | | | | | | | -- | .55** 52 | .79** 50 | .75** 50 | .62** 50 | .78** 50 |
| 12. HADS-D | | | | | | | | | | | | -- | .57** 50 | .46** 50 | .47** 50 | .62** 50 |
| 13. IES-R-T | | | | | | | | | | | | | -- | .91** 50 | .86** 50 | .92** 50 |
| 14. IES-R-I | | | | | | | | | | | | | | -- | .61** 50 | .86** 50 |
| 15. IES-R-A | | | | | | | | | | | | | | | -- | .66** 50 |
| 16. IES-R-H | | | | | | | | | | | | | | | | -- |

** p≤.01; * p≤.05

Table 5

*Model summaries for HADS Anxiety at six-month follow-up*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .729 | | | .782 | | | .808 | | |
| **$\Delta R^2$** | | .729 | | | .053 | | | .026 | | |
| **P value** | | <0.001 | | | .048 | | | .167 | | |
| **F value** | | F[1,47]=126.48 | | | F[4,43]=2.61 | | | F[3,40]=1.78 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline HADS-A** | 58 | .74 | <.001 | [.61, .87] | .71 | <.001 | [.56, .86] | .60 | <.001 | [.41, .79] |
| **Group (Ablation vs. Control)** | 61 | | | | -.01 | .99 | [-1.33, 1.31] | -.01 | .98 | [-1.31, 1.28] |
| **Shocks (0-4 vs. ≥5)** | 61 | | | | .07 | .92 | [-1.31, 1.44] | .12 | .86 | [-1.23, 1.46] |
| **Age** | 61 | | | | .02 | .40 | [-.03, .07] | .02 | .45 | [-.03, .07] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | 2.63 | .005 | [.84, 4.41] | 2.29 | .009 | [.63, 4.15] |
| **Baseline LOT** | 60 | | | | | | | -.002 | .98 | [-.13, .12] |
| **Baseline PHE** | 60 | | | | | | | .03 | .55 | [-.07, .12] |
| **Baseline MAT I** | 60 | | | | | | | -.52 | .03 | [-.98, -.05] |

*Note*. n = 52 for follow-up HADS Anxiety.

Table 6

*Model summaries for HADS Depression at six-month follow-up*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .629 | | | .720 | | | .743 | | |
| **$\Delta R^2$** | | .629 | | | .028 | | | .023 | | |
| **P value** | | <.001 | | | .384 | | | .322 | | |
| **F value** | | F[1,47]=105.78 | | | F[4,43]=1.07 | | | F[3,40]=1.20 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline HADS-D** | 58 | .90 | <.001 | [.72, 1.07] | .87 | <.001 | [.67, 1.07] | .87 | <.001 | [.64, 1.11] |
| **Group (Ablation vs. Control)** | 61 | | | | -.66 | .32 | [-1.99, .66] | -.68 | .30 | [-2.00, .64] |
| **Shocks (0-4 vs. ≥5)** | 61 | | | | -.82 | .22 | [-2.15, .51] | -.70 | .30 | [-2.06, .65] |
| **Age** | 61 | | | | .02 | .48 | [-.03, .06] | .02 | .31 | [-.02, .07] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | 1.17 | .22 | [-.72, 3.05] | 1.10 | .25 | [-.80, 3.00] |
| **Baseline LOT** | 60 | | | | | | | .08 | .21 | [-.05, .20] |
| **Baseline PHE** | 60 | | | | | | | -.06 | .18 | [-.15, .03] |
| **Baseline MAT I** | 60 | | | | | | | -.19 | .39 | [-.62, .25] |

*Note*. n = 52 for follow-up HADS Depression.

Table 7

*Model summaries for IES-R-Total at six-month follow-up*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .564 | | | .638 | | | .710 | | |
| **$\Delta R^2$** | | .564 | | | .073 | | | .072 | | |
| **P value** | | <0.001 | | | .088 | | | .029 | | |
| **F value** | | F[1,47]=60.87 | | | F[4,43]=2.18 | | | F[3,40]=3.32 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IESR-T** | 60 | .62 | <.001 | [46, .78] | .56 | <.001 | [.37, .74] | .46 | <.001 | [.24, .69] |
| **Group (Ablation vs. Control)** | 61 | | | | .02 | .88 | [-.23, .27] | .03 | .80 | [-.21, .27] |
| **Shocks (0-4 vs. ≥5)** | 61 | | | | -.03 | .79 | [-.28, .22] | -.02 | .83 | [-.26, .21] |
| **Age** | 61 | | | | .001 | .76 | [-.01, .01] | .001 | .81 | [-.01, .01] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .45 | .007 | [.13, .77] | .40 | .011 | [.10, .70] |
| **Baseline LOT** | 60 | | | | | | | .01 | .33 | [-.01, .03] |
| **Baseline PHE** | 60 | | | | | | | .007 | .40 | [-.01, .02] |
| **Baseline MAT I** | 60 | | | | | | | -.12 | .003 | [-.20, -.04] |

*Note*. n = 50 for follow-up IES-R Total.

Table 8

*Model summaries for IES-R-Intrusion at six-month follow-up*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .522 | | | .617 | | | .750 | | |
| **$\Delta R^2$** | | .522 | | | .096 | | | .132 | | |
| **P value** | | <0.001 | | | .044 | | | .001 | | |
| **F value** | | F[1,47]=51.28 | | | F[4,43]=2.69 | | | F[3,40]=7.04 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R-I** | 60 | .58 | <.001 | [.42, .74] | .52 | <.001 | [.33, .71] | .39 | <.001 | [.18, .59] |
| **Group (Ablation vs. Control)** | 61 | | | | -.05 | .69 | [-.33, .22] | -.02 | .86 | [-.26, .22] |
| **Shocks (0-4 vs. ≥5)** | 61 | | | | .14 | .32 | [-.14, .41] | .12 | .30 | [-.11, .35] |
| **Age** | 61 | | | | .001 | .82 | [-.01, .01] | -.001 | .87 | [-.01, .01] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .51 | .005 | [.17, .86] | .41 | .009 | [.11, .71] |
| **Baseline LOT** | 60 | | | | | | | .000 | .98 | [-.02, .02] |
| **Baseline PHE** | 60 | | | | | | | .02 | .01 | [.01, .04] |
| **Baseline MAT I** | 60 | | | | | | | -.16 | <.001 | [-.24, -.09] |

*Note*. n = 50 for follow-up IES-R Intrusion.

Table 9

*Model summaries for IES-R-Avoidance at six-month follow-up*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .236 | | | .310 | | | .363 | | |
| **$\Delta R^2$** | | .236 | | | .074 | | | .053 | | |
| **P value** | | <0.001 | | | .348 | | | .354 | | |
| **F value** | | F[1,47]=14.54 | | | F[4,43]=1.15 | | | F[3,40]=1.12 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IESR-A** | 60 | .43 | <.001 | [.20, .66] | .35 | .01 | [.08, .61] | .29 | .06 | [-.02, .59] |
| **Group (Ablation vs. Control)** | 61 | | | | .18 | .91 | [-.21, .56] | .18 | .36 | [-.21, .57] |
| **Shocks (0-4 vs. ≥5)** | 61 | | | | -.04 | .86 | [-.44, .36] | -.02 | .94 | [-.42, .39] |
| **Age** | 61 | | | | .000 | .99 | [-.01, .01] | .002 | .79 | [-.01, .02] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .42 | .11 | [-.09, .94] | .37 | .16 | [-.15, .89] |
| **Baseline LOT** | 60 | | | | | | | .01 | .41 | [-.02, .05] |
| **Baseline PHE** | 60 | | | | | | | -.01 | .68 | [-.03, .02] |
| **Baseline MAT I** | 60 | | | | | | | -.10 | .13 | [-.23, .03] |

*Note*. n = 50 for Follow-up IES-R Avoidance.

Table 10

*Model summaries for IES-R-Hyperarousal at six-month follow-up*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .536 | | | .620 | | | .700 | | |
| **$\Delta R^2$** | | .536 | | | .084 | | | .080 | | |
| **P value** | | <0.001 | | | .066 | | | .022 | | |
| **F value** | | F[1,47]=54.24 | | | F[4,43]=2.38 | | | F[3,40]=3.58 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IESR-H** | 60 | .61 | <.001 | [.44, .77] | .52 | <.001 | [.34, .70] | .40 | <.001 | [.19, .61] |
| **Group (Ablation vs. Control)** | 61 | | | | .01 | .95 | [-.27, .29] | .03 | .82 | [-.23, .29] |
| **Shocks (0-4 vs. ≥5)** | 61 | | | | -.14 | .32 | [-.42, .14] | -.16 | .23 | [-.42, .11] |
| **Age** | 61 | | | | -.003 | .60 | [-.01, .01] | -.002 | .71 | [-.01, .01] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .53 | .01 | [.16, .91] | .48 | .01 | [.13, .83] |
| **Baseline LOT** | 60 | | | | | | | .004 | .73 | [-.02, .03] |
| **Baseline PHE** | 60 | | | | | | | .008 | .38 | [-.01, .03] |
| **Baseline MAT I** | 60 | | | | | | | -.14 | .002 | [-.23, -.05] |

*Note*. n=50 for Follow-up IES-R Hyperarousal.

Table 11

*Baseline characteristics of demographic and clinical variables for all participants recruited to the ablation and control groups*

| **Variable** | **Ablation Group (n=34)** | **Control Group (n=27)** |
|---|---|---|
| Age (years), mean (SD) | 63.03(14.78) | 64.44(13.99) |
| Male | 94.1 | 88.9 |
| Greater than high school education | 70.6 | 77.7 |
| Living alone | 2.9 | 11.1 |
| Clinical Variables | | |
| Cardiac Diagnosis | | |
| Ischaemic CMP | 52.9 | 55.6 |
| Non-Ischaemic CMP | 35.3 | 44.4 |
| Other | 11.8 | 0 |
| NYHA class I & II | 70.6 | 96.3 |
| NYHA class III & IV | 26.5 | 3.7 |
| NYHA unknown | 2.9 | 0 |
| ICD implantation | | |
| Primary | 39.4 | 70.4 |
| Secondary | 60.6 | 29.6 |
| Unknown | 2.9 | 0 |
| Medications | | |
| Psychotropic | 35.3 | 19.2 |
| Class I | 23.5 | 3.8 |
| Class II | 88.2 | 88.5 |
| Class III | 85.3 | 30.8 |
| Class IV | 2.9 | 11.5 |
| Class V | 14.7 | 23.1 |
| ICD therapy pre-baseline | | |
| ATP | 5.9 | 14.8 |
| 1-2 | 38.2 | 44.4 |
| 3-4 | 14.7 | 18.5 |
| More than 4 shocks | 41.2 | 22.2 |

*Note*. Data are shown as percentages unless stated otherwise. CMP = Cardiomyopathy; NYHA = New York Heart Association Functional Classification; ICD = Implantable Cardioverter Defibrillator; VT = Ventricular Tachycardia.
[x] = completers defined as individuals who completed all questionnaires at follow-up; [z] = non –completers defined as individuals who were missing at least some questionnaires at the follow-up.

Table 12

*Baseline characteristics – psychological variables for ablation and control groups*

| Variable | Ablation (n) | M (SD) | Range | Control (n) | M (SD) | Range |
|---|---|---|---|---|---|---|
| MCS | 33 | 44.09 (12.98) | 16.68 – 62.77 | 27 | 48.95 (10.64) | 26.97 – 62.80 |
| PCS | 33 | 42.68 (9.52) | 18.37 – 54.87 | 27 | 41.75 (9.20) | 22.29 – 58.05 |
| HADS-A | 33 | 6.79 (5.53) | 0 – 18 | 25 | 5.28 (4.08) | 0 – 16 |
| HADS-D | 33 | 4.92 (3.28) | 0 – 12 | 25 | 5.00 (3.84) | 0 – 14 |
| IES-R-T | 33 | 1.03 (.76) | 0 – 2.73 | 27 | .54 (.61) | 0 – 2.05 |
| IES-R-I | 33 | 1.05 (.88) | 0 – 2.75 | 27 | .50 (.58) | 0 – 1.75 |
| IES-R-A | 33 | 1.00 (.80) | 0 – 2.75 | 27 | .54 (.71) | 0 – 2.25 |
| IES-R-H | 33 | 1.04 (.91) | 0 – 3 | 27 | .58 (.63) | 0 – 2.33 |

*Note*. *M* = Mean; *SD* = Standard Deviation; HADS = Hospital Anxiety and Depression Scale; IES-R = Impact of Event Scale – Revised; IES-R-T = IES-R Total score; IES-R-I = IES-R Intrusion subscale; IES-R-A = IES-R Avoidance subscale; IES-R-H = IES-R Hyperarousal subscale; MCS = Mental Health Component Summary Score on the SF-36; PCS = Physical Component Summary Score on the SF-36.

Table 13

*Ablation participants – correlations among predictor, control, and dependent measures*

| Variable (n) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Age | -- | .40* 34 | .12 34 | .02 34 | -.26 34 | -.02 33 | .23 29 | -.31 29 | -.39* 29 | -.07 29 | -.32 29 | -.35 29 | -.20 29 | -.32 29 |
| 2. Gender | | -- | -.13 34 | -.30 34 | -.13 34 | -.13 33 | .25 29 | -.07 29 | -.24 29 | -.11 29 | -.37 29 | -.43 29 | -.20 29 | -.42 29 |
| 3. Time since implant | | | -- | .43* 34 | -.14 34 | -.22 33 | .02 29 | .21 29 | -.07 29 | -.14 29 | -.002 29 | .17 29 | -.13 29 | -.08 29 |
| 4. Shocks | | | | -- | -.06 34 | .16 33 | -.27 29 | .00 29 | .34 29 | .15 29 | .26 29 | .36 29 | .20 29 | .10 29 |
| 5. LVEF | | | | | -- | -.12 33 | -.08 29 | -.03 29 | .09 29 | .09 29 | .03 29 | .02 29 | .06 29 | -.02 29 |
| 6. NYHA | | | | | | -- | -.35 28 | -.31 28 | .32 28 | .40* 28 | .35 28 | .33 28 | .24 28 | .38* 28 |
| 7. MCS | | | | | | | -- | .52** 29 | -.73** 29 | -.79** 29 | -.79** 29 | -.70** 29 | -.70** 29 | -.76** 29 |
| 8. PCS | | | | | | | | -- | -.28 29 | -.70** 29 | -.30 29 | -.14 29 | -.35 29 | -.33 29 |
| 9. HADS-A | | | | | | | | | -- | .48** 29 | .79** 29 | .73** 29 | .67** 29 | .75** 29 |
| 10. HADS-D | | | | | | | | | | -- | .65** 29 | .46* 29 | .70** 29 | .61** 29 |
| 11. IES-R Total | | | | | | | | | | | -- | .92** 29 | .87** 29 | .92** 29 |
| 12. IES-R Intrusion | | | | | | | | | | | | -- | .63** 29 | .84** 29 |
| 13. IES-R Avoidance | | | | | | | | | | | | | -- | .70** 29 |
| 14. IES-R Hyperarousal | | | | | | | | | | | | | | -- |

** p≤.01; * p≤.05

Table 14

*Control participants – correlations among predictor, control, and dependent measures*

| Variable (n) | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Age | -- | .62** 27 | -.16 27 | -.09 27 | -.21 27 | -.32 27 | .18 22 | -.01 22 | -.18 23 | -.28 23 | -.27 21 | -.35 21 | -.12 21 | -.27 21 |
| 2. Gender | | -- | -.16 27 | -.09 27 | .06 27 | -.56** 27 | .26 22 | .12 22 | -.45* 23 | -.26 23 | -.55** 21 | -.65** 21 | -.32 21 | -.50* 21 |
| 3. Time since implant | | | -- | .32 27 | .06 27 | -.16 27 | -.02 22 | .21 22 | -.09 23 | -.03 23 | -.38 21 | -.16 21 | -.44* 21 | -.30 21 |
| 4. Shocks | | | | -- | -.07 27 | -.11 27 | .22 22 | .02 22 | -.12 23 | -.33 23 | -.24 21 | -.15 21 | -.20 21 | -.25 21 |
| 5. LVEF | | | | | -- | -.20 27 | .19 22 | .26 22 | -.21 23 | -.19 23 | -.31 21 | -.23 21 | -.27 21 | -.28 21 |
| 6. NYHA | | | | | | -- | -.50* 22 | -.33 22 | .78** 23 | .60** 23 | .85** 21 | .83** 21 | .59** 21 | .81** 21 |
| 7. MCS | | | | | | | -- | .30 22 | -.74** 22 | -.79** 22 | -.60** 20 | -.74** 20 | -.19 20 | -.75** 20 |
| 8. PCS | | | | | | | | -- | -.44* 22 | -.52* 22 | -.60** 20 | -.53* 20 | -.43 20 | -.61** 20 |
| 9. HADS-A | | | | | | | | | -- | .77** 23 | .79** 21 | .86** 21 | .44* 21 | .83** 21 |
| 10. HADS-D | | | | | | | | | | -- | .70** 21 | .79** 21 | .32 21 | .83** 21 |
| 11. IES-R Total | | | | | | | | | | | -- | .87** 21 | .81** 21 | .89** 21 |
| 12. IES-R Intrusion | | | | | | | | | | | | -- | .43 21 | .94** 21 |
| 13. IES-R Avoidance | | | | | | | | | | | | | -- | .47* 21 |
| 14. IES-R Hyperarousal | | | | | | | | | | | | | | -- |

** p≤.01; * p≤.05

Table 15

*Within group comparisons between baseline and follow-up measures for ablation and control participants*

| Variable | *n* | Ablation *M* (*SD*) | $t^a$ | *p* | *d* | *n* | Control *M* (*SD*) | $t^b$ | *p* | *d* |
|---|---|---|---|---|---|---|---|---|---|---|
| **MCS** | | | | | | | | | | |
| Baseline | 29 | 45.89 (11.55) | -3.35 | .002 | .45 | 22 | 49.13 (10.54) | -1.51 | .146 | .33 |
| Follow-up | 29 | 50.76 (8.88) | | | | 22 | 52.63 (10.70) | | | |
| **PCS** | | | | | | | | | | |
| Baseline | 29 | 42.15 (9.91) | -.75 | .457 | .09 | 22 | 42.30 (9.65) | -1.24 | .227 | .22 |
| Follow-up | 29 | 43.11 (10.68) | | | | 22 | 44.45 (9.90) | | | |
| **HADS-A** | | | | | | | | | | |
| Baseline | 28 | 6.32 (5.40) | 1.86 | .073 | .18 | 21 | 5.05 (4.26) | 2.49 | .022 | .34 |
| Follow-up | 28 | 5.39 (4.89) | | | | 21 | 3.67 (3.60) | | | |
| **HADS-D** | | | | | | | | | | |
| Baseline | 28 | 4.66 (3.19) | .917 | .367 | .13 | 21 | 5.19 (3.87) | .118 | .908 | .01 |
| Follow-up | 28 | 4.25 (3.33) | | | | 21 | 5.14 (4.49) | | | |
| **IES-R-T** | | | | | | | | | | |
| Baseline | 28 | .95 (.75) | 3.05 | .005 | .37 | 21 | 0.55 (.61) | 2.20 | .04 | .45 |
| Follow-up | 28 | .69 (.68) | | | | 21 | 0.30 (.42) | | | |
| **IES-R-I** | | | | | | | | | | |
| Baseline | 28 | .94 (.83) | 3.04 | .005 | .40 | 21 | 0.51 (.57) | 2.18 | .041 | .49 |
| Follow-up | 28 | .63 (.75) | | | | 21 | 0.27 (.38) | | | |
| **IES-R-A** | | | | | | | | | | |
| Baseline | 28 | .97 (.81) | 1.17 | .254 | .24 | 21 | 0.55 (.68) | 1.32 | .201 | .29 |
| Follow-up | 28 | .78 (.74) | | | | 21 | 0.36 (.59) | | | |
| **IES-R-H** | | | | | | | | | | |
| Baseline | 28 | .95 (.88) | 2.95 | .007 | .38 | 21 | 0.60 (.67) | 2.63 | .016 | .53 |
| Follow-up | 28 | .64 (.75) | | | | 21 | 0.27 (.54) | | | |

*Note*. *M* = Mean; *SD* = Standard Deviation; *d* = Cohen's d; MCS = Mental Health Component Summary Score on the SF-36; PCS = Physical Component Summary Score on the SF-36; HADS = Hospital Anxiety and Depression Scale; IES-R = Impact of Event Scale – Revised; IES-R-T = IES-R Total score; IES-R-I = IES-R Intrusion subscale; IES-R-A = IES-R Avoidance subscale; IES-R-H = IES-R Hyperarousal subscale.
$^a$ = Paired sample t-test examining within group difference for the ablation group between baseline and follow-up; $^b$ = Paired sample t-test examining within group difference for the control group between baseline and follow-up.

Table 16

*Regression of baseline MCS and demographic, control, and grouping variables on MCS*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .381 | | | .475 | | | .477 | | |
| **$\Delta R^2$** | | .381 | | | .094 | | | .002 | | |
| **P value** | | <.001 | | | .12 | | | .68 | | |
| **F value** | | F[1, 48]=29.58 | | | F[4,44]=1.97 | | | F[1,43]=.17 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline MCS** | 60 | .49 | <.001 | [.31, .67] | .47 | <.001 | [.28, .66] | .48 | <.001 | [.28, .67] |
| **Age** | 61 | | | | -.03 | .73 | [-.21, .15] | -.03 | .77 | [-.21, .15] |
| **Gender** | 61 | | | | 9.28 | .051 | [-0.3,18.58] | 8.86 | .07 | [-.76, 18.48] |
| **Time since ICD implant** | 61 | | | | -.01 | .74 | [-.05, .03] | -.01 | .69 | [-.05, .03] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | -3.53 | .26 | [-9.76, -2.70] | -3.98 | .24 | [-10.65, 2.69] |
| **Group** | 60 | | | | | | | .96 | .68 | [-3.74, 5.65] |

*Note*. n = 51 for MCS follow-up.

Table 17

*Simple model – regression of baseline MCS and grouping variable on MCS*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .381 | | | .382 | | |
| **$\Delta R^2$** | | .381 | | | .001 | | |
| **P value** | | <.001 | | | .81 | | |
| **F value** | | F[1,49]=30.20 | | | F[1,48]=.06 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline MCS** | 60 | .49 | <.001 | [.31,.67] | .50 | <.001 | [.31,.68] |
| **Group** | 61 | | | | .54 | .81 | [-3.95, 5.03] |

*Note*. n = 51 for MCS follow-up.

Table 18

*Regression of baseline PCS and demographic, control, and grouping variables on PCS*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .533 | | | .597 | | | .597 | | |
| **$\Delta R^2$** | | .533 | | | .064 | | | .001 | | |
| **P value** | | <.001 | | | .16 | | | .81 | | |
| **F value** | | F[1, 48]=54.73 | | | F[4,44]=1.74 | | | F[1,43]=.06 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline PCS** | 60 | .81 | <.001 | [.59, 1.02] | .78 | <.001 | [.55, 1.02] | .78 | <.001 | [.55, 1.02] |
| **Age** | 61 | | | | -.07 | .37 | [-.24, .09] | -.08 | .36 | [-.24, .09)] |
| **Gender** | 61 | | | | -1.91 | .66 | [-10.59,6.77] | -1.67 | .71 | [-10.69, 7.34] |
| **Time since ICD implant** | 61 | | | | -.01 | .57 | [-.05, .03] | -.01 | .61 | [-.05, .03] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | -6.52 | .02 | [-12.00, -1.04] | -6.26 | .04 | [-12.22, -.30] |
| **Group** | 60 | | | | | | | -.52 | .81 | [-4.89, 3.86] |

*Note*. n = 51 for PCS follow-up

Table 19

*Simple model – regression of baseline PCS and grouping variable on PCS*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .533 | | | .543 | | |
| **$\Delta R^2$** | | .533 | | | .010 | | |
| **P value** | | <.001 | | | .30 | | |
| **F value** | | F[1,49]=55.87 | | | F[1,48]=1.09 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline PCS** | 60 | .81 | <.001 | [.59,1.02] | .81 | <.001 | [.59,1.02] |
| **Group** | 61 | | | | -2.09 | .30 | [-6.12, 1.94] |

*Note*. n = 51 for PCS follow-up.

Table 20

*Regression of baseline HADS-A and demographic, control, and grouping variables on HADS-A*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .729 | | | .803 | | | .804 | | |
| **$\Delta R^2$** | | .729 | | | .074 | | | .001 | | |
| **P value** | | <.001 | | | .007 | | | .65 | | |
| **F value** | | F[1, 47]=126.48 | | | F[4,43]=4.01 | | | F[1,42]=.22 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline HADS-A** | 58 | .74 | <.001 | [.61, .87] | .72 | <.001 | [.58, .85] | .72 | <.001 | [.58, .85] |
| **Age** | 61 | | | | .05 | .08 | [-.01, .10] | .05 | .08 | [-.01, .10] |
| **Gender** | 61 | | | | -2.65 | .04 | [-5.17,-.13] | -2.79 | .04 | [-5.40, -.17] |
| **Time since ICD implant** | 61 | | | | -.001 | .84 | [-.01, .01] | -.002 | .78 | [-.01, .01] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | 2.31 | .01 | [.63, 3.99] | 2.17 | .02 | [.36, 3.97] |
| **Group** | 61 | | | | | | | .30 | .65 | [-1.00, 1.60] |

*Note*. n = 52 for HADS-Anxiety follow-up.

Table 21

*Simple model – regression of baseline HADS-A and grouping variable on HADS-A*

| | | **Step 1** | | | **Step 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .729 | | | .733 | | |
| **$\Delta R^2$** | | .729 | | | .004 | | |
| **P value** | | <.001 | | | .40 | | |
| **F value** | | F[1,47]=126.48 | | | F[1,46]=.72 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline HADS-A** | 58 | .74 | <.001 | [.61,.87] | .73 | <.001 | [.60,.87] |
| **Group** | 61 | | | | .56 | .40 | [-.77, 1.90] |

*Note*. n = 52 for HADS-Anxiety follow-up.

Table 22

*Regression of baseline HADS-D and demographic, control, and grouping variables on HADS-D*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .629 | | | .730 | | | .736 | | |
| **$\Delta R^2$** | | .629 | | | .038 | | | .006 | | |
| **P value** | | <.001 | | | .22 | | | .35 | | |
| **F value** | | F[1, 47]=105.78 | | | F[4,43]=1.51 | | | F[1,42]=.88 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline HADS-D** | 58 | .90 | <.001 | [.72, 1.07] | .93 | <.001 | [.73, 1.13] | .91 | <.001 | [.71, 1.11] |
| **Age** | 61 | | | | .04 | .10 | [-.01, .09] | .04 | .14 | [-.01, .09] |
| **Gender** | 61 | | | | -2.40 | .07 | [-5.00, .19] | -2.09 | .12 | [-4.78, .59] |
| **Time since ICD implant** | 61 | | | | .004 | .43 | [-.01, .02] | .005 | .36 | [-.01, .02] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .40 | .65 | [-1.38, 2.18] | .76 | .43 | [-1.18, 2.70] |
| **Group** | 61 | | | | | | | -.62 | .35 | [-1.96, .72] |

*Note*. n = 52 for HADS-Depression follow-up.

Table 23

*Simple model – regression of baseline HADS-D and grouping variable on HADS-D*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .692 | | | .698 | | |
| **$\Delta R^2$** | | .692 | | | .006 | | |
| **P value** | | <.00 | | | .36 | | |
| **F value** | | F[1,47]=105.78 | | | F[1,46]=.84 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline HADS-D** | 58 | .90 | <.001 | [.72,1.07] | .90 | <.001 | [.72,1.07] |
| **Group** | 61 | | | | -.56 | .36 | [-1.79, .67] |

Note. N=52 for HADS-Depression follow-up.

Table 24

*Regression of baseline IES-R Total and demographic, control, and grouping variables on IES-R Total*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .564 | | | .734 | | | .742 | | |
| **$\Delta R^2$** | | .564 | | | .170 | | | .007 | | |
| **P value** | | <.001 | | | <.001 | | | .28 | | |
| **F value** | | F[1, 47]=60.87 | | | F[4,43]=6.88 | | | F[1,42]=1.19 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Total** | 60 | .62 | <.001 | [.46, .78] | .60 | <.001 | [.45, .75] | .58 | <.001 | [.42, .73] |
| **Age** | 61 | | | | .01 | .03 | [.001, .02] | .01 | .03 | [.001, .02] |
| **Gender** | 61 | | | | -.79 | <.001 | [-1.20,-.37] | -.83 | <.001 | [-1.26, -.41] |
| **Time since ICD implant** | 61 | | | | -.002 | .09 | [-.003, .00] | -.002 | .07 | [-.003, .00] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .31 | .03 | [.03, .59] | .27 | .07 | [-.02, .56] |
| **Group** | 61 | | | | | | | .12 | .28 | [-.10, .33] |

*Note*. n = 50 for IES-R Total follow-up.

Table 25

*Simple model – regression of baseline IES-R Total and grouping variable on IES-R Total*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .564 | | | .570 | | |
| **$\Delta R^2$** | | .564 | | | .006 | | |
| **P value** | | <.001 | | | .43 | | |
| **F value** | | F[1,47]=60.87 | | | F[1,46]=.63 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Total** | 58 | .62 | <.001 | [.46,.78] | .60 | <.001 | [.43,.76] |
| **Group** | 61 | | | | .10 | .43 | [-.15, .35] |

*Note*. n = 50 for IES-R Total follow-up.

Table 26

*Regression of baseline IES-R Intrusion and demographic, control, and grouping variables on IES-R Intrusion*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .522 | | | .708 | | | .709 | | |
| **$\Delta R^2$** | | .522 | | | .186 | | | .001 | | |
| **P value** | | <.001 | | | <.001 | | | .77 | | |
| **F value** | | F[1, 47]=51.28 | | | F[4,43]=6.87 | | | F[1,42]=.09 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Intrusion** | 60 | .58 | <.001 | [.42, .74] | .56 | <.001 | [.41, .72] | .56 | <.001 | [.39, .72] |
| **Age** | 61 | | | | .01 | .04 | [.00, .02] | .01 | .05 | [.00, .02] |
| **Gender** | 61 | | | | -.85 | .001 | [-1.32,-.39] | -.87 | .001 | [-1.35, -.39] |
| **Time since ICD implant** | 61 | | | | .00 | .85 | [-.002, .002] | .00 | .89 | [-.002, .002] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .42 | .008 | [.11, .72] | .40 | .02 | [.08, .73] |
| **Group** | 61 | | | | | | | .04 | .77 | [-.21, .28] |

*Note*. n = 50 for IES-R Intrusion follow-up.

Table 27

*Simple model – regression of baseline IES-R Intrusion and grouping variable on IES-R Intrusion*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .522 | | | .524 | | |
| **$\Delta R^2$** | | .522 | | | .002 | | |
| **P value** | | <.001 | | | .63 | | |
| **F value** | | F[1,47]=51.28 | | | F[1,46]=.24 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Intrusion** | 58 | .58 | <.001 | [.42,.74] | .57 | <.001 | [.39,.74] |
| **Group** | 61 | | | | .07 | .63 | [-.21, .35] |

*Note*. n = 50 for IES-R Intrusion follow-up.

Table 28

*Regression of baseline IES-R Avoidance and demographic, control, and grouping variables on IES-R Avoidance*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .236 | | | .377 | | | .410 | | |
| **$\Delta R^2$** | | .236 | | | .141 | | | .033 | | |
| **P value** | | <.001 | | | .06 | | | .13 | | |
| **F value** | | F[1, 47]=14.54 | | | F[4,43]=2.43 | | | F[1,42]=2.38 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Avoidance** | 60 | .43 | <.001 | [.20, .66] | .42 | .001 | [.18, .66] | .38 | .003 | [.14, .63] |
| **Age** | 61 | | | | .01 | .36 | [-.01, .02] | .01 | .31 | [-.01, .02] |
| **Gender** | 61 | | | | -.60 | .11 | [-1.34,.13] | -.72 | .06 | [-1.46, .02] |
| **Time since ICD implant** | 61 | | | | -.003 | .06 | [-.01, .00] | -.003 | .03 | [-.01, .00] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .32 | .21 | [-.18, .81] | .20 | .45 | [-.32, .71] |
| **Group** | 61 | | | | | | | .28 | .13 | [-.09, .66] |

*Note*. n = 50 for IES-R Avoidance follow-up.

Table 29

*Simple model – regression of baseline IES-R Avoidance and grouping variable on IES-R Avoidance*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .236 | | | .266 | | |
| **$\Delta R^2$** | | .236 | | | .029 | | |
| **P value** | | <.001 | | | .18 | | |
| **F value** | | F[1,47]=14.54 | | | F[1,46]=1.83 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Avoidance** | 58 | .43 | <.001 | [.20, .66] | .39 | .002 | [.15, .62] |
| **Group** | 61 | | | | .25 | .18 | [-.12, .62] |

*Note*. n = 50 for IES-R Avoidance follow-up.

Table 30

*Regression of baseline IES-R Hyperarousal and demographic, control, and grouping variables on IES-R Hyperarousal*

| | | **Model 1** | | | **Model 2** | | | **Model 3** | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **$R^2$** | | .536 | | | .687 | | | .692 | | |
| **$\Delta R^2$** | | .536 | | | .152 | | | .004 | | |
| **P value** | | <.001 | | | .002 | | | .46 | | |
| **F value** | | F[1, 47]=54.24 | | | F[4,43]=5.22 | | | F[1,42]=.56 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Hyperarousal** | 60 | .61 | <.001 | [.44, .77] | .52 | <.001 | [.36, .67] | .50 | <.001 | [.34, .67] |
| **Age** | 61 | | | | .01 | .33 | [-.01, .02] | .01 | .30 | [-.01, .02] |
| **Gender** | 61 | | | | -.80 | .003 | [-1.30, .30] | -.84 | .002 | [-1.36, .32] |
| **Time since ICD implant** | 61 | | | | -.001 | .30 | [-.003, .001] | -.001 | .23 | [-.003, .001] |
| **NYHA (I&II vs. III&IV)** | 60 | | | | .41 | .02 | [.07, .75] | .37 | .05 | [.01, .72] |
| **Group** | 61 | | | | | | | .10 | .46 | [-.17, .36] |

*Note*. n = 50 for IES-R Hyperarousal follow-up.

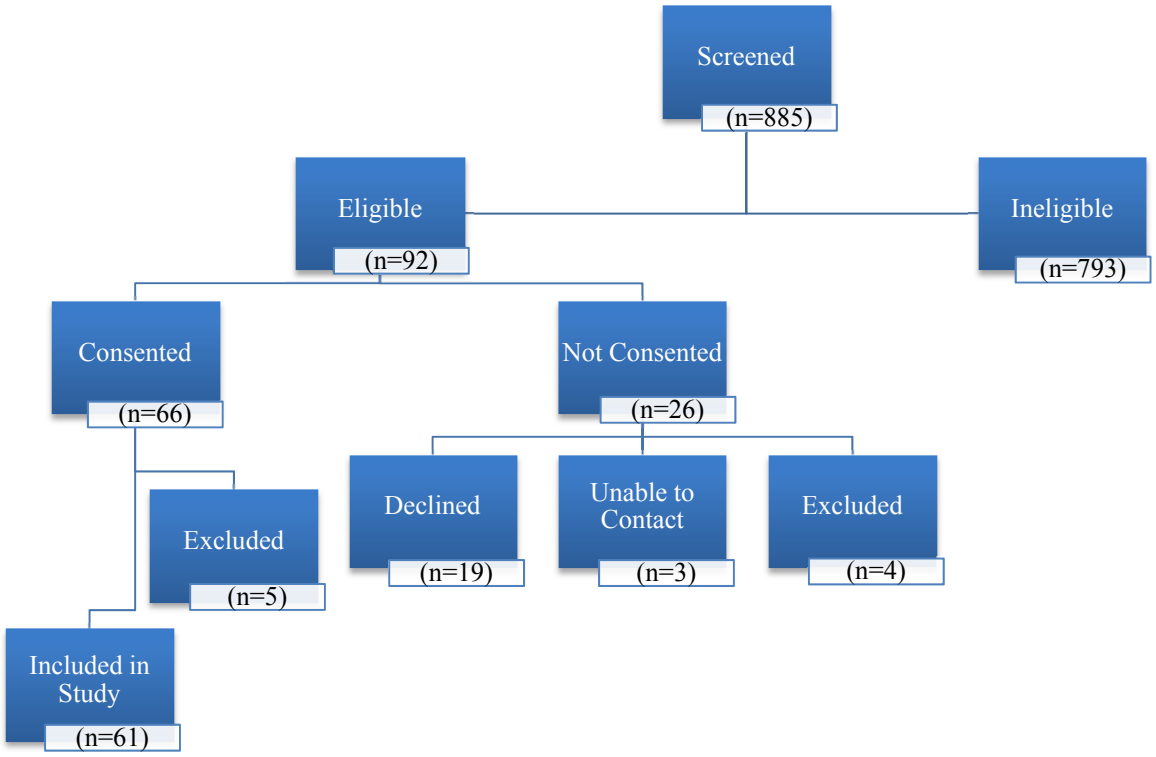
Table 31

*Simple model – regression of baseline IES-R Hyperarousal and grouping variable on IES-R Hyperarousal*

| | | **Model 1** | | | **Model 2** | | |
|---|---|---|---|---|---|---|---|
| **$R^2$** | | .536 | | | .539 | | |
| **$\Delta R^2$** | | .536 | | | .003 | | |
| **P value** | | <.001 | | | .57 | | |
| **F value** | | F[1,47]=54.24 | | | F[1,46]=.32 | | |
| | *n* | *B* | *p* | 95% CI | *B* | *p* | 95% CI |
| **Baseline IES-R Hyperarousal** | 58 | .61 | <.001 | [.44, .77] | .59 | <.001 | [.42, .76] |
| **Group** | 61 | | | | .08 | .57 | [-.21, .37] |

*Note*. n = 50 for IES-R Hyperarousal follow-up.

*Figure 1.* Patient Accrual



Appendix A: Information Letter


Quality of Life and Psychosocial Well-Being Following VT Ablation
Information Letter

We are writing to let you know about an opportunity to participate in a study which aims to better understand how treatments for ventricular tachycardia (VT) influence health and well-being. This study will involve two groups of patients. One group consists of individuals who have an implantable cardioverter defibrillator (ICD) and who are undergoing an ablation procedure. The other group consists of individuals who have an ICD and who are not undergoing an ablation procedure. The general aim of this study is to better understand the impact of various types of treatment for VT on health and well-being. Individuals who choose to participate will fill out one questionnaire package at the time of recruitment and one following a 6-month period.

We are sending you this letter as you have been contacted by your health care provider and have expressed interest in learning more about this study. In addition to this letter, we are sending you a consent form, and a questionnaire package. A member of our study staff will explain the study in detail, review the consent form with you, and answer any questions or concerns that you may have.

You will be asked to sign the consent form, complete the questionnaire package, and send back the signed consent form and the questionnaire package in a stamped, self-addressed envelope which will be provided to you. The questionnaires ask about your experiences, general mood, and feelings.

Please note that participating in this study is completely voluntary and that you are free to withdraw at any point during the study. Your medical care will not be affected in any way by whether or not you choose to participate in this research study. All information obtained for this study will be kept strictly confidential and will be used for research purposes only. Your name will not be used or associated with the information which you provide, and any identifying information, such as names or locations, will be removed from the study.

If you have not already returned the completed questionnaire package, a member of our study team will contact you by phone to follow up in approximately two weeks.

If you have any questions about the research study, please feel free to contact Dr. Jane Irvine at [redacted] or Dr. Nanthakumar at [redacted].

Sincerely,

Dr. Jane Irvine and Dr. Nanthakumar

Appendix B: Informed Consent Form – University Health Network


**Consent Form for Participation in a Research Study**

Title: Quality of Life and Psychosocial Well-Being Following VT Ablation

Principal Investigators: Dr. Nanthakumar [redacted], FRCPC, MD, Division of Experimental Therapeutics, Dr. Jane Irvine, D. Phil, C. Psych, Affiliate Scientist, Division of Behavioural Sciences and Health, [redacted], Leora Wanounou, RN, BScN, CCN(c), [redacted], Co-investigator, and Ana Bilanovic, MA, Co-investigator, [redacted]

You are being asked to take part in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time. In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study staff to explain any words you don't understand before signing this consent form. Make sure all your questions have been answered to your satisfaction before signing this document.

**Background**

To date, much of the research in arrhythmia populations has focused on examining the impact of having an implantable cardioverter defibrillator (ICD). In these studies, issues such as quality of life, anxiety, and depression levels have been examined. However, less research has been conducted on catheter ablation, an increasingly common method for treating ventricular tachycardias (VT), and the associated quality of life and psychosocial well-being.

**Purpose**

This study aims to better understand how treatments for ventricular arrhythmias influence health and well-being. It aims to study two groups of patients. One group consists of individuals with an ICD who are undergoing an ablation procedure. The other group consists of individuals with an ICD who are not undergoing an ablation procedure. The general aim of this study is to better understand the impact of various types of treatment for VT on health and well-being over a 6-month period.

**Procedures**

Your healthcare team has noted that you are eligible to participate in this research study. You have either been approached by a member of your health care team during your regularly scheduled hospital visit or you have been contacted by a member of your health care team by phone. Because you expressed interest in hearing about this study you are receiving this consent form, in addition to

an information letter, and a questionnaire package. Our study coordinator will review this consent form with you either while you are at the hospital for your regularly scheduled visit or by phone. At that time, the study coordinator will explain the study to you in detail and address any questions or concerns that you may have. In this package you will find several questionnaires which will ask about your experiences, general mood, and feelings. You will be asked to please send back the completed questionnaire package with a signed consent form in a stamped, self-addressed envelope which will be provided to you in a timely manner. The study will follow all participants for a 6-month period. This means that you will receive another package, similar to the one you received when you enrolled in the study, after 6 months. At that time, you will be asked to send back the questionnaire package in a stamped, self-addressed envelope which will be provided to you. The questionnaire packages will take approximately 30-45 minutes to complete.

Additionally, we would like your permission to review information about your previous medical history by examining your hospital chart.

**Risks**

This is a minimal risk study. It is possible that you may find some questions in the questionnaires to be personal in nature, and you may choose to not answer these questions. In the unlikely event that you experience great distress as a result of a questionnaire, a psychologist on our research team will provide you with assistance in finding appropriate counseling resources should you ask for such assistance.

**Benefits**

While you will not receive any medical benefit from participating in this study, your participation will help provide a further understanding of the quality of life and psychological well-being following a catheter ablation procedure. Information learned from this study may help improve patient care by enhancing the healthcare provider's ability to determine the plan of care for these patients.

**Confidentiality**

All information obtained during the study will be held in strict confidence. You will be identified with a study number only. No names or identifying information will be used in any publication or presentations. No information identifying you will be transferred outside the investigators in this study or this hospital. The information obtained from this study will be used for research purposes only. The University Health Network Research Ethics Board (a body that oversees the ethical conduct of research studies) may look at the study information for auditing purposes. Following their completion and return, the questionnaire packages will be kept confidential by being stored within a double-locked cabinet within a locked office for five years following the completion of this study. Once five years have passed, data will be destroyed by shredding. Upon completion, the study results and research dissertation will become public property and may be published. Your identity will remain anonymous at all times.

**Participation**

Participation in this study is voluntary. At any time you may choose not to answer a given question. You can choose not to participate in the study or you may withdraw at any time without affecting your medical care.

**Questions**

If you have any general questions about the study, please contact the Principal Investigators:

Dr. Nanthakumar [redacted] or Dr. Jane Irvine, [redacted],
or one of the co-investigators
Leora Wanounou, [redacted] or Ana Bilanovic, [redacted]

For any questions about your rights as a research participant, please contact the Chair of UHN Research Ethics Board, at [redacted].
This person is not involved with the research project in any way and calling them will not affect your participation in the study.

**Consent**

I have had the opportunity to discuss this study and my questions have been answered to my satisfaction. I consent to take part in the study with the understanding I may withdraw at any time without affecting my medical care. I have received a signed copy of this consent form. I voluntarily consent to participate in this study.

| _____ | _____ | _____ |
|---|---|---|
| Participant's Name (Please Print) | Participant's Signature | Date |

I confirm that I have explained the nature and purpose of the study to the study participant named above. I have answered all questions.

| _____ | _____ | _____ |
|---|---|---|
| Name of Person Obtaining Consent | Signature | Date |

Appendix C: Informed Consent Form – St. Michael's Hospital

St. Michael's
Inspired Care.
Inspiring Science.

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**Title: Quality of Life and Psychosocial Well-Being Following VT Ablation**

**Investigator:**

**Principal Investigator:**
Dr. Paul Angaran

**Sub-Investigator:**
Dr Iqwal Mangat

**Research Coordinator**
Zana Mariano

[redacted] [redacted] [redacted]

**24 Hour / 7 Day Emergency Number: St. Michael's Hospital, Locating [redacted]**
***Ask for the Electrophysiologist on call***

## 1. INTRODUCTION

You are being invited to consider taking part in a research study. Before agreeing to take part in this research study, it is important that you read the information in this consent form. It includes details we think you need to know in order to decide if you wish to take part in the study. If you have any questions, ask a study doctor or study staff. You should not sign this form until you are sure you understand the information. All research is voluntary. You may also wish to discuss the study with your family doctor, a family member or close friend. If you decide to take part in the study, it is important that you are completely truthful about your health history and any medications you are taking. This will help prevent unnecessary harm to you.

This document describes the purpose, procedures, benefits and risks of the study. It also describes your right to withdraw from the study at any time. Please read this consent form carefully and ask as many questions as you like before deciding whether you want to take part in this study.

## 2. PURPOSE OF THE RESEARCH

The purpose of this study is to better understand how treatments for ventricular arrhythmias (abnormal rapid heart rhythm that originates in the lower chamber of the heart called the ventricles) influence health and well-being. It aims to study two groups of patients. One group consists of individuals with an implantable cardioverter defibrillator (ICD) who are undergoing an ablation procedure. The other group consists of individuals with an ICD who are not undergoing an ablation procedure. The general aim of this study is to better understand the impact of various types of treatment for ventricular tachycardia (VT) on health and well-being over a 6-month period.

To date, much of the research in arrhythmia populations has focused on examining the impact of having an implantable cardioverter defibrillator (ICD) to prevent sudden death in patients with ventricular tachycardia (VT). In these studies, issues such as quality of life, anxiety, and depression

levels have been examined. However, less research has been conducted on catheter ablation. Catheter ablation involves placing catheters (wires) inside your heart. The wires are used to destroy the abnormal electrical impulses that are thought to cause VT. This is an increasingly common method for treating VT, and the associated quality of life and psychosocial well-being.

**3. DESCRIPTION OF THE RESEARCH**

This study aims to evaluate the long term outcomes (6 months) of various types of treatment for VT on quality of life and psychosocial well-being in patients with an ICD. It is anticipated that St. Michael's Hospital will enroll between 20-30 participants.

The study has 2 parts:

1. This initial contact requesting your consent to access your medical chart (there is no other action required of you); and

2. A follow-up health survey shortly after your clinic visit and at 6 months

**Enrollment**

Your healthcare team has noted that you are eligible to participate in this research study. You have either been approached by a member of your health care team during your regularly scheduled hospital visit or you have been contacted by a member of your health care team by phone. Since you expressed interest in hearing about this study, you are receiving this consent form, in addition to an information letter, and a questionnaire package. Our study coordinator will review this consent form with you either while you are at the hospital for your regularly scheduled visit or by phone.

At that time, the study coordinator will explain the study to you in detail and address any questions or concerns that you may have. In this package you will find several questionnaires which will ask about your experiences, general mood, and feelings. You will be asked to please send back the completed questionnaire package with a signed consent form in a stamped, self-addressed envelope which will be provided to you, in a timely manner. If you are willing to participate in the study, please read and sign this consent form. Contact details of your family doctor and/or specialist (who looks after your heart) will be extracted from your hospital records.

At St Michael's Hospital, providing contact information is required to ensure complete follow-up of all patients and to make sure that data collected are precise. No identifiable information or data will be sent to the sponsor. Your doctors will be notified about your participation in this study and the details of this research.

Additional clinical information such as details regarding other medical disorders that you may have, results of blood/urine tests, results of a heart sonogram (if done) will be obtained from your hospital record and if necessary, by contacting one of your physicians. If you are on blood thinning medications, we will attempt to get results of relevant testing (INR result) from your family doctor or specialist doctor.

**Follow-up**

**After 6 months, you will be contacted (in person, telephone and/or mail) and asked satisfaction questions regarding your health.**

You will be asked to send back a set of questionnaires, similar to those received upon enrollment into the study, in a stamped, self-addressed envelope, which will be provided to you and asked to mail it back within three weeks of receiving the questionnaires. If you have not returned a questionnaire package within the 3-week time period, you will be contacted up to three times and reminded to please return the questionnaire package. The questionnaire packages will take approximately 30-45 minutes to complete.

If additional information is needed, we would like your permission to review information about your previous medical history by examining your hospital chart.

## 4. POTENTIAL HARMS (INJURY, DISCOMFORTS OR INCONVENIENCE)

**This is a minimal risk study.** It is possible that you may find some questions in the questionnaires to be personal in nature, and you may choose to not answer these questions. In the unlikely event that you experience great distress as a result of a questionnaire, a psychologist on our research team will provide you with assistance in finding appropriate counseling resources should you ask for such assistance.

## 5. POTENTIAL BENEFITS

While you will not receive any medical benefit from participating in this study, your participation will help provide a further understanding of the quality of life and psychological well-being following a catheter ablation procedure. Information learned from this study may help improve patient care by enhancing the healthcare provider's ability to determine the plan of care for these patients.

## 6. PROTECTING YOUR HEALTH INFORMATION

All St. Michael's Hospital (SMH) study staff (study investigators, coordinators, nurses and delegates) are committed to respecting your privacy. No other persons will have access to your personal health information or identifying information without your consent, unless required by law. The study staff will make every effort to keep your personal health information private and confidential in accordance with all applicable laws, regulations, guidelines and privacy legislations, including the Personal Health Information Protection Act (PHIPA) of Ontario.

Any personal health information or personal information collected about you will be "de-identified" by replacing your personal identifying information with a "study number". The SMH study staff is in control of the study code key, which is needed to connect your personal health information/personal information to you. The link between the study number and your personal identity will be safeguarded by the SMH study staff. Our guidelines include the following:

- All information that identifies you, both paper copy and electronic information, will be kept confidential and stored and locked in a secure place that only the study staff will be able to access.
- Electronic files will be stored securely on hospital or institutional networks or securely on any portable electronic devices.
- No information identifying you will be allowed off site in any form. Examples include your hospital or clinic charts, copies of any part of your charts, or notes made from your charts.
- Questionnaires and data will be stored in a secure server at Toronto General Hospital. No identifying information will be sent off site.

It is important to understand that despite these protections being in place, there continues to be the risk of unintentional release of information. The SMH study staff will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will be accidentally released is small.

Although all of your study data will be kept confidential, your medical records may be accessed by the study staff or the St. Michael's Hospital Research Ethics Board. Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality to the extent permitted by applicable laws and regulations.

Federal and Provincial Data Protection regulations, including the Personal Information Protection and Electronic Documents Act (PIPEDA 2000) and the Personal Health Information Protection Act (PHIPA 2004) of Ontario, protect your personal information. They also give you the right to control the use of your personal information (including personal health information) and require your written permission for this personal information to be collected, used, or disclosed for the purposes of this study, as described in this consent form. You have the right to review and copy your personal information collected in this study. However, if you decide to be in this study or choose to withdraw from it, your right to look at or copy your personal information related to this study will be delayed until after the research is completed.

Study data will be retained for 10 years.

## 7. STUDY RESULTS

The results of this study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations. At the end of the study, the study results, and conclusions may be disclosed to you, if you so wish.

## 8. POTENTIAL COSTS/REIMBURSEMENTS

There will be no charge to you for your participation in this study.

## 9. PARTICIPATION AND WITHDRAWAL

Participation in any research study is voluntary. At any time you may choose not to answer a given question. If you do decide to take part you will be asked to sign this consent form. If you choose not to participate, you and your family will continue to have access to customary care at St. Michael's Hospital. If you decided to participate in this study and signed the consent form you can change your mind without giving a reason, and you may withdraw from the study at any time without affecting the care you and your family will receive at St. Michael's Hospital. You should talk to your study doctor to determine how best to complete the withdrawal process.

## 10. NEW FINDINGS OR INFORMATION

We may learn new things during the study that you may need to know. You will be notified about any new information in a timely manner.

You will be kept informed, in a timely manner, of any information that may relate to your willingness to continue participation in the study. At the discretion of your doctor(s), you may be asked to sign a revised informed consent or consent addendum that provides this information.

You may ask questions at any time about this study. You should contact **Research Coordinator, Zana Mariano at [redacted].**

## 11. RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding your rights as a research participant, you may contact **Dr David Mazer, Chair, Research Ethics Board at [redacted]** during business hours.

## 12. STUDY CONTACTS

If you have any questions about this study, or if you feel you have experienced a research-related injury, contact the study doctor:

**Dr. Paul Angaran**, Cardiologist
[redacted]

**In case of emergency, please go to the nearest emergency department and let them know that you are in a study, and the principal investigators name.**

Title: "**Quality of Life and Psychosocial Well-Being Following VT Ablation**"

**Consent Signature:**

**I acknowledge that the study described above has been explained to me and that any questions that I have asked have been answered to my satisfaction. I have been informed of the alternatives to participation in this study, including the right not to participate and the right to withdraw without compromising the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms have been explained to me and I also understand the benefits (if any) of participating in the research study.**

**I understand that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept confidential and that no information that will be disclosed without my permission unless required by law. I have been given sufficient time to read and understand the above information.**

**I hereby voluntarily consent to participate in the research study described above. I will receive two copies of the consent form - one signed copy which I will keep and the other which will be returned to the study team.**

☐ **I understand that my family physician and/or specialist and pharmacist will be informed of my participation in this study.**

_____ _____

Participant's Signature Date

_____

Participant's Printed Name

Participant's telephone number: _____

***STUDY PERSONNEL STATEMENT***

The person signing this consent form has had the study fully and carefully explained and has been given an opportunity to ask any questions regarding the nature, risks and benefits of the subject's participation in this research study.

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Participant #: _____ Date: _____

Appendix D – Baseline Questionnaire

**STUDY QUESTIONNAIRE**
**Baseline**

Thank you for completing the following questionnaire. Your answers will help us assess the results of this study and get a better understanding of how treatments for ventricular arrhythmias influence health and well-being.

Please return the completed questionnaire in the pre-stamped self-addressed envelope provided.

You may find some of the questions in this survey to be personal in nature and we appreciate your willingness to complete the items. Your replies will be kept strictly confidential and only the research team will see your answers. If you have any questions, please contact the study co-ordinators at [redacted].

## DEMOGRAPHIC INFORMATION

**Please try to answer all of the questions. However, if there are any that you would rather not answer, you are free to leave them blank.**

**There is no single correct answer to the following questions. The correct response is the one which comes closest to describing you.**

1. Sex: □ Male □ Female 2. Year of Birth:_____ 3. Age:_____

4. How many years of school did you finish?
   - □ Less than high school
   - □ High school graduate
   - □ Trade or technical training after high school
   - □ Community college graduate
   - □ University graduate
   - □ Postgraduate university degree

5. What is your current living situation:
   - □ Living with a partner or a family member
   - □ Living with a friend or a roommate
   - □ Living alone
   - □ Living in a residential setting

## Health

Ablations

6. Have you had an ablation?
   - □ No
   - □ Yes

7. How many ablations have you had to-date? _____

8. How many of your ablations were deemed successful? ___

ICD

9. How many recorded ICD shocks have you experienced to-date?
   - □ None
   - □ 1 – 2 shocks
   - □ 3 – 4 shocks
   - □ more than 4 shocks

10. Have you ever experienced a shock and been told that it was not recorded?
   - □ No
   - □ Yes If yes, how many times have you had a shock and been told it was not recorded? ____

11. Are you currently taking any antiarrhythmic medication?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

12. Are you currently taking any beta blockers?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

13. Are you currently taking any medications to help with mood?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

14. Are you currently taking any medications to help you sleep?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

## Your Health and Well-Being (SF-36)

This portion of the questionnaire asks for your views about your health. For each of the following questions, please mark an 'x' in the box that best describes your answer.

**1. In general, would you say your health is:**

| Excellent | Very good | Good | Fair | Poor |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**2. Compared to one year ago, how would you rate your health in general now?**

| Much better now than one year ago | Somewhat better now than one year ago | About the same as one year ago | Somewhat worse now than one year ago | Much worse now than one year ago |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

| | | Yes, Limited a lot | Yes, limited a little | No, not limited at all |
|---|---|---|---|---|
| a | <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports | ☐ 1 | ☐ 2 | ☐ 3 |
| b | <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | ☐ 1 | ☐ 2 | ☐ 3 |
| c | Lifting or carrying groceries | ☐ 1 | ☐ 2 | ☐ 3 |
| d | Climbing <u>several</u> flights of stairs | ☐ 1 | ☐ 2 | ☐ 3 |
| e | Climbing <u>one</u> flight of stairs | ☐ 1 | ☐ 2 | ☐ 3 |
| f | Bending, kneeling, or stooping | ☐ 1 | ☐ 2 | ☐ 3 |
| g | Walking <u>more than a kilometre</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| h | Walking <u>several hundred metres</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| i | Walking <u>one hundred metres</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| j | Bathing or dressing yourself | ☐ 1 | ☐ 2 | ☐ 3 |

**4.During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

| | | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|
| a | Cut down on the <u>amount of time</u> you spent on work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b | <u>Accomplished less</u> than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c | Were limited in the <u>kind</u> of work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d | Had <u>difficulty</u> performing the the work or other activities (for example, it took extra effort) | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a Cut down on the amount of time you spent on work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b Accomplished less than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c Did work or other activities less carefully than usual | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

| Not at all | Slightly | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**7. How much bodily pain have you had during the past 4 weeks?**

| None | Very mild | Mild | Moderate | Severe | Very severe |
|---|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |

**8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

| | | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|
| a | Did you feel full of life? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b | Have you been very nervous? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c | Have you felt so down in the dumps that nothing could cheer you up? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d | Have you felt calm and peaceful? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| e | Did you have a lot of energy? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| f | Have you felt downhearted and depressed? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| g | Did you feel worn out? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| h | Have you been happy? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| i | Did you feel tired? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**11. How TRUE or FALSE is <u>each</u> of the following statements for you?**

| | | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|---|---|---|---|---|---|
| a | I seem to get sick a little easier than other people | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b | I am as healthy as anybody I know | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c | I expect my health to get worse | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d | My health is excellent | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

## EMOTIONS IN THE PAST WEEK (HADS)

The following questions ask about how you have been feeling. Health care professionals are aware that emotions play an important part in most illnesses. If your health care professional knows about these feelings he or she will be able to help you more. **Read each item below and place a check (✓) in the box beside the reply which comes closest to how you have been feeling in the past week.**

**1. I feel tense or "wound up"**

□ Most of the time
□ A lot of time
□ From time to time
□ Not at all

**2. I still enjoy the things I used to enjoy**

□ Definitely as much
□ Not quite so much
□ Only a little
□ Hardly at all

**3. I get sort of frightened feeling as if something awful is about to happen**

□ Very definitely and quite badly
□ Yes, but not too badly
□ A little, but it doesn't worry me
□ Not at all

**4. I can laugh and see the funny side of things**

□ As much as I always could
□ Not quite so much now
□ Definitely not so much now
□ Not at all

**5. Worrying thoughts go through my mind**

□ A great deal of the time
□ A lot of the time
□ Not too often
□ Very little

**6. I feel cheerful**

□ Never
□ Not often
□ Sometimes
□ Most of the time

**7. I can sit at ease and feel relaxed**

□ Definitely
□ Usually
□ Not often
□ Not at all

**8. I feel as if I am slowed down**

□ Nearly all the time
□ Very often
□ Sometimes
□ Not at all

**9. I get a sort of frightened feeling like "butterflies" in the stomach**

□ Not at all
□ Occasionally
□ Quite often
□ Very often

**10. I have lost interest in my appearance**

□ Definitely
□ I don't take as much care as I should
□ I may not take quite much care
□ I take just as much care as ever

**11. I feel restless as if I have to be on the move**

□ Very much indeed
□ Quite a lot
□ Not very much
□ Not at all

**12. I look forward with enjoyment to things**

□ As much as I ever did
□ Rather less than I used to
□ Definitely less than I used to
□ Hardly at all

**13. I get sudden feelings of panic**

□ Very often indeed
□ Quite often
□ Not very often
□ Not at all

**14. I can enjoy a good book or radio or TV program**

□ Often
□ Sometimes
□ Not often
□ Very seldom

## RESPONDING TO STRESSFUL EVENTS (IES-R)

The following is a list of difficulties people sometimes have after stressful life events. Please read each item and then indicate how distressing each difficulty has been for you *during the past 7 days* with respect to your arrhythmia (i.e., heart rhythm problem) or its treatment (i.e., having an ICD or ablation) by checking off under the most appropriate response. How much were you distressed or bothered by these difficulties?

| | | Not at all 0 | A little bit 1 | Moderately 2 | Quite a bit 3 | Extremely 4 |
|---|---|---|---|---|---|---|
| 1. | Any reminder brought back feeling about it. | | | | | |
| 2. | I had trouble staying asleep. | | | | | |
| 3. | Other things kept making me think about it. | | | | | |
| 4. | I felt irritable and angry | | | | | |
| 5. | I avoided letting myself get upset when I thought about it or was reminded of it. | | | | | |
| 6. | I thought about it when I didn't mean to. | | | | | |
| 7. | I felt as if it hadn't happened or wasn't real. | | | | | |
| 8. | I stayed away from reminders about it. | | | | | |
| 9. | Pictures about it popped into my mind. | | | | | |
| 10. | I was jumpy and easily startled. | | | | | |
| 11. | I tried not to think about it. | | | | | |
| 12. | I was aware that I still had a lot of feelings about it, but I didn't deal with them. | | | | | |
| 13. | My feelings about it were kind of numb. | | | | | |
| 14. | I found myself acting or feeling like I was back at that time. | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 15. | I had trouble falling asleep. | | | | | |
| 16. | I had waves of strong feelings about it. | | | | | |
| 17. | I tried to remove it from my memory. | | | | | |
| 18. | I had trouble concentrating. | | | | | |
| 19. | Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart. | | | | | |
| 20. | I had dreams about it. | | | | | |
| 21. | I felt watchful and on guard. | | | | | |
| 22. | I tried not to talk about it. | | | | | |

## LIFE STRESS

The next set of questions asks about possible difficulties or stresses that you may have experienced in your life.

Have you experienced any of the following in the past year?

| | | NO | YES |
|---|---|---|---|
| 1. | Serious illness or injury | | |
| 2. | Serious illness or injury to a close relative or friend | | |
| 3. | Marriage | | |
| 4. | Death of a spouse or partner | | |
| 5. | Death of a close relative or friend | | |
| 6. | Death of a pet | | |
| 7. | Marital separation/divorce | | |
| 8. | Financial difficulties | | |
| 9. | Loss of job | | |
| 10. | Retirement | | |
| 11. | Business failure | | |
| 12. | Major family conflict | | |
| 13. | Pregnancy | | |
| 14. | Gaining a new family member through birth or marriage | | |
| 15. | Change in residence | | |
| 16. | Other major stress or difficulty – please specify _____ | | |

## EXPECTATIONS OF OUTCOMES (LOT)

In the next few sections, we are interested in measuring peoples' expectations for certain events or results. Please be as honest and accurate as you can throughout. Try not to let your response to one statement influence your responses to other statements. There are no "correct" or "incorrect" answers. Answer according to your own feelings, rather than how you think "most people" would answer. (Check one answer for each question)

| | **I agree a lot**<br><br>**0** | **I agree a little**<br><br>**1** | **I neither agree nor disagree**<br><br>**2** | **I disagree a little**<br><br>**3** | **I disagree a lot**<br><br>**4** |
|---|---|---|---|---|---|
| 1) In uncertain times, I usually expect the best. | | | | | |
| 2) It's easy for me to relax. | | | | | |
| 3) If something can go wrong for me, it will. | | | | | |
| 4) I always look on the bright side of things. | | | | | |
| 5) I'm always optimistic about my future. | | | | | |
| 6) I enjoy my friends a lot. | | | | | |
| 7) It's important for me to keep busy. | | | | | |
| 8) I hardly expect things to go my way. | | | | | |
| 9) Things never work out the way I want them to. | | | | | |
| 10) I don't get upset too easily. | | | | | |
| 11) I'm a believer in the idea that "every cloud has a silver lining." | | | | | |
| 12) I rarely count on good things happening to me. | | | | | |

## HEALTH EXPECTATIONS (PHE)

1. How confident are you that your cardiac arrhythmia intervention (i.e., ICD, ablation therapy, or medication) treatments will work?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

2. To what extent do you anticipate that you will lead a full and healthy life?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

3. To what extent do you anticipate that you will return to full physical functioning?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

4. To what extent do you anticipate that you will survive for at least 5 more years?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

5. Overall, to what extent do you expect that medical treatments will change your life?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Will be much worse than before | | | Will be about the same as before | | | Will be much better than before |

6. Overall, how would you rate your future outlook?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Extremely negative | | | Neutral | | | Extremely Positive |

7. How would you rate your feelings about yourself?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Extremely negative | | | Neutral | | | Extremely positive |

**Managing Arrhythmia Treatments**

**Please rate the confidence you feel today:**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 1. I am able to deal with the physical changes caused by my arrhythmia treatment | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 2. I can manage my own nervousness since my arrhythmia treatment | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 3. I feel confident that I can eventually get back to my normal activities around the house and at work | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 4. I have the skills to deal with the pressures my arrhythmia treatment is causing in my close relationships | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 5. I am able to manage interactions with my doctors, nurses, and other health care providers | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 6. I have the ability to deal with an arrhythmia event should it occur in the future | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |

**Rate your agreement or disagreement as of today:**

| | | | | |
|---|---|---|---|---|
| 1. If I have a plan in place for dealing with arrhythmia events, then I feel safer if this occurs | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 2. If I address my emotional reactions to the arrhythmia treatment, then I am less likely to be distressed by them | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 3. If I share information related to my arrhythmia treatment and heart symptoms, then my health care providers can more effectively treat them | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 4. If my partner and I are open to each other's experiences about my arrhythmia treatment, then we can begin to deal with this together | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 5. If I follow the safe activity suggestions prescribed by my health care providers, then complications related to my arrhythmia treatments will be reduced | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 6. If I am physically active during my recovery from the arrhythmia treatment, then my physical recovery will be faster | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 7. My arrhythmia treatment will prevent me from having a life-threatening arrhythmia event | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |

Participant #: _____ Date: _____

Appendix E – Follow-up Questionnaire

**STUDY QUESTIONNAIRE**
**Follow-Up**

Thank you for completing the following questionnaire. Your answers will help us assess the results of this study and get a better understanding of how treatments for ventricular arrhythmias influence health and well-being.

Please return the completed questionnaire in the pre-stamped self-addressed envelope provided.

You may find some of the questions in this survey to be personal in nature and we appreciate your willingness to complete the items. Your replies will be kept strictly confidential and only the research team will see your answers. If you have any questions, please contact the study co-ordinators at [redacted].

## DEMOGRAPHIC INFORMATION

**Please try to answer all of the questions. However, if there are any that you would rather not answer, you are free to leave them blank.**

**There is no single correct answer to the following questions. The correct response is the one which comes closest to describing you.**

1. Sex: □ Male □ Female 2. Year of Birth:_____ 3. Age:_____

4. How many years of school did you finish?
   - □ Less than high school
   - □ High school graduate
   - □ Trade or technical training after high school
   - □ Community college graduate
   - □ University graduate
   - □ Postgraduate university degree

5. What is your current living situation:
   - □ Living with a partner or a family member
   - □ Living with a friend or a roommate
   - □ Living alone
   - □ Living in a residential setting

## Health

Ablations

6. Have you had an ablation?
   - □ No
   - □ Yes

7. How many ablations have you had to-date? _____

8. How many of your ablations were deemed successful? ___

ICD

9. How many recorded ICD shocks have you experienced to-date?
   - □ None
   - □ 1 – 2 shocks
   - □ 3 – 4 shocks
   - □ more than 4 shocks

10. Have you ever experienced a shock and been told that it was not recorded?
   - □ No
   - □ Yes If yes, how many times have you had a shock and been told it was not recorded? ____

11. Are you currently taking any antiarrhythmic medication?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

12. Are you currently taking any beta blockers?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

13. Are you currently taking any medications to help with mood?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

14. Are you currently taking any medications to help you sleep?
   - □ No
   - □ Yes If yes, please list the medications:
     _____
     _____

## Your Health and Well-Being (SF-36)

This portion of the questionnaire asks for your views about your health. For each of the following questions, please mark an 'x' in the box that best describes your answer.

1. **In general, would you say your health is:**

| Excellent | Very good | Good | Fair | Poor |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

2. **Compared to one year ago, how would you rate your health in general now?**

| Much better now than one year ago | Somewhat better now than one year ago | About the same as one year ago | Somewhat worse now than one year ago | Much worse now than one year ago |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

| | | Yes, Limited a lot | Yes, limited a little | No, not limited at all |
|---|---|---|---|---|
| a | <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports | ☐ 1 | ☐ 2 | ☐ 3 |
| b | <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | ☐ 1 | ☐ 2 | ☐ 3 |
| c | Lifting or carrying groceries | ☐ 1 | ☐ 2 | ☐ 3 |
| d | Climbing <u>several</u> flights of stairs | ☐ 1 | ☐ 2 | ☐ 3 |
| e | Climbing <u>one</u> flight of stairs | ☐ 1 | ☐ 2 | ☐ 3 |
| f | Bending, kneeling, or stooping | ☐ 1 | ☐ 2 | ☐ 3 |
| g | Walking <u>more than a kilometre</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| h | Walking <u>several hundred metres</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| i | Walking <u>one hundred metres</u> | ☐ 1 | ☐ 2 | ☐ 3 |
| j | Bathing or dressing yourself | ☐ 1 | ☐ 2 | ☐ 3 |

**4.During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?**

| | | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|
| a | Cut down on the <u>amount of time</u> you spent on work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b | <u>Accomplished less</u> than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c | Were limited in the <u>kind</u> of work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d | Had <u>difficulty</u> performing the the work or other activities (for example, it took extra effort) | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|
| a Cut down on the amount of time you spent on work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b Accomplished less than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c Did work or other activities less carefully than usual | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

| Not at all | Slightly | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**7. How much bodily pain have you had during the past 4 weeks?**

| None | Very mild | Mild | Moderate | Severe | Very severe |
|---|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |

**8. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**9. These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

| | | All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|---|---|
| a | Did you feel full of life? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b | Have you been very nervous? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c | Have you felt so down in the dumps that nothing could cheer you up? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d | Have you felt calm and peaceful? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| e | Did you have a lot of energy? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| f | Have you felt downhearted and depressed? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| g | Did you feel worn out? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| h | Have you been happy? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| i | Did you feel tired? | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

| All of the time | Most of the time | Some of the time | A little of the time | None of the time |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

**11. How TRUE or FALSE is <u>each</u> of the following statements for you?**

| | | Definitely true | Mostly true | Don't know | Mostly false | Definitely false |
|---|---|---|---|---|---|---|
| a | I seem to get sick a little easier than other people | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| b | I am as healthy as anybody I know | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| c | I expect my health to get worse | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |
| d | My health is excellent | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

## EMOTIONS IN THE PAST WEEK (HADS)

The following questions ask about how you have been feeling. Health care professionals are aware that emotions play an important part in most illnesses. If your health care professional knows about these feelings he or she will be able to help you more. **Read each item below and place a check (✓) in the box beside the reply which comes closest to how you have been feeling in the past week.**

**1. I feel tense or "wound up"**

□ Most of the time
□ A lot of time
□ From time to time
□ Not at all

**2. I still enjoy the things I used to enjoy**

□ Definitely as much
□ Not quite so much
□ Only a little
□ Hardly at all

**3. I get sort of frightened feeling as if something awful is about to happen**

□ Very definitely and quite badly
□ Yes, but not too badly
□ A little, but it doesn't worry me
□ Not at all

**4. I can laugh and see the funny side of things**

□ As much as I always could
□ Not quite so much now
□ Definitely not so much now
□ Not at all

**5. Worrying thoughts go through my mind**

□ A great deal of the time
□ A lot of the time
□ Not too often
□ Very little

**6. I feel cheerful**

□ Never
□ Not often
□ Sometimes
□ Most of the time

**7. I can sit at ease and feel relaxed**

□ Definitely
□ Usually
□ Not often
□ Not at all

**8. I feel as if I am slowed down**

□ Nearly all the time
□ Very often
□ Sometimes
□ Not at all

**9. I get a sort of frightened feeling like "butterflies" in the stomach**

□ Not at all
□ Occasionally
□ Quite often
□ Very often

**10. I have lost interest in my appearance**

□ Definitely
□ I don't take as much care as I should
□ I may not take quite much care
□ I take just as much care as ever

**11. I feel restless as if I have to be on the move**

□ Very much indeed
□ Quite a lot
□ Not very much
□ Not at all

**12. I look forward with enjoyment to things**

□ As much as I ever did
□ Rather less than I used to
□ Definitely less than I used to
□ Hardly at all

**13. I get sudden feelings of panic**

□ Very often indeed
□ Quite often
□ Not very often
□ Not at all

**14. I can enjoy a good book or radio or TV program**

□ Often
□ Sometimes
□ Not often
□ Very seldom

## RESPONDING TO STRESSFUL EVENTS (IES-R)

The following is a list of difficulties people sometimes have after stressful life events. Please read each item and then indicate how distressing each difficulty has been for you *during the past 7 days* with respect to your arrhythmia (i.e., heart rhythm problem) or its treatment (i.e., having an ICD or ablation) by checking off under the most appropriate response. How much were you distressed or bothered by these difficulties?

| | | Not at all 0 | A little bit 1 | Moderately 2 | Quite a bit 3 | Extremely 4 |
|---|---|---|---|---|---|---|
| 1. | Any reminder brought back feeling about it. | | | | | |
| 2. | I had trouble staying asleep. | | | | | |
| 3. | Other things kept making me think about it. | | | | | |
| 4. | I felt irritable and angry | | | | | |
| 5. | I avoided letting myself get upset when I thought about it or was reminded of it. | | | | | |
| 6. | I thought about it when I didn't mean to. | | | | | |
| 7. | I felt as if it hadn't happened or wasn't real. | | | | | |
| 8. | I stayed away from reminders about it. | | | | | |
| 9. | Pictures about it popped into my mind. | | | | | |
| 10. | I was jumpy and easily startled. | | | | | |
| 11. | I tried not to think about it. | | | | | |
| 12. | I was aware that I still had a lot of feelings about it, but I didn't deal with them. | | | | | |
| 13. | My feelings about it were kind of numb. | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 14. | I found myself acting or feeling like I was back at that time. | | | | | |
| 15. | I had trouble falling asleep. | | | | | |
| 16. | I had waves of strong feelings about it. | | | | | |
| 17. | I tried to remove it from my memory. | | | | | |
| 18. | I had trouble concentrating. | | | | | |
| 19. | Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart. | | | | | |
| 20. | I had dreams about it. | | | | | |
| 21. | I felt watchful and on guard. | | | | | |
| 22. | I tried not to talk about it. | | | | | |

## LIFE STRESS

The next set of questions asks about possible difficulties or stresses that you may have experienced in your life.

Have you experienced any of the following in the past year?

| | | NO | YES |
|---|---|---|---|
| 1. | Serious illness or injury | | |
| 2. | Serious illness or injury to a close relative or friend | | |
| 3. | Marriage | | |
| 4. | Death of a spouse or partner | | |
| 5. | Death of a close relative or friend | | |
| 6. | Death of a pet | | |
| 7. | Marital separation/divorce | | |
| 8. | Financial difficulties | | |
| 9. | Loss of job | | |
| 10. | Retirement | | |
| 11. | Business failure | | |
| 12. | Major family conflict | | |
| 13. | Pregnancy | | |
| 14. | Gaining a new family member through birth or marriage | | |
| 15. | Change in residence | | |
| 16. | Other major stress or difficulty – please specify _____ | | |

## HEALTH EXPECTATIONS (PHE)

1. How confident are you that your cardiac arrhythmia intervention (i.e., ICD, ablation therapy, or medication) treatments will work?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

2. To what extent do you anticipate that you will lead a full and healthy life?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

3. To what extent do you anticipate that you will return to full physical functioning?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

4. To what extent do you anticipate that you will survive for at least 5 more years?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Certain this will not occur | | | Somewhat sure this will occur | | | Certain this will occur |

5. Overall, to what extent do you expect that medical treatments will change your life?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Will be much worse than before | | | Will be about the same as before | | | Will be much better than before |

6. Overall, how would you rate your future outlook?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Extremely negative | | | Neutral | | | Extremely Positive |

7. How would you rate your feelings about yourself?

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| Extremely negative | | | Neutral | | | Extremely positive |

**Managing Arrhythmia Treatments**

**Please rate the confidence you feel today:**

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 7. I am able to deal with the physical changes caused by my arrhythmia treatment | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 8. I can manage my own nervousness since my arrhythmia treatment | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 9. I feel confident that I can eventually get back to my normal activities around the house and at work | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 10. I have the skills to deal with the pressures my arrhythmia treatment is causing in my close relationships | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 11. I am able to manage interactions with my doctors, nurses, and other health care providers | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |
| 12. I have the ability to deal with an arrhythmia event should it occur in the future | | | | | | | | | | |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all confident | | | | | | | | | | Very Confident |

**Rate your agreement or disagreement as of today:**

| | | | | |
|---|---|---|---|---|
| 8. If I have a plan in place for dealing with arrhythmia events, then I feel safer if this occurs | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 9. If I address my emotional reactions to the arrhythmia treatment, then I am less likely to be distressed by them | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 10. If I share information related to my arrhythmia treatment and heart symptoms, then my health care providers can more effectively treat them | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 11. If my partner and I are open to each other's experiences about my arrhythmia treatment, then we can begin to deal with this together | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 12. If I follow the safe activity suggestions prescribed by my health care providers, then complications related to my arrhythmia treatments will be reduced | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 13. If I am physically active during my recovery from the arrhythmia treatment, then my physical recovery will be faster | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |
| 14. My arrhythmia treatment will prevent me from having a life-threatening arrhythmia event | | | | |
| 5 | 4 | 3 | 2 | 1 |
| Definitely True | | | | Definitely not true |

## Managing Arrhythmia Treatments II

**Mark the number that best describes the extent to which you have:**

| 13. Dealt with the physical changes caused by your arrhythmia treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all | | | | | | | | | | Totally |

| 14. Managed your nervousness since your arrhythmia treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all | | | | | | | | | | Totally |

| 15. Resumed normal household and work activities | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all | | | | | | | | | | Totally |

| 16. Dealt with pressure in your close relationship since the arrhythmia treatment | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all | | | | | | | | | | Totally |

| 17. Managed interactions with doctors and nurses successfully | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all | | | | | | | | | | Totally |

| 18. Dealt satisfactorily with arrhythmia events when they occurred | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| Not at all | | | | | | | | | | Totally |

Appendix F: Thank You Letter


Thank You Letter to Participants

Date_____
Dear Mr./Mrs._____

We are sending you this letter along with the 6-month follow-up questionnaire. When you have completed the questionnaire package, please use the self-addressed, stamped envelope to mail it back to us.

We want to thank you very much for participating in our study "Quality of Life and Psychosocial Well-Being Following VT Ablation." Your participation is greatly appreciated. By participating in this study you will help us better understand both the positive and negative effects of arrhythmia treatments on health and well-being.

Thank you,

Dr. Nanthakumar, Dr. Irivne, Leora Wanounou, and Ana Bilanovic